European Commission

Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation

Annexes I to V

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Annexes I - V Glossary

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Regulation on the carriage of dangerous goods by roads
AISE	International Association for Soaps, Detergents and Maintenance Products
AND	Regulation on the carriage of dangerous goods by inland waterway
ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation AISBL
ASPE	Animal Skincare Products Europe
ASO	Accredited Stakeholder Organisations
ATD	Access to documents
ATP	Adaptation to Technical Progress
BAT	Best Available Techniques
BEUC	The European Consumer Organisation
BOELVs	Binding Occupational Exposure Limit Values
BP	Biocidal Product
BPC	Biocidal Products Committee
BREF	Best Available Techniques Reference Document
BPR	Biocidal Products Regulation- Regulation (EU) No 528/2012
CAD	Chemical Agents Directive
CARACAL	Competent Authorities for REACH and CLP
C&L	Classification and Labelling
CBA	Cost-benefit analysis
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
Cefic	European Chemical Industry Council
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CLEAPSS	Consortium of Local Education Authorities for the Provision of Science Services
CLH	Classification and Labelling, Harmonised
CLI	Classification and Labelling Inventory
CLP	Classification, Labelling and Packaging
CMD	Carcinogens and Mutagens Directive
CoRAP	Community Rolling Action Plan
CR	Cosmetic Products Regulation
CRA	Cumulative risk assessment
CRED	Criteria for Reporting and Evaluating Ecotoxicity Data
DAR	Draft Assessment Report
DMF	Dimethylfumarate
DOI	Declaration of interest
DPD	Dangerous Preparations Directive
DR	Detergents Regulation
DSD	Dangerous Substances Directive
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECOS	European Environmental Citizens' Organisations for Standardisation
ECPA	European Crop Protection Association
EDCs	Endocrine disrupting chemicals
EEA	European Environment Agency
EFSA	European Food Safety Authority

EINECS	European Inventory of Existing Commercial Chemical Substances
ELV	Emission Limit Value
EMEA	European Medicines Agency
EQS	Environmental Quality Standards
eSDS	Extended Safety Data Sheet
ESR	Existing Substances Regulation
ETUI	European Trade Unions Institute
EU	European Union
FCM	Food contact materials
FET	Fish Embryo Acute Toxicity Test
GHS	Globally Harmonised System
GLP	Good Laboratory Practice
GPSD	General Product Safety Directive
HLG	High Level Group on the Competitiveness of the European Chemicals Industry
HPVCs	High Production Volume Chemicals
IA	Impact Assessment
IARC	International Agency for Research on Cancer
ICRT	International Consumer Research & Testing
IED	Industrial Emissions Directive
IFRA	International Fragrance Association
INCI	International Nomenclature Cosmetic Ingredient
IOELV	Indicative occupational exposure limit value
IPBC	Iodopropynyl Butyl Carbamate
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
LC50	Lethal Concentration for 50% of the population
LD50	Lethal Dose for 50% of the population
LoW	List of Waste
LQ	Limited quantities
MAPP	Major Accident Prevention Policy
MBM	N,N-Methylenebismorpholine
MIT	Methylisothiazolinone
MoS	Margin of Safety
MS	Member State
MSCA	Member State Competent Authority
NAMs	New Assessment Methods
NGO	Non-Governmental Organisation
NIAS	Non-intentionally added substances
OECD	Organisation for Economic Cooperation and Development
OELV	Occupational Exposure Limit Value
OJEU	Official Journal of the European Union
OME	Ordnance munitions and explosives
OPC	Open Public Consultation
OSH	Occupational Health & Safety
PAH	Polyaromatic hydrocarbons
PBDs	Polybrominated diphenyls
PBDEs	Polybrominated diphenyl ethers
PBT	Persistent, bioaccumulative and toxic (substance)
PFOA	Perflourooctanoic acid
PHMB	Poly(hexamethylene) biguanide hydrochloride
PIC	Prior Informed Consent Regulation
POP	Persistent Organic Pollutant

PAN	Pesticides Action Network
PPP	Plant Protection Product
PPPR	Plant Protection Products Regulation
QSAR	Quantitative Structure Activity Relationship
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
RAPIX	European Commission Rapid Information System
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
RID	Regulation on the carriage of dangerous goods by rail
RMM	Risk Management Measure
RMS	Rapporteur Member State
SCCPs	Short chain chlorinated paraffins
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SCL	Specific Concentration Limit
SCOEL	Scientific Committee on Occupational Emission Values
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SME	Small and Medium sized Enterprises
STOT	Specific Target Organ Toxicity
SVHC	Substances of very high concern
TCEP	tris(2-chlorethyl)phosphate
TIE	Toy Industries of Europe
ToR	Terms of Reference
TSD	Toy Safety Directive
TWD	Tactile warnings of danger
t/y	Tonnes per year
US OSHA	United States Occupational Health and Safety Administration
vPvB	Very Persistent and very Bioaccumulative (substance)
VCI	Verband der Chemischen Industrie e.v. (German Chemical Industry Association)
VOCs	Volatile Organic Compounds
WEEE	Directive on waste electrical and electronic equipment
WoE	Weight of Evidence
WTO	World Trade Organisation
WFD	Water Framework Directive

Annex I: Study Methodology

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1 Methodological Considerations

1.1 The study approach

The work required for this study has been organised into a series of main tasks and sub-tasks as follows, with the main tasks being as follows.

- Task 0: Scoping Work
    - Task 0-i: Kick-off Meeting
    - Task 0-ii: Inception Paper – including development of the Intervention Logic and consultation to identify potential case studies for the latter stages of the work
- Task 1: Evaluating the implementation of CLP Regulation
    - Task 1-i: Estimate the overall costs and benefits of CLP Regulation implementation
    - Task 1-ii: Evaluate the implementation of GHS revisions in accordance with the building block approach
    - Task 1-iii: Compare EU implementation of GHS against legislation in other countries
    - Task 1-iv: Assess the mechanisms mandated by CLP, notably the CLH process, including the impact of transitional periods
    - Task 1-v: Assess past uses of the urgency procedure and the safeguard clause
    - Task 1-vi: Assess the performance of the CLP Regulation against its objectives - assess the effectiveness, efficiency, relevance and EU added value of the provisions and processes established under the CLP Regulation
- Task 2: Evaluating the horizontal links between EU legislation on hazard identification and communication
    - Task 2a: Identify and assess gaps, overlaps and inconsistencies in horizontal links
        - Sub-tasks 2a-i and 2a-ii: Mapping of horizontal links
        - Sub-tasks 2a-iii: Identification of gaps, overlaps, inconsistencies and other issues affecting the performance of the legislation
        - Sub-task 2a-iv: Assessment of adaptability
        - Sub-task 2a-v: Case studies
    - Task 2b: Assess relevance, effectiveness, efficiency, coherence and EU added value of hazard/risk communication
        - Sub-task 2b-i: Assess awareness of communication obligations
        - Sub-task 2b-ii: Assess strengths and weaknesses of hazard and risk communication
- Task 3: Evaluating the vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification
    - Sub-task 3a: Mapping the vertical links
        - Sub-task 3a-i: Identification of the reference to CLP Regulation
        - Sub-task 3a-ii: Analysis of the risk management measures in downstream legislation triggered by CLP classification

- Sub-task 3b: Assess the relevance, efficiency, effectiveness, coherence and EU added value of the vertical links
  - Sub-task 3b-i: Assess the relevance, coherence, efficiency, effectiveness and EU added value of mechanisms
  - Sub-task 3b-ii: Assess the relevance, coherence, efficiency, effectiveness and EU added value of processes and procedures
  - Sub-task 3b-iii: Costs and benefits of the main legislative provisions
  - Sub-task 3b-iv: Case studies
  - Sub-task 3b-v: Differences in the transposition of relevant downstream Directives

- Task 4: Supporting the Commission in organising a public consultation and workshop
  - Sub-task 4a: On-line open public consultation
  - Sub-task 4b: SME Panel Survey
  - Sub-task 4c: Organisation of a Stakeholder Workshop.

The remainder of this section sets out our approach to data collection and addresses other methodological issues. Further details of the case studies are provided in Section 2, while Section 3 sets out the evaluation questions that acted as the basis for assessment undertaken for the study.

1.2 Data collection

A range of different data sources were used to inform this evaluation:

- Information gathered through consultation activities undertaken specifically for this evaluation;
- Additional targeted consultation of key stakeholder groups; and
- Policy and position papers produced by varying stakeholder interests;
- Impact assessments and evaluations, together with other reports commissioned to support policy development and implementation;
- Reports prepared by scientific bodies/agencies, as well as minutes of committee meetings or expert bodies and submissions to public consultations; and
- Review of the relevant academic scientific and economics literature.

There were three formal consultative requirements under the Terms of Reference for the study, as part of Task 4. These included an open public consultation, a survey of the Commission's SME Panel, and a Stakeholder Workshop. Further details of the approach taken to each of these is provided in Annex V, which also presents the findings from the SME Panel survey and the on-line open public consultation. The report on the Stakeholder Workshop was published separately by the Commission in June 2016.

In addition to the formal consultation activities, the study team undertook targeted data collection from key stakeholder groups in order to collect responses to more detailed information requests than would have been appropriate through the open public consultation or SME Panel survey. This targeted consultation covered: Member State authorities, civil society (as represented by various non-governmental organisations), workers representatives, consumer representatives and industry (via the main EU industry associations). Details with respect to response rates and key characteristics of the respondents are provided in Annex V. Findings from the targeted data collection are reported on in Annexes II to IV, as part of the evaluations carried out for these tasks. It should also be noted that the findings from these consultations form an important part of the evidence base used in developing the conclusions presented in this evaluation summary report.

As well as undertaking the suite of consultation activities, extensive desk-based research was used in order to validate and substantiate the evidence collected through consultation, as well as to fill data gaps. This included review and collation of information from impact assessments, position papers, academic and scientific research, papers and reports prepared by the relevant scientific bodies, regulatory submissions and other grey literature. The information gathered from the literature review carried out in the early phases of the study helped guide the questions that were asked as part of the various consultation activities and, in particular, helped in forming discussion topics for the Stakeholder Workshop. It also informed the study team's proposals for the case studies to be examined in more detailed as part of the three main tasks.

1.3 Triangulation of data

The information obtained from the desk-based research carried out in both the early and later stages of the study was compared against the information received from the range of consultation activities to draw key conclusions relating to the various aspects covered by the fitness check, as well as to identify any differing views or inconsistencies in opinions. This enabled a triangulation of the results in line with tool #41 of the European Commission Better Regulation "Toolbox"[1]). In particular, the desk-based research has helped in determining the impact and significance of the issues raised (both positive and negative), as well as validating information provided by stakeholders; the latter was particularly important when evidence was provided mainly from a particular type of stakeholder.

It should be recognised, however, that there is no relevant body of literature to cover all of the issues falling within the scope of this Fitness Check. As a result, the evaluation has had to rely for some aspects mainly on evidence provided in response to the consultation activities. Every effort was made to ensure that there is a balanced perspective within the assessment. However, it was not possible to gain the degree of participation desired from some stakeholder groups, in particular, from some of the NGOs representing civil society views across the range of evaluation issues. It should not automatically be assumed that this is due to a lack of interest or even concern; rather, it may reflect a lack of resources and the need for such organisation to prioritise their efforts. In order to address this issue, literature research was undertaken to identify position papers that had been published by relevant stakeholder groups that had a lower degree of participation in the consultations.

1.4 Baseline considerations

This study has had to consider the functioning of over 40 pieces of different legislation, which has been introduced and amended over an extended period of time. As a result, it has not been possible to develop a straightforward counterfactual for the assessment of CLP or other legislation.

By way of example, the CLP Regulation replaced the pre-existing Directive led legislation of which the key components were the Dangerous Substances Directive (DSD – 67/548/EEC) and the Dangerous Preparations Directive (DPD) which was first introduced in 1988 (88/379/EEC) and recast in 1999 (1999/45/EC). As such, classification, packaging and labelling legislation has existed in some form or other since 1967 for substances and 1988 for preparations. It is therefore not clear what counterfactual one would adopt for an evaluation of CLP, which carries over many of the pre-

[1] European Commission (2015): Better Regulation "Toolbox". Available at: http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf

existing requirements. Therefore, in order to calculate the costs, the total costs of classification and labelling requirements were considered, as well as the costs of transition to the CLP Regulation. In order to estimate the benefits of classification and labelling requirements, a pragmatic baseline reflecting both the availability of data on occupational and other diseases and the timing of classification and labelling requirements for mixtures was developed (see Annex II for further details).

As this study was not required to develop new estimates for the costs and benefits of actions under other related chemicals legislation, the qualitative assessment reflects a baseline of varying national requirements, with data used from impact assessments and evaluations acting as supporting information.

1.5 Limitations

As with any study of this scale, numerous challenges were encountered in gathering the data needed to provide a robust evidence base, as well as in providing quantitative estimates of impacts. Although extensive efforts were made to overcome the challenges and to ensure that accurate and reliable information acted as the basis for the evaluation, many remained and some could not be overcome. There are therefore limitations that ultimately impact on the study conclusions.

Further details of the limitations encountered and the work undertaken are as follows:

- Given the broad scope of the study and the number of pieces of legislation to be considered, there is a limit on the level of detail given to any one piece of legislation. The aim of this study was to consider the legislative framework as a whole (and whether it meets its overall objectives in relation to the evaluation criteria), thus efforts have been made to ensure that the key positive and negative aspects have been considered and reported upon. However, the sheer magnitude of the exercise has meant that more focus had to be given to the most relevant legislation and the most relevant aspects of the framework.

- In relation to the above point, other studies are being undertaken that are of direct relevance to this study (e.g. the study on the cumulative benefits of chemicals regulation being carried out for DG Environment). Therefore, wherever possible, efforts were made to avoid repetition with these.

- Although an extensive literature review was undertaken, and this identified both areas where the legislation was functioning well and where issues were arising, there was generally a lack of published information on the scale of the problems arising from such issues. In addition, there were few to no papers addressing many of the concerns raised by stakeholders. As a result, the evaluation has had to rely in many cases on stakeholder opinion and information (qualitative and quantitative) provided by stakeholders.

- A good level of response to consultation activities was received from Member State authorities. The highest level of response in terms of numbers was by industry. Industry's (associations and companies) level of response to the Open Public Consultation and the targeted consultation was much higher than that received from civil society in the form of either citizens or non-governmental organisations. Many of the civil society stakeholders approached to provide input to the targeted consultation and case studies indicated that they were unable or would not be providing input. This has potential implications for the study results as a greater proportion of responses were received from other stakeholders (such as industry). In order to address this issue literature research was undertaken to

identify position papers that had been published by NGOs and could be used to inform the study and support or refute the opinions/conclusions drawn by other stakeholder groups. Moreover, in the analysis of the open public consultation (Annex V), the responses are pooled in four stakeholder groups (citizens, industry, public authorities, NGOs and others) in order to give equal prominence to each stakeholder group.

- In some cases, an issue was raised by a single stakeholder. It has been suggested that such cases should not be reported, even though they may reflect a significant effect for a larger number of stakeholders. Efforts have been made to establish the significance of different issues and to make it clear whether a view is shared by multiple stakeholders. However, in order to also protect stakeholders indicating that their responses were confidential, many of the views are not attributed to a specific organisation.

- Throughout the study extensive literature research has been undertaken to provide information that can be used in contextualising the aspects of the legislative framework discussed, as well as further informing and contributing to the issues (both positive and negative) raised through consultation with stakeholders. However, it is clear from this research that there is a general lack of publically available information to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms). Although considerable efforts were made to identify this type of evidence, the lack of publically available information can be considered an important limitation.

- In relation to the above point (and with regard to Case Study 1), in order to understand the true effect of CLP and the other legislation on the functioning of the single market and the competitiveness of EU industry, detailed commercial data would be required. Companies were not able or willing to provide some of the data requested for the study, making it difficult to quantify impacts.

- In order to understand the effect of the CLP Regulation on consumer behaviour (particularly in relation to consumer communication) an extensive consumer survey would have been needed. However, this up-to-date consumer data is currently not available and can therefore be seen as a limitation.

2 Case Studies

Table 2-1 below provides a summary of the case studies carried out as part of the study. The purpose of the case studies was to explore in detail some of the more pertinent issues associated with EU chemicals legislation, both in relation to the implementation of the CLP Regulation and the interface between this and other related chemicals legislation. Importantly, the aim of the case studies was not to re-consider specific decisions that have already been taken; instead, it was to examine the mechanisms and procedures of the CLP Regulation and to assess whether the current linkages are appropriate (which may necessitate examining some of the impacts of past decisions).

The approach to identifying and proposing case studies was as follows.

1. The work to be undertaken as part of each sub-task was reviewed and the aims and role of the case studies in relation to these summarised (where not specified in detail in the Terms of Reference).

2. Relevant evaluation questions were developed for the purposes of identifying case studies.

3. The CLP Regulation and key guidance documents (e.g. ECHA's guidance documents) were reviewed to identify potential issues for deeper consideration.

4. Internet searches and literature review were undertaken to try and identify those aspects of the legislation, and the interface between different pieces of legislation, that are giving rise to either potential problems or examples of where the system works well and may provide lessons for other legislation or that it may be of value to investigate in detail (a top down approach).

5. Targeted interviews were held with a range of different stakeholders, in order to identify potential case studies based on their experiences (a more bottom up approach). These interviews were also used to examine the merits of some of the case studies originally suggested in the Terms of Reference (i.e. stakeholders with potential interest in the cases were contacted), and to assess the extent to which industry would assist with such a case study through the provision of information, etc.

6. All of the issues identified by stakeholders that could potentially form a case study were grouped into themes. These themes were then used as the basis for further desk based research, with this used to identify the most relevant issues for case studies under each of the themes.

7. Finally, potential case studies were screened against a set of "key characteristics", with this leading to several of the case studies raised by stakeholders being rejected and to the development of additional suggestions.

The study team combined information from the literature review with that gained from consultation with stakeholders to identify potential case studies. The scope of the individual cases was then refined with input from the Steering Group, together with further research and analysis, and reconsideration of the stakeholder responses. In addition, six factors for characterising potential case studies were developed, with these acting as the basis for determining the potential contribution of each case study to the tasks set out in the Terms of Reference and hence this exercise to support the Commission in undertaking the fitness check. Applying these factors to case study proposals led to their further refinement and adaptation; in some cases, it also led to case

studies initially proposed being removed from the list for further consideration. It should also be noted that certain case studies (e.g. relating to fertilisers) were not included in separate case study reports because it was deemed more appropriate to incorporate their conclusions in the main task reports. The final decision on case studies lay with the Commission. The six factors used for the characterisation process were as follows:

- scope of the issue – global, EU or national;
- nature of the issue – CLP specific, horizontal, vertical;
- evaluation criteria – addressing specific evaluation questions;
- significance of the problem – significance in terms of meeting the objectives of the legislation; significance at sectoral level, broader EU level or more specific;
- small and medium sized enterprises; and
- the feasibility of data collection – desk-based or broader.

The final agreed list of case studies is set out in Table 3-1. The individual case studies are reported on in Annex VI to this report. Information and findings are drawn from them and incorporated into the task reports presented in Annexes II to IV as appropriate.

Table 2-1: Case studies carried out to support the evaluation			
Reference number	**Lead Team Member**	**Case study title**	**Case study description**
1	RPA	Comparison of **implementation of UN GHS** in the EU and other key economies	Different countries have adopted different building blocks both in terms of hazards covered and sectors covered. This case study is part of the work carried out to inform the evaluation of GHS implementation as part of Task 1 to the study (presented in Annex II). It looks at the following four aspects of implementation individually and then together to provide a more comprehensive assessment of their impact on international trade of chemicals and the competitiveness of the EU chemicals industry: 1. Differences in adoption of GHS building blocks; 2. Differences in transition times for adopting GHS and revisions to GHS; 3. Differences in labelling and packaging requirements; and 4. Differences in classification requirements.
2	RPA	**Metals classification** and the CLP Regulation	It may be the case that there is a gap in the legislation as the CLP contains no criteria for the classification of metal alloys, with this potentially impacting on their treatment under other horizontal legislation, e.g. REACH, waste legislation, etc. The case study would identify problems arising from this gap. It could also consider the extent to which default classification rules under the CLP regulation may trigger under/over classification of metals more generally. The main aim of this case study is to answer the following questions: 1. Are CLP classification rules appropriate for the classification of metals (i.e. metallic forms)? 2. What are the impacts of risk management measures triggered by metal classifications?
3	Milieu	**Parallel hazard assessments**	Different bodies are responsible for the hazard assessment and classification of a substance/mixture under the CLP Regulation and Plant Protection Products Regulation. This case study examines those cases where separate bodies are required to recommend classification of a substance under the CLP Regulation and the Plant Protection Products Regulation which can result in different conclusions being reached on the proposed classification of a substance, and draw conclusions on the effectiveness, efficiency, relevance and coherence of such procedures.
4	Oekopol	Relevance and coherence as regards the introduction of **new test methods** within chemicals legislation	The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. This case study examines the relevance of the CLP classification criteria in terms of their ability to respond to changes in scientific methods, and the horizontal coherence of these also taking into account prohibitions on animal testing under the Cosmetics Regulation.
5	RPA	Coherence of classifications, definitions and the **labelling requirements**	This case study investigates the coherence, consistency, gaps and overlaps related to classification and labelling requirements for detergents under the Detergents Regulation, the Biocidal Products Regulation, and the CLP Regulation. Issues arising regarding definitions and differences in relation to transport legislation are also examined. This case study considers the detergents industry across the whole of the EU. Furthermore, it indirectly

Table 2-1: Case studies carried out to support the evaluation			
Reference number	**Lead Team Member**	**Case study title**	**Case study description**
		for detergents	assesses the effectiveness of the CLP Regulation at communicating hazard information, contributing to a second consumer-focused case study (Case Study 9).
6	Oekopol	DIfferences in assessment procedures for **PBT and vPvB** as properties of concern	The CLP Regulation does not include classification and labelling requirements based on PBT and vPvB properties. This case study looks at whether there are inconsistencies or overlaps in the identification or risk management of PBTs, what types of risk management measures are triggered by PBTs, what issues arise in relation to the coherence of risk management, whether the current processes are effective and views on integration of PBT/vPvB into CLP.
7	RPA	**Awareness of SMEs** of their hazard and risk communication obligations	This case study focusses on the awareness of SMEs of the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years. It also looks at issues regarding SME understanding of packaging requirements under CLP and international transport legislation.
8	RPA	Awareness of chemical safety assessment and labelling requirements for **toys**	The Toy Safety Directive lays down toy safety rules which include requirements for Chemical Safety Assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.), and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. This case study examines SMEs awareness of this range of obligations as well as their awareness of labelling requirements, including traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings.
9	RPA	**Consumer comprehension** of and relevance of safety information on product **labels**	The focus of this case study is on the hazard pictograms that the CLP introduced when implementing the GHS. This case study analyses the available information on consumer understanding of hazard labelling, draws conclusions on the effectiveness of hazard communication to consumers and considers the potential for the use of more innovative communication approaches.
10	NCEC	Linkages between **CLP** and **OSH** legislation	The case study looks at whether there are overlaps and inconsistencies between CLP and Occupational Safety and Health (OSH) legislation and –if so – what are their causes and implications. Formaldehyde is used as a case study substance to illustrate some of the issues.
11	RPA	**Risk management measures triggered by classification for CMR** under CLP	This is an overarching case study involving a comparative assessment of the procedures triggered by a CMR or other health classification (e.g. sensitiser). It will cover REACH, the Plant Protection Products Regulation, Biocidal Products Regulation, Cosmetics Products Regulation, Toy Safety Directive, food contact materials and the Carcinogens and Mutagens Directive (CMD). The case study reviews the requirements under the different legislation in terms of risk management and the potential for derogations or exemptions. It also considers

Table 2-1: Case studies carried out to support the evaluation			
Reference number	**Lead Team Member**	**Case study title**	**Case study description**
			effectiveness and efficiency issues by considering a series of case study substances and information on costs available from the literature. The case studies relate to N, N-Methylenebismorpholine (MBM), gallium arsenide, formaldehyde (also linked to Case Study 10), tris(2-chlorethyl)phosphate (TCEP), lead (also linked to Case Study 2) and nickel.
12	Oekopol	Use of CLP classifications as the basis for **waste management**	This case study examines the nature of the linkages between waste legislation and CLP, with respect to reliance on CLP for classification purposes. It also considers the impact of reliance within the waste framework on the CLP ecotoxicity classification for the aquatic environment with respect to any impacts that the transition to CLP has had on disposal or re-use of certain waste streams. In addition, the case study examines issues regarding the classification of a waste as hazardous and the consequences of such classification for recycling (in particular it investigates the legislative and non-legislative constraints to recycling). The focus is on consideration of the presence and (potential) bioavailability of substances of concern in certain waste streams as a constraint to allowing their recycling (metal/alloys, plastics, etc.).
13	Oekopol	**Linkages between the CLP and Seveso III** Directive, including risk management under Seveso III	Seveso III aligns, amongst others, requirements for establishments using or storing hazardous chemicals with the CLP Regulation. Due to the alignment some establishments may change tier or fall out of scope all together because for some hazard classifications the criteria in the Dangerous Substances Directive and CLP are not identical. The case study reviews the procedures for risk management under Seveso as a potential example of best practice, and the procedures for excluding substances from the scope of the Directive and whether the linkages between CLP and Seveso III are efficient and effective.

3 The Evaluation Criteria

3.1 Introduction

The intervention logic provides the starting point for the evaluation and for the development of the evaluation questions that were to be answered under each of the five main criteria (effectiveness, efficiency, relevance, coherence and EU valued added).

The main elements of the intervention logic can be summarised as follows:

- **Needs:** The 'needs' that EU chemicals legislation and the CLP Regulation were introduced to address are similar and interlink[2]. They can be summarised as:

  - Protection of human health and the environment;
  - Business environment favourable to innovation and competitiveness of EU companies; and
  - Efficient functioning of the internal market.

  Over time, the awareness and understanding of the damage that can arise from the use of hazardous chemicals has grown, allowing the progressive refinement of the needs for protection and the responses to those needs. At the same time, the framework conditions for innovation, competitiveness and the trade within the Single Market have evolved, inter alia through increasing complexity of legislation. This has created new needs for simplification and adaptation of legislation.

- **Objectives:** The general objectives of chemicals legislation are to:

  - Ensure a high level of protection of human health and the environment;
  - Ensure the efficient functioning of the internal market; and
  - Enhance competitiveness and innovation.

  More specific objectives include, for example, controlling the use of and/or exposure to hazardous substances by identifying, communicating and managing their risks; giving appropriate incentives to develop suitable alternatives and to substitute hazardous chemicals where better alternatives exists; reducing the number of animals used for testing chemicals, etc. Some of the legislation covered by this fitness check may also include other objectives related to other policy areas; these do not fall within the scope of this study.

- **Inputs:** The inputs to the legislative framework include information on the hazardous properties of chemicals; scientific opinions on the classification of those properties and on appropriate risk management measures; risk assessments carried out by manufacturers and importers of substances as well as by employers; scientific input from other stakeholders; analyses of the costs and benefits of different risk management requirements carried out by different stakeholders and as appropriate to meeting varying regulatory needs; monitoring data; enforcement activities and other stakeholder contributions.

[2] These fundamental needs are also enshrined in the EU Treaty.

Activities: Relevant activities include both the ongoing development and revision of the chemicals legislation framework, as well as the activities required as part of its implementation across the set of relevant actors. Under the CLP Regulation, actions must be undertaken by manufacturers, importers, downstream users (formulators and re-importers), distributors (including retailers), producers of articles, ECHA, Member State competent authorities, and enforcement authorities related to the classification, labelling and packaging of chemicals. Some of these actors, as well as other similar stakeholders, must take varying actions under the broader legislative framework, with more voluntary activities carried out by various trade associations, consumer, workers and environmental organisations. There is inadequate space to detail the full list of potential activities in Figure 2-1 for the broader chemicals legislative framework, and instead the range of relevant legislation has been highlighted (framework legislation such as REACH, consumer product legislation such as the Toy Safety Directive, health and safety legislation such as the Chemical Agents Directive, professional products legislation such as the Pressure Equipment Directive, and environmental protection legislation such as the various waste related legislation).

- **Outputs:** Regulators have introduced different legislation and measures at the EU, national and regional levels for assessing, communicating, and managing the hazards and risks associated with the day to day use of chemicals. In order to respond to innovation, rapidly changing technologies and changes in scientific knowledge, legal acts are updated on an ongoing basis and new directives and regulations (such as REACH and CLP) are introduced to better ensure that the EU delivers on the high-level, fundamental needs outlined above. On the other hand, these changes result in increasing legislative complexity.

  These pieces of legislation and measures trigger direct effects and outputs. For CLP, this will include classification based on criteria that are globally applicable; hazard communication, including labelling and the preparation and supply of safety data sheets to downstream users; packaging substances and mixtures in order to ensure both safe storage, transport and use; the agreement of Harmonised Classifications; improved preparedness for accidents; as well as making publicly available information on the classification of chemicals via the Classification and Labelling Inventory.

  Other “horizontal” chemicals legislation also has criteria for the scientific classification of chemicals, and may include its own hazard communication and labelling requirements, as well as packaging requirements. Vertical or downstream legislation draws on the outputs of the CLP Regulation as the basis for implementing risk management, risk mitigation and/or risk control measures in the related downstream legislation.

- **Results:** For chemicals legislation and the CLP Regulation, the results reflect the outcomes from the combination of outputs over the short, medium and longer term. These changes in practices due to improved information for users concerning the hazardous properties of chemicals, which is globally consistent/harmonised; the ability of consumers to make more informed choices and to ensure that they adopt appropriate safe use of chemicals; improved protection of the environment from the adverse effects of chemicals due to better communication on their hazards and safe use; reductions in occupational exposures to chemicals, particularly the most hazardous chemicals (i.e. carcinogens, mutagens and reproductive toxins); reductions in exposures of particular populations, such as children, pregnant women, young workers, recyclers, etc. to hazardous chemicals; reductions in discharges/emissions to the environment of chemicals that can cause environmental damage; harmonised rules for manufacture/use/placing on the EU market etc.

- **Impacts:** The impacts of the legislation reflect the concrete changes that the results deliver. This includes a higher protection of health and environment through reduced levels of occupational accidents and diseases associated with chemical usage and exposures; a reduced chemicals related disease burden amongst the general population; reductions in health impacts on consumers; reductions in poisoning incidents; and reductions in damages to the environment, including the services provided by different ecosystems as well as more intrinsic considerations. All of these impacts also translate to reduced costs for employers, governments (e.g. health services) and society (e.g. due to the avoidance of damages which later require remediation) within the EU. On the other hand, impacts also include costs/savings to enterprises involved in the manufacture and use of substances and mixtures; improved freedom of movement of chemical substances and mixtures within the internal market and more globally, with this including reductions in non-tariff barriers to international trade; preserving growth and competitiveness; enhancing innovation; safeguarding and/or increasing employment; and more jobs and social cohesion.

3.2 The evaluation criteria

This fitness check requires evaluation of the performance of the CLP and other related chemicals legislation against five evaluation criteria, where these are effectiveness, efficiency, coherence, relevance and EU added value. Each of these criteria is considered briefly in turn below.

The evaluation questions to act as the basis for the fitness check were provided to the consultants by the Commission. These are given in Table 3-1, presented at the end of this section.

As there is overlap and complementarity within these questions, responding to each of them individually would result in a lengthy report. As a result, we have grouped evaluation questions together for the purposes of reporting on the study findings; evidence and conclusions are therefore discussed in relation to groups of questions, where these are considered to reflect a common theme or a related set of issues, to avoid repetition.

3.2.1 Effectiveness

According to the Better Regulation Methodology, the aim of the effectiveness analysis is to consider how successful EU action has been in achieving or progressing towards its objectives. The evaluation is to form an evidence base on the progress made to date and the role of the EU action in delivering the observed changes. If the objectives have not been achieved, an assessment should be made of the extent to which progress has fallen short, what factors have had an influence on the success of the EU action, or why the objectives have not yet been achieved. The analysis should also try and identify any unintended or unexpected effects.

In assessing effectiveness, the starting point has been consideration of to what extent the EU legislative framework for the risk management of chemicals meets its objectives. Four sets of questions have then been developed to act as the basis for the analysis (with numerous sub-questions underlying each of these):

1) To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?

2) What are the consequences or effects (whether socio-economic, environmental, or health-related, both positive and negative) that were not originally planned (for instance,

unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?

3) What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?

4) To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedures)?

3.2.2 Efficiency

Efficiency as an evaluation criterion explores, in the first instance, the relationship between the inputs and the outputs of the chemicals legislation framework, which involves looking at the procedures and processes demanded by the set of legislation and ascertaining whether they can be justified by the outcomes. It also requires examination of whether there may be more efficient (i.e. less costly) ways of achieving the objectives of the legislation, or whether the effectiveness of the legislation could be improved for the same level of costs.

The starting point for the analysis of efficiency is given by the following two questions:

1) What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drives for those costs and benefits? A specific focus will be given to SMEs.

2) What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

It is of note that some of the more detailed sub-questions that have been specified by the Commission for the assessment of efficiency overlap with questions on effectiveness. As a result, these questions have often been grouped together for the more detailed analysis carried out under Tasks 1 to 3.

3.2.3 Relevance

The relevance of the legislative framework is analysed with reference to the identified problems that necessitated the introduction of classification, labelling and packaging originally, as well as the need for risk management under other legislation. Alternatively, it may be the case that, due to scientific advances or changes in economic conditions, our understanding of the problems or changes in economic conditions has made the identified problems more urgent. The analysis therefore considers the extent to which the activities and the effects and results from implementation of the CLP Regulation, as well as the other horizontally and vertically linked chemicals legislation[3], actually

[3] As indicated in Section 1, this study covers all legislation that is related to CLP either because it covers the same aspects of hazard identification and communication or because it sets downstream risk management

address the identified needs. It may be the case that the problems that the legislation initially sought to address are no longer relevant or no longer exist, or that the objectives of the CLP Regulation or the related chemicals legislation no longer accord with the wider goals of the EU chemicals legislative framework.

In this case, the evaluation focuses on answering questions grouped under the following three headings:

- To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)
- To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?
- To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

3.2.4 Coherence

In terms of assessing the coherence of the CLP Regulation and the related chemicals legislation, we have considered how various activities and outputs of the CLP Regulation and the other legislation interact to deliver the results and impacts; this includes both how they interact internally to achieve the objectives of the chemicals legislation and how they interact externally with other legislation. More specifically, we have looked at how the objectives, inputs, activities and outputs of the CLP Regulation and related chemicals legislation interact with each other. Indeed, a fundamental aspect has been in identifying the synergies, inconsistencies and gaps between the CLP Regulation and legislation that horizontally and vertically governs different sectors; this has included assessing how they work together within the legislative framework and where there is scope for improvement. It should be noted that the assessment has focussed on coherence between the legislation within the legislative framework, whilst also considering coherence with other EU policies.

The evaluation questions providing the basis for this assessment fall into two groups:

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

3.2.5 EU added value

Assessment of EU added value is focused on answering the following high level question:

- What is the added value of regulating the risk management of chemicals at an EU rather than at national level?

measures. This scope varies from that of the fitness check which covers all legislation related to chemicals whether or not it is linked to CLP.

Evaluating EU added value will require an assessment of whether having legislation on classification, labelling and packaging at the EU level creates added value, as well as whether the implementation of the other related chemicals legislation at the EU level creates added value. This aspect of the assessment may be particularly challenging in relation to the broader set of chemicals legislation, especially that which operates at the national level only.

The assessment will draw on the findings of 'effectiveness' and 'efficiency' to determine overall EU added value. The aim will be to either justify or question the existence of the CLP Regulation and the horizontal and vertical linkages with other EU chemicals legislation in their current form. For instance, it could be the case that there are antagonisms or duplications within the current framework that should be addressed in order to ensure EU added value. The framework may also create synergies across activities and sectors that would not otherwise be possible.

Table3-1: Overview of the evaluation questions for the study overall		
1. Effectiveness		
1.1	**To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?**	
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?	
	1.1.1.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
	1.1.1.2	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the combination effects of chemicals (simultaneous exposure to chemicals)?
	1.1.1.3	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the exposure to a substance via various sources and/or routes of exposure?
	1.1.1.4	Do the risk management measures sufficiently address all risks to human health and the environment (e.g. chemicals in articles, mixtures, endocrine disruptors, nanomaterials, new toxicity endpoints)?
	1.1.1.5	Are there any gaps in ensuring a high level of protection of human health and the environment? If yes, what are they?
	1.1.1.6	Are testing methods adequate to identify all hazards to human health and the environment?
	1.1.1.7	Are data requirements (on hazards, uses, and exposures) in the chemical legislative framework adequate to identify and assess all risks to human health and the environment for all substances and uses?
	1.1.1.8	Is the scientific data on which the regulatory decisions are based of good quality, complete and reliable? Are quality requirements (e.g. GLP) appropriate?
	1.1.1.9	Have the incidences of consumer chemical-related accidents resulting in exposure/damage of human health or the environment been reduced?
	1.1.1.10	Have the incidences of industrial worker/professional chemicals-related accidents resulting in exposure/damage of human health or the environment been reduced?
	1.1.1.11	How has the chemicals legislative framework impacted the incidence of diseases in the general public?
	1.1.1.12	How has the chemicals legislative framework impacted the incidence of occupational disease?
	1.1.1.13	To what extent has the risk management addressing exposures of industrial/professional workers to chemicals improved as a result of the chemicals legislative framework?
	1.1.1.14	To what extent has the risk management addressing exposures of consumers to chemicals improved as a result of the chemicals legislation framework?
	1.1.1.15	To what extent does the chemicals legislative framework effectively take into account the protection of vulnerable groups (e.g. children, pregnant women)?
1.1.2	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring the efficient functioning of the single market?	
	1.1.2.1	To what extent does the EU legislative framework meet its objectives in relation to the functioning of the single market?
	1.1.2.2	Are harmonised communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
	1.1.2.3	Are the information requirements on chemicals (including on e.g. chemical content, hazard, risk, use) and the availability of this information sufficiently clear to allow their harmonised application throughout the single market?

Table3-1: Overview of the evaluation questions for the study overall		
1.1.3	Does the EU legislative framework for the risk management of chemicals meet the primary objective of enhancing competitiveness and innovation?	
	1.1.3.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
	1.1.3.2	To what extent has the chemicals legislative framework been effective in facilitating international trade of chemicals?
	1.1.3.3	To what extent has the chemicals legislative framework contributed to international competitiveness of the chemicals industry?
	1.1.3.4	To what extent has the chemicals legislative framework contributed to innovation in the chemicals industry?
1.1.4	Other relevant questions relating to effectiveness	
	1.1.4.1	To what extent are the classification rules for mixtures fit for purpose (e.g. for metal alloys)?
	1.1.4.2	Is the chemicals legislative framework as effective as it can be? Are there factors that limit the effectiveness of the chemicals legislative framework and would they be avoidable?
	1.1.4.3	To what extent does the chemical legislative framework requires/encourage Member States to further reduce exposure of humans and/or the environment to hazardous chemicals and are these requirements sufficiently implemented?
	1.1.4.4	To what extent does the chemicals legislative framework promote the access to and use of substances/products with a more favourable risk profile (e.g. by identifying such and providing for a simplified assessment/authorisation procedure)?
1.2	**What are the consequences or effects (whether socio-economic, environmental, or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?**	
1.2.1	Are there unnecessary regulatory burdens?	
1.2.2	Have any automatic mechanisms triggered significant costs or benefits?	
1.2.3	Has the specific risk assessment approach triggered significant costs or benefits?	
1.2.4	Are there obsolete measures or gaps in the legislative framework?	
1.3	**What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?**	
1.3.1	Which factors have the biggest positive impact on the correct functioning of the chemicals legislative framework? To what extent?	
1.3.2	Which factors have the biggest negative impact on the correct functioning of the chemicals legislative framework? To what extent?	
1.3.3	Which factors were taken into account in identifying the appropriate risk management approach, whether based on generic risk considerations or specific risk assessment (e.g. characteristics of the substance, exposure, vulnerable groups, legal certainty and predictability, transparency, flexibility, enforceability, costs/benefits for public authorities, costs/benefits for industry, costs/benefits to society)? Were these factors appropriately considered? Are any factors missing?	
1.3.4	Has the right balance been struck in the chemical legislative framework between risk management measures based on generic risk considerations and risk management measures based on specific risk assessments?	
1.3.5	To what extent do the two different risk management approaches applied in the chemicals legislation provide for predictability of the decisions?	
1.3.6	To what extent do the two different risk management approaches applied in the chemicals legislation provide for high level of protection of human health and	

Table3-1: Overview of the evaluation questions for the study overall		
	the environment?	
1.3.7	Where trade-offs are made between the different objectives of the chemicals legislative framework in the implementation of the legislation, do these trade-offs influence the effectiveness of the legislation? Are these trade-offs based on sufficient/appropriate analysis? Do such trade-offs generally go in any particular direction (e.g. towards protection of health and environment or towards the functioning of the internal market)?	
1.3.8	To what extent are there synergies between the objectives of protection of human health and the environment and the functioning of the internal market? Are these synergies immediate or do they appear over time?	
1.4	**To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedures)?**	
1.4.1	Are the main elements of the EU legislative framework for the risk management of chemicals effectively and consistently implemented across all Member States?	
1.4.2	If there is a disparity in the way legislation is implemented, what are the consequences of such a disparity?	
1.4.3	To what extent is enforcement effective and consistent across all Member States? Are the frequency of controls, sanctions and liabilities consistent and comparable in different Member States?	
1.4.4	Are there other incentives to comply with the chemicals legislative framework (e.g. other market based incentives, consumer demands)?	
1.4.5	Are there any measures in place at EU level to support enforcement? Are these tools effective and sufficient?	
1.4.6	Do all actors including regulatory agencies (e.g. ECHA, EFSA) and the Commission consistently implement all aspects of the chemicals legislative framework in accordance with its objectives and intentions?	
1.4.7	To what extent is the use of the safeguard procedure effectively and consistently implemented across Member States or by the Commission?	
1.4.8	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?	
1.4.9	Are risk management measures imposed under the EU chemicals legislative framework designed in a way which makes it plausible that they are/will be complied with and to what degree are they enforceable?	
2. Efficiency		
2.1	**What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drives for those costs and benefits? A specific focus will be given to SMEs.**	
2.1.1	What are the costs associated with the chemicals legislative framework for:	
	2.1.1.1	Regulators at EU and national level
	2.1.1.2	Industry, including SMEs
	2.1.1.3	Workers, consumers
	2.1.1.4	Society / economy in general
2.1.2	If relevant, what are the transition costs (costs to implement new legislation,) and the regular costs associated with the chemicals legislative framework for each of the above-mentioned categories of stakeholders?	
	2.1.3.1	Regulators at EU and national level
	2.1.3.2	Industry, including SMEs

Table3-1: Overview of the evaluation questions for the study overall		
	2.1.3.3	Workers, consumers
	2.1.3.4	Environment
	2.1.3.5	society/economy in general
2.1.4	To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?	
2.1.5	What are the total socio-economic costs/benefits for society resulting from approaches mainly based on generic risk considerations and from specific risk assessments?	
2.1.6	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?	
2.2	**What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?**	
2.2.1	What aspects of the functioning of the framework are the most efficient?	
2.2.2	What aspects of the functioning of the framework are the least efficient?	
2.2.3	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?	
2.2.4	Are the provisions and procedures for hazard/risk identification and assessment efficient?	
	2.2.4.1	Are the procedures fast enough to identify new hazards/risks?
	2.2.4.2	Is the level of evidence required to identify hazard and risks appropriate?
	2.2.4.3	Is the burden of proof properly allocated?
	2.2.4.4	To what extent are the stakeholders able to contribute to the procedure for hazard/risk identification?
	2.2.4.5	Are the procedures and timelines sufficiently clear and reliable?
	2.2.4.6	Is there a clear interpretation of what amount and quality of data is sufficient as basis for a risk management decision?
	2.2.4.7	Are procedures able to achieve consistent and efficient conclusions?
	2.2.4.8	Are procedures for hazard/risk identification and assessment implemented in the least burdensome manner?
	2.2.4.9	To what extent are substances assessed on an individual basis and to what extent are similar substances assessed together? What differences are there in the efficiency of these approaches?
	2.2.4.10	To what extent is it efficient to assess substances which are structurally related, used for the same purpose or otherwise similar assessed individually or together?
	2.2.4.11	To what extent do the current provisions provide for assessments of chemical groups and if so are they applied? What are the pros and cons of these approaches e.g. effectiveness, efficiency, relevance.
2.2.5	Are the provisions and procedures for the adoption of risk management measures efficient?	
	2.2.5.1	Are the procedures fast enough to adopt the necessary risk management measures?
	2.2.5.2	To what extent are the stakeholders able to contribute to the procedure for the adoption of risk management measures?
	2.2.5.3	Are the procedures and timelines sufficiently clear and reliable?
	2.2.5.4	Are procedures able to achieve timely, consistent and efficient conclusions?

Table3-1: Overview of the evaluation questions for the study overall		
2.2.6	Are the risk management measures adopted efficient?	
	2.2.6.1	Are the adopted risk management measures precise and clear enough?
	2.2.6.2	Are they easy or burdensome to put in place?
	2.2.6.3	Are the transition times for duty holders upon the adoption of the new risk management measures adequate?
	2.2.6.4	Are the risk management measures enforceable in practice or easily circumvented?
	2.2.6.5	Are the risk management measures triggered at adequate time after identification of early signals of potential risks?
	2.2.6.6	Are the risk management measures triggered automatically or does their triggering depend on the discretionary intervention of one/several actor(s) involved?
	2.2.6.7	Is access to data relevant for risk assessment efficient?
2.2.7	Are the legislative provisions for risk management measures efficient?	
2.2.8.	Could the same results/effects be achieved in a more cost-effective way?	
2.2.9	Have new tools emerged enabling a more efficient risk management of chemicals? If yes, what are they?	
2.2.10	How easy is it to launch, initiate and complete the necessary procedures to identify and assess hazards and risks of chemicals?	
2.2.11	At Member State level, are there significant differences between Member States as regard the benefits, costs and administrative burdens?	
3. Relevance		
3.1	**To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)**	
3.1.1	Do the original needs still exist or are parts of the chemicals legislative framework now redundant?	
3.1.2	Have new needs emerged in relation to the risk management of chemicals? If yes, what are they?	
3.1.3	To what extent do the objectives of the legislative framework for chemicals meet the need for enabling/promoting circular economy? Are there conflicting objectives and how can they be solved? Are there synergies? Which of the risk management approaches (based on generic risk consideration or specific risk assessment) is more effective and efficient in enabling/promoting circular economy?	
3.1.4	Does the chemicals legislative framework reflect and implement the basic principles of EU environmental policy stated in article 191 of the Lisbon Treaty (i.e. the principles of precaution, substitution, polluter pays and rectification of environmental damage at source)?	
3.1.5	In particular, to what extent does the chemicals legislative framework lead to substitution of hazardous chemicals with safer alternatives or technologies where justified by human health, environmental and socio-economic considerations (e.g. by providing mechanisms and procedures for this purpose)?	
3.1.6	Does the chemicals legislative framework ensure that the scientific and technical development is taken into account on a regular basis (e.g. through periodic review of the legislation)?	
3.1.7	Is there a mechanism to ensure that the hazard identification and risk assessment are based on the latest state-of-the-art method and sufficient to identify all risks for health and environment?	
3.1.8	To what extent are the chosen approaches to risk management (based on generic risk considerations or specific risk assessment) still relevant?	
3.1.9	To what extent does the legislative framework allow for innovative approaches to hazard and risk communication?	
3.2	**To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?**	

Table3-1: Overview of the evaluation questions for the study overall		
3.2.1	To what extent is the information on chemicals provided to workers and citizens relevant and understandable? To what extent could new technologies facilitate more targeted/relevant/complete information to workers and citizens?	
3.2.2	To what extent are information requirements in the current legislative framework adequate to enable informed choices, promotion of safer alternatives, safe handling and use throughout the life cycle of chemicals and products/article?	
3.2.3	To what extent are socio-economic consequences with relevance for citizens and stakeholders taken into account in the implementation of the legislative framework?	
3.3	**To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?**	
3.3.1	To what extent do the risk assessment procedures and risk management decisions take into account the latest scientific findings?	
3.3.2	To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?	
4. Coherence		
4.1	**To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?**	
4.1.1	To what extent are the legal acts of the chemicals legislative framework consistent in attempting to reach the stated objectives?	
4.1.2	To what extent are the legal acts of the chemicals legislative framework coherent in terms of:	
	4.1.2.1	Hazard identification
	4.1.2.2	Risk assessment and risk communication
	4.1.2.3	Risk management measures and provisions
4.1.3	To what extent are the legislative provisions referring to various hazards (e.g. CMRs, PBTs, vPvBs, POPs, endocrine disruptors) coherent?	
4.1.4	To what extent are the criteria for identification of hazards coherent (e.g. PBT and vPvB criteria)?	
4.1.5	Can differences in hazard identification, risk assessment and risk management measures and provisions between different pieces of legislation be justified?	
4.1.6	To what extent does the legislative framework meet its objectives consistently in cases where the same chemical is used for different purposes and where the uses falls under different pieces of legislation?	
4.1.7	Are references to other legislation clear and unambiguous?	
4.2	**What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?**	
4.2.1	Is the chemicals legislative framework consistent in using approaches based on generic risk considerations or approaches based on specific risk assessment where these are required? If not, what are the inconsistencies?	
4.2.2	Are there inconsistencies or contradictions in what is required by the chemicals legislative framework from different actors (under different pieces of legislation)?	
4.2.3	Are there duplications or overlaps that make some parts of legislation obsolete? Are there unexpected advantages or disadvantages due to the overlaps in the legislation?	
4.2.4	Is the chemicals legislative framework consistent with wider EU policies and strategies, in particular in areas of environment and sustainability, circular economy, non-toxic environment strategy, innovation, competitiveness and job creation?	

Table3-1: Overview of the evaluation questions for the study overall	
4.2.5	Does the chemicals legislative framework establish thresholds and limit values in a coherent way?
4.2.6	Does the chemical legislative framework ensure that the substances/products are assessed under the most relevant piece of legislation, especially when a specific claim is made about its function or positive effects? Does the chemicals legislative framework enable regulators to reach evidence-based decisions and identify false claims/misleading information?
4.2.7	Are there any inconsistencies (e.g. resulting from multiple committees) as regards hazards and risk assessments performed under the chemical legislative framework?
4.2.8	Is there any inconsistency as regards format for data provisions? If yes, are they justified
4.2.9	Are there any inconsistencies as regards quality requirements for data?
4.2.10	Are there any inconsistencies in allocation of burden of proof?
4.2.11	Are there any national discrepancies in the implementation of chemicals legislation?
5. EU added value	
5.1	**What is the added value of regulating the risk management of chemicals at an EU rather than at national level?**
5.1.1	Are there national measures that could potentially reach the objectives of the chemicals legislative framework in a better way?
5.1.2	What would be the most likely consequences of withdrawing or stopping the EU intervention in terms of protecting human health and the environment, enhancing the functioning of the internal market and enhancing competitiveness and innovation?
5.1.3	Are there particular circumstances under which the regulation of chemicals is more effective at national level, and what would be the consequences for the internal market of allowing more flexibility, e.g. in the context of safeguard clauses?

Annex II: Evaluating Implementation of the CLP Regulation (Task 1 Report)

Table of Contents

1 Introduction

1.1 Scope of the evaluation

The primary objectives of the CLP Regulation are to ensure a high level of protection of human health and the environment, the efficient functioning of the internal market for chemicals and to enhance innovation and competitiveness.

The broad aim of the work under Task 1 is to assess the implementation of the CLP Regulation and the effectiveness, efficiency, coherence (internal and external), relevance and the EU added value of its classification, labelling and packaging requirements; in the process of doing this, clear conclusions need to be drawn on where and how the CLP Regulation is and is not performing appropriately against its objectives. The Task 1 findings should also provide an indication of the coherence of the CLP Regulation with GHS and, in particular, the adoption of the building blocks within the GHS and associated transition times, the harmonised classification process, and the timing of implementation of adaptations to technical progress (ATPs).

There are several complex links between the CLP Regulation and downstream (vertical) legislation, as well as horizontal legislation (such as other legislation setting classification criteria or labelling and packaging requirements). Owing to these interconnections, changes in provisions and procedures under the CLP Regulation have ramifications for other legislation (both horizontal and vertical) with the result that changes brought about by the CLP Regulation (or alterations to it through, for example, ATPs) have knock-on effects for requirements under other pieces of legislation. These, in turn, indirectly affect both the costs to industry and the benefits delivered by other legislation, in terms of providing a high level of protection for human health and the environment. Such indirect effects are considered in detail under reporting on Tasks 2 and 3.

The evaluation under this task has comprised the following main activities:

- Task 1-i: Estimation of the overall costs and benefits of implementation and of the transition from the previous EU C&L system, as well as an assessment of the costs that would have been avoided under different approaches. This is to include consideration of the impacts of moving from a directive based system to a regulation, any national differences in implementation of the CLP Regulation, and the costs and benefits of the harmonisation of information requirements across poison centres. It will also examine the impacts from different provisions, for example, CLP packaging requirements (in particular child resistant closures and tactile warning devices), labelling requirements, obligations placed on regulators and authorities, etc. The work is also to draw on the cumulative costs and the cumulative benefits studies, as well as the 2006 Impact Assessment for the implementation of CLP;

- Task 1-ii: Assessment of the process for choosing building blocks within GHS for adoption within the EU, including the impact of the 2nd and 4th ATP on the choices made in relation to transition times on the costs to businesses;

- Task 1-iii: Comparison of the EU implementation of the GHS with the systems in other main countries, with this including a case study on the consequences for the competitiveness of EU companies;

- Task 1-iv: Assessment of the existing processes on harmonised classification, and their relevance, effectiveness and efficiency, as well as the impacts of transition times on businesses and in relation to health and the environment;

- Task 1-v: Assessment of past uses of the urgency procedure and the safeguard clause and the impacts of these, as well as the ability of stakeholders to comment before decision making; and

- Task 1-vi: Summarising the elements of the above analyses together to draw conclusions on the performance of the CLP Regulation against its objectives.

The above work has been informed through a mix of desk-based research, interviews, targeted data collection and responses to the open public consultation. As noted for Task 1-iii above, it is also supported by a case study which looks at the implementation of GHS globally, comparing the impacts of differences in the uptake of building blocks for costs, competitiveness, human health and the protection of the environment. In addition, a case study on metals classification has been undertaken, supporting the Task 1-i work in terms of classification rules under CLP. Both of these case studies are currently being finalised but are not reported on at this stage.

The evaluation questions set out in the Introduction to this report (Section 0) were mapped across the various sub-tasks listed above, to identify those that should be answered, at least in part, through the Task 1 evaluation. In order to report against both the sub-tasks and the evaluation questions, a set of themes has been developed to act as the basis for reporting. Each of these themes provides reporting in relation to one of the sub-tasks (in whole or in part) and against one or more specific evaluation questions.

1.2 Organisation of Task 1 reporting

In order to provide a context for reporting on the evaluation against the six sub-tasks and associated evaluation questions, we start the discussion below (Section 2) with an overview of the requirements of CLP and the timing of its implementation in the EU. The aim here has not been to provide a detailed summary of the Regulation, but to introduce its key elements.

This introduction is then followed by discussion of the evaluation findings, which have been organised under the following 'themes':

- Section 3: Scope of CLP
- Section 4: Hazard identification and assessment under CLP
- Section 5: Harmonised classification
- Section 6: Impacts of the transition to CLP
- Section 7: On-going impacts of CLP implementation
- Section 8: Obligations in relation to the CLI and Poison Centres
- Section 9: Impacts of choosing building blocks and of transition times
- Section 10: Safeguard clause and urgency procedure
- Section 11: International comparison of GHS implementation
- Section 12: Enforcement
- Section 13: Overarching evaluation

Although a key aim and component of CLP is hazard communication, this aspect of the Regulation is not addressed in this section of the report. Instead, this is considered under the Task 2 reporting, which considers hazard communication across the range of relevant chemicals legislation.

One must note that some of the issues reported on here are not necessarily a result of CLP itself; in some cases, these issues were also present under the previous legislation relating to the management of chemicals (i.e. the Dangerous Substances Directive and the Dangerous Preparations Directive).

2 Overview of CLP Requirements

2.1 Introduction

Prior to CLP, the classification and labelling (C&L) of chemicals and mixtures was implemented primarily through three Directives:

- The Dangerous Substances Directive (67/548/EEC);
- The Dangerous Preparations Directive (1999/45/EC); and
- The Safety Data Sheet Directive (91/155/EC, as amended by 2001/58/EC).

In common with the current CLP, the main objectives of the previous system were to identify and communicate via Safety Data Sheets (SDS) and labelling requirements:

- Physicochemical hazards (explosive, oxidising and flammable properties);
- All toxicological properties of substances and preparations, which may constitute a risk during normal handling or use (effects on the health); and
- Ecotoxicological hazards (acute or long-term toxicity to aquatic or non-aquatic ecosystems).

Being a Directive led system, the common EU requirements for classification and labelling were implemented through legislation adopted at the Member State level (rather than being established by Community Regulation as now). The EU system of classification and labelling was generally considered to be one of the most effective and robust systems globally. However, at the time, different systems for the classification and labelling of substances and preparations/mixtures existed in different jurisdictions around the world. Whilst many of the requirements of the different legal jurisdictions were similar, their differences were significant enough to result in multiple labelling requirements for the varying health and safety information that had to be provided for the same product in different countries and/or markets.

As a result of these multiple systems of classification, there was recognition that companies involved in the international trade in chemicals had to closely follow the laws and regulations in each of the destination countries, prepare different labels and Safety Data Sheets (SDS) for the different jurisdictions, and keep themselves up to date with any changes to the regulations operating in multiple countries/jurisdictions.

Given the reality of the extensive global trade in chemicals, and the need to develop national programmes that ensure their safe use, transport and handling by emergency response teams, it was recognised internationally that there was a need for a globally harmonised approach. In 1992, the UN Conference on Environment and Development (UNCED) in Rio de Janeiro identified harmonisation as an action programme under Agenda 21 and more than a decade of work followed at national and international levels to develop a Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The GHS was then formally adopted by the United Nations (UN) in July 2003 and the World Summit on Sustainable Development encouraged countries to implement the new system as soon as possible (with a view to it being fully operational by 2008).

Thus, implementation of the GHS became the main driver for changing the system of classification and labelling in the EU. The GHS itself brought together the major world classification and labelling (C&L) systems into one single new system, with three main elements:

- A globally harmonised classification system for chemical substances;
- A globally harmonised classification system for mixtures/preparations; and
- A globally harmonised system for hazard communication for workers, consumers and in transport (which includes labelling and safety data sheets (SDS)).

It was anticipated that the GHS would enhance protection of human health and the environment at an international level and provide a recognised framework for those countries without an existing system. At the EU level, however, the existing system was considered to provide a high level of protection already and this was not expected to change significantly. Indeed, analysis of the scope of GHS suggested that it was not significantly different from the system already operating in the EU. As such, (and as identified in the Commission's Impact Assessment of moving to the GHS in 2007) no significant human health or environmental benefits were foreseen in the EU itself.

2.2 Implementation of GHS by CLP

The UN GHS is based on a building block approach, which was introduced to facilitate its implementation across regions, due to differences in existing classification, labelling and packaging systems. The intention within the GHS is that the currently allowed for variance will not become permanent within sectors (although variations across sectors may remain, e.g. transport versus the supply and use of chemicals), so as to ensure that a consumer in one region has the same hazard information on a label as a consumer in another region. This aim can be seen from paragraph 1.1.3.1.5 of GHS:

> "*…is hoped that the application of the GHS worldwide will eventually lead to a fully harmonised situation…"… "Therefore, while differences between sectors may persist, the use of an identical set of categories at a worldwide level* within *each sector should be encouraged".*

There are three main hazard groups within the UN GHS:

- physical hazards;
- health hazards; and
- environmental hazards.

Within each of these hazard groups there are classes and categories. Each of these parts is called a building block. Each country can determine which building blocks of the GHS it will use in their different sectors (workplace, transportation, consumers). Once the building blocks are chosen, the corresponding GHS rules for classification and labelling must be used.

The CLP Regulation applies to substances, mixtures and certain articles placed on the EU market, with some exceptions[1]. It applies to the workplace and consumers, but does not cover classification for transport purposes (which is covered by Directive 2008/68/EC), although it does set out certain rules regarding the labelling of outer packages used for transport.

[1] It does not apply to radioactive substances and mixtures; substances and mixtures which are subject to customs supervision, non-isolated intermediates; substances and mixtures for scientific research and development, which are not placed on the market provided they are used in controlled conditions; waste as defined in Directive 2006/12/EC; and substances and mixtures that are classified under other EU legislation and falling under Article 5.

The CLP adopts all hazard classes set out in the UN GHS building block approach. Some of the hazard categories within the different hazard classes were not taken up, however, because they were not reflected in the preceding Dangerous Substances Directive and Dangerous Preparations Directive requirements and would also not have been consistent with information requirements on substance properties under the REACH Regulation. Although the number of hazard classes has increased, in particular for physical hazards (from 5 to 16) to enable greater differentiation of hazardous, physical properties[2], in implementing GHS the CLP did not generally go beyond the "safety level" as provided in the Dangerous Substances Directive. Some supplemental labelling elements which were part of the Dangerous Substances Directive and Dangerous Preparations Directive were kept in CLP even though they are not included within the GHS.

The Regulation entered into force on 20th January 2009. Article 61 sets out the transitional provisions for implementation of the Regulation's requirements, with this specifying the dates for its application to substances and mixtures, as follows:

- 20 January 2009: CLP Entry into force. Dangerous Substances Directive/Dangerous Preparations Directive classification, labelling and packaging provisions still apply. CLP may be applied but the Dangerous Substances Directive/Dangerous Preparations Directive classification details must still be provided for substances and mixtures;
- 1 December 2010: Substances must be classified under both CLP and the Dangerous Substances Directive with labelling and packaging under CLP, only. Dangerous Preparations Directive classification, labelling and packaging provisions still apply for mixtures. CLP may be applied but Dangerous Preparations Directive classification details must still be provided for substances and mixtures;
- 1 June 2015: Dangerous Substances Directive/Dangerous Preparations Directive repealed; classification, labelling and packaging of substances and mixtures according to CLP only; and
- 1 June 2017: Mixtures classified, labelled and packaged under the Dangerous Preparations Directive and already placed on the market before 1 June 2015 must now be relabelled and repackaged according to CLP.

2.3 Obligations under CLP

CLP places obligations on a range of different actors, including manufacturers and importers of substances and/or mixtures, producers of specific types of articles, downstream users where this includes formulators or re-importers, and distributors including retailers. These obligations apply regardless of tonnage and before a substance or mixture is placed on the market in the EU. It also places obligations on Member State Authorities and on the European Chemicals Agency (ECHA). These obligations are set out in Table 2-1 below.

[2] ECHA (2015): Introductory Guidance on the CLP Regulation, Version 2.1.

Table 2-1: Roles and obligations under CLP

Obligations placed on different actors by the CLP can be summarised as follows.

1) Manufacturers and importers:
   a. Classification, labelling and packaging of substances and mixtures before they can be placed on the market
   b. Classify substances not placed on the market subject to registration or notification under REACH (including substances used for product and process-orientated research and development – PPORD)
   c. Notify classification and labelling elements for substances placed on the market in the EU as well as substances imported in mixtures or articles to the Classification & Labelling Inventory managed by ECHA
   d. Keep abreast of scientific and technical information and re-evaluate classifications when new information that may affect the classification becomes available
   e. Update labels for changes in classification
   f. Notify ECHA regarding new information relevant to harmonised classifications
   g. Assemble and keep available all information required for classification and labelling for a period of at least 10 years after last supply.

2) Downstream users (formulators and re-importers):
   a. Classification, labelling and packaging of substances and mixtures before they can be placed on the market (including in the event of a change of composition)
   b. Keep abreast of scientific and technical information and re-evaluate classifications when new information that may affect the classification becomes available
   c. Update labels for changes in classification
   d. Notify suppliers regarding new information relevant to harmonised classifications
   e. Assemble and keep available all information required for classification and labelling for a period of at least 10 years after last supply.

3) Distributors:
   a. Label and package the substance and mixtures placed on the market
   b. Ensure that packaging is in line with CLP requirements
   c. Update labels and packaging on the basis of new information
   d. Assemble and keep available all information required for classification and labelling for a period of at least 10 years after last supply.

4) Producers of articles:
   a. Conform to CLP requirements if producing and marketing an explosive article
   b. Classify substances not placed on the market subject to registration or notification under REACH
   c. Update labels and packaging based on new data.

5) Authorities:
   a. Proposals for and agreement of harmonised classifications (i.e. a CLH dossier)
   b. Establishment of a national helpdesk
   c. Establishment of a body or bodies (i.e. poison centres) to be responsible for receiving information on mixtures placed on the market relating to emergency health responses
   d. Enforcement.

6) ECHA:
   a. Management of the C&L Inventory
   b. Overseeing the Scientific Committee process for agreement of harmonised classifications (i.e. a CLH dossier)
   c. Operation of a centralised helpdesk
   d. Managing online system for handling downstream user requests relating to Article 24
   e. Overseeing the Forum and its practices and projects relating to enforcement and implementation of CLP

Although there are many similarities in what is required under the CLP with what was required under the Dangerous Substances Directive and Dangerous Preparations Directive, in replacing these directives the CLP Regulation introduced changes that may have given rise to additional costs and/or benefits compared to the old system. For manufacturers of substances and mixtures, distributors and importers these changes include:

- The need for self-classification for some new hazard classes and categories (particularly for physical hazards);
- Differences in classification criteria or in cut-off points for classification, which may have had an indirect effect in relation to reformulation or decisions on product portfolios (e.g. in relation to newly classified CMR substances);
- Changes in and new approaches for classifying mixtures;
- Changes in some labelling requirements;
- Changes in packaging requirements for substances and mixtures given certain classifications;
- Changes to the systems for agreeing harmonised classifications (CLH) at the EU level;
- The need to notify self-classifications for substances placed on the market to ECHA, who maintain the Classification and Labelling Inventory (CLI) with the aim of making such information publicly available; and
- Obligations under the urgency procedure and safeguard clause.

The CLP also introduced revised provisions and procedures for agreement of the harmonised classification and labelling of substances at the EU level. Other provisions introduced by the CLP Regulation for Member States and ECHA that are changes from the Dangerous Substances Directive and the Dangerous Preparations Directive include:

- The establishment of help desks;
- The appointment of responsible bodies for receipt of information relating to emergency health response as part of the European system of poison centres; and
- For ECHA, a series of obligations in relation to its role as implementing Agency.

For the sake of brevity, the details of each of these changes are not discussed further here, but are elaborated on below as part of the more detailed assessment.

3 Scope of CLP

3.1 Introduction

As noted above, the CLP legislation does not apply to substances and mixtures that are classified under other EU legislation and falling under Article 1(5). This includes substances and mixtures in the following forms (in the finished state, intended for the final user):

- Medicinal products as defined in Directive 2001/83/EC;
- Veterinary medicinal products as defined in Directive 2001/82/EC;
- Cosmetic products as defined in Directive 76/768/EEC;
- Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;
- Food or feeding stuffs as defined by Regulation (EC) No. 178/2002, when they are used (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC; (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217.EC; (iii) as an additive in feeding stuffs within the scope of Regulation (EC) no 1831/2003; and (iv) animal nutrition within the scope of Directive 82/471/EEC.

Member State authorities in particular have commented on whether or not it is appropriate that substances and mixtures falling under such legislation should be exempted. This is considered further below, with the relevant evaluation questions being as follows.

Table 3-1: Evaluation questions to be addressed relating to efficiency of procedures

Q #	Evaluation Question
1.1.1.5	Are there any gaps in ensuring a high level of protection of human health and the environment? If yes, what are they?
1.1.4.2.	Is the chemicals legislative framework as effective as it can be? Are there factors that limit the effectiveness of the chemicals legislative framework and would they be avoidable?
1.1.4.3	To what extent does the chemical legislative framework requires/encourage Member States to further reduce exposure of humans and/or the environment to hazardous chemicals and are these requirements sufficiently implemented?
4.1.2.1	To what extent are the legal acts of the chemicals legislative framework coherent in terms of: - Hazard identification
4.2.2.	Are there inconsistencies or contradictions in what is required by the chemicals legislative framework from different actors (under different pieces of legislation)?

3.2 Coherence (including gaps and inconsistencies)

Key findings:

- Gaps and inconsistencies in classification and labelling have been identified with respect to linkages between CLP and the Cosmetics Regulation, the legislation on food and feeding additives and medical devices
- These gaps are considered to impact on the effectiveness of the framework in ensuring a high level of protection of human health and the environment as well as potentially leading to confusion for some employers and/or consumers

Member State authorities and NGOs have identified a series of gaps and inconsistencies with the legislative framework, in terms of linkages between sector legislation and CLP classification and labelling requirements. The key gaps or inconsistencies that have been identified are as follows:

- **Cosmetic Products Regulation**: several Member States noted that the Cosmetic Products Regulation does not provide for the same level of protection as the CLP with respect to the classification and labelling of cosmetic products for environmental hazards. There are no requirements under the Cosmetic Products Regulation for classification for intrinsic environmental hazard properties, as these are considered to be dealt with under REACH. Although REACH may ensure safe use of individual raw materials, it does not address the hazards of mixtures such as cosmetics. This gap is therefore considered to result in a lack of information for consumers and authorities;

- **Food and feeding additives**: Member States note that because food and feeding additives in their finished state are exempted from classification and labelling, there is a lack of information available to both employers and consumers on their intrinsic hazard properties. Member States note that this gap also reflects an inconsistency because these same products may be subject (as they can be toxic and corrosive) to labelling under international transport requirements (ADR) and are subject to risk management as appropriate under the Seveso III Directive. The Commission has noted though that these chemicals do not benefit from the exemption as, in practice, feed additives and premixtures are neve to be fed to animals as such, and some handling (e.g. mixing with water) is always required[3];

- **Medical devices**: The derogation for medical devices in Article 1(5) of CLP is not written in the same way as the derogation under REACH and therefore represents an inconsistency. This leads to the situation where there is no labelling obligation for medical devices which would otherwise require classification and labelling under CLP, but there is a need for these devices to have a safety data sheet (SDS) under REACH. It is not clear that this relates to a significant gap in hazard communication, however, although this may be the case where medical devices are supplied directly to end consumers who may be unable to understand the information provided in a SDS.

[3] An FAQ to this effect is in preparation.

The above gaps and inconsistencies in the scope of CLP are also considered to lead to gaps in the extent to which the legislative framework ensures a high level of protection of human health and the environment, as well as the extent to which it enhances the single market and competitiveness.

- **Cosmetic products**: The lack of information on environmental hazards impacts on the ability of authorities to identify the ingredients within these products that may require regulatory action so as to reduce the environmental impacts of chemicals. It also impacts on the ability of consumers to move to cosmetic products which are more environmentally friendly in terms of their hazard profiles. This may also further enhance competitives within the single market, by providing greater information to consumers and allowing them to better differentiate between products. The environmental benefits of such a chain of effects could be significant, as most cosmetics will end up in the environment (e.g. through volatisation or through being washed off after use), and there have been examples of regulatory action in the past due to the hazards that chemicals in such products can pose (e.g. siloxanes, nonylphenols and their ethoxylates).

- **Cosmetic products and food and feed additives**: The lack of classification data together with a lack of Safety Data Sheets (SDS) for cosmetics and food/feed additives are also considered to lead to an information gap for employers and employees. Authorities note that the assessment of substances and mixtures used in cosmetics is based on safe levels for consumer use. As a result, exposure scenarios for professional users (like hair dressers and those involved in food production) are inadequate or neglected. This can result in the employer falsely perceiving that a substance/mixture can be used safely in the work environment (under Occupational Health and Safety legislation (OSH)) as the substance/mixture is not considered hazardous under other legislation (e.g. under cosmetics legislation or waste legislation).

Related issues with respect to cosmetics are picked up in more detail under Task 3. The inconsistencies identified above for food and feed additives labelling and risk management and for medical devices, have not been identified by the study team as leading to significant health and environmental impacts, or impacts in relation to the single market or trade and competition; no supporting evidence was provided in this respect either. However, these are also likely to lead to confusion and could lead to some employers or consumers having an inadequate level of information on the hazardous properties of such products.

4 Hazard Identification and Assessment under CLP

4.1 Introduction

As noted in Section 2, the CLP sets out requirements for the classification of substances and mixtures placed on the EU market for hazard identification purposes. As part of the evaluation, a range of issues have been considered with respect to these requirements of the CLP:

- the appropriateness of the CLP classification system;
- the effectiveness and efficiency of the mixture classification rules;
- classification rules for metals and special mixtures;
- the quality of data, scientific developments and innovation; and
- variations in self-classifications.

Information from targeted consultation, the open consultation, case study desk based reviews and case study interviews are used to inform the discussion set out below.

4.2 Appropriateness of the CLP classification system

4.2.1 Introduction

The CLP sets out three types of hazard classes, these are physical hazards, health hazards and environmental hazards. Guidance on these is set out for each of these, including a definition for each hazard class, information on classification criteria, hazard communication information and where applicable additional classification considerations. The full list of physical, health and environmental hazards are set out in Table 4-2. The relevant evaluation questions are set out in Table 4-1 below.

Table 4-1: Evaluation questions to be addressed relating to hazard identification and assessment

Q #	Evaluation Question
1.1.1.2.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the combination effects of chemicals (simultaneous exposure to chemicals)?
1.1.1.5.	Are there any gaps in ensuring a high level of protection of human health and the environment? If yes, what are they?
1.1.1.7.	Are data requirements (on hazards, uses and exposures) in the chemical legislative framework adequate to identify and assess all risks to human health and the environment for all substances and uses?
1.1.1.8.	Is the scientific data on which the regulatory decisions are based of good quality, complete and reliable? Are quality requirements (e.g. GLP) appropriate?
1.1.2.3.	Are the information requirements on chemicals (including on e.g. chemical content, hazard, risk, use) and the availability of this information sufficiently clear to allow their harmonised application throughout the single market?
1.1.4.1.	To what extent are the classification rules for mixtures fit for purpose (e.g. for metal alloys)?

Table 4-1: Evaluation questions to be addressed relating to hazard identification and assessment	
Q #	**Evaluation Question**
1.4.1.	Are the main elements of the EU legislative framework for the risk management of chemicals effectively and consistently implemented across all Member States?
1.4.2.	If there is a disparity in the way legislation is implemented, what are the consequences of such a disparity?
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?
2.1.6.	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
2.2.4.2	Are the provisions and procedures for hazard/risk identification and assessment efficient? Is the level of evidence required to identify hazard and risks appropriate?
2.2.4.9.	To what extent are substances assessed on an individual basis and to what extent are similar substances assessed together? What differences are there in the efficiency of these approaches?
2.2.4.10.	To what extent is it efficient to assess substances which are structurally related, used for the same purpose or otherwise similar assessed individually or together?
3.1.1.	Do the original needs still exist or are parts of the chemicals legislative framework now redundant?
4.1.2	To what extent are the legal acts of the chemicals legislative framework coherent in terms of: 4.1.2.1. Hazard identification
4.2.11.	Are there any national discrepancies in the implementation of chemicals legislation?

Table 4-2: Physical, health and environmental hazards set out in the CLP Regulation		
Physical hazards	**Chapter**	**Hazard Statements and Classification**
Explosives	2.1	H200: Unstable Explosive H201: Explosive; mass explosion hazard H202: Explosive; severe projection hazard H203: Explosive; fire, blast or projection hazard H204: Fire or projection hazard H205: May mass explode in fire
Flammable gases	2.2	H220: Extremely flammable gas H221: Flammable gas
Flammable aerosols and aerosols	2.3	H222: Extremely flammable aerosol H223: Flammable aerosol
Oxidising gases	2.4	H270: May cause or intensify fire; oxidiser
Gases under pressure	2.5	H280: Contains gas under pressure; may explode if heated H281: Contains refrigerated gas; may cause cryogenic burns or injury H280: Contains gas under pressure; may explode if heated
Flammable liquids	2.6	H224: Extremely flammable liquid and vapour H225: Highly flammable liquid and vapour H226: Flammable liquid and vapour
Flammable solids	2.7	H228: Flammable Solid

Table 4-2: Physical, health and environmental hazards set out in the CLP Regulation			
Self-reactive substance/mixture	2.8	H240: Heating may cause an explosion H241: Heating may cause a fire or explosion H242: Heating may cause a fire	
Pyrophoric liquids	2.9	H250: Catches fire spontaneously if exposed to air	
Pyrophoric solids	2.10	H250: Catches fire spontaneously if exposed to air	
Self-heating substance/mixture	2.11	H251: Self-heating; may catch fire H252: Self-heating in large quantities; may catch fire	
Water-reactive - emits flammable gases	2.12	H260: In contact with water releases flammable gases which may ignite spontaneously H261: In contact with water releases flammable gases	
Oxidising liquids	2.13	H271: May cause fire or explosion; strong oxidiser H272: May intensify fire; oxidiser	
Oxidising solids	2.14	H271: May cause fire or explosion; strong oxidiser H272: May intensify fire; oxidiser	
Organic peroxides	2.15	H240: Heating may cause an explosion H241: Heating may cause a fire or explosion H242: Heating may cause a fire	
Corrosive to metals	2.16	H290: May be corrosive to metal	
Health hazards	**Chapter**	**Hazard Statements and Classification**	
Acute toxicity	3.1	Oral	H300: Fatal if swallowed H301: Toxic if swallowed H302: Harmful if swallowed
		Dermal	H310: Fatal in contact with skin H311: Toxic in contact with skin H312: Harmful in contact with skin
		Inhalation	H330: Fatal if inhaled H331: Toxic if inhaled H332: Harmful if inhaled
Skin corrosion / irritation	3.2	H314: Causes severe skin burns and eye damage H315: Causes skin irritation	
Eye damage / irritation	3.3.	H318: Causes serious eye damage H319: Causes serious eye irritation	
Respiratory / skin sensitisation	3.4	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled H317: May cause an allergic skin reaction	
Mutagenicity	3.5	H340: May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H341: Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	
Carcinogenicity	3.6	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H351: Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	
Toxic for reproduction	3.7	H360: May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H361: Suspected of damaging fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	

Table 4-2: Physical, health and environmental hazards set out in the CLP Regulation			
		H362: May cause harm to breast-fed children	
Specific target organ toxicity (STOT - single exposure)	3.8	H370: Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H371: May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H335: May cause respiratory irritation H336: May cause drow-siness or dizziness	
Specific target organ toxicity (STOT - repeated exposure)	3.9	H372: Causes damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) H373: May cause damage to organs (state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	
Aspiration hazard	-	H304: May be fatal if swallowed and enters airways	
Environmental hazards	**Chapter**	**Hazard Statements and Classification**	
Hazardous to the aquatic environment	4.1	Acute	H400: Very toxic to aquatic life
		Chronic	H410: Very toxic to aquatic life with long lasting effects H411: Toxic to aquatic life with long lasting effects H412: Harmful to aquatic life with long lasting effects H413: May cause long lasting harmful effects to aquatic life
Hazardous to the ozone layer	5.1	H059: Hazardous to the Ozone Layer	

4.2.2 Properties of concern

Key findings:

- Most consultees agree that CLP is appropriate for identifying health, environmental and physical hazards.
- Consultees have suggested that certain hazard classes are lacking in CLP, with the most important being: endocrine disruption, persistence, bioaccumulation, and persistent organic pollutant (POP).
- Classification for terrestrial hazards is missing under CLP.
- Over-classification due to the thresholds set under the CLP system for skin corrosion/irritation and eye damage/irritation has been raised as an issue by most groups of stakeholders, and also for reproductive toxicity and carcinogenicity by a sub-set.
- There is significant variability in self-classifications; although these may be justifiable to some extent, the wide variation also raises concerns over the reliability of the data on which self-classifications have been based.

The effectiveness of CLP in ensuring a high level of health and environmental protection depends in part on whether it requires classification and labelling against the appropriate set of hazardous properties, or there are key properties which are not within its scope. As a result, as part of the consultation process, a question asked whether it was appropriate for properties of concern (Persistent Organic Pollutant (POP), Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB), endocrine disruption and allergenic properties) to be identified and classified in other EU legislation but not in CLP.

Firstly, it is important to note that stakeholders, for the most apart, agree that CLP is appropriate for identifying hazards to human health and the environment. This is the overwhelming view of consultees, Member States and industry consultees, as well as NGOs, although gaps were identified. Key responses from consultees are as follows (see also Section 4 of the Task 2 report):

- Multiple NGOs indicated that they believe that no existing hazard classes should be removed from CLP, and that hazard categories which cover endocrine disruption, neurotoxicity, allergenic properties, biodegradation, and persistence (P), bioaccumulation (B) (to inform on PBT/vPvB) should be added to CLP (even though some of these already exist in CLP (sensitisation) and others are not hazard categories per se, but properties);
- Three Member State authorities also identified gaps in CLP in relation to endocrine disruption, Persistent Organic Pollutant criteria (for POPs), P and B (for PBT and VPvB determination), and classification for the terrestrial environment;
- Two Member States also identified that bee toxicity should be considered for classification purposes;
- One Member State suggested that substances that could reach groundwater, i.e. those that are persistent, mobile and toxic (PMT) should be considered.
- A Member State also suggested broadening the class "Hazardous to the aquatic environment" to "Hazardous to the environment". It was argued that this is important as there is no longer any indication of danger – e.g. "Dangerous to the environment" - as there was under the Dangerous Substances Directive and Dangerous Preparations Directive; and
- Another Member State indicated that a classification approach was needed for powders that can emit hazardous amounts of particles when handled, with this concern mainly focused on lung impact from insoluble particles.
- Finally, a manufacturer identified a gap in relation to the GHS classification for 'Dust Explosion for solids' which is implemented in other jurisdictions such as the US and should be brought into the EU for greater harmonisation purposes.

The gaps listed in the first two bullet points were raised at the Workshop[4] held on the 19th April to support this study. In fact, neurotoxicty can be covered by STOT by specifying the affected organs and also by the hazard class on toxicity for reproduction (developmental effect). Furthermore, as noted by several Member States, there are already criteria for classification in relation to biodegradation and allergens (in terms of skin and respiratory sensitisation) within CLP, and these are considered adequate.

With respect to the terrestrial environment, it was suggested that the Commission may need to review the circumstances under which a building block for terrestrial hazard might be useful. This

[4] RPA et al (2016): Report on the Stakeholder Workshop, deliverable as part of the Study on the Regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), and in particular the CLP Regulation and related legislation, May 2016.

could be reviewed once a larger body of soil organism toxicity data have been generated under REACH. This suggestion has merit, especially given the role that CLP plays in acting as the basis for classification in legislation such as the Biocidal Products Regulation and Plant Protection Products Regulation. In any event, Member States and most other stakeholders recognised that adding classes to CLP would require changes at the UN level before they could be introduced into CLP. It is worth noting that, in the past, extensive discussions took place as to whether or not terrestrial hazards should be included in the GHS. However, proposals submitted by some Member States were not supported by the SCE GHS (UN Sub-Committee of Experts on GHS).

Although not a property *per se*, NGOs also noted that there is the lack of an explicit reference to nanomaterials in the CLP Regulation, with multiple NGOs identifying this as a gap. This comment disregards the fact that under Article 8, the CLP Regulation applies to all substances and mixtures, and the forms "in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used", which can also cover the nanoform of the substance.

With regard to the classification rules adopted from the GHS building blocks, one Member State authority noted that some GHS criteria are stricter than under the Dangerous Substances Directive and Dangerous Preparations Directive, resulting in more conservative classifications in some cases and more substances being placed into higher hazard categories within the hazard class; in this respect, toxic for reproduction, carcinogenicity and corrosivity (skin corrosion/irritation and eye damage/irritation) are identified as classes where this is arising. Although the Member State indicates that this was expected, it suggests that the Commission should review whether this approach is proportionate and appropriate, and whether Member States should take action at the GHS level to resolve these issues.

This issue, albeit from a different perspective, has also been raised by industry stakeholders. As discussed in the Task 2 report on hazard communication, there is widespread concern amongst both Member State authorities and industry that perceived over-classification in relation to corrosion/irritation is leading to hazard labels being attached to a broad range of products. It is worth noting that over 68,000 substances (around 55%) on the CLI hold a classification for skin corrosion/irritation (see also Section 7.3), and 73,655 substances (around 59%) are classified for eye damage/irritation (as of the 15th July 2016).

Industry has not expressed a similar concern with respect to reproductive toxins (the CLI holds 4,354 notified substances classified as Rep 1A, 1B or 2). Concern has been expressed by industry, however, in relation to carcinogens (there are currently 4,343 substances notified to the CLI as Carc. 1A, 1B or 2), but this is with respect to the opinions coming out from the CLH process being considered to over-classify (i.e. to be over-precautionary). This latter issue is discussed in more detail in Section 5.

In response to the targeted consultation, some manufacturers, importers, distributers and formulators of chemicals suggested that the text in CLP related to the classification process is far too complicated with extensive use of cross referencing, and that the right information is hard to find. It was suggested that CLP is technical legislation which requires companies to have a high level of knowledge and experience, which is also something that is required under other legislation such as the Biocidal Products Regulation and Plant Protection Products Regulation. As a result, companies had to assign appropriate resources to manage the process or engage external consultants. It was suggested that there needed to be easier to understand versions of ECHA's guidance with an increased use of flow charts to guide users through classification steps. It was also suggested that improved information on links with requirements under transport regulations would help.

However, many other industry stakeholders have suggested that CLP is a considerable improvement on the Dangerous Substances Directive and Dangerous Preparations Directive and is much more systematic, and how to classify substances is more readily understood.

4.2.3 Potency, routes of exposure and other CMR issues

Key findings

- The issue of including potency considerations into future CMR classifications has recently been raised by stakeholders and in recent literature
- Although classification of carcinogens can include an indication of the relevant route of exposure, there are questions over the degree to which this is then taken into account when risk management is automatically triggered in downstream legislation

In response to the Fitness Check Open Public Consultation, a paper by Hennes *et al* (2014)[5] was provided which discusses the potential for including potency as a means an indicator of the degree of hazard into classification. The issue of potency and how to take it into account was also raised at the Stakeholder Workshop (19th April 2016) and its potential application is outlined further below.

In considering the issue of potency and the paper by Hennes *et al*, it is important to recognise that CMR classification under CLP is based on (potential) effects rather than the relationship between exposure and effect. However, it has long been accepted that CMRs have differing levels of 'potency', with some substances producing significant effects at very low doses (notably dioxins). Such considerations were embodied in the guidelines for setting specific concentrations of CMRs in mixtures under the Dangerous Substances Directive[6] which have been carried forward to the current ECHA guidance[7].

Hennes *et al* (2014) suggest that 'potency' considerations should be carried forward into CLP classifications as summarised in the table below.

[5] Hennes, C., et al (2014): Incorporating potency into EU classification for carcinogenicity and reproductive toxicity, Regulatory Toxicology and Pharmacology 70, 457–467.

[6] European Commission (1999): *Guidelines for Setting of Specific Concentration Limits for Carcinogens in Annex I of Directive 67/548/EEC - Inclusion of Potency Considerations,* prepared by the Commission Working Group on the Classification and Labelling of Dangerous Substances http://bookshop.europa.eu/en/guidelines-for-setting-specific-concentration-limits-for-carcinogens-in-annex-i-of-directive-67-548-eec-pbCR2399572/

[7] ECHA (2015): Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 https://echa.europa.eu/documents/10162/13562/clp_en.pdf

Table 4-3: Classification taking account of 'potency'			
Current CLP Classification	Proposed classification* taking account of 'potency'		
	High Potency	Medium Potency	Low Potency
1A (known human CMR)	1A	1A	1B
1B (presumed human CMR)	1B	1B	2
2 (suspected human CMR)	1B	2	Not classified
** Based on Hennes C et al (2014) Incorporating potency into EU classification for carcinogenicity and reproductive toxicity, Regulatory Toxicology and Pharmacology 70, pp457–467.*			

While there is merit in the view that more regulatory attention should be given to CMRs with a greater potency to cause harm, the focus of much of the downstream legislation is on avoiding exposure to (potential) CMRs – i.e. it is 'hazard based' legislation. Unfortunately, exposure to a CMR with a low potency does not equate to a 'zero' risk and, thus, does not meet the requirements of a more precautionary hazard based approach. Nevertheless, for low potency substances, there is a case to be made for applying a less stringent classification, especially as some downstream legislation is risk-based (or allows risk-based derogations).

Industry has also noted that, under CLP, the classification of a cat 1A or cat 1B carcinogen may be qualified in terms of the associated route of exposure. For example, the Hazard statement: H350 can be qualified by the addition of the relevant route of exposure – such as inhalation – where the risk is only via a single route. Similarly, the H351 hazard statement can include the applicable route of exposure for a cat 2 carcinogen. This is similar to the classification system under the Dangerous Substances Directive and Dangerous Preparations Directive, and is considered important to communicating more specific information on the nature of the hazard.

In contrast, for reproductive toxins, there is a loss of such specific information. Under the Dangerous Substances Directive, a substance classified as toxic to reproduction cat 1 or 2 would be assigned the symbol 'T' and the Risk-phrase: R60 "May impair fertility", or the Risk-phrase: R61 "May cause harm to the unborn child". There was also the Risk-phrase R64 "May cause harm to breastfed babies". However, under CLP, the Risk-phrase is replaced for cat 1A and 1B reproductive toxins by the Hazard-statement: H360 "May damage fertility or the unborn child"; there is also the Hazard-statement: H362 "May cause harm to breastfed children". This is considered to reflect a loss of information in terms of downstream communication (i.e. is the issue related to fertility in male workers or for female/ pregnant workers) so as to ensure the most appropriate risk management.

These points underlie an additional concern with regard to the role of a CLP classification in triggering risk management under downstream legislation, as discussed in the Task 3 report. The information on the relevant route of exposure, where it is via a single route, appears to be ignored within these triggers (or at least some of these triggers). An example currently being given by industry where it is feared this will be the case is that of ethanol. It is presumed that the rationale for ignoring information on the route of exposure is based on arguments over the need to be precautionary with respect to exposures to carcinogens. However, this may also be leading to over-regulation where the route of exposure (e.g. via oral route inhalation, inhalation, etc.) is not feasible in the products covered by downstream legislation (for example REACH Annex XVII prohibits the sale to the general public of substances that are classified as CMR cat 1A or 1B or of mixtures containing them at levels above the specific concentration limit).

4.2.4 Other issues

Under CLP, differentiation between the different "severity/severities of hazards" of a substance, e.g. as a result of concentrations or physical states, is possible if respective data are available. The lead metal example illustrates this in the case of substances, and in particular metals (see Case Study 12 and 8), where differentiation between the massive and powder forms has led to variations in classification for environmental hazards and differences in specific concentration limits.

ECHA has noted a possible inconsistency in CLP with regard to the evaluation of the CMR properties of a substance, where that substance contains a CMR constituent, compared to the evaluation of that same constituent when it is contained in a mixture. Article 6(3) of CLP states that the CMR properties of a *mixture* must only be based on information on its ingredients, unless there is data on the mixture itself which demonstrates CMR properties which have not been identified from the information on the ingredient substances within that mixture. However, there is no corresponding statement about substances containing other substances in CLP. There is, in ECHA's view, no logical reason why a hazard should be different between a mixture containing (a) CMR substance(s) and (b) a substance containing the same CMR substance(s) e.g. as an impurity. ECHA suggest that this is a new problem introduced by CLP, since the Dangerous Substances Directive clearly stated that the mixture rules for evaluation should apply also for substances (if not listed in Annex I to the Dangerous Substances Directive) (see 1.7.2.1. in Annex VI to the Dangerous Substances Directive which refers to Article 6 (evaluation of health hazards), Articles 5 (physico-chemical) and 7 (environment) in the Dangerous Preparations Directive). The overarching aim when formulating CLP was that the same safety level should be kept as in the Dangerous Substances Directive. This inconsistency has reportedly led to a decision by one Member State authority to require a test for CMR properties, for a substances that was known to contain a CMR impurity above the specific concentration limits (personal communication, 2016).

The VCI (the German Chemicals Industry Association) highlighted that when translating classifications under Directive 67/548/EEC to classifications under CLP, the translations based on the data were not always exact. They indicated that for certain hazard classes, including acute toxicity and specific target organ toxicity (repeated exposure) the classification according to the criteria of Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under CLP. In these cases, the classification in the Dangerous Substances Directive Annex are to be considered as a minimum classification. They highlight that where the manufacturer or importer has access to data or other information that leads a more severe classification compared to the minimum classification, the more severe classification category must be applied.

4.3 Mixture classification

Key findings:

- Based on the views of several Member States, further guidance for mixtures is required to ensure an equal acceptability and application across Member States of weight of evidence approaches and the bridging principles
- Significant differences in mixture classifications have been identified depending on whether calculation or test methods are used, and this may be leading to distortions within the single market
- SMEs may have difficulties when trying to use the bridging principles, as this requires greater expertise and thorough documentation
- Several Member States indicated that bridging principles are applied differently by different

companies and that classifications depend on the available expertise and data for the substances/mixtures
- There appear to be national differences of interpretation of the bridging principles and the acceptance of classifications based on these. For example, there are differences in national acceptance of industry sector approaches, such as DetNet, which may lead to a lack of harmonisation across the market
- There is an inconsistency in requirements for substances containing CMR constituents and mixtures containing CMRs, which has been introduced by CLP

4.3.1 Introduction

Products placed on the EU market that are covered by CLP are subject to the mixture classification rules, with this including metal alloys. Questions have arisen over the appropriateness of the classification rules for mixtures, and these are discussed further below.

Under CLP, a mixture is defined as "a mixture or solution composed of two or more substances". Classification of a mixture can be based on available test data, data on similar tested mixtures and individual ingredients using bridging principles or based on calculation methods. Figure 4-1 below sets out the process that is to be followed, as taken from ECHA's Guidance on the Application of the CLP Criteria.

First priority is given to available test data on the mixture itself (although there is no obligation for testing to be carried for health and environmental hazards, and *in vivo* data should not be generated), followed by other data available on similar mixtures or on individual substances contained with the mixture (including epidemiological and other data). Where data on other similar mixtures or the individual ingredients form the basis for classification, then either a weight of evidence approach is to be applied or the bridging principles are to be applied. A weight of evidence determination is to be based on expert judgement, in line with requirements under the REACH Regulation, with appropriate consideration given to the quality and consistency of data, positive and negative results, as well as sites of action and mode of action. The bridging principles are a set of rules for building on the available information on similar tested mixtures, and which through their application should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.

In addition, CLP allows for industry sectors to "establish networks to facilitate exchange of data and bring together expertise in the evaluation of information, test data, weight of evidence determinations and bridging principles. Such networks may support manufacturers, importers and downstream users within those industry sectors, and in particular small and medium-sized enterprises (SMEs) in the fulfilment of their obligations under this Regulation. Those networks may also be used to exchange information and best practices with a view to simplifying fulfilment of the notification obligations. Suppliers making use of such support should remain fully responsible for the fulfilment of their classification, labelling and packaging responsibilities under this Regulation."

DetNet is an example of an industry approach towards building on the principles set out in CLP to develop an industry classification network for classifying and labelling detergent and cleaning products for skin and eye effects. It was developed to act as the Detergent Industry Network for CLP Classification ("DetNet") in response to the classification challenges for detergent and cleaning products. DetNet is a collective approach for sharing toxicological data on mixtures and classifying detergent and cleaning products for skin and eye effects.

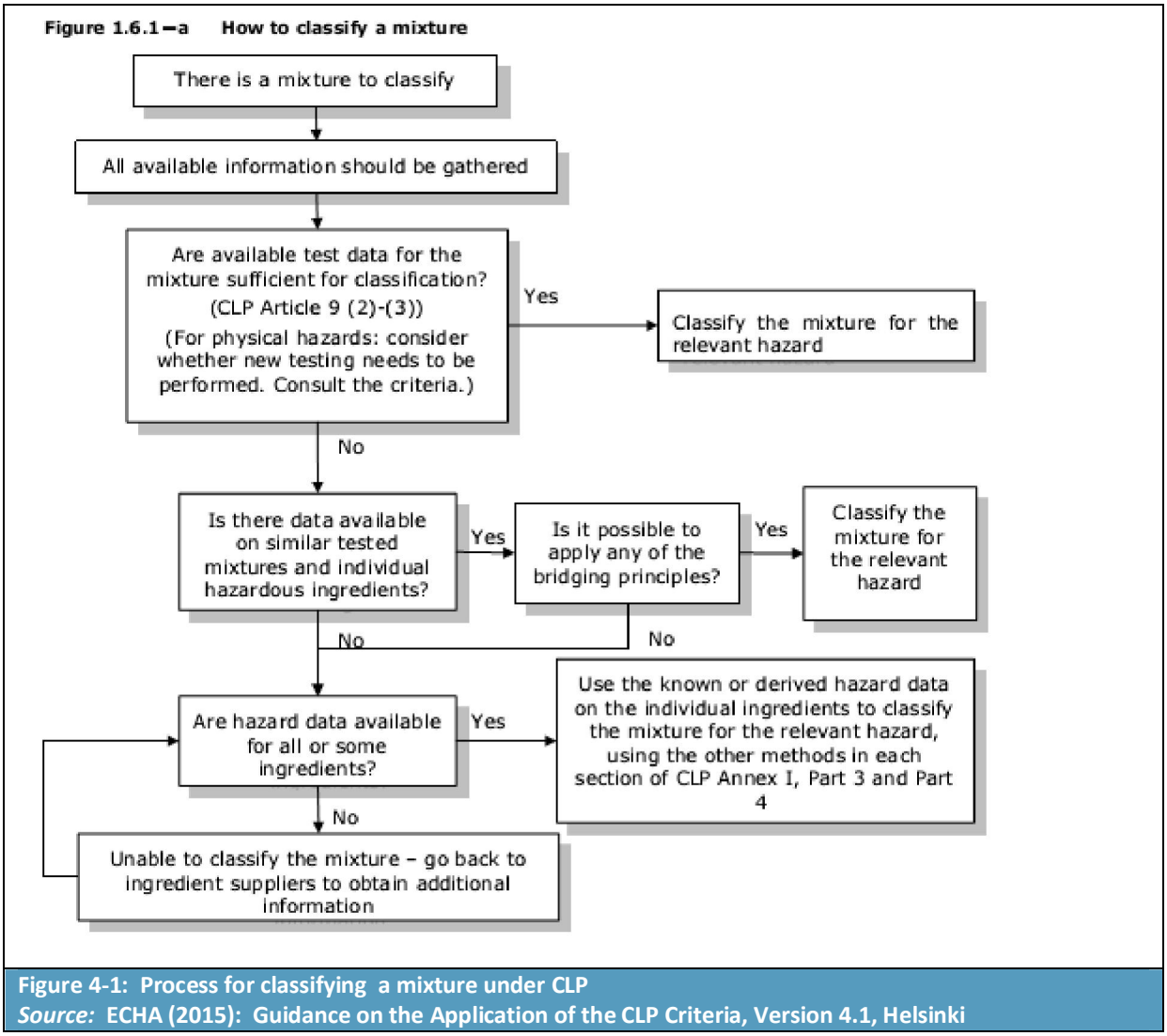


Figure 4-1: Process for classifying a mixture under CLP
Source: **ECHA (2015): Guidance on the Application of the CLP Criteria, Version 4.1, Helsinki**

4.3.2 Efficiency and approaches to classification

Manufacturers and formulators were asked what approach they took to classification of mixtures under the CLP Regulation and the appropriateness of the classification rules for mixtures. The responses of manufacturers and formulators are given in Table 4-4 below, in terms of the percentage of mixtures to which each approach was applied. A total of 93 manufacturers, importers, distributors and general formulators provided useable responses. As can be seen from Table 4-4, some companies undertook an extensive level of testing for classification purposes, although one respondent noted that this was to fill physico-chemical requirements, rather than other classification categories.

The average and median statistics indicate that there was greater reliance on expert judgement and weight of evidence approaches than there was on the use of the CLP bridging principles across the range of respondents. This suggests that companies did adopt efficient approaches based on some grouping of similar substances for assessment purposes, as well as substances used for the same purpose. The results also indicated that there was a significant level of mixture specific test data already available, although this figure was higher for formulators than for manufacturers and distributors.

Responses from detergents formulators indicate that there was a greater tendency for large companies to rely on new or existing test data than for SMEs, who were much more likely to rely on bridging principles using the sectors DetNet approach or on expert judgement and weight of evidence approaches. As use of DetNet should have been more cost-effective than one relying on substance specific data, this suggests that there were significant efficiency gains within the sector through use of this approach. However, it is of note that out of the 21 respondents to this question from the detergents sector, several indicated that they undertook new testing for classification purposes. The national sector associations suggested that more generally, companies within the sector will have used DetNet, with there being much less new testing and reliance on available data (with the exception of larger companies).

Table 4-4: Percentage of mixtures where each approach was applied by general chemicals manufacturers, importers, distributors and formulators (n=93)

Statistic	Relied on the use of the bridging principles	Relied on expert judgement or weight of evidence approaches	Already held mixture specific test data	Undertook new testing for classification purposes	Relied on the expertise of external consultants who may have applied a range of the above approaches
Median	5	30	12.5	10	0
Average	25.5	38.0	23.4	16.7	13.3
90 percentile	90	96.3	56	35.4	34.6

4.3.2.1 Over and under-classification

Many classifications changed as a result of REACH registrations. This observation is true for endpoints covering both human health and environmental hazards. This has been a common remark by industry stakeholders.

Member State authorities have also indicated that, compared to the Dangerous Substances Directive, the general concentration limits for classifying skin and eye damage/irritation are now lower under CLP (changing from 10% to 3%), with this leading to the classification of many more mixtures. As a consequence, these authorities perceive that there has been an over-classification in some cases. It is suggested that the use of more specific concentration limits might be helpful.

With respect to environmental effects, industry has found that many substances now have very high M-factors, which in turn leads to very low limit values for the classification of mixtures. The assignment of an M-factor is linked to the number of test data available. If only a few data have been included in the classification, the M-factor is very high due to the high safety factors that have to be applied to ensure a conservative assessment. This leads to situations where mixtures need to be classified as hazardous to the aquatic environment at very low substance concentrations (see also Case Study 8 on Seveso).

One Member State authority noted that, as highlighted in peer reviewed studies (Kienzler et al 2014, Kortenkamp et al. 2009, Bunke et al. 2014, Reihlen et al 2012), a hazard could be underestimated under the summation method, when the sum of components with a relevant aquatic toxicity are just

outside of the threshold for classification. This may be the case, but it is not clear to what extent this has led to the under-classification of mixtures in practice.

As noted above for substances, under CLP, differentiation between the different "severity/severities of hazards" of a substance, e.g. as a result of concentrations or physical states, is possible if respective data are available. For mixtures, this is illustrated by the examples of nitric acid (see Case Study 8), which shows that it can be useful to provide more specific data on mixtures. In this example, more specific data could justify variations in classification that might result in a less stringent risk level under the downstream legislation (e.g. Seveso III). The opposite outcome to that in the nitric acid example could also apply. New data can also cause more stringent classifications and therefore increase the risk level that needs to be applied.

4.3.2.2 Additive, synergistic and antagonistic effects

Mixtures can be combinations of substances, but in many cases are also produced by combining other mixtures (i.e. third or fourth level mixtures). The mixture classification criteria, and in particular the calculation methods, are considered to take into account the additive effects of substances within such 'mixtures of mixtures'. What they do not do is take into account any synergistic or antagonistic effects of substances contained within the mixtures and which may cause the mixture to deviate from the additivity of its effects. It is likely that such effects could only be captured by test data on the mixtures themselves. CLP, however, has no testing obligations for mixtures, and ECHA (pers. comm., 2016) notes that tests are to be performed as a last resort, especially if they involve animal studies. In addition, CMR effects and certain aquatic hazards, classification cannot be based on test data for the mixture, instead users shall only use the relevant information available for the substances in the mixture, as indicated in CLP Article 6(3) and 6(4).

This issue was also identified in the targeted consultation of Member State authorities and by NGOs. Authority respondents noted that the assessment of technical mixtures is partly addressed in several pieces of legislation and that methods are under implementation based on the various guidance documents for plant protection products, biocides, veterinary pharmaceuticals, etc. They note, though, that while REACH addresses the safe use of substances in technical mixtures falling under its remit, it does not explicitly address the joint effects and exposures of components. Combined effects and exposures of more complex environmental mixtures (e.g., sequential/parallel applications such as tank mixtures, discharge, coincidental or environmental mixtures) are not consistently addressed across all legislation, and there are still gaps to be closed for technical as well as complex mixtures in regulations.

4.3.2.3 Other effects

The Seveso Case study (see Case Study 8) has also identified an impact from changes in the CLP classification system for mixtures for the category "hazardous to the aquatic environment chronic category 1". When CLP initially entered into force, M-factors for highly toxic substances were set by assessment of LC_{50} or EC_{50} data (whichever value was more toxic). But Commission Regulation (EU) No 487/2013 of 8 May 2013, Annex I (19) changed this requirement to the use of NOEC data, which establishes a somewhat different approach. This change is likely to have resulted in changes in the classification of mixtures (even though the formulation has not been changed). This is because NOEC values obtained in ecotoxicological tests are generally lower than LC_{50} and EC_{50} values; furthermore, the NOEC values set out in Commission Regulation (EU) No 487/2013 are an order of magnitude lower than they were in the original text of CLP.

4.3.3 Effectiveness and acceptability

On the one hand, authorities and NGOs appear to believe that mixture classification under CLP is appropriate for the protection of human health and the environment and that the current methods for classifying mixtures are also appropriate in general, with some caveats. On the other hand, several stakeholders (Member States and industry) have noted, however, that some of the criteria and rules are not adequately explained or are ambiguous. As a result, they note that further information, for example, in the form of decision trees on applying GHS could be helpful. In particular, Member State authorities have noted that how some of the bridging principles are to be used is quite unclear and this makes it difficult for industry to implement the principles and for Member State authorities to enforce them.

In any event, for industry, the picture is more complex. Firstly, the choice of classification method is an issue, with the options available to companies often varying depending on size. Larger companies are much more likely to have actual test data on their mixtures than smaller companies. Responses to targeted consultation do indeed indicate that for mixtures, larger companies either already held test data or undertook new testing for classifying their mixtures, even though they were not obliged to under CLP. This means that smaller companies are more likely to rely on the use of the calculation methods compared to expert judgement and the bridging principles or test data, although use of the bridging principles was common in some sectors such as detergents where companies were able to draw on the industry network initiative for applying these.

Experience to date indicates that the choice of method can have an impact on the end classification. Both Cefic and AISE have noted that the classification outcome may depend on the method used, with the same mixture being classified differently by different companies due to the method that they have used. Specifically, the calculation methods tend to be more cautious to ensure that the mixtures are not 'under-classified'. Because SMEs are more likely to depend on the calculation methods to classify mixtures (due to cost considerations), they are also more likely to place more conservative hazard classifications on their products than companies that can do the necessary testing (e.g. for laundry detergents, using the modelling approach can lead to the need to use a corrosive pictogram whereas testing will result in a classification requiring only an exclamation mark). This finding is of concern, as it indicates that CLP is potentially leading to significant distortions and uneven competition within the single market for certain types of mixtures (for example, detergent products that are irritants rather than corrosive).

Secondly, industry reports that not all Member States accept classifications based on the use of the bridging principles (see also Case study 2b-5 in the Task 2 report), with different views and interpretations on what is permitted when applying the principles (confirming the sentiment expressed by some Member State authorities regarding the lack of clarity as to how the principles are to be used). Industry has also highlighted that this confusion includes whether the application of bridging principles for mixtures should apply to all mixtures and not only to elementary ones (as indicated in ECHA's guidance). Differences in views also arise with regard to approaches towards extreme pH and the information to be included in safety data sheets, with Member States adopting different approaches towards these. An example from the detergents sector is provided in Table 4-5 below.

Table 4-5: Experience of a detergent company with regard to mixture classification
A detergent company provided a detailed answer on mixture classification in response to targeted consultation. The company noted that assuring classification of their mixtures under CLP poses many challenges, especially when it comes to the eye irritation and skin corrosivity. For eye irritation, they face the problem of different authorities having different views on what evidence/data they accept for classification as Eye cat 2, in the absence of officially validated *in-vitro* methods for this specific classification category. For skin corrosivity, validated *in-vitro* methods exist, but they believe that these are over-predicting for acidic cleaners and to a lesser extent also for alkaline cleaners. This is leading to more products being classified for skin corrosivity and hence also for transport.

A national association representing detergents manufacturers noted that there was a need for Member State authorities to adopt a more harmonised approach with regards to the use of bridging principles. Although they acknowledged that Member States have a right to interpret the legislation, differences in the acceptance of bridging principles resulted in the same mixture having different classifications across the EU; this has created an uneven playing field and is leading to a lack of harmonisation across the single market. In particular, classifications based on the detergent sectors DetNet approach are accepted in countries such as Germany, Italy, Belgium, Luxembourg and Poland, while they may not be in France, Sweden, Ireland, and especially Greece (with other countries not yet giving a clear opinion or expressing concerns). The national association also highlighted that the enforcement framework needs better harmonisation, as there are Member States which impose product recalls/withdrawals even for small non-conformances, which do not affect the safety and health of the consumer.

AISE indicate that companies currently face diverging interpretations by Member States in the application of CLP Bridging Principles and Weight of Evidence from available tested mixtures and interpretation of test results. AISE call onto the Commission to re-affirm the prevalence of mixture data including alternative test methods when appropriate and therefore the possibility to use available test data on current and historical mixtures. AISE will also be organising a workshop in 2016 to inform Member States about the validity of industry's approach. It was also suggested that in some countries authorities do not take into account that the decision tree for classification has been changed under CLP compared to the Dangerous Preparations Directive, i.e. test data on mixtures/similar mixtures have now prevalence before the additivity approach. It was indicated that this lack of harmonisation leads to a fragmented approach, disruptions in the free movement of goods and higher costs for businesses.

However, it should also be recognised that, from their side, Member State authorities have some concerns over the use of non-validated test methods within the DetNet approach. This has led in some cases to the non-acceptance of data from Human Patch Tests and Low Volume Eye Tests in the context of a weight-of-evidence approach, as they are not listed in Regulation 440/2008/EC. Industry's response to this is that Regulation 440/2008/EC does not explicitly exclude the use of such test methods, as by reference to REACH Annex XI, 1.2., the weight-of-evidence approach may include test methods not (yet) listed in Regulation 440/2008/EC. It would appear that further guidance from the Commission or ECHA is required in order to address this issue and ensure that there is greater consistency across Member States with respect to the acceptance or not of test methods and, therefore, of the classifications.

When PPP companies were asked whether plant protection products (rather than the active ingredients) can have different classifications (resulting in different labels) across Member States,

nine out of ten respondents indicated that this situation had occurred in relation to their products. Just one respondent, a small/medium sized enterprise, answered 'no'. The companies indicated that this causes confusion as well as additional costs.

In addition to a lack of harmonisation in the classification of products, respondents also noted that different companies and Member States seem to assign different P statements to the same classification – and in many cases this is because they are not following the recommendations set out in the ECHA guidance. This lack of a harmonised approach may be leading to an uneven playing field across different PPPs.

The impact of such national differences is a lack of a harmonised market, resulting in barriers to trade which mean that the single market and free movement chemicals is not being realised to the degree which it should.

As a result of industry experience to date, through their response to the Open Public Consultation, AISE has also called upon the Commission to re-affirm there is extensive mixture data based on alternative test methods, and that it should be possible to use such data where it is available on current and historical mixtures. This reflects the experience of detergents manufacturers that some Member State authorities are not excepting the use of such data.

4.4 Classification of metals and special mixtures

Key findings

- The physical form of a metal is a key factor; massive and alloyed forms are usually less hazardous than powder forms
- There are mixed views on the adoption of additional criteria for metal alloys and special mixtures (such as plastic, glass etc.), although more Member State authorities are in favour of the adoption of new rules for metals classification than against
- The Transformation/Dissolution Protocol can be used to evaluate the aquatic toxicity of the metals and sparingly soluble metal compounds, however, further guidance is required for alloy testing
- JRC are developing a bio-elution test method which may be an alternative to *in vivo* testing; discussions are on-going concerning the potential applications (CLP Article 12) of the bio-elution test
- Further guidance is requested on the classification of metals and special mixtures

4.4.1 Metals classification

Metals are subject to several regulations, directives and recommendations[8] and those that form part of organometallic substances will be subject to the criteria and procedures to identify PBTs and

[8] Namely REACH, the Plant Protection Products Regulation, the Biocidal Products Regulation, the Directives on Medicinal Products for Human Use and for Veterinary Use, Cosmetic Products Regulation, Batteries and Accumulators Directive, Restriction of Hazardous Substances in electrical and electronic equipment Directive, End-of-life Vehicles Directive, WEEE Directive and the Toy Safety Directive. The use of some metals as natural elements or as other forms, for example oxides, will be covered by other Regulations like the Plastics in Materials and Articles intended to come into Contact with Food Regulation, Food Additives

under legislation such as the Plant Protection Products Regulation and the Biocidal Products Regulation (see also Task 2), while metals with CMR and other health hazard properties will also be subject to the risk management procedures triggered by these classifications, for example under OSH legislation (see Task 3).

Industry has raised the issue of there being a potential gap in the CLP Regulation when it comes to the classification of metals and metal alloys, as relevant criteria which have been developed for metals and their alloys have not been incorporated – such as those based on the transformation dissolution test[9] A metal alloy is not a simple mixture of metals, but a unique material of disparate intrinsic properties compared to its individual constituents (i.e. it is a 'special mixture'); as a result, there may be arguments for alloys to be classified and labelled in a more differentiated way.

This issue has been examined in the case study on metals classification (Case Study 2). Proponents of the need for more differentiation in the classification and labelling of alloys argue that to assume that a mixture will have the same intrinsic properties as those of its components could result in an over/under-classification in the case of metal alloys. In this respect, appropriate classification of metals is a concern for the extraction and processing industry, manufacturers, importers and downstream users of metals. There are workplace exposure limits for various metals which may be based upon CLP classifications, and which may result in over/under protection of workers. Similarly, classifications may lead to market restrictions on the use of a metal alloy in particular applications or products. Classifications may also trigger other legislation, such as requirements under the Seveso III Directive (see Case Study 8).

An interview with Eurometaux highlighted that the CLP rules for mixtures classification do not fit with the matrix effect seen in a number of metal containing materials, unless Article 12(b) can be used with a bioelution test. They suggest that a new EU-testing method or a new OECD testing protocol should be developed and recognised. Particular issues raised are as follows:

- Inhalation toxicology and lung overload: STOT-RE cut-offs are too low for poorly soluble particles of no intrinsic toxicity. Such materials will be classified as STOT-RE, which could be considered as being of 'equivalent concern' under REACH. In addition, it may be important for the concept of lung overload and secondary effects to be discussed by RAC and within the CLP guidance, as it appears that these are being discussed at UN GHS level but not presently at EU level. Finally, the reversibility of some inflammatory effects should be debated as well: do they justify a classification? If not, what criteria should be used?

- Environmental classification of complex metal substances and materials/mixtures: there is a need for further guidance on how to apply appropriate classification schemes.

- Degradability: there is not a level playing field between organics and inorganics for "degradability". For example, if iron and aluminium remained soluble then they would have effects but, in practice, those effects do not occur. This is due to the fact that they form complexes in the water column preventing them from being bio-accessible for organisms.

Regulation and OSPAR Recommendation 2010/4. There are also EU standards for the concentration of metals within different media, for example, in relation to drinking water and the quality of water intended for human consumption Directive sets out the maximum concentration values of metals in drinking water.

[9] OECD (2001): Guidance document on transformation/dissolution of metals and metal compounds in aqueous media, Guidance Document No. 29 avaiable from: www.oecd.org/chemicalsafety/testing/seriesontestingandassessmenttestingforenvironmentalfate.htm

Although industry is developing a concept for assessing the degradation of metals, it has yet to be widely accepted.. For organics degradability is seen as part of the hazard system whilst for inorganics it is considered as risk.

An industry stakeholder highlighted how the concept of rapid removal of metals from water has been discussed at an ECHA workshop[10]. The participants concluded that there is no overall consensus on whether and how the concept of 'rapid removal' should be used in the environmental hazard classification of metals and metal compounds and that further discussions are needed. Broad agreement is however, evident on certain 'rapid removal' mechanisms for certain types of metals - metals that quickly hydrolyse and form different species that precipitate in the water column (including Fe, Al, Sb, Sn, Mo and Cr).

As part of the targeted consultation, Member State authorities were asked whether they would support the inclusion of additional criteria within CLP for the classification of metals in different forms. Of the 11 Member State authorities that responded to this question, six agreed, three disagreed and two didn't know. Some of the comments provided were similar to those for special mixtures (see discussion below). A summary of key points made by authorities is as follows:

- One Member State stated that the intrinsic properties of a metal are same regardless of the physical form, but noted that there are examples of split classifications for some metals based on the different physical forms. They also indicated that differences in bioavailability should be qualified by subsequent risk assessment and that it may be difficult to include within the CLP criteria that are more substance-specific.

- One Member State highlights that testing exists for the environmental classification (T/D) but for human health hazards there are less developed testing and/or classification strategies for different forms. They suggest that criteria for classification should be for a substance independent of the different forms. The authority recommends that a guidance document should be developed for how to use data from tentative bioavailability tests for alloys and notes that the current guidance for calculating Specific Concentration Limits is developed for substances in solution but no guidance is available for solid forms.

- A national authority also suggests that bio-elution methods could be generated not just for metals – as JRC are currently doing – but also for other substances; for example, they argue that it might also be applicable to polymers.

- Another Member State noted that they do not support the introduction of additional criteria for the classification of metals in different forms, into CLP as, in their view, too many classification criteria could call into question the 'fitness' of CLP. However, the authority also indicated that the classification of alloys for health effects is a longstanding unresolved issue in CLP; and they understood that ECVAM has recently agreed to take forward the development of a standardised OECD test method based on bioelution. The Member State supports the initiative and, if successful, its incorporation in CLP. The Member State also suggested that additional guidance could be produced to deal with the classification of specific forms, noting that such an approach may be of particular help to the waste and major hazards (Seveso) sectors.

[10] ECHA (2012): Report from the Workshop on the validity of the use of the concept of 'rapid removal', 8th February 2012.

- An opposing Member State does not support the use of bio-elution generated data (whether for metals or also for other substances) for the classification (or non-classification) of mixtures classified as CMR. They also indicate that they do not support the use of bio-elution based on "effective concentrations" for the calculation of acute toxicity and that, in general, exposure/risk based approaches should not be mixed with hazard assessment.

With respect to such concerns about bio-elution, in November 2015 as part of the 19th meeting of competent authorities for REACH and CLP (CARACAL), a number of issues surrounding biological availability were discussed. Austria highlighted a number of scientific and legal points as to why bioavailability should not yet be used in the assessment for the classification of alloys. The points included references that Eurometaux were making to Article 12, the term not biologically available, the exclusion of Article 6(3) for CMR substances, and test method reproducibility and development. Austria suggested that, for the time being, it may be preferable in terms of regulatory practicality to pragmatically adapt concentration limits for alloys with high particle sizes that effectively prevent ingestion and inhalation.

In addition to comments made at Caracal, an industrial stakeholder indicated that some Member States do not support the use of a test method, as they maintain that it would not be appropriate under CLP (based on recital 22), which says testing should not be carried out for mixtures containing CMRs. In addition, ECHA has noted however that not all test methods are appropriate for testing mixtures, and that mixtures with CMR ingredients should in principle always be classified based on these ingredients (Article 6(3), CLP) (e.g. by applying the generic concentration limits for classification). However, industry argues that bioelution is not a test *per se* but a calculation method, so should still be allowable for CMRs and that the original intention of recital 22 in CLP was to prohibit animal testing in relation to mixtures, not to prevent any other testing. It is understood that these issues continue to be discussed at CARACAL meetings and that a legal interpretation document is being developed by the Commission.

Three further Member States made similar comments to ones presented above (with one also noting that it is necessary to check whether the existing GHS classification criteria are applicable for nanomaterials). One of these authorities also noted that an informal working group[11] has been set up at UN level and that pilot projects are currently being carried out which may result in recommendations for adaptations to the classification system.

It is of note though that requirements for the classification of metals is an area where there is divergence in the implementation of the CLP building blocks. For example, not all jurisdictions (e.g. Australia and Japan) require the application of GHS to the classification of metal alloys. There are also differences in labelling requirements. Under CLP metals in the massive form, as well as alloys, do not require a label if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market (point 1.3.4 of Annex I to CLP), even if they are classified as hazardous.

As part of the metals case study, industry stakeholders highlighted that the physical form of the metal is an important factor as it will influence the hazard classification. This point has recognised by the Commission in that CLP classifications take account of the form and physical states for some metals (for example, massive and powder forms may havce different classificiation thresholds. However, some industrial stakeholders were worried about this approach and what it may mean for

[11] Under the UN's Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals.

their alloys. Data produced by industry using the transformation dissolution protocol suggests that the alloying effect can have a decreasing and increasing effect on the release of metal ions.

Various peer viewed publications also support the view that there are differences in hazard classification when the physical form is considered. Skeaff et al (2008)[12] highlighted differences in GHS classification proposals when powders and alloys were tested with the transformation dissolution protocol. Midander et al (2006)[13] suggests that that metal release rates are strongly influenced by the physico-chemical properties of the test medium and the effective surface area of particles during exposure. Henderson et al (2014)[14] found the bio-elution test method overall to be satisfactory within-laboratory variability in bioaccessibility data for synthetic gastric fluid, lysosomal fluid, interstitial fluid, and perspiration fluid for all treatment conditions, it was also recommended that the degrees of freedom within the SOP should be addressed to achieve better concordance in absolute metal releases.

When indicating whether or not they would support additional criteria for the classification of metals, Member States also highlighted that there are various physical forms not just powder and massive, for example there are also nano metal and metal chips. The lack of metal alloy guidance and the need for this to be developed was also noted, for example current guidance for calculating Specific Concentration Limits is developed for substances in solution but no guidance is developed for solid forms, and further guidance on how to use tentative bioavailability test data for alloys should be developed.

Metals can be used either in powder form or as massive metals e.g. in the form of slabs, sheets or wires. Registration data of metals, e.g. copper[15], zinc[16] or lead[17] shows that hazardous properties may vary depending on the physical form of the substance. In the case of metals, it is the massive form that shows less leaching from the substance in the respective tests. This leads to the non-classification (self-classification) of any of the massive forms, while the powder forms are classified.

[12] Skeaff, J., et al (2008): A new approach to the hazard classification of alloys based on transformation/dissolution. Available at: http://onlinelibrary.wiley.com/doi/10.1897/IEAM_2007-050.1/full

[13] Midander, K., et al (2006): Elaboration of a test method for the study of metal release from stainless steel particles in artificial biological media. Available at: http://www.sciencedirect.com/science/article/pii/S0010938X05003252

[14] Henderson, R., et al (2014): Inter-laboratory validation of bioaccessibility testing for metals. https://ir.library.oregonstate.edu/xmlui/bitstream/handle/1957/54911/AndersonKimEnvironmentalMolecularToxicologyInterLlaboratoryValidationBioaccessibility.pdf?sequence=1

[15] ECHA Database of registered substances http://echa.europa.eu/registration-dossier/-/registered-dossier/15562/2/1/?documentUUID=378f4a57-a18a-4fbb-b4f2-315afd1d68b1

[16] ECHA Database of registered substances http://echa.europa.eu/registration-dossier/-/registered-dossier/16146

[17] ECHA Database of registered substances http://echa.europa.eu/registration-dossier/-/registered-dossier/16063

4.4.2 Special mixtures

Member State authorities were also asked questions regarding the potential for inclusion of additional criteria into CLP for the classification of special mixtures (such as plastics[18], glass etc.). There was no corresponding question on this issue in the targeted industry questionnaire, and this was not otherwise raised as a significant issue by multiple respondents to either the targeted consultation or the Open Public Consultation.

It appears that the views of the authorities are split 50:50 on this issue. While some authorities believe that plastics and glass should be classified in the same way as other mixtures, others argue that they should not. The position of those opposed to additional criteria for special mixtures is similar to ECHA's argument regarding the classification of metal alloys; if, for example, exposure is to be taken into account for special mixtures that are bound in matrix-like structures, then the hazard evaluation will move towards a more risk based and case-by-case approach than the hazard based approach underlying the CLP Regulation (and GHS).

Some Member States highlighted issues that currently arise. For example, one Member State indicated that there are still questions surrounding bioavailability and that further guidance is needed. Another Member State highlighted that the derogation in Annex I, point 1.3.4.1, only applies when the "special mixture" do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment and that further guidance based on the application of this is needed. Regardless of any change in criteria in the future, they argue that more clarity on interpretation of these rules is required now. For example, it should be made clear how a polymer containing more than 1 % of an allergenic monomer should be classified, as there is an argument that mixtures containing epoxy constituents with an average molecular weight > 700 should not be classified as allergenic.

Authorities also highlighted that special labelling requirements and exemptions already exist for such mixtures (CLP article 23). Key comments made by authorities include that:

- The existing classification rules for glass, plastics and alloys do not work, as they are not simple mixtures. Instead minor adjustment of the existing rules, for example, by using effective concentration rather than actual concentration, together with additional clear, consistent guidance would be welcomed. These adjusted rules could also be linked to standardised extractivity / bioavailability / degradation testing.
- Additional criteria may be considered but these should be specific to a given matrix and provided that data are produced in accordance with a recognised standard; if that matrix specific data were to be lacking, then the CLP criteria would have to be applied.
- The above suggests that new classification and testing strategies would have to be developed, including additional guidance. Any new classification guidance would need to be followed up by related guidance on labelling and labelling derogations.

[18] Essentially, a mixture typically comprising polymer and additives (such as colourant, stabiliser, plasticiser, etc) bound in a fixed or flexible matrix.

4.5 Quality of data, scientific development and innovation

Key findings:

- GLP compliant data underlies the EU classification system and ensures that data produced by studies are reproducible
- Constraining data to that which is only GLP compliant may result in exclusion of data generated using more innovative test methods
- Although there are arguments that requirements for data to meet GLP should be relaxed (particularly with respect to physical hazards), hazard classifications should be based on reliable and reproducible data if they are to provide the basis for regulatory action
- Consideration could be given to developing less onerous, streamlined GLP procedures for use in an academic setting, but which also ensure reproducibility and that study results are an accurate reflection of hazards

4.5.1 GLP requirements

The quality requirements for new data generated for the purpose of hazard classification are outlined in CLP Article 8(4) and 8(5). New ecotoxicological and toxicological tests should be carried out in compliance with the principles of Good Laboratory Practice (GLP) or other international standards which are recognised as being equivalent. ECHA has confirmed in its online Questions & Answers (Q&A 0117) that no other international standard has so far been recognised as being equivalent. Moreover, physical hazard tests must be carried out in compliance with a relevant recognised quality system (GLP) or by laboratories complying with a relevant recognised standard (ISO/IEC 17025 or other internationally recognised standards of comparable scope)[19]. Other chemicals legislation (e.g. the Plant Protection Products Regulation) also includes GLP requirements.

It is important to recognise what GLP is and is not. It is a quality system of management controls for laboratories aimed at ensuring the reconstructability and thereby the reliability, reproducibility, quality and integrity of non-clinical safety tests, ranging from those carried out on physico-chemical properties through acute to chronic toxicity tests.

The question of whether the principles of GLP are appropriate under CLP was discussed at the April 19 Stakeholder Workshop (see also the Test Methods Case under Task 2 study which discusses GLP and the need for new test methods more generally). At the Workshop, there was general agreement that high quality data is needed to ensure a sound basis for regulatory decisions making. In this respect, it was acknowledged that the GLP requirement ensures there is rigorous documentation of how a study was conducted and that study details can be checked for classification purposes. It was also agreed though that GLP on its own does not help in ensuring that a scientific study is of high quality or is of high accuracy. In this respect, stakeholders views were both positive and negative:

- GLP is outdated, as the problems that led to it do not exist anymore;
- GLP is helpful to ensuring that human and eco- toxicological data that already exist and meet data quality requirements are used, with this in turn helping to ensure that no unnecessary animal tests are conducted (recognition); and

[19] ECHA (2015): Guidance on the Application of the CLP Criteria, version 4.1, p. 90

- GLP is good to have but not sufficient to ensure high quality and that GLP may be best used as "general approval of data".

In particular, requirements on GLP for physico-chemical data were questioned, as no animal tests are carried out and there is considerable information that was generated pre-GLP and that is still applicable; thus, these stakeholders argue that there are no added benefits of now requiring new GLP based information. Member States also noted that setting a strict GLP requirement for all existing data would create difficulties, given that a significant proportion may not be compliant but is still of sufficient quality. However, it must also be recognised that for some tests, especially physic-chemical tests – it is sufficient for these to be carried out by laboratories in accordance with ISO 17025 and other internationally recognised standards.

It was also noted that although most commercial laboratories implement GLP for most endpoints, this is less often the case for academic labs; some of the Workshop participants argued that this leads to the GLP requirement excluding the use of data from academia. In this respect, it is important to reflect on the aims of GLP, which are essentially to ensure the reproducibility and integrity of test results. For regulatory purposes this is important. If a test is not reproducible, then it is not clear how it can be considered a reliable basis for regulating chemicals. It was also suggested that by a Member State that by accepting non-GLP data, one runs the risk of increasing the amount of animal testing that is carried out, as the tests will need to be repeated under GLP to be regarded as reliable and trustworthy.

In addition, it was noted by authorities that standardised quality requirements such as GLP are important instruments to ensure the reliability of the information used for hazard and risk assessment. Such requirements are needed to counter criticism over industry being responsible for performing studies on their own chemicals. In this respect, GLP ensures a sufficiently detailed description of experimental studies, even if it does not guarantee the reliability and relevance of the study results by itself. New endpoints without respective harmonized OECD guidelines are generally supported by the Commission or Industry, but might be ignored due to validity and plausibility issues.

With regard to risk assessment and risk management, Member State authorities note that reproducibility and standardisation of study designs is much more important and thus standardised protocols such as OECD guidelines are needed. However, when it comes to identifying risks and hazards, some also argue that all information including non-GLP and non-guideline studies should be taken into account using a weight of evidence approach, especially if the hazards/risks to be regulated are not assessable by standardized studies. In this context, the CRED method is suggested for the evaluation of the reliability and relevance of experimental studies as an alternative to the established Klimisch method, due to the application of more objective quality criteria.

As part of the Open Public Consultation, the Royal Society of Chemistry (RSC) suggests that legislative frameworks will always have difficulty in dealing with advances in science and technology, and that here will nearly always be a significant information deficit. In this respect, it is almost inevitable that regulatory actions will lag behind scientific developments. They highlight the difficulties of identified long-term or chronic effects (e.g. lung cancer and asbestos), how toxicity can be species dependant (e.g. pyrethroids have little or no effect on humans but are very toxic to aquatic wildlife) and doses are an important factor (e.g. warfarin is an effective rat poison but low doses are used clinically to prevent blood clots after a stroke or heart attack). The RSC therefore argue that for the EU to remain at the forefront of innovation in both scientific understanding and developments, it is essential that overly precautious regulatory action should not inhibit the early

stages of research, discovery and innovation. At the same time, regulation needs to be based on sound science and reliable information.

Issues concerning test methods, scientific developments and technological innovation more generally are addressed under Task 2.

4.5.2 Use of weight of evidence approaches

Consultation suggests that companies do not make use of weight of evidence approaches as much as might be expected (with the exception of through DetNet and the sectors guidance on application of the bridging principles), particularly with respect to mixture classification, potentially due to a lack of expertise or due to SMEs being unfamiliar with these approaches.

Authorities, however, argued that a weight of evidence approach can provide a stronger scientific basis for chemical assessment while improving transparency. Another Member State suggested that the approach might only be taken into account by companies which register substances under REACH Regulation. A Member State indicated that they had seen arguments to downgrade an environmental classification based on weight of evidence arguments that are not entirely consistent with CLP requirements, but that these arguments are not made frequently or in large numbers anymore. Member States indicated that an exception is where the detergent sector uses the weight of evidence approach through DetNet and bridging principles.

As part of the Open Public Consultation, a paper by Ågerstrand *et al* (2016)[20] was submitted which highlights the fact that the use of weight of evidence approaches is promoted across most of the relevant EU chemicals legislation (CLP, REACH, Biocides, Plant Protection Products Regulation, Cosmetics, contaminants in food, and the water framework directive). Even if it is not explicitly referred to in the legislation, it is in supporting guidance. However, the authors conclude that there is insufficient guidance for generating robust and reproducible weight of evidence or systematic reviews and there is a need for more structured and detailed guidance, in particular to safeguard the reproducibility and credibility of assessments.

4.6 Variations in self-classifications and numbers of substances changing classification

Key findings:

- There are significant variations in the self-classifications assigned to many substances; some of these may be justified but they also raise issues regarding data quality
- Member State authorities were split on the extent to which differences were significant and whether this was due to different approaches
- Although some manufacturers indicated that high percentages of their substance portfolios changed classification due to the introduction of CLP (and associated changes in threshold/ boundary values), the majority of manufacturers indicated that only a small percentage (less than 10%) of their substance portfolio changed classification.
- With respect to mixtures, significant percentages (30% to 100%) of some companies'

[20] Ågerstrand, M. and Beronius, A., (2016): Weight of evidence evaluation and systematic review in EU chemical risk assessment: Foundation is laid but guidance is needed. Environment International Volumes 92–93, pages 590–596.

portfolios changed classification with the introduction of CLP

- Responses to such changes varied by sector, with formulators supplying consumer facing sectors – such as detergents - more likely to re-formulate
- In general, there is agreement that differing classifications for the same substance are not new but they are now more evident due to the C&L Inventory. Member State authorities commented that, due to new testing and registration requirements (e.g. through REACH) and the CLP notification requirements, classifications are now far more consistent across companies.

4.6.1 Variations in self-classifications

4.6.1.1 Substances

Many stakeholders have commented on the fact that there are wide variations in the self-classifications being assigned to different substances, with this being readily observed from notifications to ECHA's Classification & Labelling Inventory (CLI). A guide published[21] by ECHA sets out reasons for why differences may exist (e.g. different hazardous impurities, additives or ingredients might be present, properties such as the physical form, the pH, the flash point might be different and suppliers might reach a different scientific conclusion) and actions for when different classifications are identified (e.g. take a precautionary approach and adopt the most stringent classification, adopt the classification you are most confident of, or ask for advice when self-classifying).

From the authority perspective, Member States were split on the extent to which differences were significant and whether this was due to different approaches (six no versus five yes).

Concern was also raised over whether companies understood their obligations in relation to substances on Annex VI of CLP. In particular, there appears to be some confusion as to whether to self-classify for those hazard classes that are not covered by an entry in Part 3 of Annex VI even though the requirements are set out in Recital (17) of the CLP Regulation[22] .

In general, there is agreement that differing classifications for the same substance are not new but they are now more evident due to the C&L Inventory. Member State authorities commented that, due to new testing and registration requirements (e.g. through REACH) and the CLP notification requirements, classifications are now far more consistent across companies. Member States emphasised though the value of further incentives or new obligations being placed on companies to arrive at an agreed single, self-classification for substances.

This issue is discussed further in Section 8, with respect to industry concerns over the quality of the data that has been used for some self-classifications.

[21] ECHA (2016): Tips for users of Chemicals in the work place, A short guide for users of chemicals in the workplace on how to get the most from the classification and labelling information you receive.

[22] "*Where a decision has been taken to harmonise the classification of a substance for a specific hazard class or differentiation within a hazard class by including or revising an entry for that purpose in Part 3 of Annex VI to this Regulation, the manufacturer, importer and downstream user should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.*" Recital (17) CLP Regulation

4.6.1.2 Mixtures

One Member State noted that different industries may use different expert judgement approaches and they fear that decisions concerning the commercial importance of mixtures may have had an impact on the C&L assessment. They also indicated that classifications may be different due to differences in composition (impurity profiles), lack of resources, and non-application or differing interpretations of the CLP criteria. Another Member State suggested that inconsistencies and differences in classifications across companies may be due to a lack of expertise or sufficient resources in the SME sector; for example, the bridging principles are applied differently by different companies, and SMEs may have difficulties when trying to use the bridging principles, as this requires deep expert knowledge and thorough documentation. Member States also noted that the classification criteria and toxicity data are interpreted differently by companies, and of course that access to relevant data may vary between companies.

One Member State also highlighted that differences in expert judgement and the calculation method for the same product may have significant consequences for a company in the context of Seveso III and the authorization of industrial facilities. The same Member State also suggests that the classification criteria of the GHS and CLP Regulation are intended to be applied for all chemicals and are to be applied to the actual form in which a substance is brought onto the market. This means that manufacturers, importers and subsequent users must take into account whether the chemical substance in question is, for example, a nanomaterial, and base their decision for the classification on form-specific data. The Member State suggested that there is a strong indication that this is mostly not put into practice at present.

4.6.2 Numbers of substances and mixtures changing classification

As part of the consultation process the questionnaires asked industry for information about the number of substances and mixtures that had changed classification.

From the targeted consultation of manufacturers, importers, distributors and formulators (MIDFTC) were asked what percentage of substances and/or mixtures changing classification as a result of CLP. As can be seen from Figure 4-2, data from the MIDFTC shows that a significant percentage of mixtures changed classification as a result of the move from the Dangerous Preparations Directive to the CLP Regulation. Most respondents indicated that (53% in total) either less than 10% or none, for the number of their substances that changed classification as a result of CLP. A further 22% indicated that 30% or less of their substances changed classification, and around 14% indicated that more than 60% of substances changed classification. Around 5% (three in total) - of respondents indicated that all of their substances changed classification. In comparison, as might be expected, the picture for mixtures is more complex.

Responses of the general chemicals sector for mixtures indicated that a great amount of product mixtures had changed classification, only 13% indicated that 10% or less changed classification, with 29% indicating less than 30% changed classification and a further 26% indicating that between 30% and 60% changed classification. For 21%, more than 60% of their mixtures changed classification, this included four responders that indicated 100% of their mixtures changed classification. As a result, there are added comments that the rules are over-stringent and lead to a false indication of the real hazard potential of some mixtures.

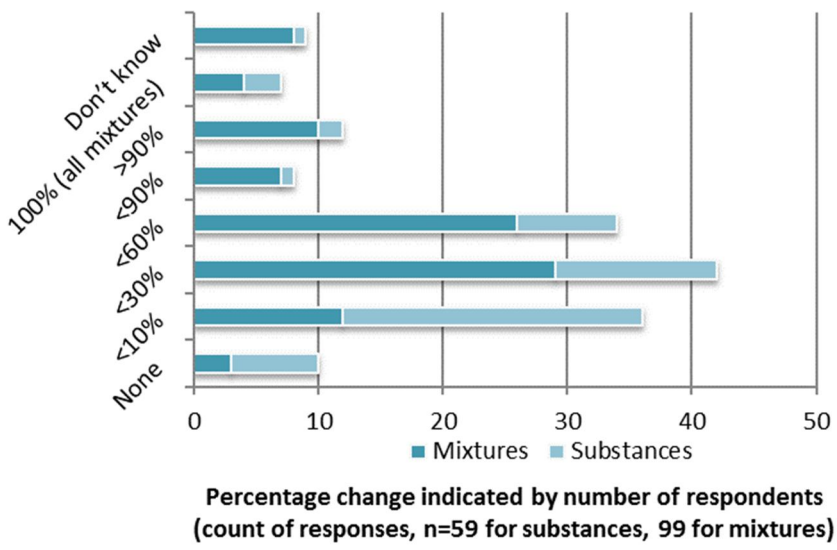


Figure 4-2: Percentages of substances and/or mixtures changing classification as a result of CLP (n=123 in total, count equals number of responses indicating each percentage)

Detergent companies were also asked how many mixtures had changed classification within their portfolio, with the results presented in (Figure 4-3).

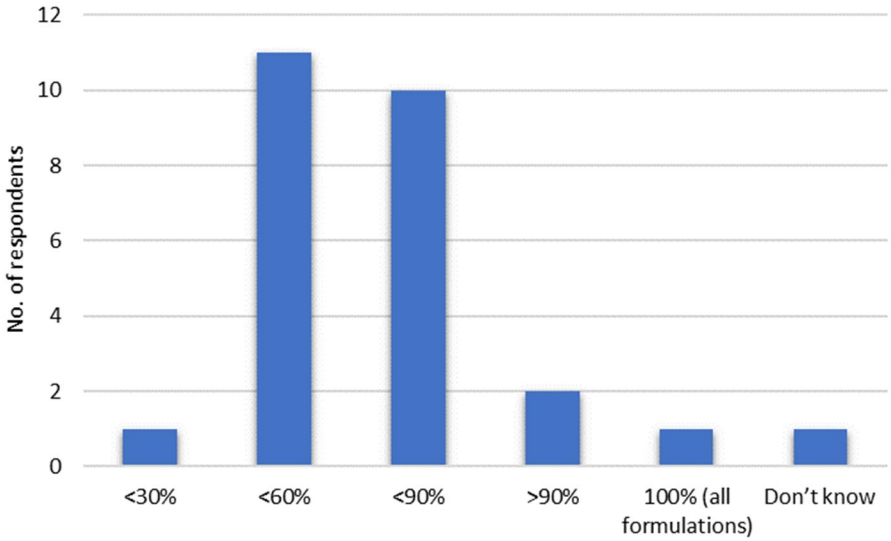


Figure 4-3: Percentage of detergent/cleaning product mixtures changing classification due to CLP (n=28)

No respondents indicated that less than 10% of their mixtures changed classification as a result of CLP with less than 30% acting as the lower bound of the quoted range. As can be seen from the figure, between 30%-60% was the most common answer, followed by 60%-90% of mixtures changing classification. Larger companies generally indicated a greater percentage of their formulations had changed classification, compared to SMEs although the sample sizes are too small to be conclusive on this point.

4.6.3 Responses to changes in classification

The targeted consultation asked industry whether re-classification under CLP had had a significant impact on their product portfolios. The aim of this question was to establish how companies responded to changes in classification. In particular, did changes in classification act as an incentive to manufacturers to shift towards the use of less hazardous substances within their mixtures. Responses from the targeted consultation are set out below in Tables 4-6 and 4-7 for the detergents sector and the more general chemicals sector respectively. As can be seen from the tables, there are significant differences in the responses of these two groups, with the detergents sector much more likely to withdraw more hazardous inputs from their formulations than the more general industrial chemicals sector (which also includes some companies supplying the detergents sector).

From Table 4-6, one can see some other product related impacts for the detergents sector, including significant levels of reformulation (reductions in concentrations of certain substances and mixtures, as well as the loss of the ability to eco-label some products.

Table 4-6: Number of detergents sector companies adopting different types of responses to changes in mixture classification (n=17)

Answer options	Number indicating this as part of response to changes in classification
We removed some substances/mixtures from our formulations	13
We lowered concentrations of some substances/mixtures in our formulations	15
We stopped producing the end formulations	6
We have lost our ability to eco-label our formulations	2
Other	3

Table 4-7: Number of manufacturers, importers, distributors and general formulators adopting different types of responses to changes in substance or mixture classifications (n=111)

Answer options	Number indicating this as part of response to changes in classification
Our product offering did not change as a result of changes in classifications under CLP	88
We stopped importing some substances/mixtures	52
We substituted some chemicals with less hazardous ones	44
We removed some substances and mixtures from our portfolio due to their becoming more stringently classified	26
We increased the number of lower hazard products that we offer across our portfolio	20

For the more general chemicals sector, 111 respondents provided a useable answer in terms of a percentage figure or yes and no answers. In some cases, these yes / no answers could be converted to a number (e.g. yes for no change in product offering and no under all other responses). Table 4-7 reports on the number of respondents indicating that they took each of the following actions.

Most general chemicals sector respondents indicated that their overall product offering did not change as a result of changes in classification, with this achieved through a combination of

substitution or the introduction of lower hazard products. Where substances and/or mixtures were removed from a manufacturer's product portfolio, the majority of respondents indicated that this applied to a small percentage or "some". However, there were numerous respondents indicating that they did remove a significant or major product from their portfolio or that a very large percentage of their product offering changed.

In terms of substitution, this was important across 100% of some of the general chemical sector respondents' mixture portfolios, although these are very much outliers, with most numeric responses indicating much lower levels (e.g. 10%) of mixtures to have been affected. The same pattern can be seen in relation to removing substances in mixtures due to their being more stringently classified. For example, one respondent indicated that they undertook substitution of hazardous chemicals used within their mixture portfolio to ensure that none of their mixtures are classified.

Some general chemicals formulators indicated a high level of reformulation (e.g. 80% in or order to retain a similar classification, with this sometimes being undertaken jointly with substance suppliers), but most indicate only around 5% of mixtures were affected in this manner. However, actions did include dilution in order to not have significant changes in the severity of the hazardous classification. Similarly, only a few respondents indicated that a high proportion of their portfolio was affected in terms of offering an increased number of lower hazard products being offered.

Respondents did indicate that they have stopped importing some hazardous substances, but they could not put a figure on it. One company noted that they "supply commodities that meet international specifications, to downstream users. Substitution of a substance is often not an option. If substitution would be possible, it would often require a change at the downstream users' process and therefore would take significant time."

5 Harmonised Classification and Labelling

5.1 Introduction

Recital 16 of CLP states that there should be "a possibility to provide for harmonised classifications of substances for hazard classes of highest concern and of other substances on a case-by-case basis which should be applied by all manufacturers, importers and downstream users of such substances and of mixtures containing such substances." Where harmonized classification and labelling (referred to hereafter as CLH) has been agreed at the EU level, suppliers of those substances must apply the harmonised classification but also self-classify for the remaining non-harmonised classes (Recital 17).

Indeed, the creation of a list of such substances at the Community level is identified in Article 1 of CLP as forming one of the key actions that will help ensure a high level of protection of human health and the environment. Commentators have indicated that the CLH provisions can be viewed as one of the key cornerstones to the EU chemicals legislative framework, as the triggers for risk management in much of the downstream legislation is based on these harmonised classifications.

Title V of the Regulation sets out the provisions for the establishment of a harmonised classification. The ability to propose harmonised classifications is open to competent authorities and manufacturers, importers and downstream users; they are all able to submit proposals to ECHA for a CLH of substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity categories 1A, 1B or 2, for respiratory sensitisation, or in respect of other effects on a case-by-case basis[23].

ECHA's Risk Assessment Committee (RAC) is then to adopt an opinion on any proposal submitted to it within 18 months, with this period including allowance (45 days) for interested parties to have an opportunity to comment (public consultation). ECHA then forwards the opinion with any comments to the Commission; if the Commission finds that the proposal is appropriate, it must then submit a draft decision on the final classification and labelling elements (Article 37.5), with the procedure then being one of "regulatory procedure with scrutiny" (following Article 54(3)).

In addition, all harmonised classifications agreed under the Dangerous Substances Directive (i.e. in Annex I) were converted into new harmonised classifications using the new criteria set out in CLP (Recital 53) and added to Annex VI of CLP.

The evaluation questions that have been identified as being relevant to the CLH procedure and its implementation in practice are given in Table 5-1 below.

[23] Article 36.2 also states that a substance which is an active substance in the meaning of Directive 91/414/EEC on plant protection products or Directive 98/8/EC on biocidal products shall normally be subject to harmonised classification and labelling, with this reflected in the more recent regulations for these products.

Table 5-1: Evaluation questions to be addressed relating to efficiency of procedures	
Q #	**Evaluation Question**
1.1.1.3.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the exposure to a substance via various sources and/or routes of exposure?
1.1.1.8	Is the scientific data on which the regulatory decisions are based of good quality, complete and reliable? Are quality requirements (e.g. GLP) appropriate?
1.1.4.3.	To what extent does the chemical legislative framework require/encourage Member States to further reduce exposure of humans and/or the environment to hazardous chemicals and are these requirements sufficiently implemented?
1.2.1.	Are there unnecessary regulatory burdens?
2.1.6.	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
2.2.3.	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?
2.2.4.1.	Are the provisions and procedures for hazard/risk identification and assessment efficient? Are the procedures fast enough to identify new hazards/risks?
3.2.3.	To what extent are socio-economic consequences with relevance for citizens and stakeholders taken into account in the implementation of the legislative framework?
3.3.2.	To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?

5.2 Efficiency and effectiveness of the procedures

Key findings:

- The process is perceived by most stakeholders to be more efficient and effective than under the Dangerous Substances Directive, however, data suggest no improvement in the speed of decision making on harmonised classifications under the new system
- Between 6,000 and 7,000 substances are now likely to have a CLH, and as of January 2017, 323 CLH dossiers have been submitted to RAC. Most of these relate to plant protection and biocidal product active substances, rather than industrial chemicals
- There is room for improvement in terms of the coordination between ECHA and EFSA
- Steps are being taken to speed up the opinion forming process for non-controversial end-points

5.2.1 Numbers of CLH proposals

The efficiency and effectiveness of the CLH procedure as assessed here are interpreted as relating to the number of substances for which CLH are agreed and that are added to Annex VI of CLP, as well as the overall speed of the process.

As for CLP, harmonised classifications were added to the Dangerous Substances Directive through Adaptations to Technical Progress, with changes in classification proposed and agreed by a Technical Committee. CLP itself incorporated all harmonised classifications agreed under the Dangerous Substances Directive up to the 29th ATP of the Dangerous Substances Directive, with the 1st ATP to CLP (5 September 2009) then adopting the 30th and 31st ATPs to the Dangerous Substances Directive which occurred while CLP was awaiting adoption. These two ATPs introduced or modified the classification and labelling for 800 and 600 substances respectively, with this including around 490 new CMRs and additional entries for substances with sensitising and other properties. Importantly, the initial proposal the 30th ATP for example, was agreed in the Commission in March 2005 and then took more than 3 years to be adopted at the Commission level in 2008, due in part to notifications under the WTO but also consultation processes within the EU.

Under CLP, both companies[24] and Member States are able to submit proposals to ECHA for the harmonised classification of a substance, with detailed guidance available from ECHA on the process. The process provides all stakeholders with an opportunity to comment on these proposals via ECHA's website, which provides details of proposals in a transparent manner. The overall timeframe for this process is set out in Article 37(4) of the Regulation, with the RAC needing to form an opinion on proposals within 18 months. After this, a decision is to be submitted by ECHA to the Commission and adopted without undue delays.

Analysis of the data presented in ECHA's table of additions to Annex VI indicates that immediately after the introduction of CLP there were 3,370 entries in Annex VI (inherited from the Dangerous Substances Directive, i.e. CLP00). These entries do not all refer to a single substance, but in some cases reflect a group of substance (e.g. a group of lead compounds). The actual number of substances represented by this number of entries will therefore have been significantly higher.

As of the 4th January 2017, there are 4,537 entries in the CLI with a harmonised classification, with these added through the seven ATPs that have taken place up to this date; ECHA indicates that in total between 6,000 and 7,000 substances are likely to now have a CLH. Even though large numbers of the substances were effectively adapted from the 30th and 31st Adaptations to Technical progress (ATPs) to the Dangerous Substances Directive, the total number that has now been added to Annex VI shows a level of efficiency within the process.

As of the 4th January 2017, 323 CLH proposals had been submitted to the RAC between December 2008 and May 2016. Large numbers of these relate to active substances under the Plant Protection Products Regulation or the Biocidal Products Regulation. Similarly, there are 41 additional substances listed on the Registry of Intentions for CLH proposals; of these 15 relate to industrial chemicals, with the remainder relating to active substances under the Plant Protection Products Regulation or the Biocidal Products Regulation.

This highlights the workload that the CLH process has placed on, and will continue to place on, the activities of the RAC. Recognising the need for increased efficiency due to RAC's overall workload (also taking into account REACH related activities), ECHA recently introduced a fast track procedure for discussing non-controversial end points. ECHA[25] have indicated that in the RAC meeting where this was introduced, 65% of classification proposals for such end-points went through without discussion. This means that the RAC is able to handle some CLH proposals within a single meeting rather than over two meetings, as had previously been the case. Speeding up the process for

[24] Companies can submit proposals for declassification and for classification against new endpoints.

[25] Personal communication.

agreeing non-controversial classification proposals should be welcomed by both Member State and industry, for example some concern has been expressed by industry in consultation responses that the time constraints on RAC for agreeing an opinion could mean that too little attention was given to more controversial or difficult proposals, given the number that had to be processed.

5.2.2 Efficiency and effectiveness compared to the system under the Dangerous Substances Directive

Most Member States and ECHA expressed the view that the process is much improved over that which was in place prior to the implementation of REACH and CLP. It is understood that an informal review of the process also supports this view due to the work that has been undertaken to better integrate the processes for identifying those substances where further scrutiny may be required, undertaking the substance evaluation and agreeing on a CLH where this is identified as the most appropriate option is considered faster and more efficient. An increase in the efficiency in the process is expected as steps are undertaken to carry out these activities based on the grouping of substances. This is also expected to help ensure that hazards are identified more quickly and more cost-effectively and the greater use of grouping approaches may provide greater certainty for industry and help in further creating a level playing field.

Whilst the process is perceived by many stakeholders to be an improvement on the previous system (under DSD), analysis of the time taken to finalise harmonised classifications for incorporation into Annex VI of CLP suggests that there is no improvement in the speed of decision making. When the start dates for consultation on harmonised classifications[26] are compared with the table of harmonised entries in Annex VI to CLP[27] this suggests an average of around two years between the opening of the consulation and insertion/update in an ATP to CLP (over the 138 substances appearing on both lists).

For comparison, a 1998 Commission working document on the operation of several pieces of chemicals legislation[28] identifies the following in relation to harmonised classification under the previous system:

> *"To reach agreement classification and labelling of every recently notified "new" substance is circulated by the ECB to the national CAs with a minimum six month deadline for confirmation or modification. Under this procedure classification and labelling of a range of notified substances is agreed before presenting them to an Adaptation to Technical Progress (ATP) to update Annex I. Since the procedures for an ATP require approximately a further six months a total of one to two years is required on average from acceptance by a national CA of the classification and labelling proposal in the notification dossier until the entry into Annex I.*
>
> *The CMR Working Group discusses the available toxicological data of an "existing" substance during three meetings on average. The Group also takes into account special data and views that industry may provide. As this discussion process takes nearly a year and a certain number*

[26] https://echa.europa.eu/harmonised-classification-and-labelling-previous-consultations

[27] https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp

[28] COM (1998): Commission Working Document: Report on the operation of Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the - classification, packaging and labelling of dangerous substances… Brussels, .18.11.1998 SEC(1998) 1986 final (see archive version http://aei.pitt.edu/3331/1/3331.pdf)

of agreed substances are collected before presentation to an ATP, the total time necessary adds up to between one and two years.

The time period of one to two years to update Annex I for both "new" and "existing" substances is unsatisfactory since potential users of the substance are not officially informed during this period. The delay may even be longer depending upon the available resources. Questions should be raised on how to accelerate the updating of Annex I."

Thus, for elements of efficiency that can be measured in terms of time, the data suggest no improvement on the previous system under the Dangerous Substances Directive. It is more difficult to compare effectiveness and efficiency in terms numbers of harmonised classifications under the Dangerous Substances Directive and CLP. CLP started with 3,370 substances added to Annex VI, with 763 added through ATP01 (from the 30th and 31st ATPs to the Dangerous Substances Directive). Since then, there have been a further 371 insertions or up-dates, and 92 substances which are newly added (i.e. new insertions).

The two other key shortcomings of the current system compared to the Dangerous Substances Directive are its focus on CMR properties, with this meaning that harmonised classifications are not given to other endpoints (an issue also raised by industry) and the fact that the process to date has been more focused on agreeing harmonised classifications for active plant protection substances rather than industrial chemicals.

Indeed, it is of note though that some Member States do not necessarily agree that the process is more effective or efficient for them, compared to the approach that was in place under the Dangerous Substances Directive. One Member State noted that:

"*The current process is not as efficient as the previous Dangerous Substances Directive regime as far fewer industrial substances are submitted and considered, although the current approach of targeting certain substances and prioritising certain hazard classes may be an improvement. However, the reduction in the number of industrial substances being considered may be resulting in a more effective process, reflecting the thorough, scientifically sound decision-making described above. In respect to environmental hazards, decisions are now seen as much more transparent with a tangible audit trail."*

Whilst another commented that:

"We consider that this question concerns the RAC and the Reach Committee. In general for the Reach Committee meetings, the efficiency and effectiveness of the meetings are considerably limited due to late arrival of relevant documents prior to the meetings."

Member States have also suggested that there is a need for more coordination between ECHA and EFSA, and a need to ensure the minimisation of a duplication of effort for the Plant Protection Products Regulation and Biocidal Products Regulation active substances. This issue is discussed in more detail in the Task 2 report, it is noted that steps are being taken in this regard with the development of a common template/format, and authorities indicate this should be useful. They also recognise the difficulties as different competent authorities may be responsible for these substances and implementation of the Plant Protection Products Regulation and Biocidal Products Regulation than for CLP. Thus it may be that better collaboration is required amongst the different competent authorities within each Member State.

Industry has also indicated that the process is an improvement over the previous system. However, consultees note that there are problems with some of the deadlines set in CLP for effective

interaction within the process (and one would expect this to also be relevant to mon-governmental organisations (NGOs)). Indeed, the 45 day time period for the public/stakeholders to comment on a CLH proposal may be too short for many types of organisations. Industry has noted that it can take longer than this to organise themselves so as to agree and feed comments into the process (especially if SMEs are to be effectively involved within the process). For this reason, industry believes that extending the period of the public consultation to 6 months would not impact significantly on the speed of the process (in terms of efficiency) but would improve its effectiveness for all parties. In response, ECHA have recommended that stakeholders should begin to organise themselves earlier, at the stage when the substance is notified to the RoI. This may be feasible for larger manufacturers and importers, but more difficult due to resource constraints for SMEs; it may also be more difficult for NGOs due to resource constraints.

Although not directly related to the process, the VCI indicated that assessment by the RAC according to the CLP Regulation directly influences other regulatory fields too, without sufficiently taking into account the specific criteria of other legislation, for example the evaluation of active substances and biocidal products pursuant to Biocidal Products Regulation. The VCI suggest that the harmonised classification according to the CLP Regulation should not be taken as an absolute exclusion criterion in other regulatory fields. Instead, this harmonised classification should be included in the upcoming risk assessment with an open decision. The VCI highlight that releasers classified as CMR 1B in biocidal products are an example.

5.3 Role of Member States

Key findings:

- Most CLH proposals to date relate to active substances under the Plant Protection Products Regulation and the Biocidal Products Regulation which may imply that there are some constraints on Member State ability to focus on industrial chemicals
- The level of effort across Member States in bringing forward CLH dossiers is uneven, suggesting that more could be done to require/encourage Member States in this regard
- Issues identified by consultees include the lack of a CLH Roadmap – which may also be of benefit to industry – and financial support for Member States in preparing dossiers.

Although CLP allows both companies (where no CLH already exists) and Member States to submit new CLH proposals, it is clear that most proposals are submitted by Member States. Discussions with ECHA suggest that industry does submit proposals directly, with most of these being for the declassification of substances; such proposals can be successful if industry has new data relevant to updating an older harmonised classification. Industry may also try and submit such dossiers via the competent authority in the Member State in which a substance is placed on the market, but industry responses to consultation for this study indicate that Member States often (indeed usually) refuse to support such proposals.

As noted above, a high percentage of the CLH proposals submitted to date have related to active substances under the Plant Protection Products Regulation and Biocidal Products Regulation. Given the need to have harmonised classifications under these Regulations (see also Task 3 reporting), this suggests that there have been some constraints on Member States' abilities to focus on industrial chemicals. ECHA suggests that for industrial chemicals (i.e. those falling under REACH) between 10

and 20 substances per year go through the CLH process, with a significant proportion of these being industry's declassification proposals.

A review of the Registry of Intentions available on ECHA's website reveals that not all Member States have been active in submitting proposals, or indeed are currently developing proposals. Some Member States have themselves indicated a lack of resources in general and/or in terms of the expertise required, when responding to consultation.

For example, the survey of Member State authorities undertaken for this study highlights that there is a subset of Member States that are very active in bringing forward proposals, another set that has been less active but continues to develop proposals, and a further set that has not brought forward any proposals for CLH and has none in preparation. Germany has been the most active of the countries, with 37 CLH proposals having gone through the process, 27 proposals reportedly currently before the RAC (as of June 2016), and a further 34 in preparation. The UK has had 24 proposals go through the process, another 11 have been submitted, and 16 are in preparation. Similarly, Sweden has had 9 proposals go through the process, another 15 are currently before the RAC and 12 are in preparation. These three countries therefore account for more than one third (123) of the substances listed in ECHA's Registry of Intentions of submitted proposals.

This suggests that the current provisions are resulting in an uneven level of effort by Member States in bringing forward CLH proposals. This issue has been recognised by some of the more active Member States, with one noting that, while in their view the process is accessible to and encourages Member States to submit CLH proposals, it may be difficult for less experienced Member States due to both a lack of resources and a lack of the necessary competencies. It has also been suggested that the complexity of the process may discourage Member States from submitting CLH proposals. Indeed, it is suggested that this is a possible weakness in the current process as its expectation is that every Member State is equal and has equal responsibilities, which "may be asking too much". However, when responding to targeted data collection, most (but not all) Member States, including those that have not yet submitted any/many proposals to ECHA, indicated that it is accessible to all Member State authorities and does indeed encourage them to put forward CLH proposals.

Industry responses to consultation have indicated that they are less satisfied with the speed at which Member States have brought forward proposals for the CLH of substances which are active substances under the Biocidal Products Regulation and Plant Protection Products Regulation and where harmonized classifications are required as part of the approvals process. This issue is discussed further under Task 3[29]. However, it is understood that all relevant parties are working on addressing this issue, including through the development of a common format for draft opinions.

The overall conclusion is that if the CLH process is truly the cornerstone of EU chemicals legislation, then this suggests that more needs to done to encourage or assist Member States in developing or supporting CLH proposals, if the objective or reducing exposures is to be achieved. As suggested below, two actions that might help in further encouraging Member States include the publication of a CLH roadmap and financially supporting Member State's work in preparing CLH dossiers. Alternatively, the Commission could be given the ability to ask ECHA to develop CLI dossiers for industrial chemicals.

[29] In brief, problems arise when EFSA agrees a harmonised classification for an active substances before the RAC does, and the Commission has to make a decision regarding approval based on EFSA's classification. If RAC then reaches a different conclusion on the appropriate harmonised classification, this would lead to inconsistencies as the RAC opinion is legally binding on the Commission.

5.4 Costs and unnecessary burdens

Key findings:

- Preparation of CLH dossiers places a high burden on Member State authorities and some may need additional support due to a lack of resources and/or expertise
- However, due to the importance of reliability and transparency in the process, the burden is considered acceptable by Member State authorities
- Industry proposals for re-classification of substances on Annex VI of CLP find little support from Member State authorities
- There may be merit, however, in order to speed up the rate at which CLH are agreed for industrial chemicals in allowing industry to develop proposals for review and opinion forming by the RAC. If this were the case, one would have to accept that RAC may spend a disproportionate amount of time and resources on such dossiers.
- The transition time following agreement of CLH and its entry onto Annex VI is considered too short by many in industry, given the implications that this can have in relation to downstream legislation

As part of targeted data collection, authorities were asked what the impacts of the CLH process were on them in terms of burdens. Around two thirds (8 out of 13) agreed that it placed a high burden on the responsible Member State, but most (10 out of 13 responses) also agreed that the process is both clear and reasonable (proportionate) in terms of the burden that is placed on authorities; those disagreeing indicated that the process did place an undue burden on authorities. Most (8 out of 13) also agreed that the process was more efficient for Member State authorities than the process that existed under the Dangerous Substances Directive (with more mixed views on whether it was more effective than the approach that existed under the Dangerous Substances Directive).

The cost burden was identified by a number of Member State authorities (ten) as restricting the number of dossiers that an authority could develop. As noted by three authorities:

- *"Preparing a CLH dossier is hard work. Collecting information and preparing IUCLID file takes a lot of time and effort. Some Member States do not have enough staff to prepare CLH dossiers. Sometimes Member States do not have enough experts to assess certain hazard endpoints (for example carcinogenicity or toxic to reproduction)."*[30]

- *"The requirements of the process for harmonisation of the classification and labelling of the substances are clear and reasonable. However submission of a dossier for harmonised classification and labelling is a challenge for some Member States who have limited resources (both in terms of expertise and finance) and experience* (by a Member State who has not submitted anything yet to the process)*."*

- *"The process still demands a lot of work and scientific input. While this is needed to base the decision on facts (and we don't see any alternative), there is apparently no "easy" or "fast" way to achieve a harmonised classification."*

[30] In response to this comment, ECHA noted that the information requirements for IUCLID files are almost at a minimum and that ways in which to reduce this burden are currently being looked into by ECHA.

Another authority noted that certain resources are needed for carrying out the CLH process. If the goal is a reliable and transparent process which is acceptable for all stakeholders, then it is hard to reduce the burden involved in preparing a dossier. As a result, the number of dossiers that can be developed will depend on the available resources, making it necessary for authorities to prioritise those substances that are subject to CLH. Thus, although the costs may be high for authorities, they are not viewed as representing an unnecessary burden.

It was suggested by one Member State authority that if the costs of making a CLH proposal were subsidised for those Member States with limited resources, then this may encourage them to be more active. Another indicated that due to the cost burdens involved, Member States should be paid a fee to help meet costs; this would then encourage more Member States to prepare CLH dossiers.

An alternative approach may be to enable companies to put forward more CLH dossiers. Presently, if industry wishes to submit a CLH dossier they must do so under Article 37(2) of CLP, which restricts such proposals to new hazard classes for substances on Annex VI. Alternatively, they must rely on Article 37(6), and ask a Member State to submit a proposal.

There is a high level of awareness of this ability, with 75% of industry respondents to targeted data collection indicating they were aware of this possibility. Furthermore, 44% of respondents (out of 83 manufacturers, importers and formulators) indicated that they had thought about taking advantage of this possibility. Interestingly, seven manufacturers and one importer indicated that they had submitted a proposal for a harmonised classification to a Member State authority for a substance in Part 3 of Annex VI due to new information that could lead to a change in the classification.

In four of these cases, the proposals were forwarded to ECHA, but in the other four they were not. Where they were not, respondents indicated that Member States refused to support a harmonised classification due to a lack of capacity. In one case, the REACH consortium approached a number of different Member States:

> *"Various REACH consortia of which we are a member have approached different member states to ask if they would support a change to a harmonized classification. In general member states have refused due to lack of capacity."*

It is also of note that one respondent indicated that ECHA did not support an industry request for a harmonised classification covering additional endpoints, stating that the focus was on CMRs rather than other endpoints. This is of concern to industry due to issues with the reliability of the classification data held in Part 3 of Annex VI. However, ECHA notes that it requests a justification from industry for CLH proposals other than for CMR or respiratory sensitisers (as well as a fee), and it is not clear without further details what the basis was for rejecting the industry request (and industry cannot submit proposals with respect to biocidal or plant protection product active substances).

This issue has been raised by the VCI and is further supported by respondents to the manufacturers' targeted data collection. As noted by one respondent:

> *"There is a lot of confusion arising from the Annex VI to CLP which is now not fully harmonized. Thus for endpoints not covered by an entry in part 3 of Annex VI, classification for these hazard classes has to be included by manufacturers/importers. Minimum classifications (Annex VI, 1.2.1) which result from the switch from Directive 67/548/EEC (the Dangerous Substances Directive) to the CLP Regulation (acute toxicity and target organ toxicity/repeated exposure) entails that for some substances there is no direct correspondence between the former Dangerous Substances*

Directive Annex I classification and the new CLP Annex VI. Therefore, if the manufacturer or importer has information or data suggesting a more severe classification, this more severe classification has to be applied. This results in an Annex VI which is not fully harmonized anymore. So either Annex VI should be removed or it should only keep CMRs 1A, 1B and 2 and respiratory sensitisers (Article 36) with full harmonisation."

Further related comments are given in Table 5-2 below.

Table 5-2: Industry comments regarding Annex VI of CLP

"Unlike in the earlier Annex I to the Dangerous Substances Regulation (67/548/EEC), which laid down the classification across all available endpoints for the listed substances, the present procedure departs from this approach. Article 4(3) CLP stipulates the following: Where a substance is subject to harmonised classification and labelling through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry for all hazard classes covered. For the listed hazard classes or differentiations, no classification under Title II CLP shall be carried out by manufacturers or importers. However, where the substance also falls within one or more hazard classes not covered by an entry in part 3 of Annex VI, classification for these hazard classes by manufacturers or importers becomes necessary. Thus, for substances listed in Annex VI the hazard classes not covered there need to be added. This leads to different classifications on the market of the substances in part 3 of Annex VI CLP.

Also problematic is the determination of so-called minimum classifications (CLP Regulation, Annex VI, 1.2.1 "Minimum classification") in Annex VI, part 3, table 3.1 CLP. When translating classifications under Directive 67/548/EEC to classifications under CLP, the translations based on the data were not always exact. For certain hazard classes, including acute toxicity and specific target organ toxicity (repeated exposure) the classification according to the criteria of Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under CLP. In these cases, the classification in this Annex shall be considered as a minimum classification. Where the manufacturer or importer has access to data or other information that lead to classification in a more severe category compared to the minimum classification, classification in the more severe category must then be applied.

Annex VI was designed as a listing of substances with harmonised classifications and labelling elements at Community level. Therefore, the goal should be to lay down in a binding manner the classification and labelling of these substances for all endpoints. The entries in Annex VI should be harmonised fully, also with a view to a future, globally harmonised substance list."

Source: *Industry respondent to the targeted consultation*

Given the above comments, it is therefore likely that these industry respondents would submit the dossiers themselves if they were allowed to. The fees for submitting CLH dossiers to ECHA are small (e.g. the standard fee is currently €12,000, lower for a SME). The costs of submitting the dossier are therefore not prohibitive, and clearly for these companies the costs of preparing the dossiers are also not likely to be considered disproportionate.

We also understand that some of the companies were seeking the support of a Member State in relation to a Biocidal Products Regulation or Plant Protection Products Regulation dossier, while others were referring to industrial chemicals. Although a strong peer-review of the dossier would be required by authorities of any industry prepared dossier related to active substances or industrial chemicals, allowing industry submission of such dossiers may help in reducing the burden on authorities. Indeed, most Member State respondents to the targeted data collection indicated that companies should be enabled and encouraged to develop and submit dossiers to ensure coherence with other legislation, such as the Plant Protection Products Regulation.

A related issue regarding costs and unnecessary burdens is the transition time allowed following the CLH for a substance being added to Annex VI. These additions occur through ATPs, which generally allow a transition period both for adaptations of labelling and packaging, but also to enable operators to comply with any registration (or other) obligations that the changes in classification trigger under REACH. The transition periods allowed for vary from over one year (e.g. 18 months) to two years.

With regard to the actions triggered by a new CLH, manufacturers, importers and formulators were asked to provide an indication of the extent to which they expected future expenditure in relation to CLP to be due to different factors, one of which was the agreement of new harmonised classifications. The average proportion of future expenditure linked to a new CLH was around 12% of classification, labelling and packaging expenditure (with 10% also being the mode); a high of 75% was given by one company, but also a low of 0%. Of course, the real costs of a new CLH will not be linked to classification or labelling activities, but to the need for reformulation or to other consequences under downstream legislation.

5.5 Data quality and burden of proof

Key findings:

- Views are mixed on the quality of CLH dossiers, with some arguing for greater checks by ECHA or consultation between the RAC Rapporteur and the dossier submitter
- Views are also mixed on the role of non-GLP evidence
- It is important though that CLH opinions are based on reliable and reproducible data, whether GLP-based or otherwise, given their potentially far reaching implications
- Many in industry wish to see greater consultation by Member States prior to preparation of a CLH dossier; RMOA is seen as one approach for ensuring this

Data quality is interpreted here as relating to the quality of a CLH proposal, and more generally whether or not a dossier has been handled properly within ECHA's Risk Assessment Committee (RAC) and whether the RAC has based its opinion on the most reliable set of data. Views on this are mixed, although there are several different issues underlying the reason why views are mixed:

- Some commentators have indicated that the quality of CLH dossiers varies a lot and that there is a need for a better accordance check by ECHA. This would help improve the overall process and would also help ensure that time planning was more reliable for both dossier submitters and for the RAC;

- It has been suggested that there should be greater consultation and ongoing dialogue between member states and registrants before a classification proposal is made to allow industry to provide additional clarifications on the data and to assess together with the Member State authority whether a revised classification is warranted;

- It has also been suggested that there is a missing step within the overall classification process. The dossier submitter should be allowed to review and comment upon the draft opinion and classification proposal of the RAC rapporteur ahead of the RAC meeting. This would help avoid misunderstandings concerning the decision forming basis and ensure that the end classification was reliable; and

- There are varying opinions on extent to which the RAC should base its decisions on consideration of all available scientific evidence, or should give increased importance to data developed in line with Good Laboratory Practice.

NGOs have argued that there is a need for all available scientific evidence to be taken into account and not just data developed in line with GLP, as academic studies may not meet its requirements. This point was also made in the April 19th Stakeholder Workshop held to support this study.

Member State authorities generally (but not all) agree that all available scientific evidence should be taken into account. However, some of these respondents also qualified their responses but noting that the data did need to be 'reliable'. Another noted that this depends on one's definition of 'evidence'. If only reviewed data are allowed (as in the US system), then they do not believe that such a constraint would work, as the requirement should only be for evidence to have been 'scientifically derived'. It is assumed here that 'reviewed' refers to peer review; in other words, the data would have to have gone through some form of scientific validation process. Given that the data are to act as the basis for regulatory action that may have far reaching implications, however, it would not seem that ensuring that some minimum standard of reproducibility and reliability has been met is inappropriate. This may not mean that full compliance with GLP is necessary, but that some minimum requirements are developed if it is not.

On their part, industry is concerned by the potential use of scientific evidence which has not been peer reviewed or developed in line with GLP, with the reliability of some of the data that has been used and the lack of transparency and consistency that this can give rise to. Multiple industry respondents commented on such concerns with these summarised by the following remarks:

- *"New harmonised classifications are often over-conservative and sometimes don't follow the EU guidelines. In addition these over-conservative classifications are often in contradiction with other EU goals (e.g. increase trade and resource efficiency)."*

- *"…, with regard in particular to the lack of a scientific and robust weight of evidence approach… Member states' ability to put forward classification proposals without any prior consultation with the registrant creates significant unpredictability for manufacturers."*

- *"… there was no contact from the Member State and there was even a failure to check what data was available in the registration dossier. As a result, they used data which were discounted in the registration dossier and did not even report on the key data used for registration."*

As a result, industry stakeholders responding to the targeted data collection did not in general agree that the process was leading to reliable results. Indeed, only 28% indicated that they felt the process was objective. One respondent summarised many of the views expressed with the following remarks:

- *"The RMOA should serve as a platform for authorities and registrants to agree on a risk assessment and management plan for the substance, which should only be amended if significant new data becomes available. In this respect, ECHA should:*

    - *Establish safeguards to control the launch of a classification process for substances that have already undergone in-depth risk assessment, have been recognised as safe and for which no new data is available; the accordance check could be a way for ECHA to play its role as gatekeeper to avoid the multiplication of regulatory processes for a substance without clear scientific justification;*

- *Ensure a robust scientific and weight of evidence approach when assessing the data available to ensure classification decisions are proportionate and adapted; specific guidance on weight of evidence should be developed and consistently applied through all chemicals legislation."*

Turning to the burden of proof, this question is interpreted with respect to whether or not the burden of proof is appropriately allocated between different stakeholders within the overall process. Within the context of CLH, the question then relates to whether there are sufficiently robust justifications for a proposed CLH, based on the available tox- and ecotoxicological data.

When asked about the allocation of burden of proof, Member State authorities were less positive on whether or not the burden of proof was currently properly allocated. Half of the respondents agreed that it was, while the other half either disagreed or indicated "don't know". The latter could reflect a lack of experience with the process, as some of those responding "don't know" have not moved a CLH proposal through the process; however, it may also reflect the view that the burden of proof on authorities is too high within the overall process.

5.6 Transparency, stakeholder involvement (including SME support) and burden of proof

Key findings:

- The CLH process is generally considered to be well understood, but there is a lack of understanding within industry on how they can participate; this is more of an issue for SMEs
- There is more transparency in opinion forming than after the opinion is sent to the Commission
- Although stakeholders agree that CLH should remain hazard based, the lack of transparency leads in part to industry submitting other (e.g. socio-economic) information into the process
- Long time periods for final decision can lead to questions over objectivity and predictability of the process

Following the receipt of a CLH proposal from a Member State, ECHA will undertake an accordance check and the proposal (dossier) will be published for public consultation. Consultation responses are then taken into account by the RAC when forming their opinion on the proposal. This opinion is then sent to the Commission for decision making.

The issues of transparency and stakeholder involvement within this process are more complex, and are assessed here in terms of the following:

- Is the process transparent and clear to stakeholders in terms of the steps involved?
- Are stakeholders able to participate in a timely and meaningful manner, and is it as accessible to SMEs as to larger companies?
- Are there any barriers to participation?

The view from many stakeholders (across all groups) is that there is a well understood and transparent process in place in terms of the period up to a RAC opinion. There is also a relatively good understanding by key stakeholders of how the system functions and how stakeholders can participate in the process. One industry respondent noted that*:*

- *"As a CLH dossier submitter, we could take part in RAC meetings to follow the outcome of discussion of classification which we proposed for the substance. We also had a choice to take part in Webex."*

Responses suggest that it is harder for SMEs with fewer resources and less knowledge on how the system overall operates making it more difficult for them to follow-up on all steps of the process. This suggests that there may be a need for further support to be provided to SMEs whose portfolios may be affected by a CLH.

There also appears to be a more general lack of understanding of how industry and other stakeholders can effectively engage with authorities throughout the process. ECHA has introduced a series of pre-regulation processes, and this has helped make the processes more understandable. In particular, it has helped industry follow and predict what is coming and to take the measures needed to ensure that their registration dossiers are up to date, as these act as the basis for the pre-CLH processes. Stakeholders have also expressed the view that ECHA's guidance has helped in making the process more transparent and accessible.
In contrast to the pre-regulatory and RAC processes, there does appear to be an issue in relation to transparency and stakeholder involvement in the period after RAC has developed its opinion. The process that takes place after the opinion has gone to the Commission has been described by some as a "black box". As a result, it is clear that this part of the process is not transparent. Since it can take many months for final decisions to be taken, this lack of clarity leads to considerable uncertainty for companies, which impacts on their activities.

In this respect, only 47% of companies responding to the targeted data collection agreed with the statements that "the process is clear and transparent" and "that it is appropriate for agreeing harmonised classifications". An even smaller percentage - at 39% - agreed that the process is accessible to SMEs as well as to larger companies, while only 35% agreed that there were no barriers to participation in the process. There was a greater likelihood of a SME not agreeing with these statements than the larger company respondents.

Member States have also noted that it can take too long for decisions to be reached during this stage of the process, noting that "time limits are not foreseeable"; indeed, it has been suggested that this is also the point within the process where there may be a lack of objectivity and hence predictability in the final outcome if the RAC opinion is not adopted.

Such views concerning the lack of transparency are also likely to be the reason that some in industry feel that they need to submit non-scientific information on the consequences of a CLH to ECHA's public consultation on RAC's draft opinion. Although industry agrees that CLH proposals should be based only on the intrinsic properties of a substance, some parts also see the public consultation as the only opportunity to ensure that ECHA, the Commission and Member States are made aware of potential socio-economic implications. Authorities also noted that this is likely to be occurring because stakeholders want to provide such comments and it is not clear how and when to do it. As a result, they submit comments on socio-economic factors to the public consultation, even though know such comments are outside the CLH process.

More generally, it has been suggested that transparency would be increased if a CLH road map were to be produced. This may not only encourage a Member State to prioritise those substances that it was putting forward for harmonised classification (and possibly encourage them to develop dossiers), but also increase predictability for industry and NGOs, and help industry in its own planning (e.g. highlighting the need to update registration dossiers), etc.

5.7 Consideration of socio-economic consequences

Key findings:

- The CLH process is considered to work well and provide a good mechanism for identifying hazardous substances
- Most commentators agree that the CLH process should remain hazard based up to the point of the RAC opinion
- There is less agreement on whether (and how) socio-economic factors should or should not be taken into account in the final decision by the Commission on a change in substance classification. Some commentators believe they should and others (the majority) indicate that instead the linkages in downstream legislation should be addressed if they are not logical or proportionate (see also the Task 3 report)
- Suggestions put forward by stakeholders during the consultation process for enabling socio-economic issues to be raised before downstream legislation is triggered include greater use of RMOA analyses, including a mechanism for SEAC opinion-forming; providing a concrete step for submission of socio-economic data to the Commission; including a new risk assessment / socio-economic step prior to the triggering of downstream legislation; or amending downstream legislation to ensure the potential for derogations based on such arguments are included

One of the key debates regarding the CLH process is whether it should remain a scientific and hazard based process, or whether the process should also take into account the socio-economic consequences of a harmonised classification due to the hazard based and risk based triggers that exist in downstream legislation. Although these triggers are discussed further under Task 3, it is more appropriate to discuss this debate here.

Most commentators, with this including NGOs, Member State authorities, industry associations and companies, support the process remaining a purely scientific one, at least up to the point of the RAC delivering its opinion. In this respect, CLP is considered to work well, as it provides a good mechanism for identifying hazardous substances to enable appropriate risk management. In this respect, the CLH process is viewed as providing industry with certainty.

Views are split though on whether there is a need to consider the implications of a CLH decision at some point within the process. For example, it is argued by some authorities that socio-economic factors should not be taken into account in the CLH decision making process – the current system provides a good approach, as it allows flexibility in the downstream legislation for risk reduction to be introduced as appropriate to a specific sector. For such an approach to work they argue, it remains vital that the classification is based on intrinsic hazardous properties and nothing else, so that this information provides a reliable starting point for all downstream legislation.

Interestingly, though, over one third of Member State authorities responding to the targeted data collection indicated that they believed that the EC and REACH Committee should consider the consequences of a change in substance classification under other chemical-related legislation when making its final determination on a new harmonised classification. Other authorities and ECHA do not agree with this position (nor do many industry associations). Instead, these stakeholders believe that further consideration should be given as to how downstream legislation links to these classifications and whether the consequences of such linkages are appropriate. In other words, there is a need to consider whether the linkages are logical and proportionate in terms of the potential consequences. It is the downstream legislation, therefore, that may need to better take

into account other aspects – economic as well as social ones – when regulating the use of substances having a harmonised classification.

As noted above, for industry there is a frustration that there is currently no mechanism for alerting decision makers of the potential downstream consequences of a CLH, and/or where the usual transition time of 18 to 24 months is unlikely to be sufficient. In their view, such information is relevant for policy makers and Member States when they vote in the REACH committee.

There are different potential suggestions from authorities and industry on how to address this problem :

1) Ensure that the Risk Management Options Analysis process that ECHA has introduced includes consideration of the impacts on industry and human health and the environment. The RMOA should more clearly recognise classification as one of the possible risk management options resulting from the Risk Management Option Analysis (RMOA), which should be conducted on a systematic basis for all substances before any regulatory action is taken. The RMOA could include consideration of the consequences of classification, so that these are highlighted early on. It should also serve as a platform for authorities and registrants to agree on a risk assessment and management plan for the substance, which is then only be amended if significant new data becomes available.

2) Require the SEAC to develop an opinion on the socio-economic impacts arising from the classification due to automatic triggers in downstream legislation as part of the opinion forming stage and in parallel to RAC's opinion on the harmonised classification. Such an approach would have to rely on stakeholders submitting cost and benefit data to the SEAC, which would then be used to form an opinion. This would ensure that the EC and the REACH Committee have independent information available to them for decision making purposes. The implication of this is, of course, that this opinion would also have an impact on what actions were then triggered by the CLH in downstream legislation;

3) Provide a more concrete means after ECHA has sent RAC's opinion on a CLH to the Commission for industry and NGOs to submit information on the potential impacts of the CLH should be it formally adopted. At present there is no transparent point in the process to enable all parties to provide a view on the impacts (positive or negative) of a CLH, and introduction of a formal public consultation phase would provide such a mechanism. This could be followed by a socio-economic analysis phase; and/or

4) Revise as appropriate the linkages between the CLP (and a CLH decision) and downstream legislation, by introducing further risk assessment steps or enabling socio-economic factors to be better taken into account (regardless of whether any of the above are also implemented).

Arguments against the first option are that industry may overpredict the consequences of a CLH at the RMOA stage, and it may therefore be more appropriate to ensure that there is a more detailed consideration of socio-economic impacts at a later stage; the RMOA stage would be inappropriate for these purposes, as its aim is to identify what the hazards are and what type of risk management might be appropriate rather than to decide on the appropriate level of risk management.

Arguments in favour of the second and third option are that at present there is no open consultation step within the process to enable industry to provide an understanding of the consequences of a CLH. As a result, the Commission and Member States are subject to a high degree of lobbying, the outcome of which may depend on how active different stakeholders are. Arguments against the

second and third options are that this is too late and would require a change in the current regulatory process that applies to decision making under the CLH process (regulatory decision with scrutiny). These two options are therefore considered to be unrealistic.

One Member State has indicated that, in their view, once a CLH opinion has been delivered by RAC, then companies should be aware of the need to start responding to the decision; there is no need for them to wait until the CLH is added to Annex VI of CLP (indeed, it has been suggested that suppliers of the substance could be considered to have an obligation to up-date there self-classifications at this point in time). This is a position that is obviously not shared by industry, which is strongly of the view that until the CLH has been added to Annex VI, the classification does not yet apply; and, indeed, they would also argue that if the CLH is legally challenged, that it should not apply until the end of the legal process to avoid a situation where risk management is automatically triggered but later found to be unjustified.

6 Impacts of the Transition to CLP

6.1 Introduction

There are two components to the assessment of costs within Task 1: assessing the transition costs of moving to the CLP Regulation; and assessing the costs arising from the implementation of the CLP Regulation across the various actors. The focus of this section is on the assessment of the transition costs arising from the move to CLP (with on-going implementation costs assessed in Section 7).

The section starts by setting out the approach to calculating transition costs, including specification of what types of costs are taken into account. Key assumptions on the number of substances and mixtures affected, the sectors incurring costs and per unit costs are then set out. These are followed by presentation of the calculated direct and indirect transition costs.

The relevant evaluation questions associated with the calculations provided below are set out in Table 6-1.

Table 6-1: Evaluation questions relevant to the costs of classification, labelling and packaging

Q #	Evaluation Question
2.1.1.	What are the costs associated with the chemicals legislative framework for: 2.1.1.1. regulators at EU and national level 2.1.1.2. industry, including SMEs 2.1.1.3. workers, consumers 2.1.1.4. society / economy in general
2.1.2.	If relevant, what are the transition costs (costs to implement new legislation,) and the regular costs associated with the chemicals legislative framework for each of the above-mentioned categories of stakeholders?
2.1.4.	To what extent are the costs proportionate to the benefits? What are the key drivers or those costs and benefits?

6.2 Approach to calculating impacts of transition to CLP

Figure 6-1, adapted from a resource in the Better Regulations Toolbox, gives an overview of the approach followed here to categorising and calculating the costs and benefits of transitioning to CLP. The cost types outlined in this diagram are described in further detail as follows:

- **Direct Costs:** Within this category are two sub-categories of costs: ***direct compliance costs*** and ***hassle costs***. The first of these consists of ***regulatory charges*** which include fees, levies and taxes; ***substantive compliance costs*** which entail the costs of investing in human and physical capital, as well as other expenses incurred in complying with legal requirements introduced by new legislation; and, ***administrative burdens*** which encompass the costs borne in performing administrative activities for complying with the information obligations

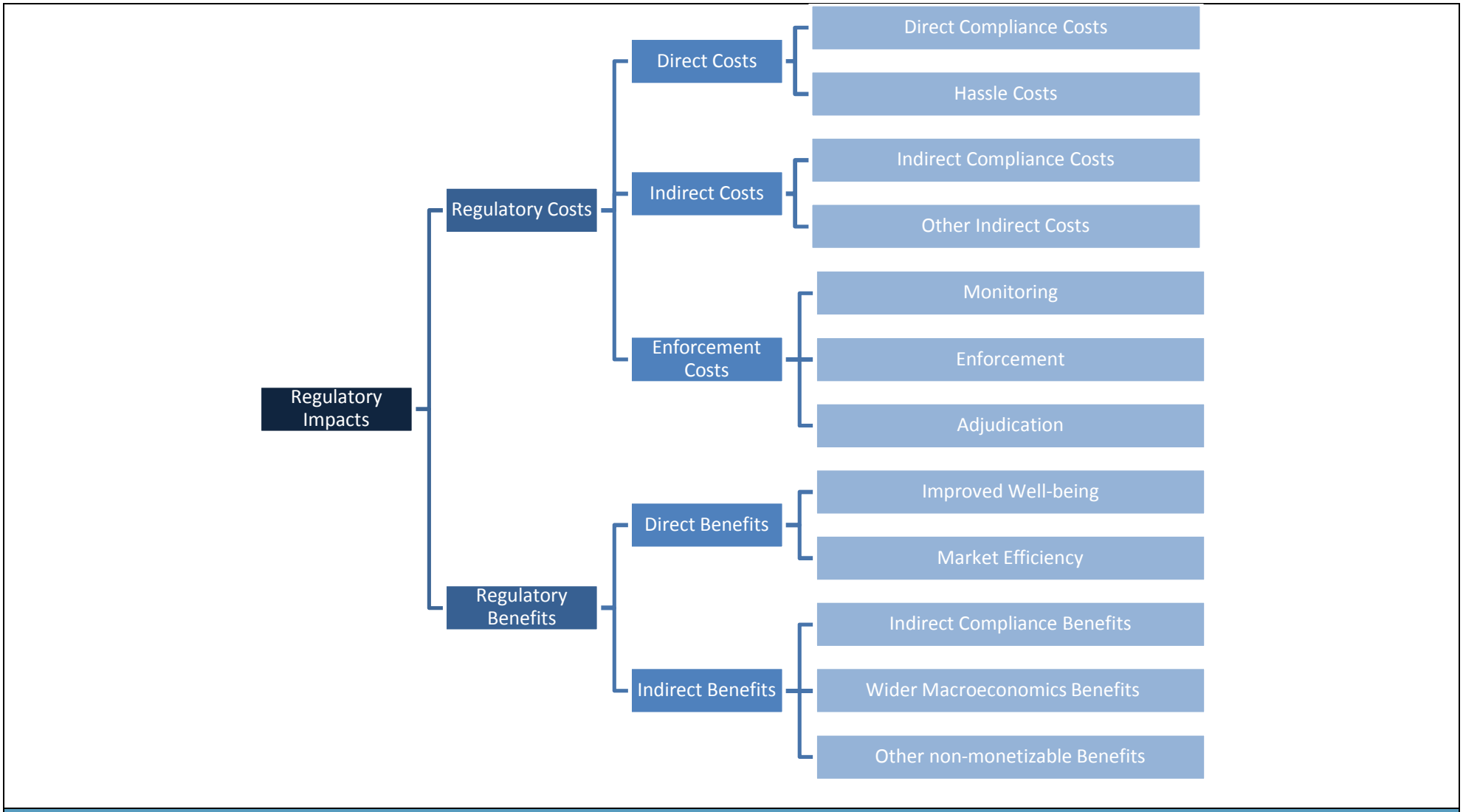


Figure 6-1: A map of regulatory costs and benefits, adapted from Better Regulation Toolbox

set out under the legislation. Hassle costs include the costs associated with corruption, annoyance and waiting times. Note that direct compliance costs can be further categorised as CAPEX where they relate to capital expenditure, OPEX where they are annual operating costs and administrative costs where they relate to reporting obligations. These categorisations were adopted in the Cumulative Cost Assessment for the EU Chemicals industry, for example. This study also categorised regulatory charges under the monetary obligations category.

- **Indirect Costs:** Indirect costs are those incurred in the sector targeted by the legislative measures, which are not directly related to the measure, or by other sectors or stakeholders which are not directly targeted by the legislative measure (i.e. downstream sectors). These indirect costs can be transmitted through price increases or changes in the supply of certain goods and services to the market. In some cases, this can have a multiplier effect (for example if a subject is withdrawn when the impact downstream was actually higher than the cost of keeping it on the market). For the purposes of this study, our attention will be focused on the indirect costs relating to re-formulating products or removing certain product lines from the market due to the changes induced by the CLP.

- **Enforcement Costs:** Enforcement costs are those incurred by Member States, public bodies and the European Commission through activities relating to the implementation of legislative measures. Costs can be categorised under the following: monitoring; enforcement; adjudication. (Note that these are assessed in Chapter 10 below).

The benefits of transitioning to the CLP Regulation will be assessed in terms of the categories listed in Figure 6-1, described in greater detail below:

- **Direct Benefits:** these relate to the direct benefits of the regulatory measures for the well-being of individuals; in terms of the CLP Regulation, this includes improving the health and safety of both consumers and workers who handle chemicals, as well as enhancing protection of the environment. It also encompasses the benefits to the market or the sector being targeted by the regulation such as improved market efficiency which, in this case, reflects better functioning of the single market and associated cost savings due to the removal of any non-tariff barriers to trade.

- **Indirect Benefits:** this category encompasses the benefits of the regulatory measures which were not an intended outcome. Such benefits include improvements in productivity, increased employment, increased GDP, etc.

The following table summarises how different stakeholders are impacted by different types of costs and benefits associated with the implementation of CLP.

Table 6-2: Impacts of CLP implementation by stakeholder

Stakeholder	Costs			Benefits	
	Direct Costs	Indirect Costs	Enforcement Costs	Direct Benefits	Indirect Benefits
Industry	✓	✓		✓	✓
Member State Authorities	✓		✓		✓
Workers	✓	✓		✓	✓
General Public		✓		✓	✓

6.3 Numbers of substances and mixtures

6.3.1 Approach

As with the original 2006 assessment of GHS, the costs of transitioning from the system of classification and labelling under the Dangerous Substances Directive and Dangerous Preparations Directive to the GHS based system set out in CLP requires consideration of the additional costs of classification, labelling and packaging to the new requirements.

This requires that one differentiates between changes in classification (and resulting changes in labelling and packaging) that are the result of new information generated under REACH and changes brought about only by changes to hazard classes, classification thresholds, hazard statements, labelling, packaging, etc. under the CLP. In particular, any new physicochemical, toxicological or ecotoxicological information on a substance stemming from new information generated under REACH that resulted in a change in an existing classification or the addition/subtraction of an endpoint for classification will have also resulted in the need to adjust safety datasheets, packaging and labelling. As such changes would have been required under the Dangerous Substances Directive (or the Dangerous Preparations Directive) as well as under CLP, such costs should be discounted from the analysis of transitional costs because they are not additional (i.e. attributable to the introduction of CLP).

The previous (2006) assessment of GHS costs paid particular attention to this because one of the main questions to be answered concerned what was likely to be the optimal timing for the introduction of the GHS based system, considering the flow of information from each of the three REACH registration deadlines (2010, 2013 and 2018) for phase-in substances (and which could result in changes in classification for a number of substances under the old or new systems). Excluding other considerations, the optimal (lowest cost) option was likely to be one of phasing-in GHS over time such that:

- Substances changing in classification owing to new information from REACH registration requirements would classify and label under the new system; and

- Substances for which new information had been generated for registration but there was no change in classification would also classify and label under the new system.

While both cases represent a shift to the new system, transition costs only apply to the second group of substances (because the first group would have to change their classification and labelling anyway).

Minimising these transitional costs was not, however, the only consideration. Such a cost minimising approach would have required that the system was not fully operational until 2018 for substances and later for mixtures. This would have meant maintaining both the old and the new systems of classification from 2010 until 2018 (at the earliest), and not having (full) access to the foreseen trade benefits of GHS for substances and mixtures until a period of time after 2018 (into the 2020s).

Taking these (and other) factors into the account, the 2006 study assessed various scenarios as to the timing of CLP's requirements and concluded that a timescale similar to that eventually adopted under CLP was likely to be the most economically optimal.

To do this, the 2006 assessment had to make predictions concerning the numbers of substances that were:

- Known to have hazardous properties for classification and, within this, the number for which new information generated under REACH would:
  - result in a change in classification; or
  - result in no change in classification;

- Not known (at the time) to have hazardous properties and, within this, the number for which new information generated under REACH would:
  - result in a new classification for one or more hazardous properties; or
  - confirm that there were no hazardous properties for classification.

Where the previous (*ex ante*) assessment was forced to make complex predictions on the outcome of REACH, this (current) assessment can draw on more definitive data concerning the above numbers (even though the final REACH 2018 registration deadline is still some two years away). Coupled with the fact that the timescale is now known, the assessment (for substances at least) is far simpler.

6.3.2 Number of substances

6.3.2.1 Starting point

All substances had to be classified, labelled and packaged according to the new CLP system from 1 December 2010 onward. As such, all substances known to have hazardous properties at the end of 2010 would be required to apply the new system of classification (while also maintaining information on the old system). The starting point for the assessment of transition costs for substances, then, is that there would have been a cost for transferring from the old system to the new one for all of these substances.

However, as the timing for the system of classification under CLP for substances coincided with the first (2010) REACH registration deadline, some substances would also have been registered under REACH at the same time. For a subset of these, the new information generated for registration purposes would have indicated a need for a change in classification under the old or the new system. In these cases, then, the transition to CLP is not responsible for the change in classification and, thus, the transition costs should be considered as zero (or close to zero). As a result, these substances need to be excluded from the assessment of the transition costs of CLP for substances.

The sub-sections below provide a description of the starting numbers for the assessment.

6.3.2.2 Numbers of substances known to have hazardous properties

A review of data used in models and assessments undertaken in the past has allowed the identification of the starting numbers for the assessment. This suggests the following:

Annex I of 67/548/EC

European Chemicals Bureau (ECB) data from the 2006 GHS assessment identifies that the total number of dangerous substances in Annex I of the Dangerous Substances Directive was 3,366. The same data identifies that 1,045 of these were 'new substances' according to the definitions used in Dangerous Substances Directive, meaning 2,321 were 'existing substances'.

Under REACH, all 'new substances' are regarded as automatically registered (NONS – Notifications of New Substances). The 'existing substances' are regarded as phase-in substances and must be registered for continued manufacture and use. Thus, of the 2,321 substances:

- Some will have been registered in 2010;
- Some will have been registered in 2013;
- Some are yet to be registered; and
- Some may no longer be in use/may never be registered.

For all of the substances in use (whether registered or yet to be registered), industry costs are associated with the initial changes reflecting new requirements on:

- Classification
- SDS;
- Labelling; and
- Packaging.

As all of the substances listed in Annex I of the Dangerous Substances Directive were subsequently transferred to form the initial list of harmonised classifications in Annex VI of CLP, the initial re-classification to reflect the CLP system was undertaken at the community level (and so the costs were not borne by industry). The exception to the above costs will be those dangerous substances registered in 2010 for which there was a change in classification owing to new information generated for the 2010 registration. At this point in time we have no data on the exact number of 'existing' (or phase-in) substances that changed classification owing to new information generated during the course of registration.

In terms of the number of existing substances and new substances listed on Annex VI by CLP by 1 December 2010, this comprises:

- The original list of dangerous substances with a harmonised classification transferred from the Dangerous Substances Directive (known as CLP00) – numbering 3,316; and
- Those added in the first Adaptation to Technical Progress (ATP) to CLP (ATP01) in 2009 – numbering 760.

Hazardous substances with a self-classification under 793/93/EC

Whilst all 'new' substances with hazardous properties were classified and listed on Annex I of the Dangerous Substances Directive, not all 'existing substances' with hazardous properties were listed. 'Existing substances' were those substances which were deemed to be on the European Market before September 18, 1981 and listed in the EINECS inventory (European Inventory of Existing Commercial chemical Substances).

The 1993 Existing Substances Regulation (793/93/EC, hereafter referred to as ESR) required the submission of all readily available data on High Production Volume Chemicals (HPVCs). To facilitate this, the ECB developed the IUCLID (International Uniform ChemicaL Information Database) to collect data for evaluation within the EU Risk Assessment Programme established under the same regulation.

As part of previous work on benefits indicators (for DG ENV) a list of those substances with self-classifications for human health and environmental hazards was retrieved from a 2005 extract[31] of the IUCLID system. This list was then compared with the CLI to identify:

[31] The last version of IUCLID before the entering into force of the REACH Regulation.

- Which substances are also on the CLI (and so notifications under CLP must have been completed); and
- How the classifications have changed due to REACH and CLP.

The analysis revealed that a total of 7,709 substances are common to the 2005 extract and the CLI. In other words, at the time that CLP came into force, around 7,700 substances were known to have hazardous properties (and were also notified to the CLI with the appropriate CLP classification). Further comparison of this list of substances with those listed on the REACH registration database provides information on the current registration status of these substances. This is provided in Table 6-3 below.

Table 6-3: Number of substances listed on REACH registration database	
Registered at >1000t	1,497
Registered at 100-1000t	719
Registered at 10-100t	226
Registered at 1-10t	198
Registered (Confidential)	45
Registered as an intermediate	1,304
Not yet registered	3,720

As noted previously, for all substances registered under REACH in 2010 and for which new information resulted in a change classification, there are no transition costs for CLP. For the remainder, the full costs of changing to the new system apply.

In terms of the number of these IUCLID listed substances that registered in 2010, as we do not have access to a previous image of the REACH registration database, it is difficult to establish how many of the 7,709 were registered in 2010 and how many were registered afterwards. In order to provide an estimate, we have assumed that:

- Consistent with REACH requirements, all those registered at >1000t were registered in 2010; and
- For substances registered at other tonnages, intermediates and those declared confidential, all of those now identified as Carc. 1A/1B on the CLI were registered in 2010.

Using and comparing the datasets, we have also estimated the (minimum[32]) number of substances registered in 2010 for which new REACH information led to a change in classification. Subtracting these from those registered provides the total of number of substances for which there has been a cost of transitioning to the new CLP system. These data are provided in Table 6-4 below.

[32] As the analysis for the Indicators study (RPA & DHI, 2016) was intended to provide information on changes in the numbers of substances classified for different endpoints, it did not provide a breakdown of the overall numbers of substances changing classification. Nonetheless, the data can be used to provide an estimate of the minimum number of substances that have changed classification since REACH and CLP were introduced.

Table 6-4: Number of substances for which transition costs are incurred				
	IUCLID substances currently registered under REACH	IUCLID substances estimated to have been registered in 2010	IUCLID substances which changed classification in 2010 owing to new information under REACH	Resulting IUCLID substances for which there was a cost for initial transition to new system
Registered at >1000t	1,497	1,497	637	**860**
Registered at 100-1000t	719	139	52	**667**
Registered at 10-100t	226	44	16	**210**
Registered at 1-10t	198	45	18	**180**
Registered (Confidential)	45	12	5	**40**
Registered as an intermediate	1,304	304	122	**1,182**
Not yet registered	3,720			**3,720**
Total	7,709	2,041	850	**6,859**

6.3.2.3 Hazardous substances not covered by the above

In addition to the substances described above, the analysis first undertaken for the DG Environment Benefits Indicators study (RPA & DHI, 2016) suggests that there are 92,051 substances with hazardous properties that are on the CLI at present but which are not registered under REACH. Assuming that 3,720 of these are the substances that were self-classified on IUCLID but are not yet registered (see the Table 6-3 above), this implies that there are 88,331 substances that are as yet unaccounted for in the analysis. These substances will be comprised of:

A. Known hazardous substances to be registered under REACH at 1-10t and 10-100t in 2018;
B. Known hazardous substances produced at less than 1t per year and not subject to registration under REACH; and
C. Known hazardous substances for which notifications were completed but production and use has ceased or will cease by the 2018 REACH deadline.

In terms of A) 'Known hazardous substances to be registered under REACH at 1-10t and 10-100t in 2018', ECHA are expecting 25,000 full registrations under REACH in 2018; 20,000 of these will be in the 1-10t band and 5,000 in the 10-100 t band. However, not all of these will be substances with previously known hazardous properties that have been notified under CLP. In past assessments, it has been assumed that 70% of substances will be identified with hazardous properties during REACH registration. Applying this to the 25,000 substances expected to be registered in 2018 suggests that around 17,500 substances will be identified with one or more hazardous properties. Assuming that for 25% of these 17,500 substances there was already information indicating hazardous properties demanding a notification under CLP, then this would imply that:

- Known hazardous substances to be registered under REACH at 1-10t and 10-100t in 2018 may be around 4,375 substances; and
- The remainder (83,956) are hazardous substances produced at less than 1t per year or for which notifications were completed but production and use has ceased or will cease by the 2018 REACH deadline. There is no obvious means of differentiating between the two.

6.3.2.4 Resulting total numbers of substances subject to full or partial initial transition costs

The resulting total number of substances that were subject to some or all of the initial costs of transition to the GHS system under CLP are provided in Table 6-5 below.

Table 6-5: Total numbers of substances subject to initial transition costs	
Annex VI substances	
CLP00 (Annex I of the Dangerous Substances Directive)	3,316
ATP01	760
IUCLID self-classified substances	
Registered at >1000t	860
Registered at 100-1000t	667
Registered at 10-100t	210
Registered at 1-10t	180
Registered (Confidential)	40
Registered as an intermediate	1,182
Not yet registered	3,720
Known hazardous substances to be registered under REACH at 1-10t and 10-100t in 2018	
10-100t	875
1-10t	3,500
Hazardous substances produced at less than 1t per year (or for which notifications were completed but production and use has ceased or will cease)	
<1t (or withdrawn hazardous substances)	83,956
Total carried forward for transition cost estimation	
Total number of substances subject to initial transition costs	99,266

It is important to recognise that the total number as given in the table includes all of those substances that were notified and aer either produced at less than 1 tonne or are no longer being produced. These are only considered in part of the assessment below, but are included here in order to estimate the costs of the CLI notification obligations.

6.3.2.5 Number of manufacturers and importers per substance

In order to calculate the cost of classification in line with CLP, we had to estimate the number of companies that will be affected by the changes. To do this, data were used from a DG GROW study which calculates the average number of companies manufacturing or importing a substance (CSES, RPA & Oekopol, 2015). These are referred to as MIs in the table below. The numbers in this table are based on an analysis of detailed statistics provided by ECHA to the CSES et al study. These statistics provided the numbers of registrants for every substance registered under REACH, the size of the companies and the tonnage band registered. They provide the best insight into the numbers of MIs of substances currently available. As can be seen from the table, the average is 5.7 per fully registered substance but, being an average, some substances have many more MIs than this and some will have only 1.

Table 6-6: Average number of MIs per substance					
	SME MIs	Large MIs	Total	Substances	Weight
Fully registered and CLP00 and ATP01	0.86	4.9	5.76	98,044	99%
Intermediates: also applied to all other substances on the CLI including <1t	0.15	1.39	1.55	1,222	1%
Weighted average	**0.85**	**4.86**	5.71		
Total number of substances				99,266	
Source: CSES et al (2015): Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, Report for DG Grow, December.					

6.3.3 Number of mixtures

6.3.3.1 Assumptions from 2006 Impact Assessment

In the 2006 impact assessment work (RPA et al, 2006), the following sectors were considered to be the most relevant:

- The detergents and cleaning products industry;
- Paints, printing ink and artists' colours industry;
- The dyes and pigments industry supporting sectors such as the textile industry;
  The adhesives and sealants sectors;
- The cosmetics and perfumes sectors (in particular in relation to fragrances);
- Fine and basic chemicals producers; and
- Distributors trading in substances and mixtures.

It is important to note that the study did not consider other types of mixtures including plastics, biocides, plant protection and fertilisers when developing estimates of the number of mixtures that may be affected by the need for classification and labelling. The study will therefore have underestimated costs, albeit to an unknown extent.

In estimating the costs to formulators of the move to CLP, the following assumptions were made:

- 2 million mixtures were placed on the EU market;
- Of this 2 million, 20% (or 0.4 million) were also assumed to be exported (based on data collected from company interviews), with these exports accounting for 25% of the corresponding EU industry's turnover; and
- The 1.6 million mixtures only sold in the EU are those that are relevant to the assessment of impacts, as those that are exported would be subject to GHS in any event due to the requirements of importing countries.

The estimate of the total number of mixtures on the EU market was based on industry guestimates and interview data collected for the impact assessment study. It should be noted that there is considerable uncertainty surrounding this figure; it was a guesstimate based on the expert judgement of key figures in the chemicals industry (Cefic, FECC, etc.). The study also found that the level of exports associated with some basic chemicals producers and with consumer products producers are low (or very low) compared to the total numbers of mixtures that they appeared to produce. For example, the consumer products sector is likely to account for hundreds of thousands of mixtures. However, most of these are produced for the EU or even domestic markets (e.g. 85% of household products sold in the UK are produced in the UK). In contrast, some segments of paints, inks, dyes and pigments manufacture will correspond to much higher levels of export. Finally, this figure of 20% of mixtures produced being exported was found to correspond to 25% of the EU industry's turnover coming from exports, with exports relating to higher rather than lower value mixtures.

6.3.3.2 Revised assumptions

A review of this information suggests that the starting figure for the number of mixtures placed on the EU market is too low. For example, a review of sector websites and materials suggests:

- Individual manufacturers of household and personal care products may produce up to 50,000 different mixtures, drawing on hundreds of thousands of ingredients, including other mixtures (e.g. fragrances which may be mixtures of mixtures) (pers comm, AISE);

- The printing ink sector alone produces some 1,125,000 mixtures for use in Europe;
- The European automotive paints sector will draw on over 2,500 base formulations, which will then have different colours added to them (e.g. up to 30,000 colours to basecoats and topcoats)[33].

In addition to these types of mixtures, there will be other types of coatings, biocidal products, plant protection products, construction chemicals (which will include mixtures), adhesives, etc. Responses from mixture manufacturers to the targeted consultation indicated that over 34% produced less than 50 mixtures, but around 29% of the respondents produced over 1500 mixtures (with 48% producing greater than 500). Taking the weighted average across all respondents (and not adjusting for population bias in terms of proportion of SME versus large company respondents) generates a figure of around 1,050 mixtures per responding company.

Eurostat data for 2013 (extracted May 2016) for the number of enterprises in the EU involved in chemical formulation related activities suggests 21,400 relevant enterprises[34] across the EU 28[35]. Based on this figure, and taking the weighted average across respondents, gives an estimated number of mixtures of just under 22.5 million. This figure is unrealistically high and will be skewed by the higher proportion of large companies compared to SMEs responding to the targeted consultation (although one SME indicated that they had over 1,500 mixtures in their portfolio). If we take the lower bound figure of 50 mixtures per company, the estimated number of mixtures placed on the market is around 1.07 million, which seems too low given that some SMEs also produce large numbers. Taking these various factors into account, we have increased the number of mixtures assumed to be placed on the market to 2.5 million, with this reflecting a 25% increase over the number assumed for the original impact assessment. This figure will be used as an upper bound for our calculations, with the original 2 million figure acting as the lower bound.

6.3.3.3 Number of mixtures classified as hazardous

The 2006 Impact Assessment assumed that 47% of all mixtures, pre-REACH, were known to contain one or more hazardous substances, and 30% of the mixtures that contained known hazardous substances were themselves classified.

Work carried out for AISE in 2007 (RPA, 2007) surveyed companies within the detergents and cleaning products sector and found that the following percentages of products were classified under the Dangerous Preparations Directive:

- Household products only: from 16% to 55% (for the main human health and environmental endpoints);
- I&I products: from 65% to 75%; and
- Combined portfolio of household and I&I products: <20% to 40%.

These figures suggest that the assumption of 47% of mixtures being classified already under the Dangerous Preparations Directive is reasonable, if not a bit high. However, as this is a directly consumer facing sector, one might expect an overall lower percentage of its products to be classified than for some of the other sectors. The figure of 47% of mixtures being classified as

[33] European Printing Ink Industry

[34] NACE codes: C20.17, 20.20, 20.30, 20.41, 20.42, 20.51, 20.52, 20.59, 24.10.

[35] The total number of companies operating in the EU according to Cefic in 2005 was around 27,000 (excluding pharmaceuticals and agrochemicals); 95.4% of these were classified as SMEs at the time.

hazardous pre-CLP is therefore still considered reasonable. These assumptions and the corresponding numbers are summarised in Table 6-7, as are the corresponding numbers for the updated assumptions of number of mixtures. Clearly, alterations to the assumptions delivers different estimates of the number of substances subject to transition costs and, therein, direct and indirect costs. The sensitivity of the final estimates of costs to such variations has been assessed (see Annex 6). Margins of error are reported alongside the costs presented in the text.

Table 6-7: Assumptions Applied for Numbers of Mixtures by Type		
	Lower bound	Upper bound
Total number of mixtures	2,000,000	2,500,000
Mixtures containing hazardous substances	47%	47%
Percentage of these that are classified mixtures	30%	30%
Total mixtures that are classified	282,000	352,500
Total mixtures not classified but with hazardous substances	658,000	822,500
Total mixtures with no known hazardous substances	1,060,000	1,325,000
Percentage also exported	20%	20%
Exported mixtures with hazardous substances that are classified	56,400	70,500
Exported mixtures currently not classified but with hazardous substances	131,600	164,500
Exported mixtures with no known hazardous substances	212,000	265,000

6.3.3.4 Frequency of reformulation

The frequency at which companies reformulate their products will vary across different sectors in response to changes in consumer demands/customer requirements and to legislative drivers such as changes in sectoral legislation (e.g. REACH, Biocidal Products Regulation or the Detergents Regulation). Thus, although CLP may drive some re-formulation due to more stringent classification, this should be viewed against a background of on-going reformulation activities.

The AISE study (RPA, 2007) found that many household products had a relatively short average lifetime of just a few years (or less), while institutional and industrial products had a longer life; companies stressed the fact that the average life of a mixture may vary significantly across the different product categories, with hand dishwashing liquids and fabric washing products varying every 12 to 18 months while other products have a life of up to 5 years.

Similarly, responses to the targeted data collection undertaken for this fitness check indicated that the development of new mixtures / reformulation was one of the key cost factors arising from the implementation of CLP. For the detergents sector, reformulation is likely to be more frequent and, therefore, more costly; companies indicated 10% as the minimum percentage of product portfolios being reformulated, with reformulation likely to occur across up to 50% of portfolios. Similarly, across general chemicals manufacturers, importers and formulators responding to a question covering reformulation (n=90), on average around 5% of mixtures were reformulated, with some companies undertaking much higher levels (e.g. up to 80% in one case). Of course, other companies reported no reformulation in response to changes in classification under CLP. Given the findings reported in Section 4.6.2 on the percentages of mixtures changing classification under CLP, these figures are not surprising.

6.4 Sectors affected and numbers of companies

Table 6-8 below outlines the sectors which are considered to have incurred transition costs, together with the number of companies assumed to be affected. The sectors chosen below are based on a review of Eurostat and also include those referenced in the Cumulative Cost Assessment study[36] and the study on Inspection requirements for REACH and CLP[37] (Milieu et al, 2011); this covers the sectors which are directly impacted by the transition to CLP.

Table 6-8: Sectors considered in cost analysis and number of manufacturers and formulators under each						
NACE Code	**Sector**	**Micro**	**Small**	**Medium**	**Large**	**Total**
Substances manufacturers and formulators						
19.20	Manufacture of refined petroleum products	588	247	110	92	1,037
20.13	Manufacture of other inorganic basic chemicals	677	227	119	47	1,070
20.14	Manufacture of other organic basic chemicals	1,254	420	220	87	1,981
20.15	Manufacture of fertilisers and nitrogen compounds	927	310	163	64	1,464
20.16	Manufacture of plastics in primary forms	1,568	525	275	109	2,477
20.53	Manufacture of essential oils	428	152	69	13	661
24.41	Precious metals production	499	124	84	37	744
24.43	Lead, zinc and tin production	167	41	28	12	248
24.44	Copper production	254	63	43	19	379
24.45	Other non-ferrous metal production	474	118	80	35	707
Total substances manufacturers		***6,836***	***2,227***	***1,191***	***515***	***10,768***
Mixtures manufacturers and formulators						
20.17	Manufacture of synthetic rubber in primary forms	96	32	17	7	151
20.20	Manufacture of pesticides and other agrochemical products	414	149	95	19	677
20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	2,347	1,121	474	58	4,000
20.41	Manufacture of soap and detergents, cleaning and polishing preparations	2,636	658	275	71	3,640
20.42	Manufacture of perfumes and toilet preparations	3,374	842	351	91	4,658
20.51	Manufacture of explosives	355	126	57	11	549
20.52	Manufacture of glues	344	122	55	10	533
20.59	Manufacture of other chemical products n.e.c.	2,836	1,008	455	86	4,385
24.10	Manufacture of basic iron and steel and of ferro-alloys	1,685	498	178	189	2,550
Total mixtures manufacturers		***14,087***	***4,556***	***1,957***	***542***	***21,143***
Total		**20,922**	**6,784**	**3,148**	**1,057**	**31,911**
Source: Eurostat data						

[36] Technopolis et al (2016): Cumulative Cost Assessment for the EU Chemical Industry, Final Report to DG Grow, Ref. Ares(2016)3304226 – 11/07/2016.

[37] http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study6.pdf

Given that elements of our analysis are based on a comparison of the impacts between SMEs and large companies, the following table is provided to summarise the number of enterprises falling under each category, and used in our analysis. SMEs account for 95% of all companies, whilst manufacturers / formulators of mixtures make up around two-thirds of the companies.

Table 6-9: Total number of companies under each size category			
Company Type	**Substances manufacturers and formulators**	**Mixtures manufacturers and formulators**	**Total number of companies by size category**
SME	10,254	20,600	**30,584**
Large	515	542	**1,057**
Total	**10,768**	**21,143**	**31,911**

Not all manufacturers and formulators will incur all types of transition costs. The table below sets out the costs that will have been incurred by each group and this is reflected in our calculations of transition costs.

Table 6-10: Transition costs incurred by different groups		
Cost element	**Substances manufacturers and formulators**	**Mixtures manufacturers and formulators**
Classification	✓	✓
Labelling	✓	✓
SDS revision and distribution	✓	✓
Packaging (including investment in CRC-related equipment)	✓	✓
Upgrading IT systems	✓	✓
Staff training	✓	✓
CLI notification	✓	
Reformulation and removing product lines from market		✓

6.5 Costs of classification, labelling and packaging

The CLP requires that suppliers of substances and mixtures (as well as producers or importers of certain articles) classify and label their products for physical, health and environmental hazards. In terms of hazard identification and assessment, the obligations placed on manufacturers and importers, as well as downstream users, include:

- Classifying, labelling and packaging substances and mixtures placed on the market according to CLP, as well as those subject to registration or notification under Articles 6, 9, 17 and 18 of REACH;
- Notifying classification (and labelling) elements to ECHA (note this does not apply to downstream users);
- Reviewing, evaluating and up-dating classifications when new scientific or technical information becomes available; and
- Submitting proposals for an up-dated harmonised classification, when new data becomes available that may lead to a change in an existing classification.

Table 6-11 lists the different direct costs incurred by industry stakeholders in the transition from the Dangerous Substances Directive/Dangerous Preparations Directive to the CLP Regulation, categorised according to the types of costs outlined in the Better Regulations Toolbox. These include the costs of classifying, labelling and packaging substances and mixtures in line with the

requirements of CLP. Administrative burdens in relation to notification requirements are discussed in Section 8 in relation to the Classification & Labelling Inventory and Poison Centres.

The costs per company for each of these different cost elements are calculated based on both references to previous studies and the results of the targeted stakeholder consultation. The main source of data was the targeted data collection exercise. Amongst other topics, questions were asked relating to the costs of re-classifying according to CLP, the costs of re-labelling due to changes in classifications, the number of staff involved in classification and labelling activities, costs for training staff to understand the requirements of CLP and costs of updating software, etc. Table 6-12 below outlines the data collected and the cost category under which it falls. It also explains how the value for each of these cost elements was derived for the purposes of this study.

Table 6-11: Data collected for each cost type for transition costs	
Type of Cost	**Cost elements for which estimates have been generated**
Direct Costs	
Regulatory Charges	*No regulatory charges incurred in transition to CLP from the Dangerous Substances Directive/Dangerous Preparations Directive*
Substantive Compliance Charges	Cost of classification of a single substance or mixture according to CLP Cost of re-labelling in line with CLP Cost of updating and distributing revised SDS Cost of updating IT systems Cost of training staff to understand requirements of CLP Costs of meeting packaging requirements
Indirect costs	
Indirect Compliance Cost	Re-formulation of mixtures due to changes in hazard classification

Table 6-12: Basis for value estimates assumed for each cost element		
Cost Element	**Value used in calculations**	**Results of targeted data collection exercise / verification of value**
Classification of a single substance or mixture according to CLP	€400 per substance per company	When asked what the cost of reclassification was for substances and mixtures under the CLP, the most common response across all industry respondents was that it cost less than €300 per substance or mixture to undertake reclassification activities (excluding any associated testing). In total, 46% of respondents indicated that it cost less than €500 to reclassify a substance, with 50% indicating that this was also the case for mixtures. There are, however, some outliers, with 9% of respondents suggesting costs of over €3,000 per substance on average, and 6% suggesting this level of costs also applied to mixtures. These results confirm that an average figure of around €400 per substance or mixture, as used in the GHS impact assessment, is a reasonable figure.
Cost of re-labelling in line with CLP	€388 per substance per company €475 per mixture per company	The impact assessment supporting the adoption of GHS (and hence implementation of CLP) and further work carried out for AISE expected the average cost of re-designing and modifying labels to be compliant with CLP to be around €300 per formulation, based on experiences under the Dangerous Preparations Directive. This level of cost was confirmed by the majority of respondents to the targeted data collection, with 62% and 54% indicating costs of less than €500 per substance or mixture respectively, with the majority of these indicating costs of

Table 6-12: Basis for value estimates assumed for each cost element		
Cost Element	**Value used in calculations**	**Results of targeted data collection exercise / verification of value**
		less than €250. Further significant percentages indicated costs between €500 and €1000. The weighted average cost is €388 for substances and €475 for mixtures. Note that the higher cost figures tended to be provided by SMEs.
Cost of updating and distributing revised SDS	€250 per substance	73% of respondents (n=113) indicated that the average costs per substance or mixture of updating a safety data (SDS) sheet due to changes in substance or mixture classification were less than €1,000 per SDS, with 51% indicating that the costs were less than €500 per SDS. It is expected that this is due to the fact that most IT systems will automatically generate an up-dated SDS, with the costs mainly related to checking that the changes are correct, entering any additional information, etc.
Cost of updating IT systems	€3,000 for SMEs €17,400 for large companies	44 SME respondents responded to this question, with 56% of these indicating that new IT systems cost less than €3,000, 18% indicating that they costs between €3,000 - €5,000 and 21% indicating that they cost over €5,000 (and 12% responding "don't know"). €3,000 is taken as the cost to SMEs of updating their IT systems in line with the move to CLP. 72 of the larger companies responding to the survey provided an answer to this question. A significant proportion (44%) indicated that upgrading or modifying their existing IT system with the move to CLP cost over €30,000; however, 15% indicated a cost of less than €7,000 for undertaking such an up-grade. The weighted average (based on the mid-point for each band and assuming €30,000 for the upper band) is estimated at €17,400.
Cost of training staff to understand CLP	€6,740 per SME €45,100 per large enterprise	Across manufacturers, formulators and distributors, 40 SMEs (4 of which were micro enterprises) responded to this question regarding the costs of training staff in relation to the transition of CLP. 58% of these companies indicated that they spent less than €5,000 on training their staff to understand the requirements under CLP (with 33% indicating that the costs were less than €2,500). Of the remainder, all but 8% said the costs were less than €10,000. Taking the weighted average gives €6,740 per SME. 87 of the larger enterprises answered this question, with 49% indicating an average cost of less than €25,000 rising to 60% indicating less than €50,000. However, 13% indicated that that the costs were more than €50,000, and a further 9% greater than €100,000. Taking the weighted average gives €45,100 per large enterprise.
Cost of CRCs, TWDs and other packaging requirements	Not known	See Annex 1 for a discussion on CRCs and TWDs. On-going only costs are estimated – see Section 7. It is assumed that any one-off transition costs to most companies were negligible or low, and are not quantified. This analysis excludes investment by the detergents sector in relation to laundry detergent pods and regulation through the CLP

Table 6-12: Basis for value estimates assumed for each cost element		
Cost Element	**Value used in calculations**	**Results of targeted data collection exercise / verification of value**
		urgency procedure – this is addressed in Section 10.
Re-formulation of mixtures due to changes in hazard classification	€15,000 per mixture/formulation/product line	In terms of the costs of reformulation, these were assumed to vary from €1,000 to €30,000 per mixture (with an upper bound figure of €500,000), and an average cost of €10,000 in the 2006 Impact Assessment. These estimates appear reasonable and are consistent with those quoted elsewhere: • The 2007 assessment for AISE found average costs of reformulation per mixture of between €2,000 and €3,000 (and an upper bound of around €10,000). • A 2005 CEPE position paper in relation to REACH, suggests that on average it takes the printing inks sector 10 days for changing a recipe and roughly another 25 days for testing and product approval, giving a cost per reformulation of over €8,000; • Work carried out in 2005 on a fragrance sector case study in relation to REACH found an average reformulation cost of around €30,000 for the use of fragrances in personal care products Based on these data, the original figure of €10,000 appears reasonable for 2006 prices. For the purposes of this assessment, we take an inflated figure of €15,000 although it should probably be inflated to around

6.6 Total direct cost to industry of moving from the Dangerous Substances Directive/Dangerous Preparations Directive to CLP

Key findings:

- Direct transition costs stemmed from the need to classify, label and package substances and mixtures according to CLP, as well as to update SDS
- Total classification, labelling and SDS costs for substances are estimated at around €522 million (±€157 million); the comparable costs for mixtures are estimated at €651 million (upper bound estimate for the number of mixtures). Clearly, there are significant levels of uncertainty surrounding these estimates and the combined error attached to the estimate of €651 million for mixtures is minus €195 million to plus €255 million giving a range of €456-906 million.
- Direct transition costs in relation to new/updated IT and staff training are estimated at around €104 and €206 million for substances and mixtures respectively and a total of €310 million. Again, these estimates are based on a range of resulting in an estimated error of ± €93 million (producing a cost range of €217-403 million)
- Transitional costs in relation to packaging have not been estimated (but see discussion on use of urgency procedure in Section 10.3)

6.6.1 Classifying and labelling substances in accordance with CLP

The costs of reclassifying substances and mixtures are considered to include:

- Gathering the available information (i.e. not including the costs of any testing) needed to undertake classification;
- Reviewing the available information to ensure it is adequate and reliable;
- Evaluating the available information against the classification criteria;
- Deciding on the appropriate classification for self-classification purposes; and
- Paying any consultancy fees.

6.6.1.1 Classification, SDS and labelling for substances

As given in Table 6-6, the total number of substances which are subject to initial transition costs is 99,266, based on the averge cost per substance in a company's portfolio (thus covering non-hazardous and hazardous). We multiply this by the weighted average number of MIs per substance given in Table 6-9, distinguishing between SMEs and large enterprises, and then multiply this by the cost per re-classification per substance (€400) to give the total cost to industry of re-classifying in line with the transition to CLP. This calculation is explained in Table 6-13 below.

Table 6-13: Calculating cost of re-classifying in line with the transition to CLP

$$Cost\ of\ reclassifying = No\ of\ substances\ subject\ to\ transition\ cost\ x\ MIs\ per\ substance\ x\ Cost\ of\ reclassifying\ 1\ substance$$

Applying this across SMEs and large enterprises, the total transition cost of re-classifying substances is estimated at around **€227 million**. An error of around 30% in unit costs can be expected which equates to ±€68 million around this estimate (i.e. a cost range of € 159-295 million).

Similarly, we calculate the cost of updating and redistributing SDSs by multiplying the first two elements of the above equation by the cost of updating SDS, as given in Table 6-5 (€250). The total transition cost incurred by companies for updating and redistributing SDSs is estimated as being around **€142 million** ±€42 million (i.e. a cost range of €100-184 million).

Although all 99,266 substances would be subject to the costs of classification and updating SDSs, the deadline for implementing CLP coincided with the introduction of the second ATP which included changes to labelling requirements. We estimate that 30% of the substances would have been impacted by the labelling changes under the second ATP to CLP. Therefore, in order not to overestimate costs by double-counting, in calculating the initial transition cost, we apply the labelling costs to only 70% of the substances here. This gives the total re-labelling transition costs as around **€154 million** ±€46 million (i.e. a cost range of €108-200 million).

The costs associated with the 30% of substances that would have been impacted by the labelling changes under the second ATP to CLP are addressed under Section 9.3.

6.6.1.2 Classification, labelling and SDS for mixtures

As indicated in Section 6.3.3, it is assumed here that there are between 2 and 2.5 million mixtures on the EU market based on data collected in 2006 and for this study. These are assumed to be the total number of mixtures produced, including any overlaps in mixtures across different suppliers.

As also indicated above, and set out in Table 6-7, it is assumed that only 47% of mixtures contain a hazardous substance and that 30% of these mixtures are themselves classified as being hazardous. These figures are used as the basis for estimating the costs to formulators of classification, SDS and labelling activities for mixtures, as follows:

- It is assumed that 47% of mixtures would go through reclassification due to the presence of hazardous substances within their constituents and thus incur reclassification costs;
- It is then assumed that 30% of these would be found to be hazardous, and therefore require re-labelling and the preparation of new SDS; and
- It is assumed that 20% of these mixtures would have been re-labelled and have new SDS for export purposes, so costs are only driven by EU CLP for 80% of the hazardous mixtures (i.e. 80% of 2 million mixtures or 2.5 million mixtures).

On the basis of these assumptions, the total costs are as indicated in Table 6-14. Each estimate in the table has an error of ±30% in the unit costs. In addition to this margin or error, as noted in Section 3.3.3, alterations to the assumptions on the percentage of mixtures of different types delivers different estimates of the number of substances subject to costs. The sensitivity of the final cost estimates to these factors has been assessed in Annex 6. On the basis of this sensitivity analysis the total costs and combined error variations are:

- Lower bound mixtures: €521 million (range €288-677 million); and
- Upper bound mixtures: €651 million (range €456-906 million).

Table 6-14: Transition costs incurred by enterprises during initial transition to CLP using assumptions for mixtures in Table 6-7

Cost Element	Per mixture cost (weighted average)	Lower bound (2 million mixtures)	Upper bound (2.5 million mixtures)
Classification	€400	€300,800,000	€376,000,000
Labelling	€475	€107,160,000	€133,950,000
SDS	€500	€112,800,000	€141,000,000
Total		**€520,760,000**	**€650,950,000**

Notes: Numbers are rounded to nearest hundredth and have an error of ±30% plus sensitivity to other assumptions – see main text

Data was provided by both SMEs and large companies on the numbers of mixtures in their product portfolios. This is summarised in Table 6-15 below. These data were interrogated in more detail to develop a weighted average across SME and large company respondents on the number of mixtures in their portfolios. The figures came out at around 700 for SMEs as a group and 890 for large companies.

Table 6-15: Number of substances and mixtures within product portfolio (n=187 for mixtures including formulators)

Number of mixtures	Response Percentage
<50	34.2%
50 to100	8.6%
100 to 250	9.6%
250 to 500	8.0%
500 to 1500	10.2%
>1500	29.4%
Total number of responses	**187**

However, the population of SMEs responding to the questionnaire was biased towards small and medium sized enterprises rather than micro-enterprises. As can be seen from the data presented in Section 6.4, 97% of mixture manufacturers (formulators) are classed as SMEs based on Eurostat data, with two thirds of these being micro-enterprises. For micro-enterprises responding to the targeted consultation, the average number of mixtures in their portfolios is around 10 (across the whole sample, including plant protection, detergents, etc.). Therefore the sample is not representative of the demographic and so the calculated weighted average calculated is too high. We have therefore adjusted the figure downwards, and assume the average number of mixtures in the 'average' SME portfolio is 100.

On this basis, SMEs account for 2,060,000 mixtures (100 mixtures x 20,600 SMEs), or 76% of the 2.5 million mixtures assumed to be placed on the market. Large companies account for around 480,000 mixtures (890 per company x 542 large mixture manufacturers) or around 24% of the 2.5 million mixtures.

In order to calculate a lower bound estimate of the total transition costs incurred by enterprises, we assume the same percentage of mixtures were placed on the market by SMEs and large companies as is assumed in the calculation of the upper bound estimate; that is to say, we assume SMEs account for 76% of the 2 million mixtures placed on the market (equivalent to 1.52 million mixtures) and large companies account for 24% (480,000 mixtures). This would imply that, on average, a SME has 74 mixtures in their portfolio and a large company has 886.

Under the lower bound assumptions described above, this suggests that around €400 million (±€119 million) of the above total costs were borne by SMEs, and under the upper bound assumptions described above that around €500 million (±€149 million) were borne by SMEs. Clearly, in addition to the uncertainties in the unit costs (of ±30%), there are uncertainties concerning the numbers of mixtures that would be subject to costs. Sensitivity analysis suggests that once these are combined with the ±30% error, the likely cost range for SMEs is between €219 million (lowest estimate for lower numbers of mixtures) and €688 million (highest estimate for upper estimate of numbers of mixtures).

6.6.1.3 Total classification, labelling and SDS transition costs

The total estimated transition costs for the classification, labelling and distribution of new SDS due to CLP for substances and mixtures are given in Table 6-16 below, based on the lower and upper bound estimates of the numbers of substances described earlier. This provides the following total transition costs for substances and mixtures:

- Lower bound estimate of mixtures: €1,043 million ± 313 million; and
- Upper bound estimate of mixtures: €1,173 million ± 352 million.

In addition to the uncertainties in the unit costs (of ±30%), there are uncertainties concerning the numbers of mixtures that would be subject to costs. Sensitivity analysis suggests that once these are combined with the ±30% error in the likely cost range is between €654 million (lowest estimate for lower numbers of mixtures) and €1,585 million (highest estimate for upper estimate of numbers of mixtures).

Table 6-16: Transition costs incurred by enterprises during initial transition to CLP using assumptions for mixtures in Table 6-7			
Cost Element	**SME**	**Large**	**Total**
Substances			
Classification	€ 33,800,000	€ 193,000,000	€ 226,600,000
Labelling	€ 23,000,000	€ 131,000,000	€ 153,900,000
SDS	€ 21,100,000	€ 120,500,000	€ 141,700,000
Total	**€ 77,900,000**	**€ 444,500,000**	**€ 522,200,000**
Mixtures (based on upper bound estimate)			
Classification	€285,800,000	€90,200,000	€376,000,000
Labelling	€101,800,000	€32,100,000	€134,000,000
SDS	€107,200,000	€33,800,000	€141,000,000
Total	**€495,000,000**	**€156,200,000**	**€651,000,000**
Mixtures (based on lower bound estimate)			
Classification	**€228,600,000**	**€72,200,000**	€300,800,000
Labelling	**€81,400,000**	**€25,700,000**	€107,160,000
SDS	**€85,700,000**	**€27,100,000**	€112,800,000
Total	**€395,800,000**	**€125,000,00**	**€520,760,000**
Notes: Numbers are rounded to nearest hundred thousand and have an error of ±30%.			

6.6.2 Packaging in accordance with CLP

The general requirements relating to physical packaging are set out under Article 32 and 35 of CLP. Article 35(1) specifies that packages must be:

- Well designed and constructed.
- Compatible with the contents.
- Such that fastenings will not loosen and meet stresses and strains of normal handling, and shall be capable of repeated closure without contents escaping.

If packages are to be supplied to the general public, Article 32(2) requires that they: do not have shape or design likely to attract or arouse the active curiosity of children or mislead consumers; and do not have a presentation or design used for human or animal foodstuffs, medicinal, or cosmetic products which would mislead consumers.

Article 35(2) then goes on to require that packaging supplied to the general public shall, in certain circumstances, feature a child resistant fastening (CRF, also commonly known as a child resistant closure - CRC), and/or a tactile warning of danger (TWD) (see also the discussion under Task 2). These provisions are not new, having been a feature of the former Dangerous Substances Directive and Dangerous Preparations Directive. Under CLP, the provisions requiring the fitting of CRCs and/or TWDs are triggered by the hazard classification of the substance or preparation concerned, in contrast to the Dangerous Substances Directive and Dangerous Preparations Directive where the provisions were triggered by the hazard label affixed to the packaging containing the substance or preparation. Thus, under CLP, all products classified as corrosive under CLP require CRCs and TWDs.

6.6.2.1 Detergents sector: CRCs

Work for AISE (RPA, 2007) pre-CLP looked at the increased costs that would arise in relation to requirements for child resistant closures (CRCs) and Tactile warnings of danger (TWDs) on packaging, due to an anticipated increase in the number of mixtures that would be classified as corrosive under the 27th June 2007 draft legislative proposals for CLP. The data used for these previous estimates is applied in Annex 1 to provide a basis for re-examining the cost savings from

the requirements actually adopted in CLP compared to earlier proposals. Further details of the AISE study and the conclusions drawn for the purposes of our analyses can be found in Annex 1.

The modifications required to packaging lines vary according to the packaging previously used, and were assessed in the 2007 study. Cost estimates of moving from cardboard/cartons or pouches to plastic bags ranged from around €2 – €2.5 million per product line for a larger manufacturer. The costs of moving from plastic bottles without CRCs to those with CRCs were calculated at €150,000 per pack size, with this cost applying to each pack size per product line. Assuming, an average of three pack sizes per product line (which is reasonable for the most affected types of products) gives costs per product line of €450,000 for moving from plastic bottles without CRCs to those with CRCs. These were one-off substantive compliance costs, and together with on-going increases in operating costs were calculated as leading to PV costs over 10 years for all products classified as corrosive of €2.3 billion.

However, care must be taken when building on the AISE estimates for the purposes of this study, as the final regulation did not include requirements for CRCs to be placed on products classified for serious eye damage cat 1. (or for some of the other endpoints originally considered in the draft 27 June 2007 proposal for the regulation). This was the main factor driving the cost analysis produced in 2007 and highlights the economic importance of the modifications made to the legal text when implementing it in practice.

Data was collected through the targeted data collection from companies within the detergents sector to identify the percentage of products that changed classification under the CLP, as well as the percentage of products with changed packaging requirements due to changes in classification. These data are reported in Annex 1.

The up-dated, and significantly reduced, costs reported by companies to the targeted consultation indicate:

- An annual increase in costs of €100,000 per SME; and
- An annual increase in costs of €200,000 per large company.

These figures relate to the increase in packaging costs and are therefore on-going costs rather than transition costs. It is not clear to what extent investment in new lines was actually required, given the low number of products that were affected, as reported by companies in response to the targeted consultation. As a result, it is assumed that the additional investment costs required within the sector were zero or low for most companies.

The increase in annual costs reported above is taken into account in Section 7 on on-going impacts of CLP.

6.6.2.2 Broader sectoral assessment

Questions about the need to newly place CRCs or TWDs on packaging were also asked of manufacturers, importers, and more general formulators. Figure 6-1 provides a summary of the responses to this question and indicates the percentage of products within respondents' portfolios that required new packaging or changes in packaging as a result of CLP. In total, 32% of respondents indicated that none of their products were affected by changes in packaging as a result of CLP. Around 50% indicated that none of their products required CRCs or TWDs, with a small percentage (27%) indicating no other changes were required in packaging either (e.g. packaging under ADR). However, for a significant percentage (21%), up to 20% of their products faced changes in packaging requirements due to changes in classification, with other respondents

indicating higher levels of impact. In relation to CRCs and TWDs, over 20% of respondents indicated that up to 20% of their products now require these.

Those respondents who did experience the need to change packaging were asked to provide an indication of what this involved, including the associated costs. A sub-set provided data (n=25) which indicates that a range of actions were generally required, with these varying in costs significantly across the respondents depending on packaging processes, production volumes, etc. Responses are summarised in Table 6-17.

Given wide variation in costs quoted, it is difficult to develop any overarching estimates of the one-off investment costs incurred by these companies, especially as no firm figures were given for the costs of changing production lines and in most cases only a subset of the 25 companies answering this question provided a cost figure. For some companies, the costs were clearly significant, while for others they were not.

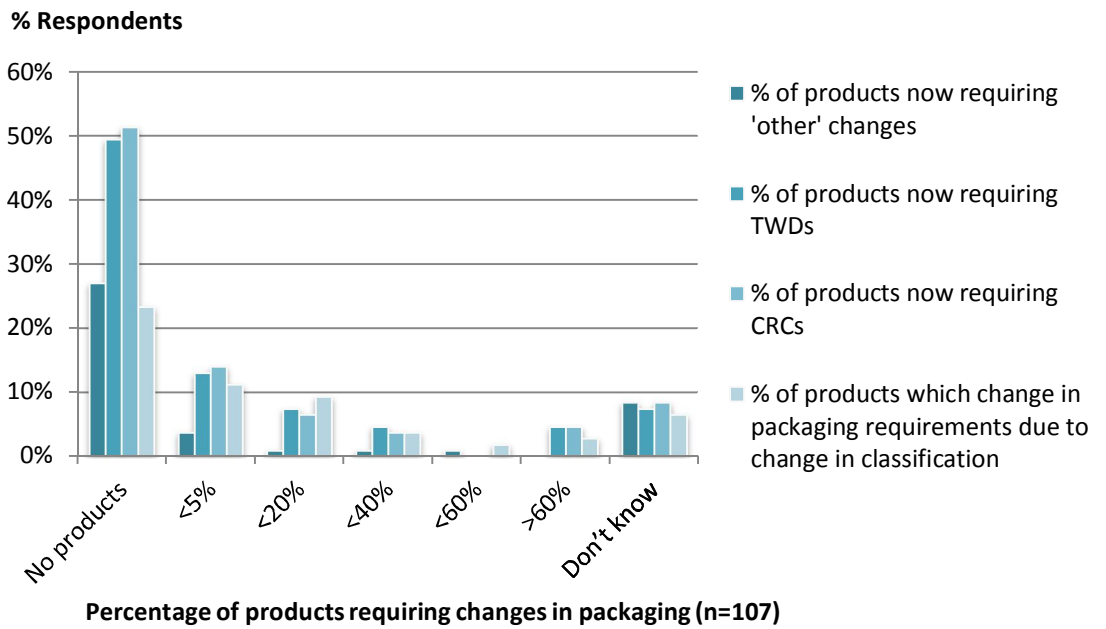


Figure 6-1: Percentage of products requiring changes in packaging due to CLP (manufacturers, formulators, distributors and importers) (n=107)

Table 6-17: Changes required to adapt packaging and associated average costs per product line (n=25)

Answer Options	Percentage of respondents	Cost range quoted (€)
Re-design and testing costs	71.4%	200 – 5,000
Change in packaging material	67.9%	300 - 50,000
Change in production lines	60.7%	unknown
Disposal of obsolete packaging	64.3%	300 – 50,000*
Change in packaging design for safety	67.9%	300 – 7,000
Other	39.3%	unknown
*Costs could be as high as €100,000 for some product lines		

In terms of the types of packaging changes required, additional information indicated that this included an inability to continue to use brown kraft paper as the regulation demands a white background for the pictograms. Other respondents indicated that impacts were triggered by transport requirements and by CLP requirements for labelling of outer packaging, with one indicating that more of their products fell under ADR due to the requirement of obligatory testing for the physical hazards like metal corrosion: "Many surprises there....So packaging has to be changed to be ADR compliant". One distributor also commented that they do not package, so that this was not a relevant issue for them.

The changes in classification that led to the need for these changes in packaging were detailed by 37 respondents, with the key classification changes identified being:

- Corrosive for skin/eye;
- Sensitisation;
- Corrosive to metals (most often identified in relation to transport);
- Aquatic toxicity (acute and chronic identified) / environmental classification (again in relation to transport); and
- Changes in physico-chemical classifications (again in relation to dangerous goods transport regulations).

For those that label directly onto their packaging, new requirements were triggered by changes in the pictograms, safety and hazard phrases, as well as the need to change the layout of labelling on packaging in order to fit the information onto the packaging (including additional translations).

6.6.3 Updating IT and staff training

As indicated in Section 6.5, companies will also have incurred the costs of updating or purchasing new IT systems for assisting with classification, labelling and SDS production activities. Companies were asked as part of the targeted consultation to provide an indication of the costs that they incurred in up-dating such systems. As noted in Table 6-12:

- For SMEs, 56% indicated that their new systems cost less than €3,000, with a significant proportion of the remainder (21%) indicating costs of over €5,000;
- For larger companies, a significant proportion (44%) indicated that upgrading or modifying their existing IT system with the move to CLP cost over €30,000; however, 15% indicated a cost of less than €7,000 for undertaking such an up-grade.

For the purposes of this assessment, we assume a figure of €3,000 for SMEs and €17,400 for larger companies (see also Table 6-12). It is of note that these estimates are very similar to the figures found in the consultation undertaken for the 2006 impact assessment study (RPA *et al*, 2006).

In addition to updating IT systems, companies will have had to undertake training to familiarise staff with the CLP and the changes that it introduced. Again, companies were asked to provide an indication of how much they spent on training as part of the targeted consultation. The majority of SMEs (58%) indicated that they sent less than €5,000 in staff training, with most of the remainder indicating that costs were less than €10,000. For large companies, 60% indicated costs of less than €50,000, but there were some companies with significantly higher training bills. For the purposes of this assessment, we assume €6,740 in training costs for a SME and €45,100 for a larger enterprise. These figures are higher than those assumed in the 2006 impact assessment study, but of a similar magnitude (€3,600 and €43,200 respectively).

Information from the SME Panel suggests that it is inappropriate to assume that all companies will have undertaken these activities (see separate Task 4 report for full details). Although roughly 90% of SMEs indicated that they undertook staff training, only 30% of SME manufacturers indicated that they purchased new software, with the figure rising to 60% of SME formulators. For the purposes of this assessment, we assume that these percentages also apply to large companies.

Table 6-18 below provides total industry cost of these elements, based on the numbers of substance and mixture manufacturers within the EU market (as given in Table 6.8), and the percentages assumed to undertake each activity.

Table 6-18: Updating IT systems and staff training			
Cost Element	**SME**	**Large**	**Total**
Substance manufacturers			
Updating IT systems	€ 9,228,00	€ 2,688,000	€ 11,916,000
Training staff	€ 69,105,000	€ 23,227,000	€ 92,332,000
Total	**€ 78,333,000**	**€ 25,915,000**	**€ 104,248,000**
Mixture manufacturers			
Updating IT systems	€ 37,100,000	€ 5,700,000	€ 42,700,000
Training staff	€ 138,900,000	€ 24,400,000	€ 163,300,000
Total	**€ 175,900,000**	**€ 30,100,000**	**€ 206,000,000**
Notes: Figures rounded to nearest hundred thousand and have an error of ±30%.			

As with other estimates, a ±30% error in the unit costs is possible but unlike the cost estimates for classification, labelling and SDS in Section 6.6.1, the unit costs for updating IT systems and training staff are applied to statistics on the number of companies from Eurostat data for 2012/13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1, and 24.4). As such they are not subject to the same uncertainties as the numbers of hazardous mixtures. Accordingly total costs for substances and mixtures are estimated to be around €310.2 million ± €93 million (i.e. a range of €217-403 million).

6.7 Indirect costs of CLP

Key findings:

- Reformulation costs are estimated at between €67.7 million (±€20 million) and €141 million (±€42 million) depending on the assumptions for numbers of mixtures and the fraction of mixtures assumed to be reformulated
- Although manufacturers indicated that they removed product lines from the market, no estimate of the associated losses could be developed

6.7.1 Reformulation

Manufacturers of mixtures that are sold as end consumer products may decide themselves or be required by their customers (i.e. retailers) to reformulate those mixtures which are more severely classified under the CLP. There is evidence from the targeted data collection exercise that this has been the case and that it is anticipated into the future across all mixture manufacturers.

The costs of reformulation will clearly vary across types of products and the extent of the required changes in composition. In the 2006 study (RPA et al, 2006) the costs were assumed to vary from

€1,000 to €30,000 per mixture (with an upper bound figure of €500,000), with an average cost of €10,000. These estimates are consistent with those quoted elsewhere:

- The 2007 assessment for AISE found average costs of reformulation per mixture of between €2,000 and €3,000 (and an upper bound of around €10,000);
- A 2005 CEPE position paper in relation to REACH, suggests that on average it takes the printing inks sector 10 days for changing a recipe and roughly another 25 days for testing and product approval, giving a cost per reformulation of over €8,000; and
- Work carried out in 2005 on a fragrance sector case study in relation to REACH found an average reformulation cost of around €30,000 for the use of fragrances in personal care products.

Discussions with company representatives for this study suggest that this cost range is reasonable for most reformulation activities, although the costs will be significant higher for some specialist products. Based on these consultation findings, and for the purposes of this assessment, we retain the figure €10,000 based on the view that many changes in formulations will have involved dilution or more simple substitutions than complex mixture changes.

As indicated in Section 6.3.3, reformulation of mixtures so as to ensure that they were not more severely classified under CLP did take place across a range of sectors, and in particular with respect to consumer facing products. In order to estimate the potential indirect costs associated with reformulation, the following needs to be taken into account:

- The number of mixtures that are classified as hazardous under CLP, are not exported and that may therefore be subject to reformulation solely due to more stringent classifications under CLP; and
- The figures presented in Section 6.3.3 on the types of percentages of substances that companies reformulated due to more stringent classifications under CLP.

From Table 6-7, the number of mixtures that are expected to be classified as hazardous under CLP and that are not exported (and so would require classification and labelling under GHS as appropriate to the importing countries' requirements) can be calculated:

- Lower bound estimate – number classed as hazardous and not exported: 225,600
- Upper bound estimate – number classed as hazardous and not exported: 282,000

The figures found from consultation for this study on the percentages of substances that were reformulated due to more stringent classifications under CLP ranged from 0% to 5% to 80%, with higher percentages associated with the more consumer facing sectors. As noted earlier, these findings are consistent with those reported in Section 4.6.2 on the percentages of mixtures changing classification under CLP, and so are not surprising. The 2007 study for AISE (RPA, 2007) assumed that 5,000 detergents sector mixtures would be reformulated in responses to changes in classification under CLP classification Categories 1 to 4.

Based on the above data, we assume here that between 3% and 5% of mixtures classified as hazardous under CLP, and not otherwise exported, would be reformulated in order to avoid more stringent classification of products being placed on the market.

This results in the following estimates (with the magnitude of the ±30% error in € millions provided in parenthesis):

- Lower bound estimate – reformulated mixtures:
  - 3%: 6,770 @ €10,000 = €67.7 million (±€20 million)
  - 5%: 11,280 @ €10,000 = €112.8 million (±€34 million)

- Upper bound estimate – reformulated mixtures:
  - 3%: 8,460 @ €10,000 = €84.6 million (±€25 million)
  - 5%: 14,100 @ €10,000 = €141.0 million (±€42 million)

These costs are assumed to be split between SME and large formulators in proportion to the numbers of mixtures that these different sets of companies are assumed to produce. As set out above, for the lower bound estimate we assume 3% of the mixtures classified as hazardous but not exported require reformulation (6,770 mixtures). For the upper bound estimate, we assume 5% of these require reformulation (14,100 mixtures). The same assumptions are applied regarding the number of mixtures formulated by SMEs and large companies as were applied in calculating the costs of classification, labelling and SDSs above. Based on the lower bound estimates for 3% of all mixtures requiring reformulation, this equates to costs of €51.4 million (±€15 million) for SMEs and of €16.2 million (±€5 million) for larger companies. For the upper bound estimates and 5% of all mixtures, €107.2 million (±€32 million) for SMEs and €33.8 million (±€10 million) for larger companies. As costs of reformulation are sensitive to assumptions on percentages of substances with different properties, sensitivity of costs to these assumptions has been calculated and is reported in the total costs in Section 0.

6.7.2 Removing product lines from market

Responses to the targeted consultation also indicated that companies removed some products from the EU market due to more severe classifications under CLP. No data are available however on the losses associated with the removal of these products.

One can assume though that where a product is removed from the market it is substituted with another product. There may be losses in net revenues associated with this substitution for the supplier (due to increased production costs, loss of co-production benefits, etc.), as well as increased costs to downstream users of adapting their activities to the substitute. These changes in costs cannot be estimated at the level at which this study is being undertaken. No estimates are therefore included here, although it is important to recognise that the removal of a product from production activities can have significant impacts on downstream users, especially where substitutes are not as efficacious or cannot meet qualification or other standards. Contrarily, substitution with a safer product may lead to a consumer benefit which may reduce the costs associated with the substitution.

It is also important to recognise that, if there is proper communication along the supply chain, then downstream users will have communicated where a product is of high value to them, for example where the available substitute is not as efficacious. In these cases, good communication could avoid high value substances being withdrawn to the detriment of downstream users.

6.8 Total direct and indirect costs

Table 6-19 provides a summary of the total direct and indirect transition costs across the range of cost items considered above. As has been noted throughout the above sections, estimates are based on a range of uncertain assumptions. An analysis of the sensitivity of costs to these factors has been carried out and is provided in Annex 6. The sensitivity analysis suggests that the costs in Table 2-1 should be treated as "best" mid-point estimates for the lower and upper bound mixture scenarios. The costs and ranges are as follows and are also provided next to the totals in Table 6-19:

- For the lower bound estimate, total direct and indirect costs are €1.4 billion (+0.4 or – 0.5 billion, i.e. a range of €0.9 to 1.8 billion); and
- For the higher bound estimate, total direct and indirect costs are €1.6 billion (+0.6 or – 0.5 billion, i.e. a range of €1.1 to 2.2 billion).

Note that costs arising from the removal of product lines due to changes in classification are not included here. Nor are the costs associated with the administrative costs of making notifications to ECHA's Classification & Labelling Inventory for the first time. Although these are transition costs, they are discussed separately in Section 8 of this report, as their consideration was identified as a separate sub-task. The costs reported here will be equivalent to some of the CAPEX costs included in estimates of annual average costs incurred by companies covered by the Cumulative Cost Assessment[38], which is discussed further in Section 7.4.

The estimates provided in Table 6-19 are significantly higher than those estimated in the 2006 Impact Assessment, with the most appropriate comparison being with between the lower bound figures for mixtures for this study and Scenario 2 of Impact Assessment. The latter estimated total costs of around €391 million. Key differences in the estimates include differences in the number of substances assumed to be affected by reclassification requirements. The 2006 study assumed only those placed on the market at above 1 tonne per year would be affected (i.e. 30,000 substances compared to the figure of 99,000 assumed inthis study). This difference will have a significant affect on the classification, labelling and SDS costs. In addition, the 2006 study did not cover all of the sectors which would be affected by CLP, with the 2006 analysis assuming less than 20,000 companies (1,150 large and 18,780 SMEs) would be affected compared to 31,000 for this study, with this having a significant affect on the mixture-related costs. As noted earlier though, per unit costs for both studies show a strong correspondence.

[38] Technopolis et al (2016): Cumulative Cost Assessment for the Chemicals Industry, prepared for DG GROW, contract 30-CE-065657/00-88.

Table 6-19: Transition (CAPEX) costs incurred by enterprises during initial transition to CLP			
Cost Element	**SME**	**Large**	**Total**
Substances (based on 99,266 classified substances)			
Classification	€ 33,800,000	€ 192,800,000	€ 226,600,000
Labelling	€ 22,900,000	€ 130,900,000	€ 153,900,000
SDS	€ 21,100,000	€ 120,500,000	€ 141,700,000
Updating IT systems	€ 9,200,000	€ 2,700,000	€ 11,900,000
Staff training	€ 69,100,000	€ 23,200,000	€ 92,300,000
Reformulation	€ 0	€ 0	€ 0
Total	**€ 156,200,000**	**€ 470,200,000**	**€ 626,400,000**
Per company average	€ 15,235	€ 913,070	
Mixtures (based on upper bound estimate of 2.5 million mixtures)			
Classification	€285,800,000	€90,200,000	€376,000,000
Labelling	€101,800,000	€32,100,000	€134,000,000
SDS	€107,200,000	€33,800,000	€141,000,000
Updating IT systems	€ 37,100,000	€ 5,700,000	€ 42,700,000
Staff training	€ 138,900,000	€ 24,400,000	€ 163,300,000
Reformulation	€ 107,200,000	€ 33,800,000	€141,000,000
Total	**€ 778,000,000**	**€ 220,000,000**	**€ 998,000,000**
Per company average	€ 37,800	€ 405,900	
Grand total (substances and upper bound mixtures)			**€ 1.6 billion (€1.1 to 2.2 billion)**
Mixtures (based on lower bound estimate of 2 million mixtures)			
Classification	€228,600,000	€72,200,000	€300,800,000
Labelling	€81,400,000	€25,700,000	€107,200,000
SDS	€85,700,000	€27,100,000	€112,800,000
Updating IT systems	€ 37,100,000	€ 5,700,000	€ 42,700,000
Staff training	€ 138,900,000	€ 24,400,000	€ 163,300,000
Reformulation	€51,400,000	€16,200,000	€67,700,000
Total	**€623,100,000**	**€171,300,000**	**€794,500,000**
Per company average	€30,200	€316,100	
Grand total (substance and lower bound mixtures)			**€1.4 billion (€0.9 to 1.8 billion)**
Notes: Numbers rounded to nearest hundred thousand			

7 Ongoing Impacts of CLP Implementation

7.1 Introduction

This chapter looks at the ongoing impacts of CLP implementation, including both the annual costs incurred by industry in meeting their obligations under CLP, as well as in relation to human health and protection of the environment. Impacts in relation to the single market, trade, competition and innovation are considered in Section 11. Other ongoing impacts, such as on Member State authorities are considered in Section 12.

The evaluation questions which are relevant to the assessment provided here are set out in Table 7-1 below.

Table 7-1: Evaluation questions relevant to ongoing impacts of CLP implementation

Q #	Evaluation Question
1.1.1.9.	Have the incidences of consumer chemical-related accidents resulting in exposure/damage of human health or the environment been reduced?
1.1.1.10.	Have the incidences of industrial worker/professional chemicals-related accidents resulting in exposure/damage of human health or the environment been reduced?
1.1.1.11.	How has the chemicals legislative framework impacted the incidence of diseases in the general public?
1.1.1.12.	How has the chemicals legislative framework impacted the incidence of occupational disease?
1.1.4.4.	To what extent does the chemicals legislative framework promotes the access to and use of substances/products with a more favourable risk profile (e.g. by identifying such and providing for a simplified assessment/authorisation procedure)?
2.1.1.	What are the costs associated with the chemicals legislative framework for: 2.1.1.1. regulators at EU and national level 2.1.1.2. industry, including SMEs 2.1.1.3. workers, consumers 2.1.1.4. society / economy in general
2.1.3.	What are the benefits associated with the chemicals legislative framework for: 2.1.1.1. regulators at EU and national level 2.1.1.2. industry, including SMEs 2.1.1.3. workers, consumers 2.1.1.4. society / economy in general
2.1.4.	To what extent are the costs proportionate to the benefits? What are the key drivers or those costs and benefits?
2.1.6.	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?

7.2 Ongoing costs of CLP Implementation

Key findings:

- Annual costs to industry include direct costs arising from annual up-dates to IT systems in line with Adaptations to CLP and new CLH, staff training costs, ongoing compliance activities, hassle costs and packaging related costs (CRCs). All costs (and benefits) are calculated on the basis of a 'null counterfactual', reflecting a situation where there is no regulation. When reflecting on the magnitude of cost burden, it should therefore be borne in mind that similar or higher costs might have been incurred under an scenario.
- Total annual costs are estimated at over €1.0 billion (€0.7-0.4 billion) for SMEs and around €260 million (€182-338 million) for larger companies, based on data submitted to the targeted consultation. The ranges are provided to reflect the uncertainty in the cost estimates.
- Per company costs are estimated at €34 thousand (€24-44 thousand) for SMEs and €247 thousand (€173-321 thousand) for larger companies, assuming costs are evenly spread across the 30,850 SME substance and mixture manufacturers and 1,057 larger substance and mixture manufactures
- The central estimate of around €1.3 billion (€0.97-1.7 billion) as the annual costs of CLP implementation compare to a maximum figure of €1.47 billion as calculated by the Cumulative Cost Assessment. Although the CCA figures cover obligations under other legislation, it also considers a smaller number of industry sectors and hence companies
- The central estimate of of €1.3 billion quoted above does not include poison centre reporting costs, which are estimated at around €1.7 billion for harmonised reporting obligations

7.2.1 Overview

Chapter 6 sets out the costs which were incurred by industry due to the transition from the Dangerous Substances Directive/Dangerous Preparations Directive to CLP. This chapter considers the regular or ongoing costs which industry incurs as a result of CLP's classification and labelling requirements.

It should be noted that the assessment of the ongoing (annual) costs and human health and environmental benefits is not a marginal analysis. In other words, this assessment does not evaluate the additional ongoing costs or benefits, over and above other specified requirements. As a result, the assessment reflects the impacts of a situation where there are no other regulatory requirements on manufacturers and importers of hazardous substances and mixtures. The reality is that, had the Dangerous Substances Directive, Dangerous Preparations Directive and subsequently CLP not been introduced to provide overarching requirements, some/all Member States are likely to have introduced their own requirements under national legislation. Some or all might have been similar in emphasis and requirements to CLP, while others might have varied significantly. Clearly there is no definitive way of knowing either way; hence, there is no means of identifying whether costs would have been higher or lower than those presented here. Thus, when considering the individual cost components presented below from the perspective of the burden on industry, it should be borne in mind that similar costs might have been incurred under an alternative reality, with this also being the case for benefits.

In line with our approach to calculating the transition costs of CLP, we employ the methodology set out in the Better Regulations Toolbox which categorises costs under the types listed in Table 7-2. The cost elements which make up our model for ongoing costs are listed under each relevant cost type.

Table 7-2: Data collected for each cost type for ongoing costs	
Type of Cost	**Cost elements for which estimates have been generated**
Direct Costs	
Regulatory Charges	Fees or penalties paid in complying with regulation
Substantive Compliance Charges	Costs of updating IT systems Costs of training staff to understand updates in requirements of CLP Costs of employing FTEs for compliance activities Costs of Child Resistant Closures and Tactile Warning Devices
Administrative Burdens	See Chapter 8
Hassle Costs	Costs of checking CLI
Indirect Costs	
Indirect compliance Cost	Opportunity cost of removing a product line from the market

7.2.2 Estimating the value of each cost element

Using data collected in the targeted questionnaire and from previous studies, estimates have been derived for each of the cost elements used in the model. These costs are expressed as per company, per annum costs, except for the annual costs of employing FTEs and the costs of reformulation. To calculate final annual costs, these are multiplied by the relevant data for the number of companies or products that would be affected. Table 7-3 below outlines the values estimated and the basis for their derivation.

Costs of reformulation and of removing a substance from a producers' product portfolio were considered in Section 6 as part of the indirect transition costs arising from introduction of CLP. Such costs may continue to arise in the future, for example, due to new information on hazardous properties coming from REACH registrations for lower volume substances. However, as these costs are triggered by REACH, it is assumed here that they should be attributed to REACH and not to CLP. For this reason, no additional indirect on-going reformulation or product removal costs are considered here. This may underestimate the ongoing costs of CLP, as one could argue that it is the combination of the new information from REACH and changes in classification thresholds that leads to reformulation or substance withdrawal.

Table 7-3: Estimating the value of each cost element		
Cost Element	**Estimate adopted**	**Results of targeted data collection exercise / verification of value**
Fees or penalties paid	None	No data collected on the value of fees or penalties, so these have not been considered further. Note that there are some relevant fees, e.g. fees to be paid to ECHA as part of the industry submission of a CLH dossier. However, no fees are attached to the main requirements of CLP.
Cost of updating IT systems	SME: €2,500 Large: €12,500	The annual costs of updating IT systems are based on those provided by consultees, the 2006 impact assessment of GHS and consultation with service providers.
Cost of training staff to understand CLP	SME: €3,040 Large: €26,670	These figures represent the weighted average of survey responses to the question about how much companies expect to spend per annum on training staff to understand

Table 7-3: Estimating the value of each cost element		
Cost Element	**Estimate adopted**	**Results of targeted data collection exercise / verification of value**
		CLP requirements. With respect to training into the future, the number of responses from SMEs and micro-enterprises increased to 45 companies (5 micro enterprises). In this case, 51% indicated that the costs of on-going training for CLP would be less than €2,000, with this rising to 64% indicating that the costs would be less than €3,000 per annum (including both micro-enterprises answering this question). Only 4 of these companies expected to spend more than €4,000 per annum on CLP related training. 82 of the larger enterprises answered this question, with 43% of these indicating expected future training costs of less than €10,000 per annum, and a further 27% expecting costs of less than €25,000 per annum. It is of note though that three of these respondents expected future training costs to be greater than €100,000 per annum. However, these are also likely to be those companies that currently employ between 150 and 200 FTE per annum on classification and labelling activities.
Cost of employing FTE for compliance activities	€41,000 per FTE, per annum, with duration of a check varying by company size	This figure gives the cost of employing 1 FTE and is calculated on the basis of the following assumptions: the total salary cost of one trained employee is €23.5 per hour, in line with this FTE cost based on Eurostat data for NACE C20; hourly rate assumes 230 working days, working day is equivalent to 7.5 hours, and each employee works 5 days a week
Cost of Child Resistant Closures (CRCs)	SME: €100,000 Large: €200,000	The data and assumptions are based on targeted consultation responses but verified by work carried out in for AISE on the costs of CRCs. It is assumed that the average per annum cost to a SME affected by CRC requirements is €100,000 and €200,000 for a large company.
Cost of checking the CLI	€23.5 per hour, with number of checks varying for substance manufacturer versus mixture manufacturer and by company size	Respondents were asked to indicate how often within the average year they referred to the CLI to check on classification information. Costs are then calculated based on the annual FTE cost, se responses, it is assumed that the CLI is checked twice a month, for an hour each time. Therefore, the monthly cost to each company is €80 (€23.5 x 2) and the annual cost is, therefore, €960 (€80 x 12).

7.2.3 Direct Costs

7.2.3.1 Regulatory charges

No regulatory charges are have been incurred by industry stakeholders relating to CLP, with the exception of the few cases where companies have submitted CLH dossiers aimed at re-classifying a substance on Annex VI to ECHA. There is a few of €12,500 for making such submissions. As only a few submissions have taken place, these costs are not substantive.

7.2.3.2 Updating IT systems

For the transition cost assessment it was assumed that 30% of substance manufacturers and 60% of formulators or mixture manufacturers bought a new IT system or up-graded their current system in order to assist with the changes in classification and labelling requirements.

Discussions with IT and classification and labelling service providers indicate that there are regular updates to software that come as part of a service package to companies. The costs of these updates will vary across a range of factors including the actual package (classification only, classification plus labelling, and with or without inclusion of SDS writing software). Some companies provide updates on a quarterly basis, others less frequently. These updates provide essential information in relation to changes in harmonised classifications, labelling requirements (e.g. wording of hazard and precautionary phrases), etc.

As discussed in more detail in Section 12, these service providers are viewed as an important source of information to a high percentage of companies within the general chemicals sector (62% based on responses to the targeted survey). Given the likelihood that most companies will have some form of software (even if they did not indicate that they purchased a new system as part of the transition to CLP), it is assumed here that at least 60% of companies will pay for an annual service that provides regular updates with respect to CLP and potentially other related legislation (i.e. the Biocidal Products Regulation and Plant Protection Products Regulation).

The resulting estimates are provide in Table 7-4, based on the cost figures set out in Table 7-3 and the data on the number of relevant substance and mixture manufacturers given in Section 6.4, together with the breakdown in terms of SMEs and large companies.

7.2.3.3 Staff training costs

The targeted consultation asked companies how much they spent annually on training, in order to keep up-to-date with changes in CLP and ensure that they met legal obligations. The resulting cost estimates for SMEs and large companies in terms of staff time and the costs of training courses are €3,040 and €26,670 respectively. It is assumed that all companies will incur such training costs, given that keeping up to date is a requirement and companies would be unable to ensure that they remained compliant without such training. The estimated ongoing annual costs for training are set out in Table 7-4, alongside the IT costs.

As with transitional costs, a ±30%. error in unit costs is possible. As such, across substances and mixtures:

- Total IT and staff training costs for SMEs are estimated as €102.6 million ± €31 million (giving a range of €72-133 million);
- Total IT and staff training costs for large enbetrprises are estimated as €36 million ± €11 million (giving a range of €25-47 million); and
- Total IT and staff training costs across all companies are estimated as €138.7 million ± €42 million (giving a range of €97-180 million).

Table 7-4: Annual costs of updates to IT systems and staff training			
Cost Element	**SME**	**Large**	**Total**
Substance manufacturers			
Updating IT systems	€15,379,000	€3,862,000	€19,242,000
Training staff	€18,701,000	€13,735,000	€32,436,000
Total	**€34,081,000**	**€17,598,000**	**€51,678,000**
Mixture manufacturers			
Updating IT systems	€30,901,000	€4,065,000	€34,966,000
Training staff	€37,576,000	€14,455,000	€52,031,000
Total	**€68,478,000**	**€ 18,520,000**	**€86,998,000**
Notes: Figures rounded to nearest hundredth and have an estimated error of ±30%.			

7.2.3.4 Staff costs associated with ongoing compliance activities

The targeted consultation collected data from companies on the staff costs associated with ensuring ongoing compliance with CLP as part of their daily activities. Information was provided by 102 companies on the number of FTEs within their company that were dedicated to CLP related activities, such as reviewing classifications, redesigning labels, etc. The averages quoted by companies of different sizes (substance manufacturers, mixture manufacturers and importers) are reported in Table 7-5 below. As can be seen from this table, the figures vary from around 0.5 FTE for a micro enterprise (which represents a significant level of staff time), to around 5 for the average large companies. It is of note that the figure for large companies is based on a trimmed set of responses to the consultation. Two global respondents indicated over 150 FTE were involved in classification and labelling activities on an annual basis; they were treated as outliers for the purposes of this assessment, but including them in the calculations would raise the average for large companies to 13.

Based on Eurostat data for the average labour cost per FTE equivalent for the chemicals sector (NACE C20), the average FTE cost across the EU 28 is assumed to be €41,000. The resulting cost estimates from applying these figures to the number of companies from Eurostat data for 2012/13 (for relevant NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1 and 24.4) provides the estimates given in Table 7-5. As with other estimates, a ±30% error in the unit costs is possible. As such, the total cost of €957 million in the table is the central estimate in a range of €670-1,245 million.

Table 7-5: Annual cost of employing 1 FTE for compliance activities based on previous cost assumptions (based on 1 FTE = €41,000)					
Enterprise size	**Micro**	**Small**	**Medium**	**Large**	**Total**
No of FTE	0.25	0.5	3	5	
No of companies	20,922	6,784	3,148	1,057	
Total cost	€214,451,000	€139,072,000	€387,204,000	€216,685,000	**€957,412,000**

Averaged over all SME and large companies in the Eurostat data for 2012/13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1 and 24.4) this is equivalent to:

- 2% of employees being engaged 100% of the time in CLP related activities; or
- Averaged across all employees, 2% of time is spent on CLP related activities.

7.2.3.5 Packaging Costs

CLP requires that CRCs and TWDs are placed on substances and mixtures that are sold to professional users or consumer and that are classified against a range of toxicity endpoints, as summarised in Table 7-6 below.

It is understood that the costs of the CRCs and TWDs themselves are relatively low, at just a few cents per cap, but they have to be applied to all containers of all products falling into a relevant classification. In addition, packaging needs to be changed so that it is appropriate to carry the CRC or TWD, which may mean a change in the nature of the packaging itself (although no estimates could be developed in Section 6 for the potential costs of modifying packaging lines due to a lack of data). The costs of changing packaging from cardboard skillets/cartons to plastic containers for CRCs are estimated at around €60 per 1000 pieces, based on data from a number of detergents manufacturers. The requirement for TWDs involves the redesign of bottle mould cavities for products sold in plastic bottles or development of new moulds for products currently sold in cardboard skillets/cartons or pouches. These are recurring compliance costs that will be realised annually.

As noted in Section 6.6.2, responses to the targeted data collection indicate annual increases in costs associated with CRCs and TWDs of as follows for SME and large companies respectively, across all sectors:

- An annual increase in costs of €100,000 per SME; and
- An annual increase in costs of €200,000 per large company.

Table 7-6: Summary of criteria for triggering the provisions for Child Resistant Closures and/or Tactile Warnings of Danger under CLP

Hazard Class	CRCs	TWDs
Acutely toxic (category 1 to 3)	✓	✓
Acutely toxic (category 4)		✓
STOT single exposure (category 1)	✓	✓
STOT single exposure (category 2)		✓
STOT repeated exposure (category 1)	✓	✓
STOT repeated exposure (category 2)		✓
Skin corrosive (category 1A, 1b and 1C)	✓	✓
Reparatory sensitisation (category 1)		✓
Aspiration hazard (category 1) *Not aerosols or if in container with sealed spray attachment*	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
Flammable liquids (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
Flammable solids (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
* Note that the TWD provisions do not apply to aerosols which are only classified and labelled as extremely flammable or flammable aerosols. *Source: ECHA (2011): Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008, Helsinki.*		

These figures relate to the increase in packaging costs and are therefore on-going costs rather than the transition costs. It is not clear to what extent investment in new lines was actually required, given the low number of products that were affected, as reported by companies in response to the targeted consultation. As a result, it is assumed that the additional investment costs required within the sector were zero or low for most companies.

As illustrated by Figure 6-1, around 50% of respondents to the targeted consultation indicated that they had no products requiring either CRCs or TWDs (although other changes in packaging may have been required, e.g. to meet transport requirements triggered by a change in classification). The remainder generally had less than 5% of their products affected (assumed to equate to 5 or less for SME mixture manufacturers and 40 or less for larger manufacturers), with only half of these companies newly requiring CRCs or TWDs. Around 10% of companies (11 in total out of 107 respondents) had greater than 5% of products newly requiring CRCs or TWDs, with most of these TWDs.

For the purposes of calculating annual costs, we assume that these costs are only relevant to a subset of mixture manufacturers, i.e. those selling products for professional or consumer use (NACE codes: 20.2, 20.3, and 20.41). These totals are then adjusted for the percentage indicating that they incurred CRC and TWD related packaging costs based on the above percentages. The annual cost figures of €100,000 per SME and €200,000 per large company are then applied to generate the estimated costs set out in Table 7-7.

Table 7-7: Annual costs of CRC and TWD packaging requirements

Enterprise size	SME	Large
No. of relevant companies	8169	148
Number of companies incurring CRC and TWD related costs (50% of 50%)	2042	37
Annual cost per company	€100,000	€200,000
Total annual costs	€204,225,000	€7,400,000
Grand total	€211,625,000	

As with other estimates, a ±30% error in the unit costs is possible. As such, the total cost of €212 million in the table is the central estimate in a range of €148-275 million. Although the central estimate of annual costs is around €212 million, these costs may be low. This figure relates to all sectors, and in practice it may under-estimate the costs incurred by companies within the detergents sector, where the previous assessment for AISE found that around 190 SMEs and 180 larger companies operating in this sector could be impacted by CRC requirements under CLP. Even though the previous assessment is no longer relevant as it addressed different requirements than those implemented in CLP, the number of large companies that are members of AISE and that were assumed to be affected by CRC and TWD packaging requirements is 5 times that given in Table 7-7. Applying the annual cost figures to the numbers of SMEs and large companies that are members of AISE and assumed to be affected gives costs of €55.2 million (±€17 millon).

7.2.3.6 Hassle costs

The cost of checking the CLI is categorised as a hassle cost because it is not necessarily a direct substantive compliance cost, rather it is an indirect requirement of ensuring that one is in compliance with the legislation. There is an obligation of suppliers to update self-classifications based on new information and to try and agree on self-classifications across all notifiers for a substance.

Based on data from the targeted questionnaires, it is assumed that large substance manufacturers check the CLI on average twice a month (see Section 8.2 for further details). SME substance

manufacturers are assumed to check six times a year on average, with this taking into account the fact that some SME consultees indicated they never checked the CLI and other SME consultees indicating that they checked it as frequently as the larger companies (one even indicating several times weekly).

It is harder to assign a hassle cost to CLI checking for formulators. It is clear that some mixture manufacturers may check the CLI on a regular basis from comments made to the targeted consultation. However, as mixture manufacturers should base their classifications on information received from their suppliers, it is harder to assign these costs to the "hassle" of complying with CLP. Given the importance of classification data to their operations, however, it seems reasonable to assume that six annual checks can be allocated to CLP compliance for SME companies and 12 annual checks for larger mixture manufacturers. The resulting costs are set out in Table 7-8.

Note that these calculations may underestimate the true cost to industry of checking the CLI, as they may not reflect the difficulties reported by stakeholders in using the CLI. As with other estimates, a ±30% error in the unit costs is possible. As such, the total cost of €4.8 million in the table is the central estimate in a range of €3.4-6.2 million.

Table 7-8: Annual hassle costs associated with checking of the Classification and Labelling Inventory

	SME companies	Large companies	Totals
Substance manufacturers			
Number of companies	10,253	515	
Frequency of CLI checks	6	24	
Total costs	**€1,450,000**	**€291,000**	**€1,741,000**
Mixture manufacturers			
Number of companies	20,601	542	
Frequency of CLI checks	6	12	
Total costs	**€2,913,000**	**€153,000**	**€3,066,000**
Grand total			**€4,807,000**
Notes: Costs are rounded to nearest thousand and have an estimated error of ±30%.			

7.2.4 Total annual costs to industry due to CLP

Table 7-9 provides the sum of the above annual cost estimates, to provide central estimates of the total annual direct compliance costs associated with CLP requirements. The total annual cost across substance and mixture manufacturers is €1.3 billion per annum where this is the central estimate in a range of €0.92-1.71 billion.

Although the total estimate of CRC costs looks low, the share attributed to SMEs (€204 million ±€61 million) appears relatively high and may be an overestimate. The estimate assumes that 2,000 plus small companies incur such costs per annum, and this figure may be high given that responses to the targeted consultation suggest only a small number of products may be affected and by only a sub-set of companies.

Offsetting this potential overestimation is the fact that not all packaging related costs are considered in the analysis, nor the full extent of the costs that may be arising from multi-lingual labelling requirements. However, the costs also exclude the administrative burdens associated with notifications to the CLI (expected to be minimal after 2018) and to poison centres. These are discussed further in Section 8.

To put these estimated costs into perspective, the total ongoing costs are less than 0.1% of total turnover for the sectors and around 1.1% of value added at factor cost, based on Eurostat data for 2012/13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1, and 24.4).

Table 7-9: Total annual direct compliance* costs to industry – substances and mixture manufacturers			
Cost Element	**Total costs by company size**		
	SME	**Large**	**Total**
Regulatory Charges			
Fees or penalties paid	**0**	**0**	**0**
Direct costs			
Costs of annual updates to IT systems	€ 46,281,000	€ 7,927,000	€ 54,210,000
Costs of staff training	€ 56,278,000	€ 28,190,000	€ 84,470,000
Costs of employing FTEs for compliance activities	€ 740,726,500	€ 216,685,000	€ 957,400,000
Costs of Child Resistant Closures	€ 204,225,000	€ 7,400,000	€ 211,600,000
Hassle costs	€ 4,362,000	€ 444,000	€ 4,800,000
Total annual costs	**€ 1,051,872,000**	**€ 260,647,000**	**€ 1.3 billion** (€0.9-1.7 billion)
Per company (assuming costs evenly distributed across all substance and mixture manufacturers)	€ 34,100	€ 246,600	
* Administrative costs are discussed in Section 8. All costs have an estimated error of ±30%.			

7.2.5 Comparison with results of Cumulative Cost Assessment

The Cumulative Cost Assessment (CCA) study[39] was commissioned by DG GROW with the of identifying and analysing the EU legislation which has had the greatest impact on EU companies within the chemicals sector over the period 2004-2014. The study quantifies the cumulative costs attributable to the following seven legislative packages: chemicals legislation; energy legislation; emissions and processes legislation; workers safety legislation; product-specific legislation; customs and trade legislation; transport legislation.

The legislation which comes under the chemicals legislative package includes (but is not limited to) REACH, PPP legislation, biocidal products legislation and CLP. The study states that the package includes "regulations whose overall objective is to improve the assessment and monitoring of hazards associated with certain chemical substances and to manage the potential risks of using them in certain applications, with a view to protecting human health and the environment."

Costs are calculated under the same categories as this study, in line with the categories listed in the Better Regulation Toolbox. Though the study covers the whole chemical sector, costs are only assessed for the subsectors for which data is available to develop a reliable estimation of costs. These are: 20.13; 20.14; 20.16; 20.20; 20.41; 20.30; 20.59.

The study found that the overall average annual costs associated with chemicals legislation over the period is approximately €3 billion, equivalent to 3.5% of the value added of the subsectors. Table 7-10 below gives the costs calculated in the CCA study for each category as being attributable to the chemicals legislative framework.

[39] Technolopolis et al (2016): Cumulative Cost Assessment for the EU Chemical Industry, Final Report to DG Grow. Available at: http://ec.europa.eu/DocsRoom/documents/17784

Table 7-10: Comparison of annual costs calculated in CLP Fitness Check and CCA		
Cost category	**Share of value added (%)**	**Share in total cost of chem leg (%)**
Monetary obligations	0.9	26
CAPEX	1.0	29
OPEX	0.7	20
Administrative burden	0.9	26
Total	3.5	100

The study estimated that REACH, PPP legislation and biocidal products legislation are the main sources of monetary obligations and administrative burden, while CLP is cited as the main source of CAPEX and OPEX costs. These two sets of costs equate to around €1.47 billion, which is comparable to the figure of €1.3 billion estimated for this study and presented in Table 7.9. The figure estimated for this study is high compared to the figure of €1.47 billion, given that this latter figure includes obligations under other legislation. However, this can be attributed in part to the fact that this study considers a broader set of industry sectors than considered in the CCA; an additional 10,000 plus companies are assumed to have faced CLP related obligations for the purposes of this evaluation.

Added to these CLP related costs of €1.3 billion would be poison centre costs which are discussed further in Section 8. Note that the CCA will have classed poison centre reporting requirements as an administrative burden (as done for this study), which in total are are estimated by the CCA to equate to roughly €780 million across all sectors. This is significantly below the estimate of €1.7 billion quoted by the poison centre study carried out by Kirhensteine et al (2015).

7.3 Ongoing benefits

Key findings:

- On-going health and environmental benefits stem from the availability of classification information and the role that this plays in hazard communication, providing incentives towards the use of less hazard substances, and reductions in accidents/ incidents and exposures to hazardous substances (see also the Task 3 report)
- Most stakeholders believe there has been a positive effect, in terms of protecting human health and the environment, from CLP in relation to more consistent hazard classifications, increased access to classification data, increased harmonised classifications and hazard communication for workers and consumers (though to a lesser degree)
- Company responses to changes in substance classification have included substituting some chemicals with less hazardous ones, and ceasing the import of some substances and mixtures
- As with previous studies (such as the recent Benefits Indicators study[46]) owing to a several methodological and data challenges, the full range of human health impact endpoints (e.g. neurodevelopmental, reproductive health, etc.) cannot be captured within a benefits assessment. Further, owing to a lack of monitoring data, impact prediction methodologies and metrics for monetary valuation, environmental benefits cannot be quantified in monetary terms at all. There is, however substantial evidence that there has been a significant change in the level of information available on environmental classifications and the availability of such data since the mid-1990s has enabled action to be taken which has led to significant declines in long term monitoring of trends in environmental concentrations of pollutants;
- In spite of this, our (necessarily partial) analysis of what human health benefits can be monetised estimates that the average annual value of reductions in poisoning incidents,

occupational skin and respiratory diseases and occupational cancers since 2000 is between €391 and €512 million per year and since 2008 between €217 and €338 million per year.

7.3.1 Introduction

The main benefits for human health and the environment from transitioning to the CLP Regulation will arise from a reduction in accidents/incidents and exposures of people and the environment to hazardous chemicals through measures taken under CLP and under downstream legislation. These will be delivered through:

- Improved cohesion with other legislation, such as REACH;
- Changes in the classification categories and criteria, particularly where these may lead to a more stringent hazard classification (unless this is considered to reflect the over-classification of substances);
- Changes in the classification of mixtures due to changes in the classification formula, with this leading to more stringent hazard classification (unless this leads to over-classification);
- For some mixtures, reformulation to reduce to mixture classification and/or hazards (leading to reductions in exposure and risk of workers and consumers);
- Improved communication of the hazards of substances and mixtures to downstream users, including through the Article 42 driven creation of the CLI;
- Increased harmonisation of classifications and of hazard symbols, leading to a more uniform system and hence less confusion for downstream users;
- Incentives to shift to lower hazard substances; and
- Once implemented, greater harmonisation of the system for notifying Poison Centres of potential chemical hazards.

As has been identified in the course of many studies on chemicals and chemicals regulation, estimating the magnitude of such benefits and, in particular, providing a full and complete monetary valuation of all of them is confounded by a number of problems including:

- The availability of monitoring and other data with sufficient resolution to precisely isolate chemicals related drivers from other factors and causes;
- The availability of such data over a suitably long timescale to enable the detection of changes;
- For certain diseases (such as cancer), the often long latency period (measured in years/decades) between exposure to a causative agent (such as a chemical carcinogen) and diagnosis of disease (with the effect that the benefits of any reduction in exposure achieved via CLP and other chemicals regulation will not be manifested until some point in the future);
- Coupled with the difficulties of isolating chemicals-related causes from other causes of mortality/morbidity, the difficulty of attributing changes to CLP in isolation from other pieces of legislation (in particular REACH); and
- The availability of suitable metrics for expressing disease cases avoided in monetary term.

In spite of the difficulties, we have endeavoured to gather together as much information as possible to enable estimates of any benefits to be made. Needless to say, however, only a subset of the likely actual benefits can be estimated and expressed in monetary terms.

The baseline

The CLP Regulation replaced the pre-existing Directive led legislation of which the key components were the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive which was first introduced in 1988 (88/379/EEC) and recast in 1999 (1999/45/EC). As such, classification, packaging and labelling legislation has existed in some form or other since 1967 for substances and 1988 for preparations. When using time series monitoring and other data to estimate the human health and environmental benefits of classification and labelling, it is clearly difficult to isolate the impacts of the transition to CLP from those of the pre-existing legislation. Impacts/benefits occurring before 2008 are associated with the Dangerous Substances Directive/Dangerous Preparations Directive legislation and so cannot be attributed to CLP. Those occurring after 2008 may be attributable to CLP but will represent a mixture of the carrying over of pre-existing requirements into the new regulation combined with additional requirements and changes to the system more generally. It is not, however, possible to disentangle the two. The baseline for the benefits assessment has been selected to be suitably long as to provide context to the transition to CLP.

When considering the appropriate baseline for the assessment of the benefits of classification and labelling a number of factors have been considered where these include:

- The timing of community legislation on classification and labelling of both substances and preparations (mixtures); and
- The availability and completeness of data on occupational diseases and numbers of substances with different classification.

In terms of the timing of community legislation, a review of the previous legislation suggests that, whilst the original legislation relating to classification of substances was adopted in 1967 (the Dangerous Substances Directive - 67/548/EEC) and for preparations in 1988 (88/379/EEC), it was not until after the revised Dangerous Preparations Directive (1999/45/EC) that classification and labelling provisions were applied fully, consistently and robustly across Member States to all substances and preparations (now termed mixtures) in a way that has parallels with today's system under CLP.

1999/45/EC was introduced to address differences in application of the rules in Member States which had resulted in considerable variations in the classification, packaging and labelling of preparations. One of the key differences related to the treatment of preparations which, although not considered and classified as dangerous within the terms of the Dangerous Preparations Directive, contained substances that nevertheless presented a danger for users. 1999/45/EC extended the packaging and labelling provisions to cover such preparations and included defining these as those that contained at 0.1% w/w of at least one CMR 1A/1B, toxic, very toxic and sensitising substance or 1% w/w other dangerous properties. Such preparations were required to provide the labels and warnings and child resistant closures set out in the Directive (and also an SDS when requested by professional users). In addition, 1999/45/EC introduced classification, packaging and labelling of preparations for environmental hazards for the first time.

Regarding data considerations, the analysis of benefits has sought to integrate data on the changes in numbers of substances with different classifications with other data sources (such as on health effects and incidents). The earliest data that are available on numbers of substances self-classified for different endpoints are those from an old version of IUCLID40 from the early 2000s. Regarding

[40] A 2005 version which, it is understood contains information from IUCLID 4, last updated somewhere between 2000 and 2003 when the decision to overhaul IUCLID 4 to provide the format for data collection/submission and dossier preparation under REACH.

data on incidents and occupational diseases, sourcing data from before 2000 is problematic, both practically (because publication of online statistics is before 2000 is patchy) and methodologically (because of methods of data collection and categorisations have changed).

Considering the issues of data availability/limitation and the timing of the changes and extensions made to the system of classification, packaging and labelling under the Dangerous Preparations Directive 1999/45/EC the year 2000 represents a suitably long timescale for the assessment of benefits. In the benefits assessment provided below, impacts and benefits accrued from 2000 to the present and also from 2008 to the present are reported.

7.3.2 Improved information on chemical hazards

As can be seen from Table 7-11, most respondents believe that CLP has had a positive impact on health and safety with respect to increased access to classification and labelling data, increases in the number of substances with harmonised classifications, and more consistent hazard classifications. The levels of agreement are lower on the latter for NGOs and SMEs, but are otherwise neutral with respect to the availability of more consistent hazard classifications. Industry is more positive with respect to the impacts of CLP in terms of hazard communication to workers, but views are more mixed with respect to communication for consumers (reflecting findings reported in Section 4 and the Task 2 report). Views are much less positive on the impacts of CLP in relation to packaging requirements (although positive overall). In terms of preparedness for accidents, respondents are generally positive with respect to the impacts of CLP, with the exception of the detergents sector. However, views vary with respect to whether the links between CLP and other national legislation have a positive or negative impact on health and safety (note that these questions were not asked in all surveys).

The picture is much the same with respect to the environmental impacts of CLP, as can be seen from Table 7-12.

The SME Panel was not asked separate questions with regard to worker safety and the environment, so the percentage figures quoted in Table 7-10 should be interpreted with caution. However, the SME Panel survey also asked about increased awareness of the potential health and environmental impacts of chemical products. In both cases, around 66% of respondents indicated that CLP and the chemicals legislation framework had had a low to large positive impact (split fairly evenly between low and large).

Table 7-11: Views on impacts of CLP with respect to health and safety – percentages indicating low to large positive impact or low to large negative impact										
Answer Options	General chemicals (n=105)		Plant protection (n=9)		Detergents (Large only, n=9)		NGOs, Worker Reps and Consumer Assoc. (n=5)		SME Panel (n=203)	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
Increased access to classification and labelling data for substances	77%	1%	78%	0%	57%	29%	66%	0%	66%	0%
Increased number of substances with harmonised classifications	71%	6%	100%	0%	57%	14%	66%	0%	66%	0%
More consistent hazard classifications across substances	68%	3%	78%	0%	57%	14%	40%	0%	40%	0%
Hazard communication for workers[1]	63%	6%	78%	0%	29%	57%	40%	0%	40%	0%
Hazard communication for consumers[2]	45%	14%	78%	11%	0%	86%	20%	0%	20%	0%
Changes in packaging requirements	21%	17%	22%	11%	14%	43%	20%	0%	20%	0%
Preparedness for accidents	35%	1%	44%	0%	0%	43%	20%	0%	20%	0%
Links between CLP and other EU legislation	43%	15%	33%	44%	14%	43%	na	na	na	na
Links between CLP and national legislation	38%	16%	33%	22%	0%	29%	na	na	na	na
1 Phrased as safe use of chemicals by workers in the SME Panel survey 2 Phrased as safe use of chemicals by consumers in the SME Panel survey Notes: There were significant percentages of respondents indicating a neutral impact or "don't know" depending on group and question										

Table 7-12: Views on impacts of CLP with respect to environment - – percentages indicating low to large positive impact or low to large negative impact								
Answer Options	General chemicals (n=103)		Plant protection (n=9)		Detergents (Large only, n=9)		NGOs (N=2)	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
Increased access to classification and labelling data for substances	77%	0%	78%	0%	71%	0%	100%	0%
Increased number of substances with harmonised classifications	76%	1%	78%	0%	71%	0%	100%	0%
More consistent hazard classifications across substances	72%	0%	67%	0%	43%	14%	100%	0%
Hazard communication for workers	57%	0%	56%	0%	29%	0%	100%	0%
Hazard communication for consumers	46%	11%	56%	11%	14%	14%	100%	0%
Changes in packaging requirements	22%	11%	11%	11%	14%	14%	50%	0%
Preparedness for accidents	37%	1%	44%	0%	0%	14%	50%	0%
Links between CLP and other EU legislation	44%	27%	33%	22%	29%	29%	Na	Na
Links between CLP and national legislation	42%	38%	33%	33%	0%	29%	Na	Na

Questions were also asked in the on-line open public consultation about the impacts of the chemicals legislative framework in terms of its importance and effectiveness in protecting human health and the environment (as well as ensuring the well-functioning of the internal market and stimulating competitiveness and innovation. The responses to these questions are summarised in Table 7-13, based on the analysis provided in the Task 4 report. As can be seen from this table, the legislative framework is considered to be more effective in relation to protecting the environment than it is in protecting human health by citizens and industry. For the other groups, the level of protection is equal and indeed rated as only being moderately effective (based on a scoring and weighting exercise – see Table notes).

Table 7-13: Summary of the views of respondents by group to Question 9, 10, 11 and 12

Group	Rating	a) Protecting human health	b) Protecting the environment	c) Ensuring a well-functioning internal market	d)Stimulating competitiveness and innovation
Group 1 Citizens	Importance	Important	Very important	Very important	Very important
	Effectiveness	Moderately effective	Mostly effective	Mostly effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake
	Value added	Moderate level of value added			
Group 2 Industry	Importance	Important	Very important	Very important	Important
	Effectiveness	Moderately effective	Mostly effective	Mostly effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not effectively implemented	Legislation is not adapted to issues at stake
	Value added	High level of value added			
Group 3 Author-ities	Importance	Moderately important	Important	Important	Important
	Effectiveness	Moderately effective	Moderately effective	Mostly effective	Mostly effective
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake = Legislation is not effectively implemented	Legislation is not adapted to issues at stake = Legislation is not effectively implemented	Legislation is not adapted to issues at stake = Legislation is not effectively implemented	Legislation is not adapted to issues at stake
	Value added	High level of value added			
Group 4 Other	Importance	Moderately important	Moderately important	Important	Important
	Effectiveness	Moderately effective	Slightly effective	Moderately effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not effectively implemented	Legislation is not effectively implemented	Legislation is not adapted to issues at stake	Legislation is not effectively implemented
	Value added	High level of value added			

Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not important/effective, 2 = slightly important/effective; 3 = moderately important/effective; 4 = important/mostly effective; 5 = very important/effective
The main reason to explain why respondents though the legislation is ineffective is based on the most common response (excluding no opinion)
Value added is based on score of 1=no value added, 2= slight, 3=moderate, 4=high, 5=very high

Most stakeholders indicated that this moderate effectiveness was due to the legislation not being adapted to the issues at stake, although both authorities and other stakeholders (e.g. NGOs, trade unions, academia, etc.) noted that it was also due to its not being effectively implemented.

7.3.3 Incentives to substitute with less hazardous substances

As noted in Section 4.6.3, as part of the targeted consultation, manufacturers and formulators were asked to indicate whether re-classification had had a significant impact on the formulation of substances that they placed on the market. The responses to this question were presented in Tables 4-6 and 4-7 for the detergents sector and the more general chemicals sector respondents. From these tables, it is clear that individual companies adopted a range of responses. However, significant percentages indicated the following:

- they removed substances from their products (13 of 17 detergents companies);
- substituted some chemicals with less hazardous ones (44 of 111, or 40% of general chemicals manufacturers, importers distributors and formulators);
- stopped importing some substances and mixtures (52 or 111, or 47% of general chemicals manufacturers, importers distributors and formulators),
- as well as removing products from their portfolios due to more stringent classifications (23% of general chemicals manufacturers, importers distributors and formulators); and
- increasing the numbers of lower hazard products offered across their portfolio (18% of general chemicals manufacturers, importers distributors and formulators).

These figures suggest that in this respect the legislative framework has provided incentives towards the supply and use of less hazardous chemicals. This is similar to the type of black list effect that ECHA has found with respect to CMR substances; as reported by ECHA in its 2015 CMR report[41], some 40% of Annex VI cat 1A and 1B CMRs have not been notified to the CLI.

7.3.4 Chemicals related accidents

7.3.4.1 Workers

Accident statistics compiled by Cefic (2014) on The European Chemicals Industry, Facts and Figures 2014 (see page 53)[42] based on data collected for Responsible Care (a global initiative set up the by the chemical industry to improve, amongst other things, the health and environmental performance of the chemical industry) suggest that health and safety at the workplace has been improving continually – see Figure 7-1. Cefic (2014) notes that these estimates are based on "historical data from Eurostat until 2007" and show that working in the chemicals sector is more than twice as safe as the European manufacturing average. The continued improvement to health and safety in the workplace has been attributed to European and national legislation as well as the Responsible Care initiative.

[41] https://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf

[42] http://fr.zone-secure.net/13451/106811/publication/contents/templates/Cefic_F_and_F_2014-Full_report_Blanc_150dpi.pdf

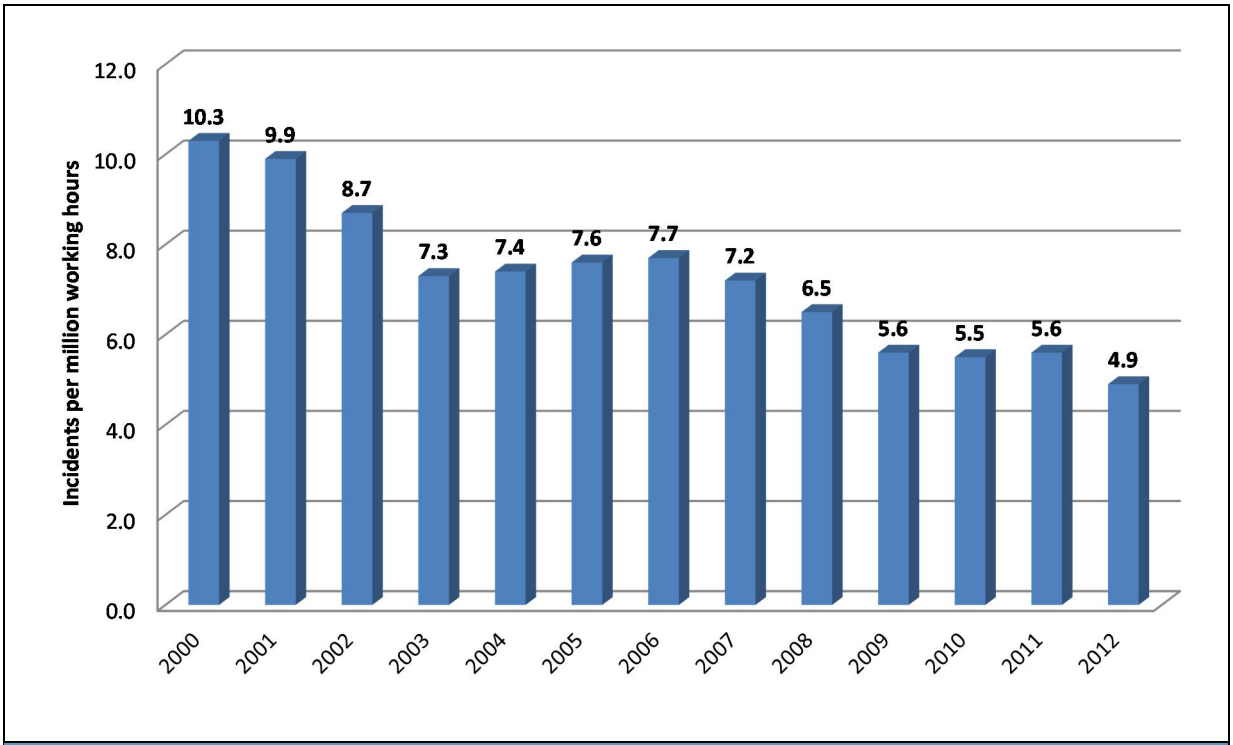


Figure 7-1: Number of lost time incidents/million working hours 2000 – 2012
Source: CEFIC (2014): The European Chemical Industry, Facts & Figures 2014, accessed at http://fr.zone-secure.net/13451/106811/publication/contents/templates/Cefic_F_and_F_2014-Full_report_Blanc_150dpi.pdf

It is important to note that these lost time incident statistics will include physical causes and other causes (such as falls, crushed limbs, electrocution, burns, etc.), as well as chemicals-related lost time incidents. To convert these figures into an estimate of the number of accidents caused by exposure to harmful chemicals, we have used data submitted to the UK HSE under the UK Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013. These annual statistical data provide a breakdown of workplace accidents including by cause, with those causes including "*exposure to, or contact with, a harmful substance*".

The figure below provides the data on the percentage of all reportable incidents caused by exposure or contact with substances by year. As can be seen in the HSE RIDDOR statistics, in 2000, 3.4% of all reportable incidents were as a result of exposure to harmful substances compared with 1.7% in 2014.

Applying these to the CEFIC data on accidents in the EU chemical industry provides the best available estimate of changes in the number of lost-time incidents in the EU chemical industry since 2000. These are given in Figure 7-3 below. Clearly, these values require extrapolation of UK RIDDOR statistics to CEFIC's data and so assume that the accidentology across Europe is similar to that observed in the UK.

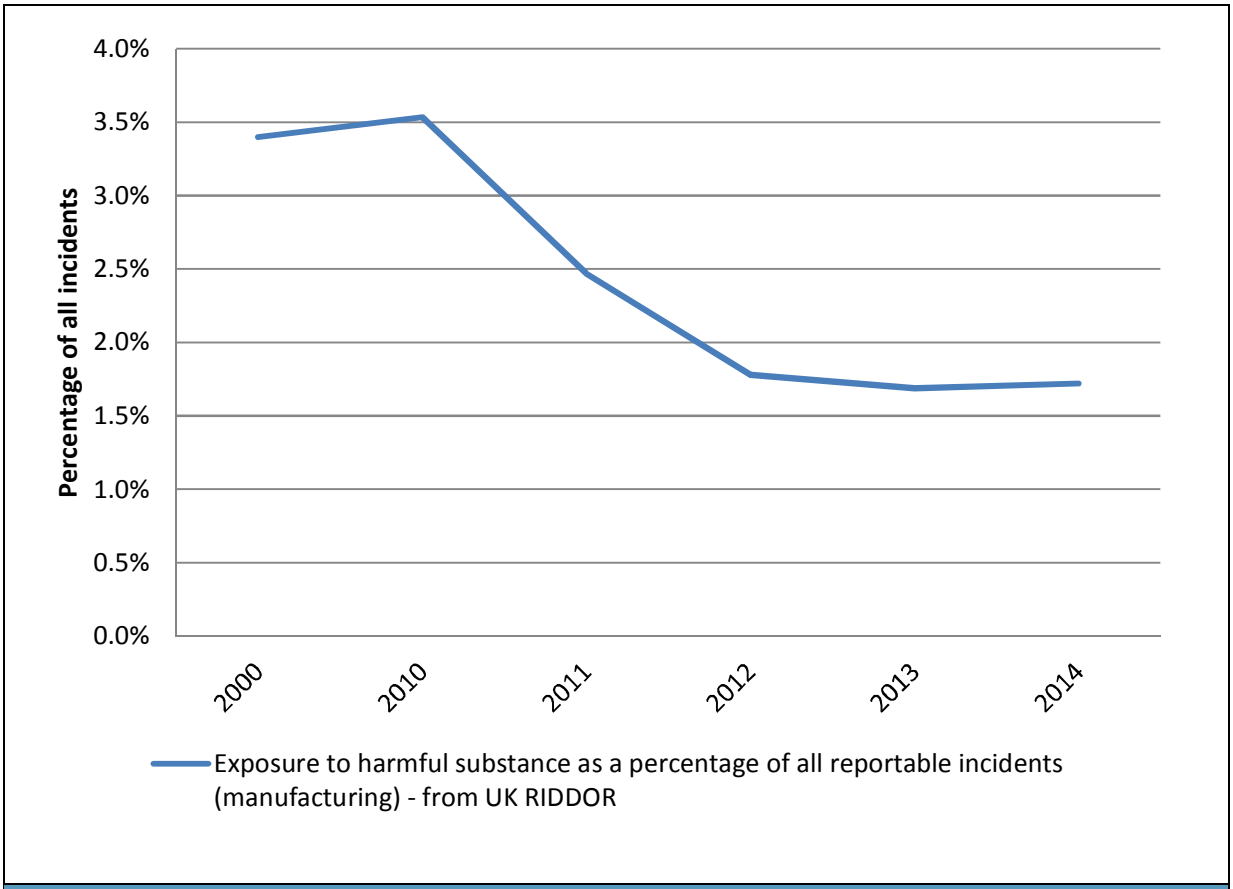


Figure 7-2: Exposure to harmful substance as a percentage of all reportable incidents (manufacturing) - from UK RIDDOR

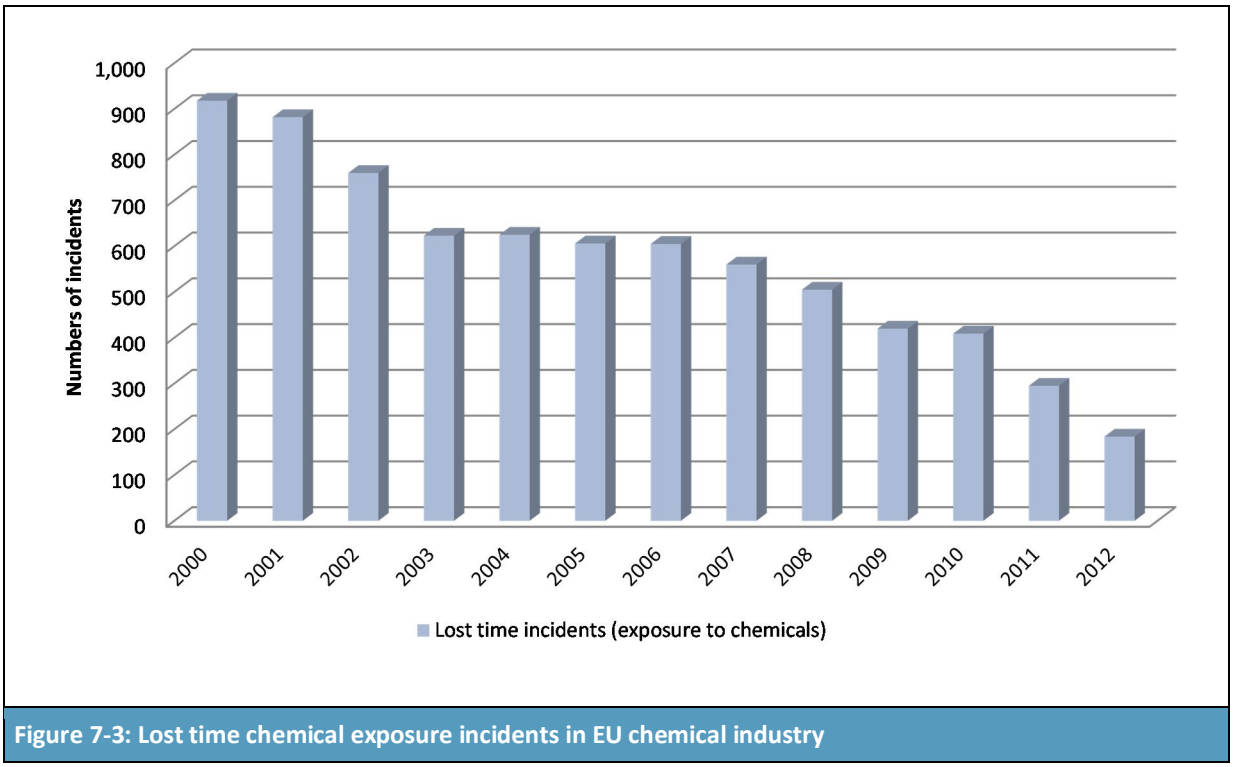


Figure 7-3: Lost time chemical exposure incidents in EU chemical industry

As can be seen from Figure 7-3, the estimates suggest a significant reduction in the number of incidents involving exposure to harmful substances since 2000. Whilst some of this reduction (around half) is associated with a general reduction in the frequency of all incidents (i.e. regardless of cause) through improved workplace safety, the remainder is due to the reduction in the incidents caused by exposure to chemicals.

In terms of the economic value of reductions in chemicals related lost time incidents in the EU chemical industry, it is not possible to provide a full quantitative assessment because the medical and physical consequences of the incidents are unknown and therefore cannot be accorded the appropriate monetary value. However, estimates of the lost time and its value[43] suggest that:

- Between 2000 and 2016 67,500 days of lost time owing to incidents caused by exposure to harmful substances have been avoided in the EU chemical industry. **This has a present value of around €20.4 million**; and

- Between 2008 and 2016 18,200 days of lost time owing to incidents caused by exposure to harmful substances have been avoided in the EU chemical industry. **This has a present value of around €5.4 million**.

As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition[44].

These changes estimated above only reflect those in the EU chemical industry. UK RIDDOR data suggests that the reduction in frequency of incidents involving exposure to harmful substances across all industries is significant (reducing from 2.7% of incidents in 2000 to 1.1% in 2014).

The figure below provides the UK RIDDOR data for incidents caused by exposure to harmful substances expressed in terms of incidents per 100,000 employed across all industries. These values have then been applied to employment data for the EU from EUROSTAT to provide an estimate of the number of incidents in the EU28 in each year since 2000.

[43] Assuming 9 days per incident based on classifications of incident severity in RIDDOR at €300 per day.

[44] Benefits from 2008 to the present represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period).

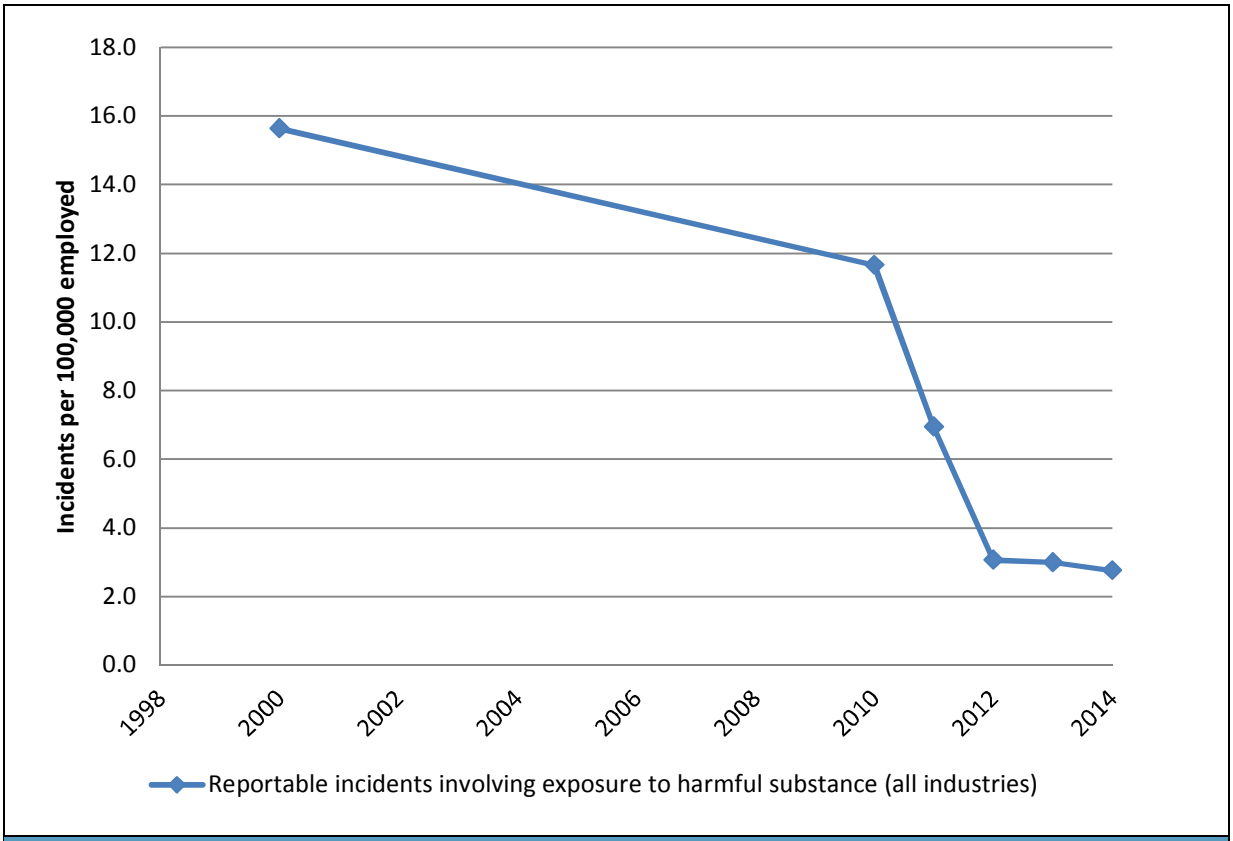


Figure 7-4: UK RIDDOR incidents involving exposure to harmful substances per 100,000 employed (all industries)

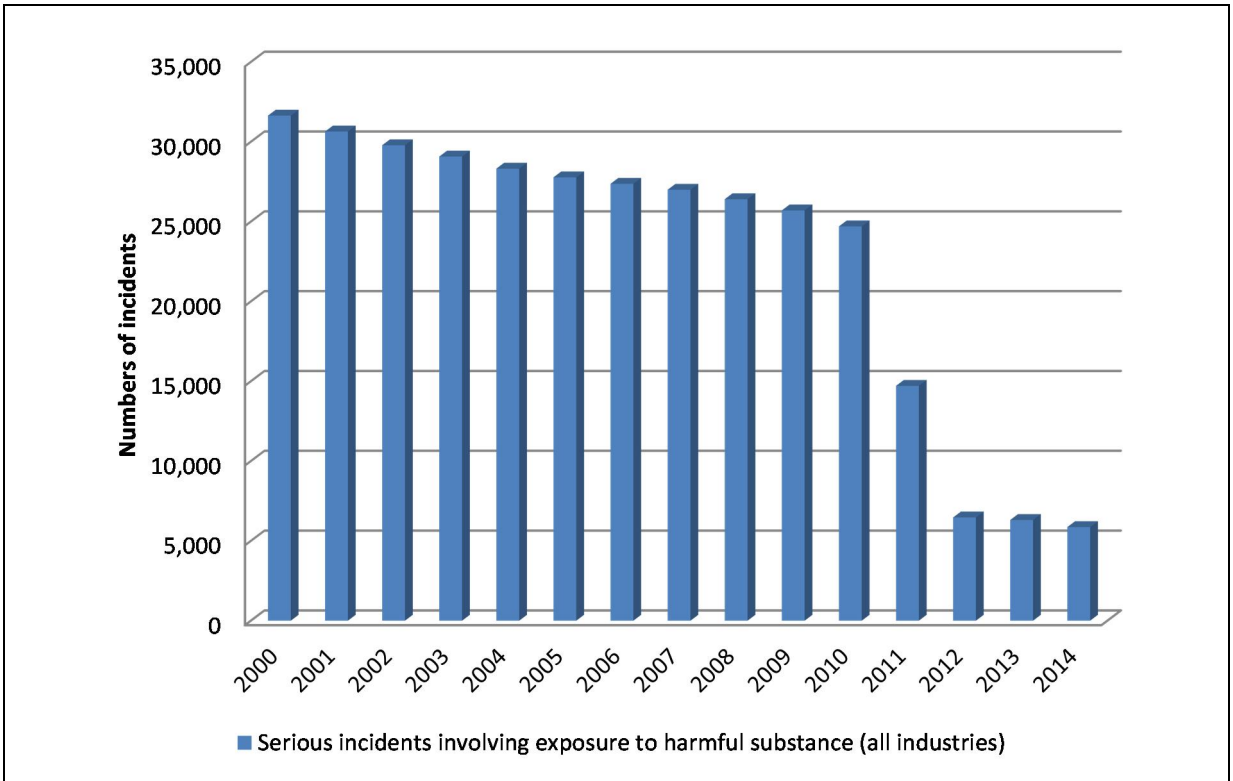


Figure 7-5: Lost time chemical exposure incidents in all industries (EU28)

The resulting values suggest a significant reduction in workplace incidents caused by exposure to harmful substances from around 31,600 in 2000 to around 5,800 in 2014. The data suggest a particularly rapid reduction in the period between 2010 (24,700 incidents) and 2012 (6,469 incidents)[45]. This coincides with transition to CLP (but is difficult to attribute to this alone). Overall, across the EU28, it is estimated that nearly 284,400 serious incidents caused by exposure to harmful substances have been avoided since 2000. **Error! Bookmark not defined.**115,750 of these have been avoided since 2008 when CLP was introduced.

As with lost-time incidents in the EU chemicals industry, it is not possible to provide a full assessment of the economic value the avoidance of these incidents without more detailed data on the consequences of each. However, measured **in terms of lost productivity alone:**

- The present value of changes **since 2000 is around €498 million**; and
- The present value of changes **since 2008 is around €312.5 million**.

As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition[46].

7.3.4.2 Consumers and the general public

Accident data on consumers and the general public are more general in nature and largely restricted to ECOSTAT data on hospital admissions for "*poisonings by drugs, medicaments and biological substances and toxic effects*" and also the European Union's Incident Database (IDB)[47] which also has data on poisoning.

In relation to the ECOSTAT data, whilst this provides a fairly complete set of data for 2000 – 2013 for Members States by age of patient, incidents caused by a variety of different agents including medical drugs and other agents not within the remit of this study are grouped together into a single dataset. The data also do not distinguish between cases of deliberate self-poisoning and accidental. EUROSTAT data on in-patients for poisonings by drugs, medicaments and biological substances and toxic effects are provided in the figure below for all ages and also those occurring in the populations aged 0-4 years (higher age groupings are relatively incomplete in EUROSTAT). As can be seen from the data presented in Figure 7-6, over time there has been a decrease in incident rate of nearly 25% viewed across all ages. For the 0-4 age group the rate of decrease is more rapid with a 50% reduction since 2000.

In contrast to EUROSTAT, IDB data provide a breakdown by deliberate versus accidental causes and also age and hospital versus non-hospital admissions for poisonings. However, these data are less complete in terms of coverage of Member States and years.

[45] Note this is not as a result of the financial crisis and changes in underlying numbers of employed persons. These have remained relatively constant in this period and increased over the whole period.

[46] Benefits from 2008 to the present represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period).

[47] https://webgate.ec.europa.eu/idb/public-access/

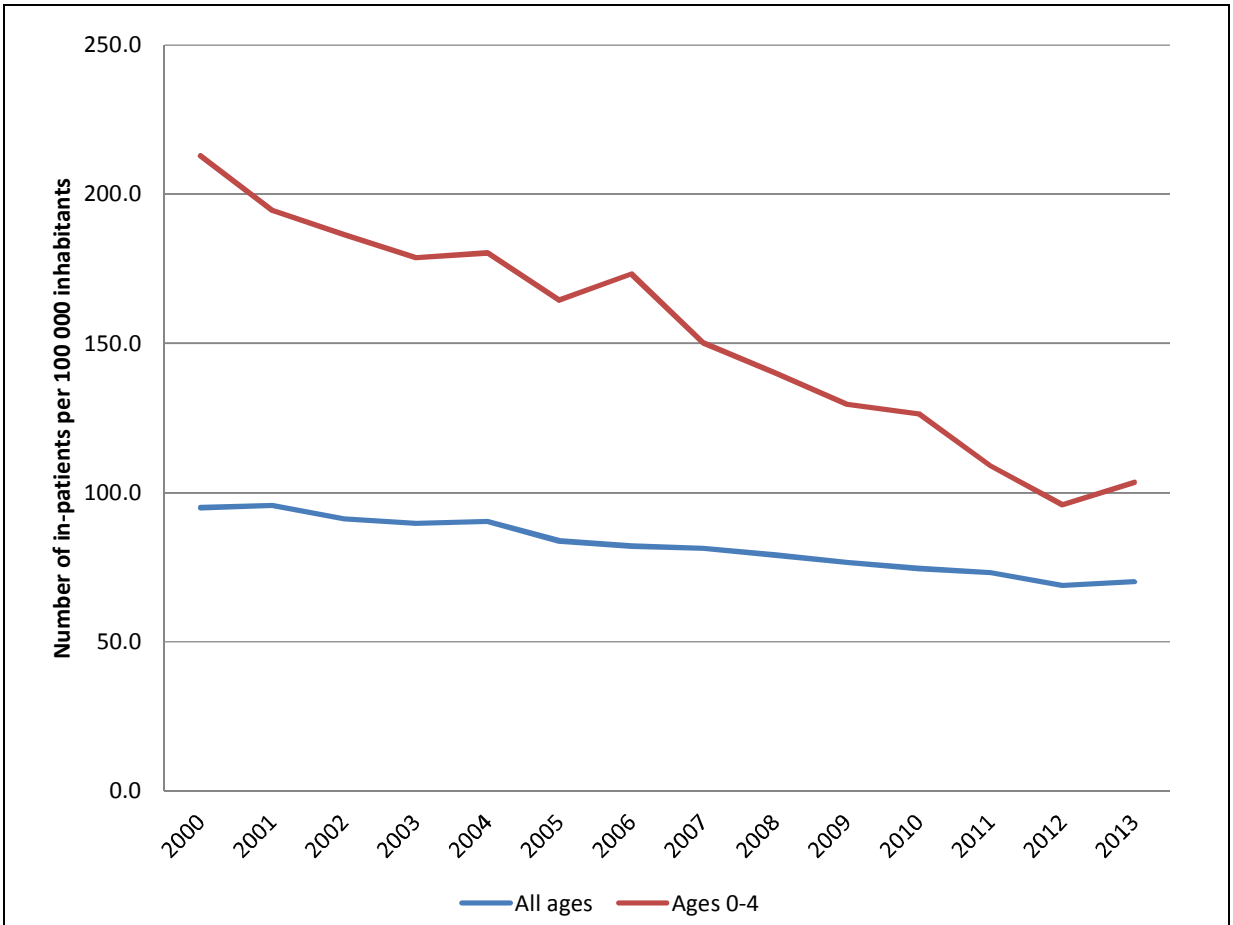


Figure 7-6: In-patients for poisonings by drugs, medicaments and biological substances and toxic effects (in-patients per 100 000 inhabitants in age group)

In order to provide estimates of any changes in the number of accidental poisoning incidents associated specifically with chemicals, we have used statistics from the IDB to subdivide and aggregate the more complete EUROSTAT data into estimates of:

- Accidental (non-deliberate) admissions for poisonings by chemicals for both all ages and the 0-4 age group; and
- Accidental (non-deliberate) non-admissions for poisonings by chemicals for both all ages and the 0-4 age group.

In both cases, we have had to make assumptions on the percentage of incidents that are attributable to chemicals as opposed to other poisoning agents. Here we have assumed that 25% of accidental (non-deliberate) poisonings are associated with chemicals across the all ages category. For the 0-4 age group one would expect this to be higher, and here we have assumed that 30% of poisoning incidents are caused by chemical agents. Applying these assumptions to the datasets provides the values in Figure 7-7 below.

From these, estimates can be derived for the percentage reduction in the annual incident rate from 2000 to the present and also the cumulative number of cases avoided since 2000. These are provided in the table below.

Table 7-14: Estimated change in non-deliberate poisonings by chemicals			
		Cumulative number of cases avoided	Percentage reduction between
2000-2016 (EU28)			
Cases requiring hospital admission	All ages	116,696	23%
	Ages 0-4	88,424	50%
Milder cases not requiring hospital admission	All ages	276,849	23%
	Ages 0-4	172,279	50%
2008-2016 (EU28)			
Cases requiring hospital admission	All ages	29,337	-10%
	Ages 0-4	17,544	-24%
Milder cases not requiring hospital admission	All ages	69,599	-10%
	Ages 0-4	34,181	-24%

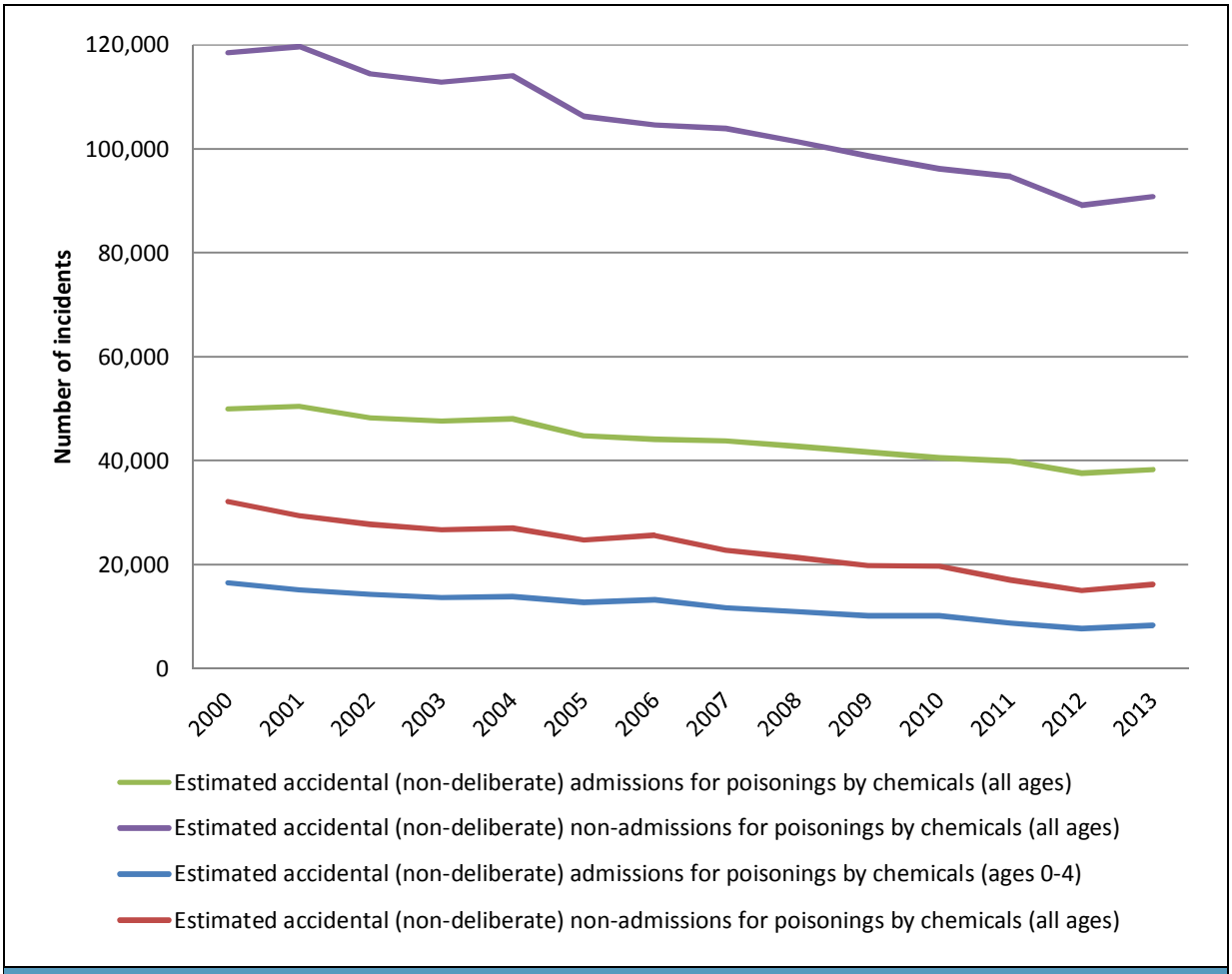


Figure 7-7: Estimated hospital admissions and non-hospital admissions for non-deliberate (accidental) poisonings by chemicals in the EU by age group

In order to estimate the economic value of the associated human health benefits, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity losses and, where available, individual's willingness to pay (WTP) to avoid the disease/discomfort in question.

In relation to medical treatment costs, the UK National Health System (NHS) reference costs[48] provide a robust source to calculate the unit costs for the treatment of non-fatal poisoning incidents. These reference costs are the average unit cost to the NHS of providing secondary healthcare to NHS patients. These suggest that the unit costs for treatment of 'Poisoning, Toxic, Environmental and Unspecified Effects' are €1,370 per case. In relation to lost productivity, it is assumed that each event results in a 5 days absence from work for the affected individual or, in the case of children, carers. At €300 per day, lost productivity per case is therefore €1,500 per case. No WTP values are available and as such the total cost per case requiring hospital admission is taken as €2,870 per case.

Applying this to the avoided number of cases requiring hospital admission suggests benefits of the order of €335 million from 2000 to the present and €84 million from 2008 to the present. For cases not requiring hospital admission a conservative estimate of one day of lost productivity at €300 per day is assumed. This suggests benefits of the order of €83 million since 2000 and €21 million since 2008. This makes **total estimated present value benefits of:**

- **€418 million** for reductions in poisoning since 2000; and
- **€105 million** for reductions in poisoning since 2008.

As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition[49].

7.3.5 Chemicals-related diseases within the general public

We believe it is more appropriate to consider the benefits of the EU chemicals to the general public in relation to the vertical linkages between CLP and downstream legislation, as the introduction of risk management measures to protect the general public will be a bigger driver of reductions in chemicals-related diseases than the availability of classification and labelling information on its own.

7.3.6 Chemicals-related occupational disease cases

In addition to accidents, exposure to hazardous substances at work is believed to contribute significantly to the incidence of diseases with fatal or non-fatal outcomes.

As has been identified in previous studies (and in particular the DG Environment study on Benefits Indicators undertaken by RPA[50]), the possibility of calculating the benefits of chemical regulation in terms of disease cases avoided is constrained by a number of factors, of which the most important are:

- the paucity of data on occupational diseases related to chemical exposure;

[48] Available at: https://www.gov.uk/government/collections/nhs-reference-costs

[49] Benefits from 2008 to the present represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period).

[50] RPA and DHI (2016): Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment Development of a System of Indicators - Final Report, DG Environment, April 2016.

- for some data that has been generated, the lack of regular collection data such that there is no (or no consistent) means of examining a trend over time (that might be related to legislative intervention); and
- the fact that many diseases have multiple causes of which exposure to chemicals in the workplace may be one. There are few datasets that actively measure the disease burden that is directly attributable to occupational exposure to chemicals.

In spite of this, there are data on occupational skin diseases and occupational respiratory diseases that provide a means to estimate benefits and may also provide a means of extrapolating for other disease outcomes. Both the UK and Germany have detailed statistics on these occupational diseases and data that allows estimation of the fraction attributable to chemical exposure.

7.3.6.1 Occupational skin diseases

UK data

The UK HSE maintains a database with statistics on the incidence of occupational skin disease through the EPIDERM scheme of the Health and Occupation Research Network (THOR), in which dermatologists report new cases. Two datasets are available:

- THORS1: Work-related skin disease: estimated number of cases reported by dermatologists to EPIDERM and by occupational physicians to 'Occupational Physicians Reporting Activity' (OPRA) by sex and diagnostic category; and
- THORS6 Occupational dermatitis: estimated number of diagnoses in which particular causative substances were identified. Reported by dermatologists to EPIDERM.

In the latter data table, on average 67% of the cases in the statistics are attributable to chemical exposure (as opposed to exposure to wet work, foods and flour, etc.). We have applied this to the THORS1 data to allow a second dataset to be included for comparison. Together these provide estimates of the actual reported cases of skin diseases caused by exposure to chemical agents in the UK per 100,000 workers. However, as is identified by the UK HSE[51] the statistics "*inevitably substantially underestimate the true incidence of work-related disease – particularly for those conditions such as contact dermatitis where there may be substantial numbers of less serious cases*" (HSE, 2014). Clearly, neither the level of underreporting of serious cases nor the numbers of less serious cases are known precisely. Statistical analysis of the self-reported occupational skin diseases suggests that the number of 'less serious cases' not presenting to physicians may be in excess of 3.8 times the more serious cases.

Statistics from Germany

Since 1969, facts, figures and long term trends on occupational diseases in Germany have been published by the associations responsible for the industrial sectors and the public sector, merged in 1993 to form the German Social Accident Insurance (Deutsche Gesetzliche Unfallversicherung – DGUV)[52].

[51] HSE (2014): Work-related skin disease in Great Britain 2014. Health and Safety Executive. Available at: http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf

[52] http://www.dguv.de/en/facts-figures/ods/index.jsp

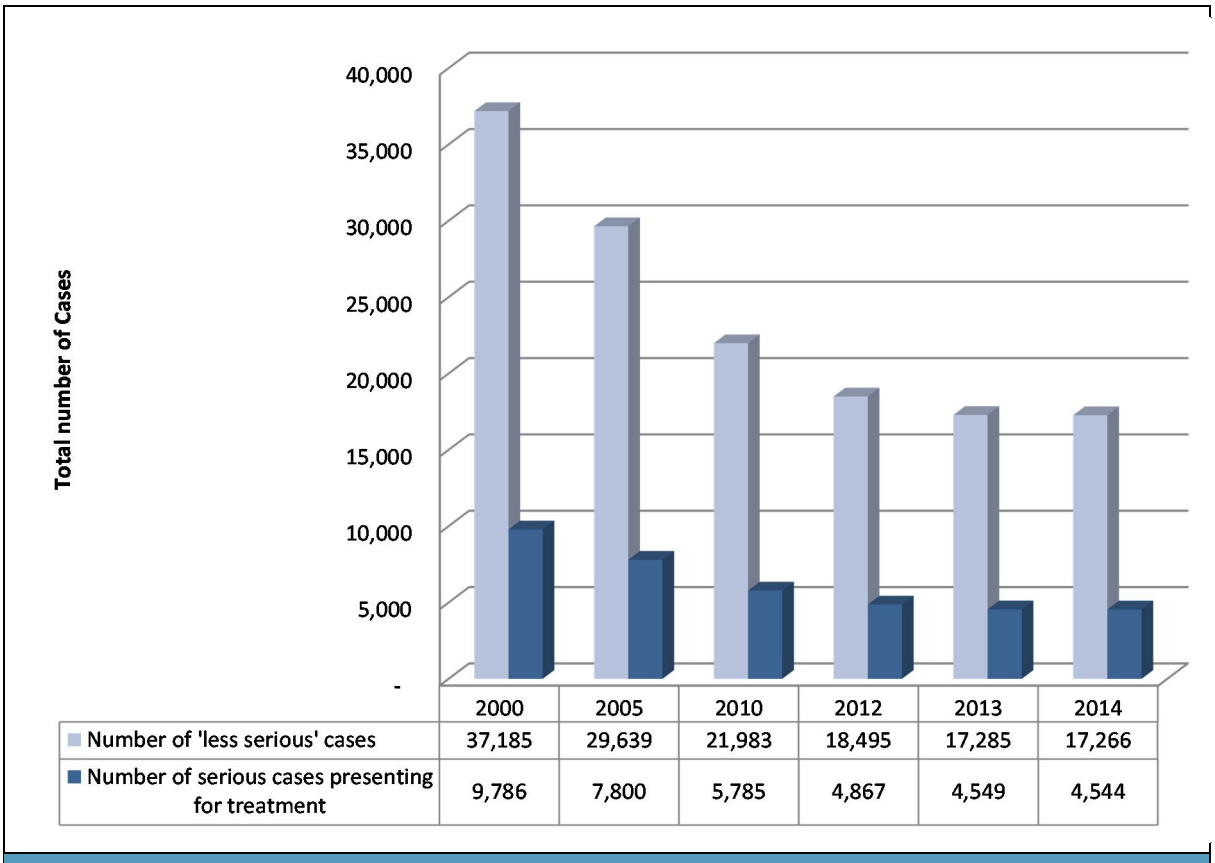
Consistent occupational diseases statistics date back to 1995 and are subdivided into a number of categories one of which is *Number 5101: severe or recurrent skin diseases which have forced the person to discontinue all activities that caused or could cause the development, worsening or recurrence of the disease* (Number 5101). Statistics are provided on:

- Listings on suspicion of an occupational disease;
- Recognised occupational diseases (i.e. cases of the above which were confirmed);
- New occupational disease pensions; and
- Deaths due to occupational disease.

As with the UK THORS1 data, there is insufficient information in the data itself to identify chemical or other causative agent. In the absence of any other data, based on the UK THORS6 data, the analysis assumes that 67% of the listings are associated with chemical exposure and that these represent the more serious cases. As with the UK statistics, the number of 'less serious' cases (not presenting to physicians) is taken at 3.8 times the serious cases.

Data across the EU28

All of the above described datasets have been converted into values per 100,000 employed in each country in each year and applied to the total number of employed persons in the EU28 to provide estimates at an EU level. The resulting sets of average aggregated estimates are provided in the figures below. The first figure in the pair provides the number of serious and less serious cases and the second provides the number of deaths.



	2000	2005	2010	2012	2013	2014
Number of 'less serious' cases	37,185	29,639	21,983	18,495	17,285	17,266
Number of serious cases presenting for treatment	9,786	7,800	5,785	4,867	4,549	4,544

Figure 7-8: Cases of occupational skin disease caused by exposure to chemical agents (EU28)

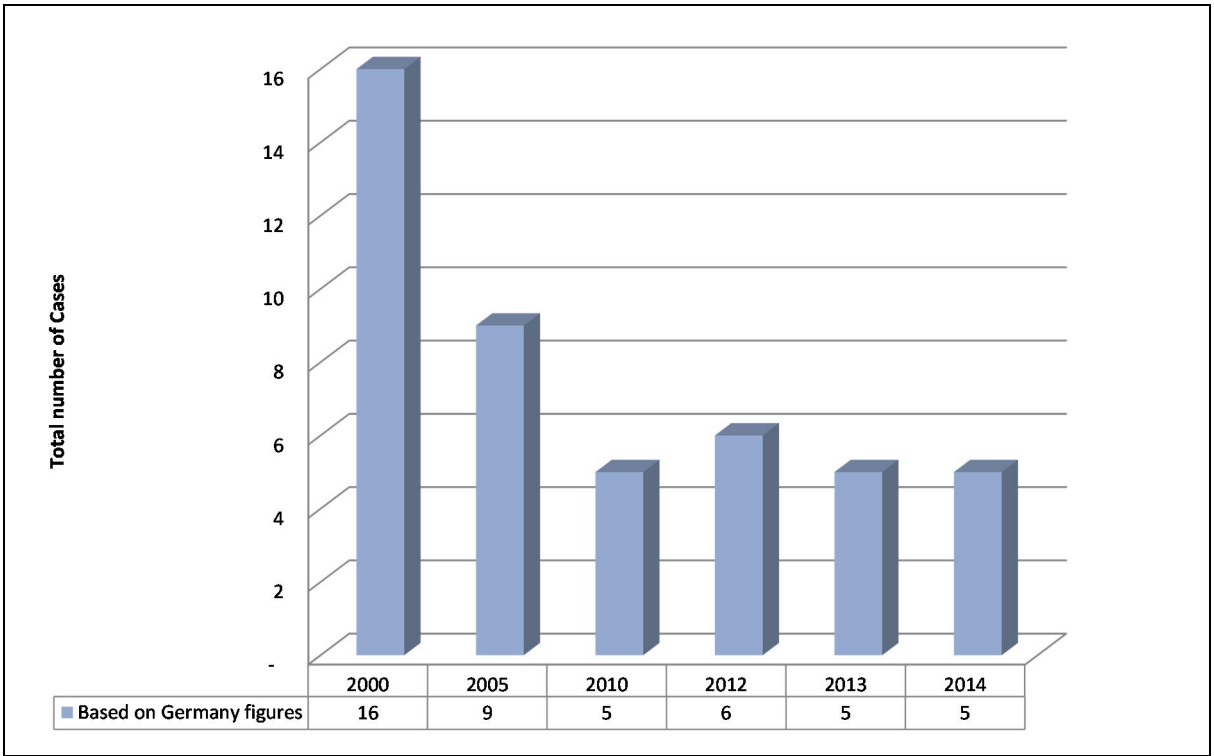


Figure 7-9: Deaths due to skin disease caused by chemical exposure (EU28)

As can be seen from the figures, all available data sources suggest a sustained reduction in the incidence of chemicals related occupational skin diseases and also mortality from skin diseases. This (or a substantial component of it) can be attributed to better and more effective regulation on chemicals and workplace exposures through CLP and downstream regulation. The table below provides summary data on the changes indicated by the data since 2000/2008. As can be seen in the table, an average of the aggregated EU28 datasets suggests that the annual incidence of occupational skin disease has reduced by more than a half (54%) since 2000 and 21% since 2008. Deaths have reduced by by 69% since 2000 and 10% since 2008. The estimated cumulative number of chemicals related skin disease cases avoided is:

- A total of 198,630 'less serious' cases, 52,270 serious cases and 133 deaths since 2000; and
- A total of 47,000 'less serious' cases, 12,400 serious cases and around 10 deaths since 2008.

Table 7-15: Change in key variables for occupational skin diseases linked to chemical exposure – EU28

	Cumulative number of cases/deaths avoided	Percentage reduction
2000-2016 (EU28)		
'Less serious' cases of skin disease	198,630	-54%
Serious cases of skin disease (presenting for treatment)	52,271	-54%
Deaths	133	-69%
2008-2016 (EU28)		
'Less serious' cases of skin disease	47,049	-21%
Serious cases of skin disease (presenting for treatment)	12,381	-21%
Deaths	10	-10%

Estimated benefits across the EU28

According to EU-OSHA "*occupational skin diseases are estimated to cost the EU €600 million each year, resulting in around 3 million lost working days. They affect virtually all industry and business sectors and force many workers to change jobs*"[53].

Again, in valuing the impacts on human health, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity losses and individual's willingness to pay (WTP) to avoid the occupational disease in question. Values in respect of occupational skin diseases are described below.

In relation to medical treatment costs, the UK National Health System (NHS) reference costs[54] provide a robust source to calculate the unit costs for the treatment of skin disorders. These reference costs are the average unit cost to the NHS of providing secondary healthcare to NHS patients. The unit costs and the number of treatments for skin disorders in 2014 and 2015 are presented in the table below.

The weighted average treatment unit cost for skin disorders has been calculated by multiplying the average unit cost by the number of treatments across the different types of interventions. The weighted average treatment cost is equal to £1,620[55] or €2,100[56].

Table 7-16: Unit costs and number of treatments for skin disorders in the UK in 2014 and 2015

Currency*	Currency description	Patients	Unit cost in GBP
JD07A	Skin Disorders with Interventions, with CC**Score 12+	2,432	£ 8,458.44
JD07B	Skin Disorders with Interventions, with CC Score 8-11	2,689	£ 6,293.22
JD07C	Skin Disorders with Interventions, with CC Score 4-7	5,627	£ 4,014.34
JD07D	Skin Disorders with Interventions, with CC Score 0-3	18,218	£ 2,192.92
JD07E	Skin Disorders without Interventions, with CC Score 19+	845	£ 4,979.63
JD07F	Skin Disorders without Interventions, with CC Score 14-18	6,918	£ 3,377.74
JD07G	Skin Disorders without Interventions, with CC Score 10-13	16,865	£ 2,450.22
JD07H	Skin Disorders without Interventions, with CC Score 6-9	34,998	£ 1,759.22
JD07J	Skin Disorders without Interventions, with CC Score 2-5	60,824	£ 1,137.32
JD07K	Skin Disorders without Interventions, with CC Score 0-1	60,390	£ 667.87

*Notes: *Currencies are defined as the units of healthcare for which a payment is to be made. **CC stands for "complications or comorbidities" and each CC recorded is assigned a score in order to reflect the increment in complexity and treatment costs.*
Source: https://www.gov.uk/government/collections/nhs-reference-costs

In terms of productivity losses for less serious cases, UK data on the average days lost for all injuries and illnesses has been used[57] to which we applied the one percent value estimated by HSE for skin conditions. This suggests an average of around 1.3 days per case at €300 per day (to be consistent

[53] EU-OSHA Factsheet 40. Available at: https://osha.europa.eu/en/tools-and-publications/publications/factsheets/40

[54] Available at: https://www.gov.uk/government/collections/nhs-reference-costs

[55] This is the cost in the UK. It is assumed the cost in the EU28 is equivalent

[56] Rounded to the nearest 100. Average exchange rate GBP/EUR 2014/2015: 1.31. Source: http://www.ukforex.co.uk/forex-tools/historical-rate-tools/yearly-average-rates

[57] Table SWIT1 available at: http://www.hse.gov.uk/statistics/lfs/index.htm

with the cost analysis). For more serious cases of occupational skin disease it has been 7 days of lost productivity have been assumed.

Regarding WTP, a recent ECHA report[58] reviewing estimates of willingness to pay to avoid certain health impacts provides a range of WTP values to avoid dermatitis, depending on its nature (acute or chronic), intensity (mild or severe), occurrence frequency in one year and over two, five and ten years. Values range from €227 for a single episode of mild acute dermatitis to €1,055 for a case of severe chronic dermatitis.

Whilst the review identifies that the €227 value for one acute episode of mild dermatitis matches previous WTP and also monetised disability weights quite well, it identifies that the value of preventing a case of severe, chronic dermatitis (€1,055) appears too low considering the duration and potential severity of the symptoms. Using valuations in Hauber *et al* (2011)[59], the review study calculates an implied value of around €1,800 per year (as opposed to €1,055 *per case*) that can be converted into a cost per case by applying estimates of average age at onset and life expectancy for those affected. Assuming an average of 30 years between onset and end of life, the value for one case of severe, chronic dermatitis would be around €54,000.

Whilst this is much higher than the €1,055 per case quoted by the ECHA study, the review of that study also identifies that values based on the weights for controlled and uncontrolled psoriasis (in Schmitt *et al*, 2008[60]) and the median value for a VOLY of €64,000 from NewExt (2003)[61] would approach €12,000 per year, i.e. €360,000 (undiscounted) per case assuming the same 30 year period.

In spite of the apparent inconsistencies identified in the abovementioned reports, for the purpose of estimation in this study we have taken the value of €1,055 per case as the estimates of incidence are based on single episode incidence data (as opposed to aggregate prevalence data) and the other values would seem too high for application to incidence statistics.

For the less serious cases we have applied the lower (€227) WTP value and no treatment cost.

For fatal cases of occupational skin diseases, the highest treatment cost in the above table has been used (£8,458 or €11,000 rounded to the nearest 100) and a value of a statistical life (VSL) of €4 million has been applied to be consistent with advice from DG Employment (pers. comm.) and based on the figure set out in the Better Regulation Guidelines (updated to 2015 values). The total values are summarised in the table below.

[58] ECHA (2015): Valuing selected health impacts of chemicals: Summary of the results and a critical review of the ECHA study. Available at: http://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf

[59] Hauber, A. B. et al. (2011): *The value to patients of reducing lesion severity in plaque psoriasis.* Journal of Dermatological Treatment, 22(5): 266-275.

[60] Schmitt, J. et al. (2008). *Assessment of health state utilities of controlled and uncontrolled psoriasis and atopic eczema: a population-based study*. British Journal of Dermatology, 158(2): 351-359.

[61] NewExt (2003). New Elements for the Assessment of External Costs from Energy Technologies. Final report. http://www.ier.uni-stuttgart.de/forschung/projektwebsites/newext/newext_final.pdf.

Table 7-17: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each		
Substance properties	**Valuation metric used**	**Monetary Value applied to metric**
Non-fatal 'less serious' cases of occupational skin disease	Medical treatment cost + Productivity loss + WTP to avoid a single episode of mild acute dermatitis = Cost of a case of severe chronic dermatitis	€ 0 + € 390 + € 277 **€ 667**
Non-fatal 'serious' cases of occupational skin disease	Medical treatment cost + Productivity loss + WTP to avoid a single episode of severe chronic dermatitis = Cost of a case of severe chronic dermatitis	€ 2,100 + € 2,100 + € 1,055 **€ 5,255**
Fatal cases of occupational skin disease	Medical treatment cost + VSL= Cost of a fatal case of skin disease	€ 11,000 + € 4,000,000 = **€ 4,011,000**

Applying these values to the cases of chemicals related occupational skin disease and deaths avoided suggests the following current value estimates of the benefits from reductions in the incidence of chemicals related skin diseases. It should be noted that these are lower bound estimate because, as noted above, the WTP value available for severe chronic dermatitis is a very low one and a fatal case is most likely preceded by a period of very low life quality which is not included in the VSL:

- Non-fatal 'less serious' cases of occupational skin disease = €132.5 million since 2000 or €31.4 million since 2008;
- Non-fatal 'serious' cases of occupational skin disease = €274.7 million since 2000 or €65.1 million since 2008;
- Fatal cases of occupational skin disease = €531.5 million since 2000 or €41.3 million since 2008;
- **Total benefits (reductions in occupational skin disease) = € 938.6 million since 2000 or €137.8 million since 2008.**

As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition[62].

7.3.6.2 Occupational respiratory diseases

UK data

As with skin diseases, the UK HSE maintains a database with statistics on the incidence of occupational respiratory disease through Health and Occupation Research Network (THOR) with the following two datasets being available:

- THORR1: Work-related and occupational respiratory disease: estimated number of cases reported by chest physicians to 'surveillance of work-related and occupational respiratory disease' (SWORD) and by occupational physicians to OPRA; and

[62] Benefits from 2008 to the present represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period).

- THORR6 Occupational asthma: estimated number of diagnoses in which particular causative substances were identified and reported by chest physicians to SWORD between 1998 and 2014.

In the latter data table, the average 73% of the cases in the statistics are attributable to exposure to identifiable causative agents (as opposed to cases where the agent was unknown). We have applied this to the THORR1 data to allow a second dataset to be included for comparison.

Regarding under-reporting, a UK HSE paper on occupational asthma[63] notes that, whilst a previous analysis had an underestimation of the true incidence of about 40%[64], the statistics are likely to underestimate the incidence of occupational asthma even by an order of magnitude (i.e. 90% underestimation). In this analysis 70% underestimation has been assumed and applied to predict actual numbers of cases.

Statistics from Germany

Under Germany's DGUV scheme, category number 4302 provides occupational disease statistics *Obstructive diseases of the respiratory tract caused by chemical irritants or agents with a toxic effect which have forced the person to discontinue all activities that caused or could cause the development, worsening or recurrence of the disease.*

As with the UK THORR1 data, there is insufficient information in the data itself to identify chemical or other causative agent. In the absence of any other data, based on the UK THORR6 data, the analysis assumes that 73% of the listings are associated with chemical exposure and that underestimation is 70% (with the exception of deaths).

Data across the EU28

As with the analysis of skin diseases, the above described datasets have been converted into values per 100,000 employed in each country in each year and applied to the total number of employed persons in the EU28 to provide estimates at an EU level. The resulting average aggregated estimates are provided in the figures below. The first figure in the pair of figures provides the number of recognized cases and the second provides the number of deaths.

[63] HSE (2015): Occupational asthma in Great Britain 2014. Available at: http://www.hse.gov.uk/statistics/causdis/asthma/asthma.pdf

[64] Carder M, et al. (2011) Improving estimates of specialist-diagnosed, work-related respiratory and skin disease. Occupational Medicine. 61:33-39

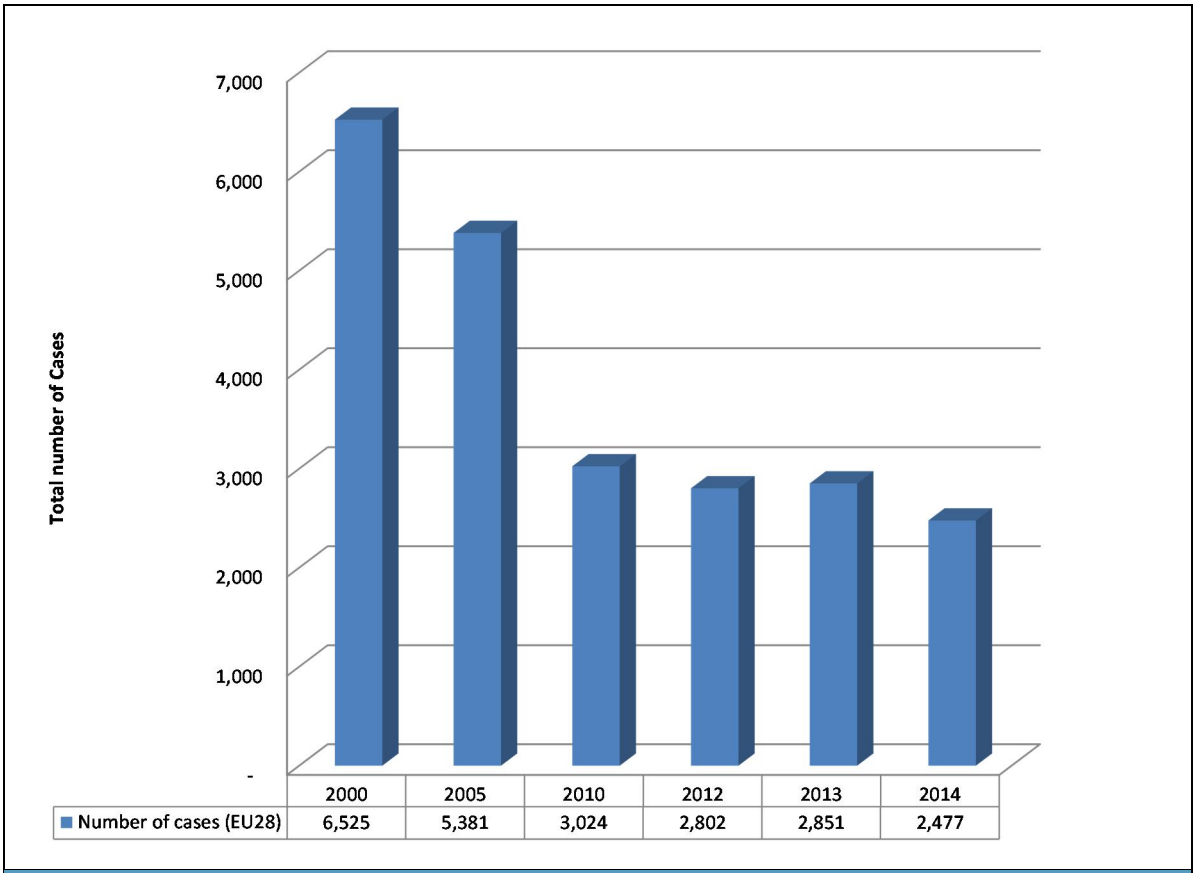


Figure 7-10: Cases of occupational respiratory disease caused by exposure to chemical agents (EU28)

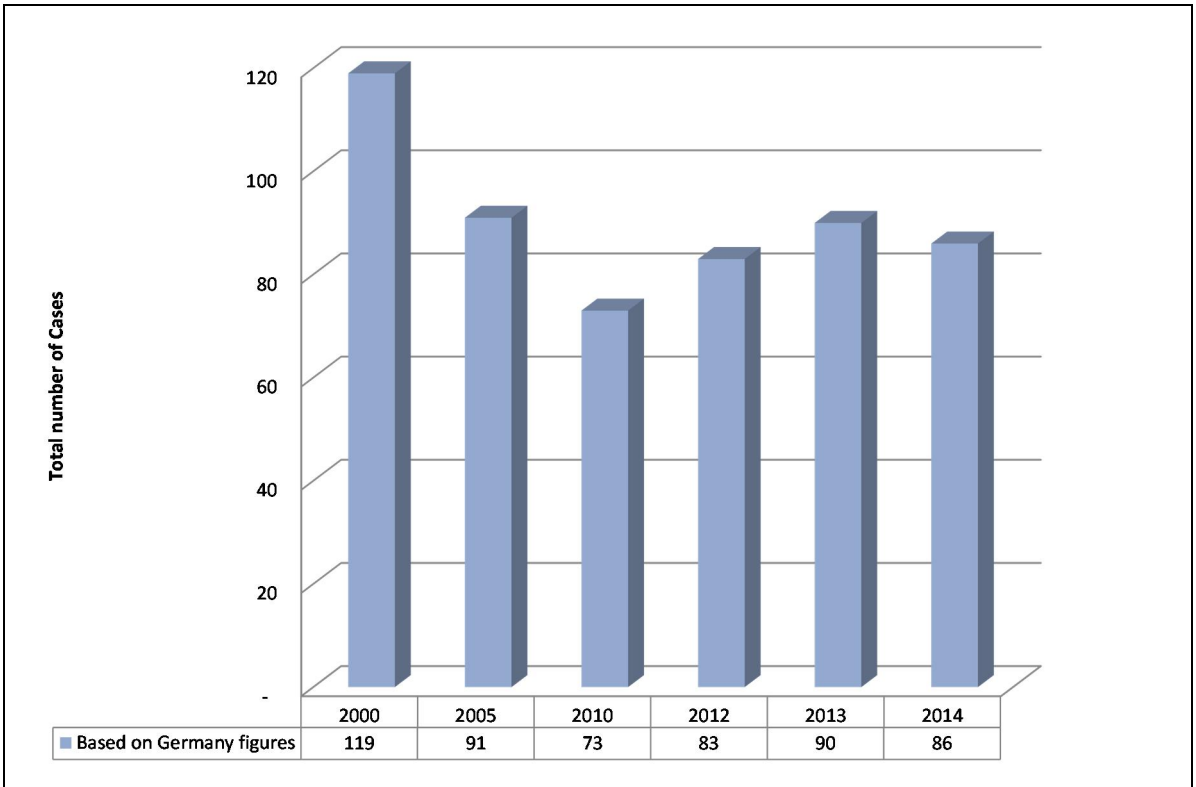


Figure 7-11: Deaths due to respiratory disease caused by chemical exposure (EU28)

As can be seen from the figures, all available data sources suggest a sustained reduction in the incidence of chemicals related respiratory diseases and also mortality from these diseases. The table below provides summary data on the changes indicated by the data since 2000/2008. As can be seen in the table, an average of the aggregated EU28 datasets suggest suggests that annual incidence of both occupational respiratory disease has reduced by around 62% since 2000 and 26% since 2008. Deaths from these diseases have reduced by 28% since 2000. The cumulative number of cases avoided is:

- a total of around 39,375 cases and 483 deaths owing to chemicals related occupational respiratory disease since 2000; and
- a total of around 10,000 cases and 133 deaths owing to chemicals related occupational respiratory disease since 2008.

Table 7-18: Change in key variables for occupational respiratory diseases linked to chemical exposure – EU28

	Cases of occupational respiratory disease		Deaths due to respiratory disease	
	Cumulative number of cases avoided	Percentage reduction	Cumulative number deaths avoided	Percentage reduction
2000-2016	39,375	-62%	483	-28%
2008-2016	9,966	-26%	13	-

Estimated benefits across the EU28

For monetisation of impacts, as for skin diseases, medical treatment costs are based on the UK National Health System (NHS) reference costs, in this case for the treatment of asthma. The unit costs and the number of treatments in 2013 and 2014 are presented in the table below.

Table 7-19: Unit costs and number of treatments for asthma in the UK in 2013 and 2014

Currency*	Currency description	Activity	Unit cost in GBP
DZ15G	Asthma with Intubation	167	£2,266
DZ15H	Asthma without Intubation, with CC Score 9+	1,666	£2,385
DZ15J	Asthma without Intubation, with CC Score 6-8	4,518	£1,389
DZ15K	Asthma without Intubation, with CC Score 3-5	14,480	£1,025
DZ15L	Asthma without Intubation, with CC Score 0-2	38,712	£695

*Notes: *Currencies are defined as the units of healthcare for which a payment is to be made. **CC stands for "complications or comorbidities" and each CC recorded is assigned a score in order to reflect the increment in complexity and treatment costs.*

The weighted average treatment unit cost for asthma has been calculated by weighting the average unit cost by the number of treatments. This is equal to £880 or €1,188[65]. In terms of productivity losses, UK data on the average days lost for breathing or lung problems has been used (as above). This suggests an average of around 18 days per case which, at €300 per day, suggests a value of around €5,400 per case.

[65] Applying an exchange rate GBP/EUR: 1.35.

To the treatment and productivity loss savings, the willingness to pay (WTP) to avoid occupational asthma has been added. Máca et al (2014)[66] suggest using €50 as central EU-wide WTP value for avoiding asthma discomfort.

For fatal cases of occupational respiratory diseases, the highest treatment cost in the above table has been used (£2,266 or around €3,000 rounded to the nearest 100) and the value of a statistical life (VSL) of €4 million has been applied. The total values are summarised in the table below.

Table 7-20: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each

Substance properties	Valuation metric used	Monetary Value applied to metric
Non-fatal cases of occupational respiratory disease	Medical treatment cost + Productivity loss + WTP to avoid a single episode of occupational asthma = Cost of a case of severe respiratory disease	€ 1,188 + € 5,400 + € 50 **€ 6,638**
Fatal cases of occupational respiratory disease	Medical treatment cost + VSL= Cost of a fatal case of respiratory disease	€ 3,000 + € 4,000,000 = **€ 4,003,000**

Applying these values to the 11,800 cases of chemicals related occupational respiratory disease and 483 deaths avoided suggests the following current value benefits from reductions in the incidence of chemicals related skin diseases. It should be noted that these are lower bound estimates given that a fatal case is most likely preceded by a period of very low life quality which is not included in the VSL:

- Non-fatal cases of occupational respiratory disease = € 261.4 million since 2000 and € 66.2 million since 2008;
- Fatal cases of occupational respiratory disease = € 1,933.4 million since 2000 and € 52 million since 2008; and
- **Total benefits (reductions in occupational respiratory disease) = € 2,194.8 million since 2000 and € 118.2 million since 2008.**

As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition[67].

7.3.6.3 Other diseases related to chemical exposure

Regarding other occupational diseases that may be caused by or linked to exposure to chemicals, as was identified in the introductory sub-section on occupational diseases, there is a paucity of data on these diseases. With the exception of the respiratory and skin diseases already described above, what data are available lack the resolution necessary to attribute cases to chemical agents.

[66] Máca V. et al (2014): Appendix: Willingness to pay for avoiding respiratory sensitisation outcomes. Report prepared for the European Chemicals Agency, Helsinki, page 10. Available at: http://echa.europa.eu/documents/10162/13630/appendix_study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf

[67] Benefits from 2008 to the present represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period).

Other studies[68] have been initiated by the Commission to address these specific issues. As such, there are limits to what can be achieved in this study.

That said, it would be most unusual if similar trends to those observed in relation to respiratory and skin diseases (as well as accidents and accidental poisonings) were not also present for other occupational diseases. The issue is not one of there being no benefits but one of access to data measuring those benefits over time. In the absence of such data, 'best estimation' based on reasonable assumptions is the only means of gauging the likely level of benefits.

As has been noted in the above analyses, the most significant driver behind the reductions in factors that have been measured (and can be attributed to chemicals) is likely to be changes in chemicals legislation including the introduction of CLP. This same legislation has led to an increase in the level of knowledge on the properties of chemicals and this, in turn, is likely to be connected with the benefits that have been/can be observed (for example in relation to respiratory and skin diseases) because each classification under CLP triggers actions to reduce and control risks and exposure. As there is information available on numbers of chemicals with different classifications at different time intervals, this increase in knowledge provides an indicator of the extent to which previously uncontrolled (or inadequately controlled) risks are now being controlled.

The figure overleaf provides a graphical representation of the numbers of substances self-classified on IUCLID in 2005, the updated (new) classifications identified for these same substances and the total number of substances presently (mid-2016) classified for different endpoints on the CLI. As is clear from the figure, over the last 10-15 years there has been a substantial increase in knowledge.

In order to provide some estimate of the likely impact of CLP (and chemicals legislation more generally) on the burden of chemicals related occupational diseases, Table 7-21 provides an attempt to connect the available data on occupational diseases (skin and respiratory diseases) to data on the relative increase in substances with classifications related to these diseases under CLP. This has then been applied to changes in the numbers of substances with classifications for carcinogenicity and mutagenicity, as well as acute toxicity, in order to predict potential level of change in incidence of cancer and poisoning associated with these classifications.

Table 7-21: Predicted change in annual incidence in disease

	Factor increase in numbers classified for relevant endpoints (REACH registered substances)	Observed reduction in annual incidence of disease since 2000	Percentage reduction per factor increase in classifications	Implied reduction in annual incidence of disease since 2000
Serious skin diseases	0.74	54%	72%	n/a
Respiratory diseases	1.35	62%	46%	
Average			**59%**	
Acute toxic substances	0.37	No data	59%	**22%**
Carcinogenic/mutagenic substances (1A/1B)	0.41			**24%**

[68] Study on the cumulative health and environmental benefits of chemical legislation.

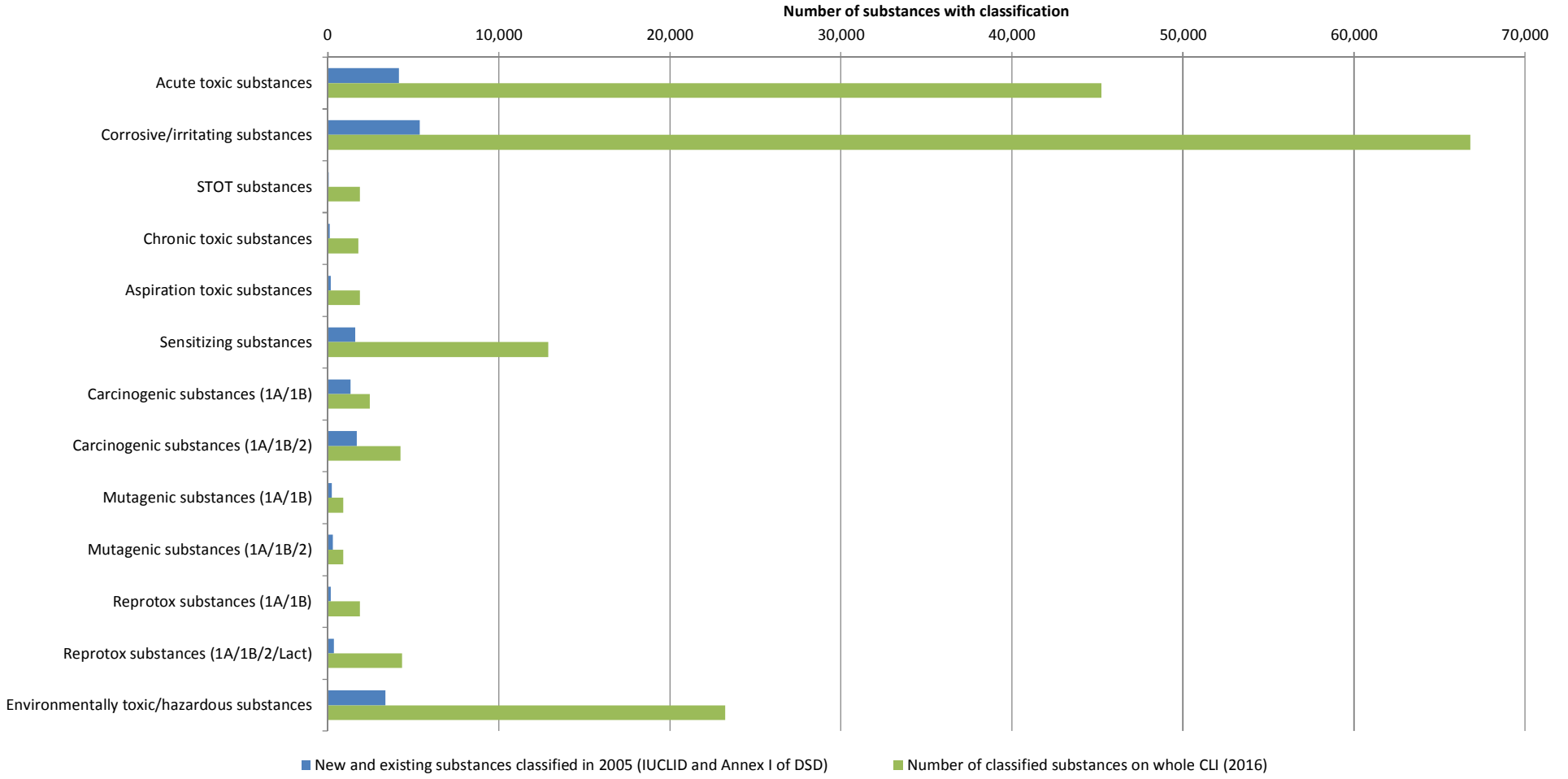


Figure 7-12: Changes in the number of substances identified with different classifications

In the table, based on information on the numbers of substances classified for endpoints relevant to skin and respiratory diseases, we have calculated the factor increase in numbers classified (where, as noted above, this is assumed to be a surrogate for levels of risk control). Thus, for example, since early 2000, the numbers of substances classified for endpoints of relevance to skin diseases has increased by a factor of 0.74 and for classifications relevant to respiratory diseases by a factor of 1.35[69]. Set against the observed reduction in annual incidence of disease over the same period, this suggests a 72% reduction in annual incidence for every factor change in relation to skin diseases and a 46% change per factor increase for respiratory diseases[70]. 59% is the average of the two.

If the average of the two (59%) is applied to the factor increases in classifications for carcinogenicity and mutagenicity, as well as acute toxicity, this provides a tentative prediction of expected reduction in diseases linked to these classifications.

In terms of these diseases, those associated with acute toxicity are less easy to identify. However, the predicted figure of a 22% reduction in relation to these substances compares well with the observed reduction in hospital admissions associated with poisoning incidents (23% over all ages); this suggests that the tentative prediction may not be too wide of the mark.

In relation to carcinogenicity/mutagenicity, the tentative predictions suggest a 24% reduction in incidence of occupational cancer compared with 2000 where this is likely to be a significant benefit. To put this in context, the total cost of cancer in the EU was estimated to be €126 billion in 2009, with health care accounting for €51.0 billion. Productivity losses because of early death cost €42.6 billion and lost working days €9.43 billion. Informal care was estimated to cost €23.2 billion[71].

For occupational cancer, meaning for the fraction of cancers attributable to working conditions, the figures vary between 4[72] and 8-12%[73]. Taking 8% as the best estimate, the cost of all occupational cancers in the EU is around €10.1 billion per year. Not all of these cancers are as a result of chemical exposure, however, so only a percentage of this is relevant to this study. At the same time, logically, until a substance is identified as a mutagenic or carcinogenic substance, any cancers caused by exposure to it will remain unexplained and not attributed to exposure to that substance. Over the last 10-15 years substances with previously unknown mutagenic/carcinogenic properties have been identified and classified. However, occupational cancers caused by exposure to these substances will not have been detected in the statistics. Assuming that occupational cancers from chemical exposure (known or unknown) represent between 5 and 10% of all occupational cancers would suggest that some €0.5 to €1.01 billion per year of costs could be attributable to chemical exposure. A 24% reduction in incidence, then, would result in a **benefit of €121 to €242 million per year.**

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[69] Factors relate to registered substances to allow a focus on substances on the market and so likely to represent most of the exposure. The factor increases in information on all substances (registered or unregistered) compared with IUCLID/Annex 1 of the Dangerous Substances Directive is much larger).

[70] Although, as noted in Section 4, there is a view that CLP may over-classify respiratory sensitisers. If this is the case, then the value for the percentage reduction per factor increase used here should be lower.

[71] Luengo-Fernandez, R. et al (2013). Economic burden of cancer across the European Union: a population-based cost analysis. http://dx.doi.org/10.1016/S1470-2045(13)70442-X)

[72] Doll, R. and Peto, R. (1981). The causes of cancer: quantitative estimates of avoidable risks of cancer in the United States today; http://www.ncbi.nlm.nih.gov/pubmed/7017215

[73] http://www.etui.org/content/download/7515/71981/file/Occupational+cancer++the+main+challenge+for+the+new+Community+Strategy.pdf

Clearly this may be an over-estimate as it assumes that there is a proportional decrease in the incidence of cancer with new classifications (including both self-classification and CLH) of carcinogens under CLP (and the Dangerous Substances Directive before it).

7.3.7 Environmental benefits

Classification of substances and mixtures in relation to their environmental hazards (and human health hazards) is important to ensuring that users have the information needed for both safe handling, use and disposal. This is important not only for workplace environments, and ensuring that chemicals are disposed of appropriately, but also in relation to consumer uses and the safe use and disposal of un-used chemical products that pose hazards to the environments. This may be particularly relevant with respect to plant protection products and biocidal products, but also other everyday consumer products, such as paints, dyes, cleaning products, etc.

Requiring products to be labelled where they are hazardous to the environment is likely to be generating reductions in the level of harm being caused by their use and, as can be seen from the Figure 7-13 below, there has been a more than 10 fold increase in the numbers of substances classified with such properties and carrying the appropriate warnings. Classifications also act as the basis for triggering regulatory action under other legislation which may have resulted in environmental benefits.

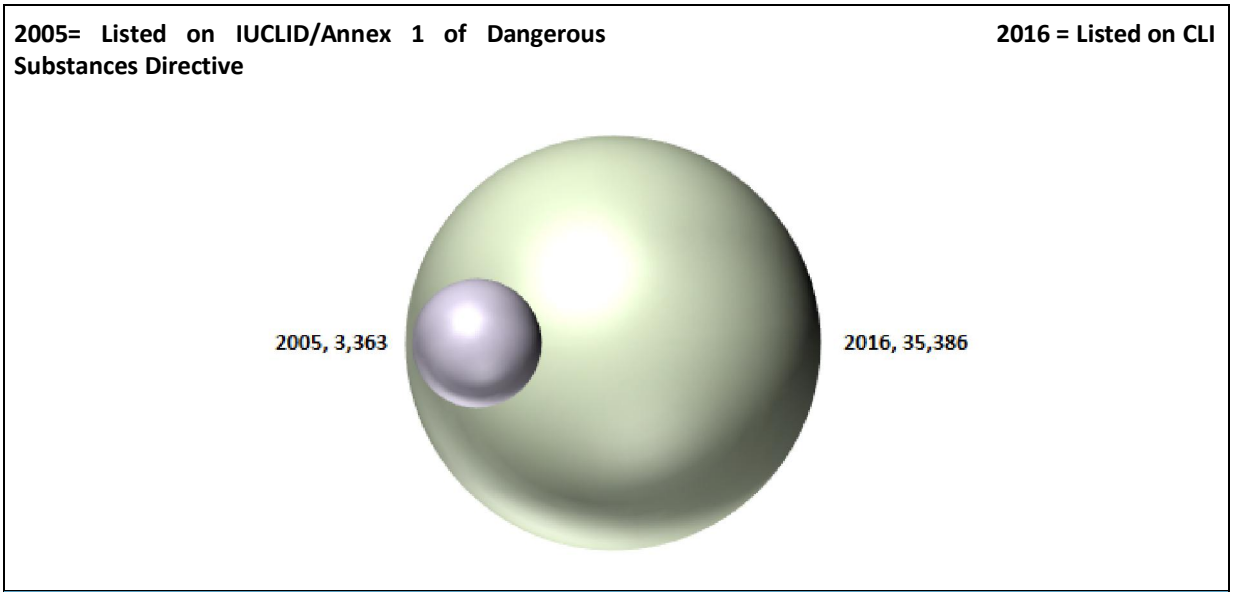


Figure 7-13: Change in information on chemicals with environmentally hazardous properties

As with the human health benefits, quantifying the impact of this expansion of information on environmental parameters is hampered by a lack of monitoring data, impact prediction methodologies and metrics for monetary valuation. This has been identified as an issue in a number of studies, most recently in the DG Environment study on Benefits Indicators undertaken by RPA and DHI (2016).

As is identified in RPA and DHI (2016), the main issue is the availability of biomonitoring data that reflect a time series and their comparability. Biomonitoring surveys are resource-intensive and expensive and therefore their availability is limited. In addition, they are often one-off studies focusing on a limited number of substances of concern which, upon detection, highlight the

importance of the legislative intervention to reduce exposure. Data are therefore often only available for a limited number of 'problem' chemicals in a limited range of species/environments. However, the available data from the European Environment Agency and the German UBA do provide evidence of continuing reductions in concentrations of key contaminants after regulatory intervention.

For example, Table 7-22 provides a summary of changes in concentrations observable in human/animal biomonitoring and environmental data for key contaminants in Germany. Almost all of the substances monitored are those which have been subject to regulation spanning across one or more decades. The observed decreases provide indications on how the regulatory pressure and other factors such as technological progress, voluntary initiatives, increased consumers' awareness, research and development of suitable alternatives, have contributed in lowering the exposure to hazardous chemicals. Classification data are a core component of this.

Table 7-22: Summary of the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples)

Substances	Sample	Average Δ %	Period
Cadmium	Whole blood (Young adult humans) – µg/l ww	+33%	2000-2009
	Saliva (Young adult humans) – ng/l ww	-58%	1995-2004
	Scalp hair (Humans) – ng/g ww	-75%	1995-2004
	Pubic hair (Young adult humans) – ng/g ww	-83%	1995-2004
	Organic layer/root network – AN extract µg/g dw	-75%	2002-2010
	Organic layer/root network – AR extract µg/g dw	-11%	2002-2010
Mercury	Whole blood (Young adult humans) – µg/l ww	-57%	2001-2010
	24h-sampling urine (Young adult humans) - µg/l ww	-92%	1995-2013
	Topsoil – AR extract - µg/g dw	-30%	2002-2010
Lead	Whole blood (Young adult humans) – µg/l ww	-58%	1995-2013
	Whole blood (Young adult humans - Münster) – µg/l ww	-85%	1981-2013
		-62%	1995-2004
	Pubic hair (Young adult humans) – µg/g ww	-57%	1995-2004
	Scalp hair (Young adult humans) - µg/l ww	+3%	2002-2010
	Subsoil – AN extract - µg/g dw		
Hexachlorobenzene	Blood plasma (Young adult humans) - µg/l ww	-79%	1995-2010
	Suspended particulate matter – ng/g dw	-66%	2005-2012
Pentachlorophenol	24h-sampling urine (Young adult humans) - µg/l ww	-92%	1995-2010
	Blood plasma (Young adult humans) - µg/l ww	-87%	1995-2010
PCB138	Blood plasma (Young adult humans) - µg/l ww	-81%	1995-2010
PCB153	Blood plasma (Young adult humans) - µg/l ww	-66%	1995-2010
PCB180	Blood plasma (Young adult humans) - µg/l ww	-68%	1995-2010
Phthalates			
DEHP	24h-sampling urine (Young adult humans) - µg/l ww	-67%	1988-2008
DINP	24h-sampling urine (Young adult humans) - µg/l ww	+67%	1988-2008
BBP	24h-sampling urine (Young adult humans) - µg/l ww	-52%	1988-2008
DnBP	24h-sampling urine (Young adult humans) - µg/l ww	-90%	1988-2008
DiBP	24h-sampling urine (Young adult humans) - µg/l ww	-15%	1988-2008
Bisphenol A	24h-sampling urine (Young adult humans) - µg/l ww	-36%	1995-2009
PFOA	Blood plasma (Young adult humans) - µg/l ww	-13%	1982-2010
PFOS	Blood plasma (Young adult humans) - µg/l ww	-71%	1982-2010
Hexabromocyclododecane	Herring Gull Eggs – ng/g lipid	+8%	1988-2008
Nonylphenol	Fish musculature (Bream) – ng/g ww	-65%	1995-2001
	Soft body (Blue mussel) – ng/g ww	-47%	1992-2001
Nonylphenol	Fish musculature (Bream) – ng/g ww	-70%	1995-2001

Table 7-22: Summary of the average changes (in percentage) of the concentration of specific chemicals in Germany in different samples (human, animal and plant tissues, soil samples)			
Substances	**Sample**	**Average Δ %**	**Period**
ethoxylates			
Methylmercury	Soft body (Zebra mussel) – ng/g dw Soft body (Blue mussel) – ng/g ww	-33% -20%	1995-2013 1992-2013
Tributyltin	Fish musculature (Bream) – ng/g ww Soft body (Blue mussel) – ng/g ww	-73% -50%	1995-2003 1992-2005
Source: RPA and DHI, 2016 (own elaboration on German ESB data)			

7.4 Total quantified health and environmental benefits

The table below provides a summary of the human health benefits for which monetary valuation has been attempted. Clearly, these cover only some of the likely benefits that are linked to the availability of classification data and the dissemination of information on hazardous properties via product labelling. Even where human health impacts have been valued, estimates may be on the lower end of the spectrum because available WTP values (notably for severe chronic dermatitis) are low. No attempt has been made to quantify environmental benefits in monetary terms for the purposes of this study, as no methods are available at the EU-wide level to achieve this at present.

Accordingly, **the estimates are approximations and should be taken as indicative of the lower bound value of benefits**. As with all benefit estimates from 2008 to the present, whilst these cover the period since transition to CLP they do not necessarily represent the benefits of CLP and CLP transition. Rather, these represent the (continuing) benefits of a system of classification, packaging and labelling in combination with enhancements delivered from transition to CLP (as well as other changes that have occurred in that period), and those realised due to the linkages between CLP and related chemicals legislation.

Table 7-23: Total quantifiable benefits (partial estimates)		
Endpoint	**Total PV**	**Average annual**
2000-Present		
Reduction in workplace lost-time incidents (productivity loss only)	€ 497.9m	€ 33.2m per year
Reduction in poisoning incidents	€ 417.9m	€ 27.9m per year
Reduction in cases of occupational skin disease	€ 938.6m	€ 62.6m per year
Reduction in cases of occupational respiratory disease	€2,194.8m	€ 146.3m per year
Reduction in occupational cancers		€ 121 to €242 million per year
Total quantifiable/quantified		**€ 391 to € 512 million per year**
2008-Present		
Reduction in workplace lost-time incidents (productivity loss only)	€ 312.5m	€ 44.6 million per year
Reduction in poisoning incidents	€ 105.1m	€ 15.0 million per year
Reduction in cases of occupational skin disease	€ 137.8m	€ 19.7 million per year
Reduction in cases of occupational respiratory disease	€ 118.2m	€ 16.9 million per year
Reduction in occupational cancers		€ 121 to €242 million per year
Total quantifiable/quantified		**€ 217 to € 338 million per year**

8 Obligations in Relation to the CLI and Poison Centres

8.1 Introduction

Article 1 of CLP sets out the actions required under the regulation that are aimed at ensuring a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and articles. These include the following administrative requirements:

- Article 1(c): requirements for manufacturers and importers of substances to notify ECHA of the classification and labelling elements for substances that they place on the EU market; and
- Article 1(e): the establishment of a classification and labelling inventory, made up of manufacturers' and importers' notifications as well as holding details of harmonised classification and labelling elements.

These requirements provide the basis for what is referred to as ECHA's Classification & Labelling Inventory (CLI), which was intended to "ensure a harmonised level of protection for the general public, and, in particular, for persons who come into contact with certain substances…" (Recital 57). The more detailed requirements placed on manufacturers and importers in relation to the CLI are set out in Articles 16, 39, 40, 41. The duties placed on ECHA in relation to the CLI are set out in Article 42.

Article 45 of CLP sets out requirements for Member States with respect to what are commonly referred to as 'poison centres'. These requirements are for:

- Member States to appoint bodies to be responsible for receiving information relating to emergency health responses to be supplied by those placing hazardous mixtures on the EU market; and
- For all importers and downstream users responsible for marketing hazardous mixtures to supply the information needed by the appointed bodies to carry out their tasks.

These provisions within CLP are evaluated below.

Table 8-1: Evaluation questions to be addressed relating to efficiency effectiveness of CLI and poison centres as components of hazard communication

Q #	Evaluation Question
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.1.1.1.	Are the communication measures to workers, consumers and businesses (in particular SMEs) effective in reaching the above-mentioned objective (of ensuring a high level of protection of human health and the environment)?
1.1.3.1.	Are the hazard communication measures to workers, consumers and businesses (in particular SMEs) effective in reaching the above-mentioned objective (of enhancing competitiveness and innovation)?
1.2.1.	Are there unnecessary regulatory burdens?

Table 8-1: Evaluation questions to be addressed relating to efficiency effectiveness of CLI and poison centres as components of hazard communication	
Q #	**Evaluation Question**
2.2.3.	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?

8.2 Obligations related to the CLI and its role in hazard communication

Key findings:

- The provisions of the CLP in creating the CLI have been effective in providing a single, readily accessible source of basic classification and labelling data on hazardous substances
- If all the information held in the CLI were reliable, it would be a highly effective communication tool. At this point in time, however, problems exist with the reliability of some of the data
- ECHA launched the C&L platform to enable notifying companies to contact each other with the aim of addressing such problems, but the response to date has been limited
- The total costs to ECHA of developing the CLI were in the range of €1 million, with annual costs of around €0.2 million
- The total estimated administrative burden for manufacturers and importers of fulfilling the first time notification obligations as part if the transition to CLP was between €49 and €63 million. Industry view this as an undue burden given the quality of the data overall, while ECHA and Member States clearly find the information of value

8.2.1 Effectiveness of hazard communication measures

The CLI is a central database of basic classification and labelling information, and holds information on notified substances subject to CLP irrespective of their volume[74]. It also includes the list of Annex VI harmonised classifications. As noted above, Article 42 of CLP gives ECHA responsibility for establishing and managing the CLI, to act as a means of communicating the hazards of substances and mixtures to downstream users and the public.

Assessing the effectiveness of the CLI as a communication measure has involved consideration of the following:

- What information is provided on the CLI and how many notifications have been made to it?
- How reliable is the information held on the CLI?
- How valuable is the CLI as a hazard communication tool? and
- Have other uses of the CLI developed which increase its effectiveness as a hazard communication tool?

[74] Schoning, G. (2011): Classification and Labelling Inventory: role of ECHA and notification requirements; Ann Ist Super Sanita, Vol 47, No 2, p 140-145.

8.2.1.1 Information held and number of notifications

Notification requirements apply to all substances registered under REACH (where this includes substances contained in articles that are subject to registration under Article 7 of REACH), as well as substances that meet the criteria for classification as hazardous and that are placed on the market either on their own or in a mixture above specified concentration limits which result in that mixture being classified as hazardous. It therefore applies to a large number of substances, especially as there is no volume threshold limiting the need to make notifications.

The CLI is refreshed regularly by ECHA. As of May 2016, information is held on over 123,000 notified and registered substances on the database[75]. In total, ECHA indicate that more than 6.5 million separate notifications have been made to the CLI.

Notifiers must provide information to ECHA on: their identity; the identity of the substance; the classification of the substance; the reasons for no classification against some hazard classes; specific concentration limits or M-factors where applicable; and labelling elements and associated hazard statements. In addition, notifiers are also obliged to update this information (and update their notification) when a decision is made to change a self-classification.

The CLI is readily accessed through ECHA's website and easy to search, providing facilities for a search either by substance name or identifier, for substances having harmonised classifications, or by hazard class. ECHA has undertaken a range of activities over time to expand and improve the information that is held on the CLI in order to increase the value of the inventory. For example, the Commission is currently developing official translations for harmonized chemical names in all EU languages, which will consequently be included in the harmonised part of the CLI system when they become available via the publication in the Official Journal. The CLI currently presents data in terms of an InfoCard, which summarises the non-confidential data of a substance held in ECHA's databases. The InfoCards are generated automatically based on the available data, with the quality and correctness of the information submitted to ECHA remains the responsibility of the data submitter. Information included in the InfoCards goes beyond CLP and provides a brief profile containing information on uses of the substance and also covers requirements under some additional regulatory frameworks (e.g. export notifications under the Prior Informed Consent Regulation, REACH status, Biocidal Products status, etc.). In addition, a Seveso III linkage has been added as an additional service for companies falling under the Directive, and information can be downloaded in an XLS extract on harmonised entries in Annex VI to CLP.

ECHA has also added a graphical presentation of hazard classifications in the "brief profiles" presented in the InfoCards, and these have been welcomed by industry. These graphical presentations show the main differences among the various classifications (plus the hazards notified by REACH registrants and by others).

In simple terms, based on the above, through the efforts put into the development of the CLI by ECHA, the provisions of the CLP have been effective in providing a single, readily accessible source of basic classification and labelling data on hazardous substances. The additional information provided in the InfoCards, through ECHA's ability to link different databases, provides added value to what is required under the CLP.

[75] http://echa.europa.eu/information-on-chemicals/cl-inventory-database

As a communication source, therefore, if all the information were reliable then the CLI would be considered to be a highly effective communication tool. However, as discussed further below, there are significant concerns over the reliability of the classification information notified to the CLI, even if these are off-set to some degree through the recent creation of the graphical presentations of hazard classes and reasons for differences in classification.

Finally, ECHA note that the CLI is currently being moved (or has moved) to a new "data warehouse" in ECHA, so the database will have better structure and possibly later in the year they will be able to have better numbers, after removal of some duplications. This move is part of the CLI being integrated with ECHA's substance-centric model. In addition, there are plans for the CLI information to be added to the eCHEM portal of OECD. A decision was taken by the OECD to include the CLI data in the portal, with this applying not just to harmonised classifications but to all of the data. ECHA notes that it is unclear when this will be carried out, but hopefully by the end of the year.

8.2.1.2 Reliability of the CLI information

Both ECHA and industry have noted problems with the quality of the data held in the CLI, and for the ability of those accessing the CLI to properly understand why there are variations in the classifications that have been notified. Issues identified by ECHA and industry include the following:

- There can be major differences in classifications for many substances due to objective reasons such as differences in impurities or physical states; in addition, in 2010 many companies notified in a hurry and at a large scale, with this likely to have led to errors or use of an inadequate set of data;
- Any manufacturer/importer can notify without any checks on the quality of the information being notified, with this putting into question the robustness of the information provided;
- Importers could be classifying under the UN GHS or in line with the classification requirements of his/her country of origin;
- The lack of a volume threshold means that some notifiers will be basing their classifications on a low level of toxicological data, as there are no corresponding testing requirements;
- ECHA is not allowed for legal reasons to correct or delete obvious mistakes or to remove entries by companies which have ceased to exist or for substances which are no longer placed on the market (especially below 1t/y); and
- Some in industry have claimed that there would appear to be evidence of frivolous notifications in order to impact products from a competitive perspective or from the perspective of stigmatizing the substance for further regulation e.g. via a CLH.

In response to such concerns, ECHA launched the C&L platform to enable notifying companies to contact each other to discuss varying classifications and labelling entries for the same substance. In addition pilot projects have been launched to invite notifiers to come to an agreed classification for the same substance. The pilot project undertaken in 2015 involved ECHA contacting some 4,000 companies that notified roughly 100 substances. These companies were asked to use the C&L platform, with the aim of removing notifications that were out of date or of agreeing on a single classification for individual substances. ECHA monitored companies' activities and noted that although roughly 1,000 individual notifications were removed, the aim of agreeing on a single classification for the selected substances was not achieved. ECHA has worked with Eurometaux on a second pilot project (June 2016); this second project has been finalized and did not provide better results than the first pilot project. On this basis, the C&L platform has been discontinued due to the lack of use of the tool by notifiers and registrants. It has been replaced by a newer version of REACH-IT, which was made available 21 June 2016.

Industry is strongly of the view that, given the problems that exist with the quality of some of the CLI data, there are questions over the extent to which CLI furthers reliable, science-based communication on chemicals. In particular, the lack of clear checks on the information submitted in notifications is considered to put into question the robustness of the information being provided. The fear is that this can have a negative impact on how a substance is perceived, without any scientific justification.

Several suggestions have been put forward on how the reliability of the CLI data could be improved, so that it acts as a more effective communication tool.

1) Give ECHA the legal powers to correct or delete obvious mistakes, or enable them to get in direct contact with notifiers/registrants, in order to initiate a correction (but also bearing in mind the burden that this could place on ECHA and that ECHA's past attempts at doing so have been unsuccessful). This could also help address any variations in classification that appear to arise between those notified by importers versus REACH registrants (some industry commentators note that hazard categories in UN GHS, which are not included in CLP will come up in the C&L Inventory. In their view ECHA should delete such entries or should undertake targeted communication with importers).

2) Improve security aspects surrounding the Classification and Labelling Platform, so that more companies will trust the security of their information when; in addition, it would be necessary to enable ECHA to share the names of notifiers so that they can contact each other in order to agree on a classification (registrants know each other, but ECHA does not have a legal basis for making known the names of other notifiers and there are concerns that there may be a greater level of confidential business information associated with notifications).

3) Give preference to classifications from REACH registration dossiers, and in particular joint registrations, as registrants have to provide detailed information on the substance and the basis for classification (and SIEFs have to agree the classification).

4) Establish clear requirements for the scientific justification of a notification, so as to make the system more effective and fairer; this could include requiring a justification from notifiers when new notifications are made that are inconsistent with information already provided by the REACH registrants. Notifiers and registrants could then be required to discuss and agree the classifications, with information provided in the InfoCards on reasons for differences in classification.

5) Implement a minimum tonnage threshold for CLI notifications, to remove the extent to which differences are arising due to notifications on very low volume substances for which less information on intrinsic properties exists, with this also likely to lead to variations in classifications (although some of these issues may be resolved after the 2018 registration period).

6) Introduce an obligation into CLP requiring all notifiers to up-date their notifications after the 2018 Reach registration deadline has passed, with this including the mandatory removal of previous notifications for substances that are no longer placed on the market. This could be linked to a requirement on ECHA to remove all notifications that have not been updated.

In ECHA's recent *Report on the Operation of REACH and CLP*[76], further suggestions of adapting the CLP Regulation to allow the sharing of contact details of notifiers and registrants and making notifications time-limited are put forward.

Several commentators indicated that in their view agreed classifications developed as part of joint registrations should be given preference over other classifications. This is because ECHA and Member State authorities use the CLI to identify substances for further regulatory scrutiny (see also discussion below). Given questions over the reliability of the data, they feel that giving equal weight to a CLI notification as the CLP classification in a REACH registration dossier is not justified and creates some confusion.

8.2.1.3 The CLI as a communication tool

Given views on the reliability of information in the CLI, there are questions over the current value of the CLI as a hazard communication tool. In particular, it is not clear that it is really fulfilling the role that it was hoped to in some respects, although it is acting as an information source for ECHA and Authorities (and indeed there are plans for further links to be made to the OECD chemicals portal). As a result, there must be questions over the extent to which the CLI is helping ensure a high level of protection for human health and the environment, or is leading to confusion or misinformation on chemical hazards.

In this respect, it should be recognised that what is available to the public is only part of the dataset held by ECHA. The full database of information is available to Member State Competent Authorities, and it is clear that these bodies use the information for a range of different purposes and may consult the CLI on a frequent basis (indeed one authority indicated that they probably refer to it on a daily basis).

Identified uses include:

- To propose substances for the Community Rolling Action Plan (CoRAP) under REACH;
- For screening projects and surveys and prioritizing further regulatory action/initiatives including;
- For substance evaluation purposes (under CLH, REACH, Plant Protection Products Regulation and Biocidal Products Regulation) to solve classification questions and help in the preparation of national dossiers;
- To answer questions from the CLP HelpDesk;
- For enforcement purposes, including checking the classifications of substances and mixtures, checking SDS, as well as for the assessment of mixtures;
- To confirm what substances have classifications against certain sub-classes, such as Acute toxicity cat 1 by inhalation; and
- For designating sites as either higher or lower tier under the Seveso III Directive;
- To aid in the period adjustment and development of criteria for the EU-Ecolabel on detergents;
- In relation to cosmetics where no SDS is available but there is a need to gather information on the possible hazards of the product;
- For responding to other queries, including other regulatory needs, providing information to public prosecutors on substances that are harmful for human health;
- To check on the possibility of substitutes.

[76] https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

More generally, authorities appear to view the CLI positively, with all respondents to the Member State targeted data collection indicating that they believed the increased public availability of information on chemical hazards through the CLI has had a low to a large positive impact on human health, worker safety and the environment. However, authorities are also aware of the problems with the Inventory. As commented by authorities:

- *"Downstream users often use the C&L Inventory. As we know, this Inventory contains substances with different classifications which may lead to confusion."*

- *"We believe that are significant inconsistencies both in the classification of substances (as reflected in the C&L Inventory) and mixtures and that it leads to confusion among downstream users."*

Companies also refer to the CLI on a regular basis, although this is for different reasons (i.e. to check what classifications others have assigned to a substance, e.g. to respond to queries from regulators, to screen substances by classification, etc.). Respondents to the targeted data collection were asked to indicate how often within the average year they referred to the CLI to check on classification information. Responses to this question are given in Table 8-2 below (and as discussed in Section 7.2.3). The responses to this question are surprising given views on the reliability of the information held in the CLI, with high percentages indicating that they refer to the CLI multiple times per week. Less than 10% never refer to the CLI, while the majority refer to it at least monthly.

Table 8-2: Frequency of referring to the Classification and Labelling Inventory in an average year

Answer Options	Percentage of responses			
	Manufacturers (n=54)	Formulators (n=48)	Distributors (n=9)	Importers (n=15)
Never	9.3%	2.1%	0.0%	0.0%
Rarely	16.7%	16.7%	33.3%	33.3%
Monthly	18.5%	25.0%	33.3%	20.0%
Weekly	14.8%	22.9%	0.0%	20.0%
Multiple times per week	40.7%	33.3%	33.3%	26.7%

8.2.2 Efficiency, costs and undue burdens

Notification to the CLI was clearly a new obligation brought in by the CLP Regulation, placing new administrative burdens on both ECHA and on industry. With respect to this evaluation, three aspects are considered further here:

- Did the systems put in place enable industry to meet this obligation in an efficient manner?
- What were the costs of these obligations for ECHA and notifiers?
- Have these costs resulted in an unnecessary or undue burden?

8.2.2.1 Efficiency of notification systems

ECHA prepared guidance for use by notifiers, setting out their obligations, what information was required, and how to make a notification (including how to get prepared and how to create a notification). Up until recently, notifications to the CLI could be made through the creation of a REACH-IT account and via IUCLID 5 for an individual substance, through a bulk submission (using a

XML file) containing multiple classification and labelling notifications or through a manual on-line entry. No comments were made by industry regarding the efficiency of these systems.

8.2.2.2 Costs to ECHA

The total costs to ECHA of developing the CLI were in the range of €1 million, with this including roughly €0.5 million for external contractors developing the CLI plus roughly €0.1 million for the necessary hardware (e.g. servers). Costs for maintenance and operation of the CLI are roughly €0.2 million (roughly about 20% of the total capital costs).

8.2.2.3 Administrative burden on notifiers

As highlighted above, ECHA's statistics show that there have been around 6.3 million notifications made to the CLI, covering some 123,000 notified substances. This does not mean, however, that there have been 6.3 million separate individual submissions. Due to the ability to make bulk applications, companies submitted duplicate notifications (e.g. ECHA has found up to 7 duplicates due to multiple submissions by different sites of the same company). In addition, bulk notifications will have included some substances that are not actually placed on the EU market by some companies. There were also examples of an individual company notifying tens of thousands of substances as part of a bulk submission.

ECHA were unable to provide an estimate of the number of notifications that were made via the different routes listed above (IUCLID 5, bulk or on-line), nor was adequate information available from industry, making it necessary to develop own assumptions for the purpose of estimating the potential costs to industry of the CLI notification obligations.

Logically, the more physico-chemical, toxicological and ecotoxicological information is available for a substance the greater the possibility to identify endpoints that can be classified and, therefore, the greater the complexity involved in completing and submitting a notification. Following this assumption, as the level of information required under REACH is greater for higher tonnage substances fully registered under REACH than the lower tonnage substances, the complexity of notifications for the former is likely to be greater than for the latter.

The starting point for estimation has been to partition the 123,000 or so substances on the CLI into groups according to registration status and tonnage band as well as other indicator of complexity. This suggests that there are some 10,832 substances that are:

- NONs (full or intermediate); or
- Fully registered under REACH (full or intermediate); or
- On the pre-CLP version of IUCLID but not yet registered.

For all of these 10,832 substances, there will be differing but a relatively significant amount of (often new) physico-chemical, toxicity and ecotoxicity data on which to base classifications. For the remaining 112,428 substances levels of data will be relatively low and, by inference, the complexity of completing the notification process is lower.

For each of those 10,832 substances where there is more complexity, there will be, on average, more than one MI submitting notifications. Based on an analysis of the registration database undertaken for the DG GROW study *Monitoring the Impact of REACH in Innovation, Competitiveness*

and SMEs[77] there are an average of 5.76 MIs per substance fully registered under REACH and 1.55 MIs for intermediate registration. Applying the appropriate figure to the appropriate registration type provides an estimated total number of initial notifications by MIs for their chemical products of 37,517. It has then been assumed that each notification has been revised and re-submitted:

- Once on average for NONs, for substances registered in 2010 (assumed to be only those >1000t) and for substances on the pre-CLP version of IUCLID but not yet registered (so two notifications on average in total); and
- Twice on average for all other categories of substance listed above (so three notifications on average in total).

This gives a total of 90,800 more complex notifications. To these have been applied estimates of the average amount of time taken (in hours) to complete each notification, with the estimated time taken varying by tonnage band (which, as noted, is a proxy for complexity). Subtracting the 90,800 substances from the total of 6.3 million notifications suggests some 6.2 million notifications for less complex substances (for which there is an expected low level of data and bulk submissions are more likely). The average time taken per notification has been estimated by consideration of:

- The percentage of less complex notifications submitted in bulk (versus individually) – 75%;
- The average size of bulk submissions - 500 substance notifications;
- The time taken for a bulk submission – one week (37.5 hours);
- The time taken for notifications not submitted in bulk (25% of the less complex notifications) – 0.5 hours;
- Providing a statistical average time per notification of 0.18 hours.

The calculated time taken to complete and submit notifications has been costed at €40 per hour to provide the estimated costs in Table 8-3 below. The table also provides the data, assumptions and calculations applied and described above. As can be seen from this table, total costs estimated by this method are around €49.4 million in total.

To provide an implied maximum value for comparison, the above times have also been applied to the average number of notifications per substance implied from dividing the total number of notifications (6.3 million) by the number of substances on the CLI (giving 51 notifications per substance). This provides an implied maximum of € 62,895,900. As such, the estimated costs of the CLI notification obligations incurred due to the transition to CLP are in the range of €49.4 - 62.9 million.

8.2.2.4 Undue burdens

With respect to the question as to whether or not the above figures represent an undue burden, this requires consideration of the extent to which the information currently held in the CLI is:

- Reducing information costs for ECHA and authorities in collecting information on substance properties for regulatory purposes;
- Through the above mechanism, improving the risk management of chemicals within the EU and thereby leading to reduced impacts on workers, consumers, the general public and the environment;

[77] http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

Table 8-3: Estimated costs of CLI notification obligations for manufacturers and importers of substances							
	Substances on CLI	Initial notifications submitted	Average number of times updated/repeated MIS	Total more complex notif. By Mis	Simple duplicated notif. (Total minus complex)	Hours to prepare and submit each	Cost of doing notifications
NONS (Full)	1,035	5,963	1	11,926		1.5	€ 715,560
NONS (intermdiate)	10	58	1	116		1.5	€ 6,960
Registered >1000t	1,732	9,978	1	19,956		2	€ 1,596,480
Registered 100-1000t	1,094	6,303	2	18,909		1.5	€ 1,134,540
Registered 10-100t	467	2,690	2	8,070		1	€ 322,800
Registered 1-10t	467	2,690	2	8,070		0.5	€ 161,400
Registered Confidential	123	709	2	2,127		0.5	€ 42,540
Registered Intermediate	2,184	3,376	2	10,128		0.5	€ 202,560
On IUCLID 2005 but not yet registered	3,720	5,750	1	11,500		0.5	€ 230,000
Implied not registered and not on IUCLID 2005 but on CLI	112,428	0			6,209,198	0.18	€ 45,016,686
Total	**123,260**	**37,517**		**90,802**	**6,209,198**		**€ 49,429,526**

- Being used by employers, workers and the public to gain further information on the risks associated with different substances, better enabling them to make informed choices regarding the products that they purchase.

In assessing whether the first two bullets are likely to be the case, one has to consider the added value of the CLI data compared to REACH registration dossiers. The latter are likely to be more reliable for substances being placed on the EU market and, in this respect, the data should otherwise be available to regulators. ECHA note though that a major benefit from the creation of the CLI is that it shows the level of divergence that exists in substance classifications and that there is work to be undertaken by companies to address why these exist.

For substances in imported mixtures and low volume (<1 t/y) substances, the CLI may have a greater added value in terms of making classification information available.

With respect to the use of CLI information by employers and workers, industry stresses that information on substance properties (and on mixture properties) should be communicated through SDS and that employers and workers should be using the information provided to them by their supplier. Indeed, there is concern that formulators are reportedly using information from the CLI for mixture classification purposes, while employers and workers are using it to make decisions regarding risk management. If such actors do not adopt the correct classification and labelling for the substances that they are using, then risk management measures may be incorrectly identified, leading to either unsafe exposures to chemicals or an over-allocation of resources towards certain forms of risk management.

ECHA notes that the publicly available CLI represents the largest database of self- and harmonised classified substances available today in the EU and is unique in the world in terms of its scope. It is considered to represent an important step in hazard communication. ECHA also note that it may "*in the long term help to improve the safe use of hazardous substances by consumers, professional users and industrial workers*".

From the perspective of manufacturers and importers, these obligations are to a significant degree an undue burden, as they represent a duplication of requirements and, therefore, efforts for substances which have to be registered under REACH in any event. Thus, where notifications had to be made to the CLI prior to submission of a registration dossier, this led to classification information having to be submitted twice in practice. Furthermore, due to the level of concern surrounding the reliability of some of the data held in the publicly available CLI, most in industry would argue that any real benefits will arise only if action is taken to improve the quality of the data being held. If it is not, then the cost and effort required of industry will not have produced significant benefits.

8.3 Obligations related to poison centres and their role in hazard communication

Key findings:

- Implementation of CLP has led to the new formation of poison centres or the equivalent in 8 Member States
- Member States report that the obligation to notify poison centres has had a large positive impact on human health and safety and the environment
- Cost to Member States of running poison centres is unknown, but could equate to around €28 million per year based on data for three countries

- Annual administrative costs to industry of meeting notification obligations under CLP are estimated to range between €485 million and €4.85 billion, with a best estimate of €2.27 billion; harmonisation of information submissions could lead to net savings of around €550 million per year.

8.3.1 Effectiveness of hazard communication measures

8.3.1.1 Poison centres before and after CLP

Under Article 12 of the Dangerous Preparations Directive the following obligation was placed on Member States:

> *"Member States shall appoint the body, or bodies, responsible for receiving information on dangerous preparations, including their chemical composition, placed on the market."* It is further stated that *"Member States shall ensure that the appointed bodies shall have at their disposal all the information required to carry out the tasks for which they are responsible from the manufacturers or persons responsible for marketing."*

However, as this was a directive, and not a regulation, not all Member States enforced this requirement, with the result that there was considerable inconsistency across Member States in terms of notification obligations. Under CLP, the provisions relating to poison centres are obligatory, and all Member States have had to appoint bodies responsible for receiving information or set up poison centres.[78] As a result, the implementation of CLP has led to the formation of poison centres or receiving bodies in the following Member States: Czech Republic; Estonia; Germany; Greece; Ireland; Netherlands; Portugal; and Slovakia.

In response to consultation, several Member State authorities have indicated that the obligation to notify poison centres has had a large positive impact on human health and safety and the environment; however, most of these represent countries that did not enforce poison centre obligations prior to CLP. Nonetheless, quantitative data specific to the benefits of poison centre obligations are not readily available across Member States and so it is not easy to prove that the obligation to notify to poison centres has been beneficial (see Section 7.3.4.2, however, for an analysis of available data on poisoning incidents and changes over time).

8.3.1.2 Proposal to harmonise submission of information to poison centres

At present, the national requirements with respect to the obligations for suppliers of mixtures that are hazardous for their health or physical effect to notify poison centres differ greatly across MS. This leads to a significant administrative burden being placed on companies which have to meet varying obligations for the markets in which their products are placed. This issue has been the subject of extensive debate since the introduction of CLP and several discussions and reviews have been ongoing (since 2010) at the European level to refine the current system, so as to minimise inefficiencies and burden to both industry and competent authorities, whilst also ensuring the protection of human health. Firstly, the Commission was mandated to review the possibility of harmonising the information provided to poison centres. This review was conducted in

[78] See Annex 2 for the list of appointed receiving bodies and poison centres for each Member State and details of when they were established.

collaboration with the European Association of Poison Centres and Clinical Toxicology (EAPCCT). It concluded that the Commission would make a proposal to harmonise the requirements and format of data submission across MSs and including the following two main components:

- A standard format for the submission of information to appointed bodies; and
- A unique formula identifier (UFI)

It is expected that this regulation will be published in early 2017[79].

The review[80] makes the case for increasing harmonisation in terms of the format of data submitted, the tools for submission, requirements for composition and concentration data and the introduction of a Unique Formula Identifier (UFI).

8.3.2 Efficiency, costs and undue burdens

8.3.2.1 Efficiency of notification systems and undue burdens

Although Article 45 of CLP lays out obligations relating to the submission of information to poison centres or other such appointed bodies, there is significant variability across MS in terms of the notification process, the information requirements relating to the product's hazards, which products need to be notified and the costs of compliance.

Analysis of stakeholder responses to targeted consultation questions about the current system for notifying poison centres suggest a significant level of inefficiency. Many argue that the costs to industry would be far lower if there were a central notification portal to which the information required were submitted. This would be particularly beneficial to companies who place products on the market in most/all MS. Benefits would stem from requiring fewer staff hours and also not having to submit information in multiple languages, which can be costly. A significant burden of the current system for notifying poison centres is the obligation for companies to notify each hazardous mixture they place on the market to poison centres in each MS in which they place their mixtures (products), where the hazard relates to health or physical effects. This is hugely burdensome for large companies who often have several hundred product lines placed on the market in most MS.

Industry stakeholders also noted that ECHA could act as the central notification portal, as it has the ability to create a system which would allow product details to be notified in any language, with these then to be translated to all other EU languages.

8.3.2.2 Costs to Member States

Data relating to the costs of operating poison centres are not readily available. One source of information is the National Poisons Information Service (NPIS), the UK's poison centre[81]. In 2005/2006, it reported that running NPIS cost £2.9 million; in 2006/2007 the cost was reported to be £3.5 million. Much of this was funded through "Government Grant in Aid" from the UK Health Department, with some revenue coming from contract income and some from research income. Data provided by Finnish Poison Information Centre (pers. comm., 2016) indicates total operating

[79] https://poisoncentres.echa.europa.eu

[80] Harmonisation of Information for Poison Centres. Available at: http://ec.europa.eu/DocsRoom/documents/14006/attachments/1/translations/

[81] http://www.npis.org/NPISAnnualReport2006-07.pdf

costs for 2015 of €1.07 million, although this also covers a Teratology information centre that takes calls from both the public and health-care professionals. Hungary also provided information on the approximate annual cost of running its poison centre, with this estimated at around €117,000 per annum.

We assume an average annual cost to each MS of running a poison centre of €1 million; across all 28 MS this equates to €28 million per year. However, this estimate should be regarded with caution given that the cost of running a poison centre will not be the same in every country, for example, some countries will have incurred additional costs in newly setting up centres and in other countries, spending on poison centres will depend on the resources available.

8.3.2.3 Costs to notifiers

The targeted questionnaires asked respondents to indicate what they expect annual costs for notifying poison centres to be from 2017 onwards. 93 manufacturer, formulator and distributor respondents answered this question, as did 15 respondents from the detergents sector. Responses were in the form of both money sums and text. The text responses indicated figures ranging from "not known/unavailable" to "no costs" (e.g. due to their not producing any relevant mixtures) to "huge" or "very substantial costs", to unknown costs due to the complex and currently unclear situation in the EU, or the need to wait until the final legislation comes out.

Respondents also commented that what will be critical to the costs is whether or not there will be one central notification portal rather than several national portals, each insisting on national languages and involving different data entry formats. Another raised the question as to why poison centres could not refer to ECHA's website for published information on chemicals, thereby reducing the duplication of notification requirements in those few cases where national poison centres also request the notification of substances that have a trade name and where it is not possible to tell what the substance is from the label or SDS, in addition to legal requirements for mixtures.

With respect to estimated costs, these varied widely, due to the varying nature of the product portfolios offered by respondents, as well as the number of products placed on the market. Figures quoted for notifications under CLP ranged from less than €10,000 for 32 of the respondents able to give a figure, to between €10,000 and €30,000 for a further 22 respondents, to between €30,000 and €100,000 for 11, and to over €100,000 for 3 of the respondents. One of these latter respondents indicated an almost trebling of costs from over €1.5 million to €4.2 million is expected with the currently proposed system based on non-harmonised national requirements.

The data collected from the targeted consultation has been used here to estimate costs of notifying poison centres. The weighted average annual costs expected to arise from the obligation to notify information on mixtures to poison centres is €25,000 per enterprise. Multiplying this by the number of manufacturers and formulators of mixtures (21,143) gives a total of **€528.6 million. This is likely to be an underestimate given the wide variations cited by some respondents.**

A more informed estimate can be generated using data taken from the EC study on the harmonisation of the information to be submitted to poison centres[82]. The study provides statistics regarding the number of submissions made annually to poison centres within the EU (and Norway). The study distinguishes between notifications made to one country only and notifications made to

[82] Kirhensteine et al (2015): Study on the harmonisation of the information to be submitted to poison centres, according to article 45(4) of the Regulation (EC) No. 1272/2008 (CLP Regulation).

multiple MS. To account for the latter, a scaling factor is applied to the number of notifications which fall under the latter category. Based on the figures in the study, and with the scaling factor applied, the annual number of notifications in total is 6,932,937. The study assumes a per submission cost ranging between €70 to €700 which gives the total annual cost to industry of notifying poison centres as **€485 million to €4.85 billion, with a best estimate of around €2.27 billion**.

However, it is important to note that actions have been taken to reduce the burden that will be placed on industry from these obligations. In September 2016, Member States voted in favour of a Commission proposal to harmonise the hazard and safety information, and the format it is to be submitted in, for use by poison centres. The proposal will lead to producers and importers of chemical mixtures providing uniform information on product composition (although the last draft left it open for Member States to request more information than the base level set out in Annex VIII). At the same time, emergency responders in all EU countries where products are registered will have the same medical information available, which for some countries will allow services to be improved. Through the new unique product identifier, poison centres will be able to exactly identify the product and its composition, leading to better and more appropriate medical response and reducing unnecessary over-treatment which is often given to be on the safe side. The Regulation will apply to mixtures for consumer use as of 2020. It also targets mixtures for professional and industrial use, for which requirements apply as of 2021 and 2024, respectively. Anything that is registered before Annex VIII comes into force is valid until 2025, in order to reduce the burden of the obligations on industry.

The study by Kirhensteine et al (2015) estimated that increasing the harmonisation of information submissions to poison centres could lead to net savings across the EU equivalent to **€550 million per year** (equivalent to €40,000 per company per year, based on there being roughly 23,500 companies in the sectors covered in the report). This cost saving is based on increased harmonisation leading to savings of up to €890 million per year, though introducing a UFI would lead to total costs of approximately €340 million.

Nonetheless, it is anticipated that, despite net savings being projected across the EU, some groups will experience net costs; for example, the study found that under the harmonised system and that the overall costs of notification could increase for SMEs who place their products on very few markets, and which have limited notification requirements; in contrast, costs are expected to decrease for companies who place their products on several EU markets.

8.4 Total administrative burden

Based on the definitions given in the Better Regulation Toolbox, we determine that the costs of notifying the CLI and notifying poison centres are categorised as administrative burdens. The following table lays out the assumptions used to calculate the administrative burden incurred by industry in fulfilling their obligations in relation to notifying the CLI and poison centres.

8.4.1.1 Transition costs

Based on the assumptions set out above, it is estimated that the cost to industry of notifying the CLI was **€49 million**. An upper bound figure of **€63** million has also been calculated for comparison. This value is an absolute maximum estimation of the costs incurred by industry in relation to CLI notification obligations during the transition to CLP.

While the cost of notifying poison centres is used in our calculation of on-going costs, we also reason that this cost would have been incurred by companies when CLP was introduced as a requirement for notifying poison centres is set out in Article 45 of the CLP Regulation. To calculate this cost we follow the same methodology, and thus derive the same result, as the on-going costs.

8.4.1.2 Ongoing costs

In addition to the one-off administrative burden of notification is the ongoing administrative burden of up-dating current notifications. ECHA indicates that there are between 1,000 - 3,000 of these per month, or between 12,000 and 36,000 per annum. If we assume that each of these take a maximum of 1 hour, then this translates to a cost of between €480,000 to €1,440,000 per annum.

The ongoing costs of notifying poison centres are estimated at between **€485.3 million** to **4.85 billion** by Kirhensteine et al (2015) **with a best estimate of around €2.27 billion**. The Regulation which was recently agreed upon and which will harmonise the hazard and safety information for use by poison centres, is expected to lead to net savings across the EU equivalent to **€550 million per year, reducing the total costs to around €1.72 billion for the best estimate.**

Based on information gathered from the targeted consultation, the costs are estated at **€529 million** by this study. The estimate developed here is based on an average annual expenditure on notifying poison centres equal to €25,000 per firm, with 21,140 incurring companies incurring these costs (compared to €40,000 and 23,500 companies affected).

9 Building Blocks and Transition Times

9.1 Introduction

In implementing the UN GHS, the CLP did not adopt all of the classification building blocks, as its adoption was linked to the information that would become available from REACH (and which was required under the Dangerous Substances Directive and Dangerous Preparations Directive). Although this decision retained consistency with REACH requirements, it also meant that the EU's adoption of CLP led in the short-term at least to a lack of harmonisation with other global systems. This latter issue is addressed in Section 1.9 below. In this section, we consider here the potential benefit and cost implications of the adoption of these here.

The second aspect of CLP implementation considered here relates to the procedures for Adaptations to Technical Progress (ATPs) to the CLP and the transition times that have been allowed for adoption of revisions to the UN GHS. The CLP Regulation is up-dated using two types of ATPs which run side-by-side:

- Proposed new harmonised substance classifications and labelling as well as revisions of existing harmonised classifications, if agreed by the Commission, are added to the list of entries in Annex VI to CLP;
- Amendments made to the classification criteria and technical annexes to the GHS. These amendments reflect the biennial rhythm of the UN GHS, and need to be incorporated into CLP in line with this (so approximately every 2 years).

The EU approach to the adoption of different building blocks and the impacts of the ATPs and their associated transition times are considered further below. Separate evaluation questions are used in both cases and are therefore presented in each sub-section.

Table 9-1: Evaluation questions relevant to the CLI and poison centres obligations	
Q #	**Evaluation Question**
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.1.3	Does the EU legislative framework for the risk management of chemicals meet the primary objective of enhancing competitiveness and innovation?
1.2.1.	Are there unnecessary regulatory burdens?
1.1.4.2	Is the chemicals legislative framework as effective as it can be? Are there factors that limit the effectiveness of the chemicals legislative framework and would they be avoidable?
2.1.1	What are the costs associated with the chemicals legislative framework?
2.1.3	What are the benefits associated with the chemicals legislative framework?
2.14	To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?
2.2.3.	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?

Table 9-1: Evaluation questions relevant to the CLI and poison centres obligations	
Q #	**Evaluation Question**
3.3.2.	To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?

9.2 Building blocks

Key findings:

- Five GHS building blocks were not adopted by CLP
- Despite the above, some substances have been notified against these to the CLI
- Up to 55% of substances have been notified for more stringent classifications, with this percentage varying by endpoint (1.5% for Aspiration hazard cat 1 to 55% for skin corrosion/irritation, cat 1A to C and cat 2)
- Some of these categories would lead to labelling using the harmful pictogram, which is considered the most misunderstood of the pictograms. Others have no pictograms so classification would be communicated via H statement on labelling
- Calculation of the implied number of cases that would need to be avoided for benefits to equal costs of classification and labelling indicates that including these building blocks would be disproportionate

9.2.1 Introduction

The CLP did not adopt the following building block categories from the UN GHS system:

- Flammable liquids, cat 4;
- Acute toxicity, cat 5;
- Skin corrosion/irritation, cat 3[83];
- Aspiration hazard, cat 2; and
- Acute hazards to aquatic environment, cat 2 and cat 3.

In 2006, the potential inclusion of some of these building blocks (referred to then as "optionalities") was assessed in terms of both the number of substances and mixtures that might be affected (RPA et al, 2006). This included: Acute toxicity, cat 5; Skin irritation, cat 3; and Eye irritation cat 2B. Aspiration hazard cat 2 and acute hazards to the aquatic environment cat 2 and cat 3 were not considered.

The optional categories that were assessed were considered to relate to "potential hazards" and to be assessed at thresholds above current testing requirements. As a result, adoption of these additional categories was predicted as resulting in significant additional costs to industry (and consumers, who would have cost passed on to them), because there was a lack of existing test data (either available or recorded) for the categories. At the same time, it was the view of experts that inclusion of these categories would lead to little additional human health benefits.

[83] Sub-categories Skin corrosion/irritation, cat 1A, cat 1B and cat 1C were adopted, as was cat 2

9.2.1.1 Flammable liquids, cat 4

Under the EU system, classification criteria for flammable substances and preparations were primarily based on flash points, with boiling point being of minor importance. Under the GHS, there are two categories for flammability based on flash points, with the most severe also dependent upon the boiling point. In an analysis undertaken for the Commission by Royal Haskoning[84] in 2004, a comparison was made between both systems based on flash points as well as on boiling points, and this found that around 90 substances would be newly classified under Flammable liquids cat 4. However, as industry will have had to make these changes under the transport regulations, experts indicated that there would be little or no additional costs (or benefits).

9.2.1.2 Acute toxicity, cat 5

Work carried out by Förster & Wiertulla (2005) concluded the proposed acute toxicity cat 5 classifications would lead to an increase in the "threshold values for toxicity", below which a product is classified as harmful, by 150% owing for all exposure routes. No indication was provided on the number of substances that this might affect, however.

In relation to mixtures, the European Chemicals Bureau published two studies – CAL-TASK1-2/015 and CAL-TASK1-2/029 (ECB, 2005) – which developed estimates of the likely change in mixture classifications using data then available from Sweden. These studies predicted that 8% more mixtures are likely to be classification as very toxic for acute oral toxicity, but that fewer mixtures would be classified for cat 3 or cat 4 acute oral toxicity. However, the study predicted that some 150,000 mixtures could be classified for cat 5 acute oral toxicity. Unfortunately, the study approach was viewed as overly simplistic by a range of experts. At the time, it was not clear if significant levels of further testing would be required, or whether the outputs of existing tests would be sufficient for undertaking classification against cat 5.

9.2.1.3 Skin corrosion/irritation, cat 3

Substances which are defined as being corrosive to skin were classified as either R35 or R34 under the EU system, with this relating to skin corrosion (where the skin tissue is actually destroyed when exposed to a substance or mixture). Under the GHS, such substances fall under cat 1, with sub-categories 1A to 1C adopted by CLP, togheter with cat 2. The risk phrase R38 referred to skin irritation that can be defined as inflammation to the skin which persists for a set amount of time; these substances would fall under GHS cat 2 or 3, with GHS setting lower limits than the EU system. As a result, it was predicted that more substances would fall under the GHS than the EU system, and that substances may move into more severe hazard categories. It was also predicted that the numbers of preparation/mixtures requiring classification would increase due to the lower concentration limits under GHS.

A preliminary analysis by Hilgers (2005) tested 198 formulations (laundry and cleaning products) for skin classification. This analysis found that GHS would lead to a significant increase in the classifications assigned to the preparations/mixtures. In particular, it found that 48% of the mixtures would not be classified under the EU system, but would be classified as either cat 2 or cat 3 under GHS. It should be borne in mind that these figures only represent one company's analysis and are presented in this Report only as a guide to the potential impacts of harmonisation.

[84] Unpublished.

9.2.1.4 Aspiration hazard, cat 2

With respect to aspiration hazard, experts were of the clear opinion that, due to the differences in cut-off levels between GHS and the Dangerous Substances Directive/Dangerous Preparations Directive criterion, the number of substances and mixtures that would be classified would increase significantly, even with the adoption of only GHS cat 1. The adoption of cat 2 therefore would lead to product groups not previously classified as falling under CLP, including e.g. lubrication oils, diesel, and potentially consumer products such as skin care oils and massage oils. In this case though, there would be no increase in test costs as the data needed would already be available for mixtures placed on the market.

9.2.1.5 Acute Aquatic toxicity, cat 2 and 3

Acute toxicity cat 2 and 3, apply to marine transport and solely to very large crude oil carriers under the GHS; they are not required for normal transport and were not therefore taken up for CLP. They were not expected to result in a significant number of additional classifications, and were not taken up for this reason.

9.2.2 Effectiveness

Although the above classification categories were not adopted in the CLP, some notifiers to the CLI have also notified substances against them. A check of the CLI in June 2016 found the following numbers of notified substances for each of the categories:

- Flammable liquids, cat 4: 38 substances
- Acute toxicity, cat 5: 66 substance
- Aspiration hazard, cat 1: 10 substances
- Skin corrosion/irritation, cat 3: 75 substances
- Aquatic acute toxicity, cat 2 and 3: 241 substances

As discussed in Section 8.2, the CLI is not currently considered to be a fully reliable data source for substance classification purposes. However, it is the single most comprehensive source of classification data for substances being placed on the EU market. As a result, it has been used as the basis for inferring to what extent introduction of the above optionalities could have resulted in both increased benefits, as well as additional test costs.

This inference is based on the numbers of substances that have been classified against more severe categories, as a means of identifying whether a significant number of additional substances might have been classified if the categories had been adopted and additional testing as necessary had been undertaken. Data on the CLI indicate the following numbers of substances have already been more severely classified[85] (and the % this equates to of all substances notified to the CLI):

- Acute toxicity, cat 1- 4: 49,284 substances (40%)
- Skin corrosion/ irritation, cats 1A,B,C - 2: 68,030 substances (55%)
- Aquatic acute toxicity, cat 1: 15,463 substances (12.5%)
- Flammable liquids, cat 1-3: 7,219 substances (5.8%)

[85] Estimates were derived using the search tool within the CLI. Numbers should be treated with caution given the lack of reliability of some of the data held in the CLI.

Given the high percentages of substances having classifications for acute toxicity and skin corrosion/irritation already, it is unclear whether there would large numbers of additional substances falling under Acute toxicity cat 5 or Skin corrosion cat 3 (see discussion below on efficiency). If there were, then there may be concerns that labelling leads to even greater confusion or lack of effectiveness as a communication tool, as Acute toxicity cat 4 requires labelling with the harmful pictogram (already considered to be overly common by most stakeholders) and Skin corrosion cat 3 would require the health hazard pictogram, which is considered the most misunderstood of the pictograms (see also the Task 2 report and a discussion on consumer understanding of pictograms). Although the low number of Aspiration hazard cat 1 substances implies that there could be a larger number of Aspiration hazard cat 2 substances, these would again be labelled using the health hazard pictogram.

In addition, it is of note that there is no pictogram for Aquatic acute toxicity cat 2 and 3 under the GHS, nor for Flammable liquids cat 4.

Consultation responses also expressed concern that adding these categories would lead to an increase in uncertainty over what is being communicated by the pictograms for consumer products in general. However, overall, when asked whether the EU's adoption of the different categories would have a positive impact on health and safety, the responses were generally positive, as can be seen from Table 9-2. The key exception in this respect is aspiration hazard cat 2 (where opinion is essentially split). With regard to protection of the environment, the majority indicated that adoption of acute aquatic hazards cat 2 and 3 could lead to benefits, if information were included on SDS.

Table 9-2: Manufacturer, Importer and PPP producer responses on the extent to which inclusion of the non-implemented categories would lead to health and environmental benefits (n=58)

Answer Options	Positive (No. agreeing)	Negative (No. agreeing)	Total response for category
Health and safety			
Flammable liquids, cat 4	10	6	16
Acute toxicity, cat 5	12	7	19
Skin corrosion/irritation, cat 3	13	5	18
Serious eye damage/eye irritation, cat 2A and Cat2B	12	7	19
Aspiration hazard, cat 2	7	6	13
Protection of the environment			
Acute hazards to aquatic environment, cat 2 and cat 3	13	9	22

Member State authorities were also asked whether there were any hazard categories in the GHS building blocks which should be added to CLP or, indeed, removed from it:

- One Member State suggested that Acute toxicity cat 5 should be added;
- Two Member States suggested that Aquatic acute toxicity cat 2 and 3 should be added, while two specifically indicated that these should not be added. The explanation provided by one of these latter authorities is that "From supply and use of packaged goods it is not anticipated that levels in the environment would arise higher than 1 mg/l and therefore, as explained in A9.2.1 of GHS, those categories are not normally used when considering packaged goods, but could be appropriate for the transport of bulk quantities";
- Another Member State suggested that explosives could be removed from CLP, as this is covered by transport regulations and resulted in an overlap between the two sets of legislation; and

- One Member State indicated that the hazard class "corrosive to metals" is only necessary in the GHS for transport reasons.

With respect to corrosive to metals, the Member State authority argues that this classification is not necessary for all other sectors, such as for the supply and use of chemicals, as corrosive to metals is not a hazard that reflects a threat to human health or safety (rather an indirect threat due to hazards for containers or infrastructure). It is therefore different from the other hazard classes in this respect, and that there are other examples of material incompatibilities (not only to metals) which pose a similar hazard but that are not covered by CLP.

The authority further argues that given labels are already crowded with information, it might make sense to remove this building block from CLP. To ensure that important information on "corrosive to metals" is not lost, more specific information regarding material incompatibilities would be required in Section 7 of SDS. It is further noted, that this may help clarify communication via the pictograms, as the same pictogram applies to corrosive for metals, a physical hazard, as for skin corrosion and serious eye damage cat 1, human health hazards.

Other Member State authorities noted that the current level of implementation was reviewed by CARACAL and considered appropriate, noting that the hazard categories from the GHS that are not included in CLP are not very "stringent" and it is not necessary to add them. With respect to CARACAL's role, the sub-group on ATPs to CLP was considered to have appropriate procedures in place for making decisions on whether new building blocks should be added to CLP.

9.2.3 Efficiency – costs

For the 2006 impact assessment study (RPA et al, 2006), consultees developed estimates of the number of mixtures that would change classification for the some of the non-implemented building blocks. This included work by one company which ran a sub-set of their mixtures (various consumer products) through GHS in order to develop predictions for the assessment. This company found the following (see RPA et al, 2006 for further details):

- Acute oral toxicity cat 5: 75% of detergent marketed products, 5 to 15% of perfume pre-mixes' and over 30% of hair dye pre-mixes;
- Acute dermal toxicity cat 5: between 10 and 30% of detergent marketed products and some unknown percentage of hair dye pre-mixes; and
- Skin irritation cat 3 (mild irritation): around 1.5% of detergent marketed products and 10% of hair dye pre-mixes (estimated).

A further six responses to the consulation carried out for the 2006 study, reflecting non-consumer product companies, also highlighted relatively high percentages of mixtures being classified for Acute oral toxicity in particular, and Acute dermal toxicity cat 5 (for 4 out of the 6), for example, varying from 20% to 50% of mixtures. In addition, two highlighted that Skin irritation cat 3 was likely to lead to between 20% and 50% of mixtures being classified (although the others thought none of the mixtures in their portfolios would be affected).

The modelling work carried out for the 2006 study (RPA et al, 2006) used the above data and combined them with a series of assumptions regarding the number of substances that would be classified as hazardous following REACH registration (within a Monte Carlo analysis). The model predicted that an estimated 24% of mixtures (an estimated 112,750 based on a starting assumption of 2 million mixtures being placed on the EU market) would be affected by the introduction of Acute toxicity cat 5 and Skin irritation cat 3 classifications into CLP. The associated additional costs of

including these classifications into CLP in terms of increased classification and labelling requirements for consumer products were estimated at €147 million, with a further €539 million in predicted reformulation costs due to a desire to ensure some consumer products remained unclassified[86]. No costs were included in these estimates for any testing of mixtures for classification purposes.

9.2.4 Efficiency – benefits

Given the mixed views held by Member State authorities on the value of adding these additional classifications into CLP, it is questionable whether the health and safety benefits would outweigh the estimated costs.

In order to provide an indication of what they would need to translate to in terms of the numbers of avoided future cases of skin or respiratory effects, willingness to pay values for the avoidance of a minor case of ill-health are used to calculate the number of cases that would need to be avoided to achieve a breakeven between costs and benefits.

In Section 7.3 values of €227 and €50 are used as the notional values for (or willingness to pay to avoid) the pain and suffering associated with minor cases of skin disease and occupational asthma. The figure of €50 is used here to reflect the more minor nature of the expected impacts, and to calculate the breakeven number of cases that would have to be avoided for costs to equate to benefits. The breakeven number of cases is then calculated by spreading the costs reported above for classification, labelling and reformulation over 5 years (starting in year 2 out of 10) and discounting them at 4%. The annual equivalent values were then estimated to provide the basis for estimating the number of cases of ill-health that would need to be avoided per annum to achieve breakeven. The results are:

- Classification and labelling:
  - Equivalent annual value of costs = €14,366,000
  - Implied breakeven number of cases avoided per annum: 285,080
- Reformulation:
  - Equivalent annual value of costs = €52,674,000
  - Implied breakeven number of cases avoided per annum: 1,045,310
- Total:
  - Equivalent annual value of costs = €67,039,000
  - Implied breakeven number of cases avoided per annum: 1,330,390

Note that these estimates assume that there would be no co-benefits in terms of, for example, reduced impacts on the environment or reductions in other health effects.

Although around 112,750 mixtures may be affected by this need for reclassification and labelling (and a smaller set would also be reformulated to avoid any classification), these figures for the breakeven number of cases look high, when compared to the data set out in Section 7.3. In particular, around 284,400 serious incidents were estimated to have occurred across industry due to exposure to harmful substances for the period from 2000-2016 (Section 7.3.4), and a total of around 393,500 cases of non-deliberate poisonings are estimated for the EU 28 for the period between 2000-2016. These figures reflect an average of 45,190 per year (not taking into account the

[86] For Scenario 2, which is the closest to the actual implementation deadlines within CLP. Note that the assumptions adopted in 2006 with respect to reformulation costs are comparable to those adopted for this study, and as applied in Section 6.7 above.

significant annual declines in incidents post 2010). Furthermore, these cases would need to be on top of the self-reported cases already taken into account in the numbers of occupational skin disease and asthma cases estimated in Section 7.3.6.

Given this, it is unlikely that a million more minor cases would be avoided per annum due take-up of the additional building blocks.

Furthermore, the above figures do not take into account any potential testing costs that companies may incur where the thresholds required for these additional building blocks are not adequately covered by existing studies (i.e. the studies do not report on effects at the relevant thresholds).

9.3 ATPs and transition times

Key findings:

- The EU has, to date, fully adopted and implemented changes made at the UN level into CLP, in line with the original intentions of the CLP
- Although most industry respondents to targeted consultation indicated that the 18 to 24 month transition period is adequate, others noted that it may not be for those with large product portfolios, complex supply chains and slow moving products
- SMEs that do not rely on automatic IT systems for updating classifications and labelling may face particular challenges in remaining up-to-date on changes introduced through ATPs; as a result, summary tables on the changes introduced by an ATP may help
- Approximately 81,100 substances are estimated to have been affected by the changes introduced by ATP02, with this resulting in labelling related costs of around €94.6 million
- Approximately 95,500 substances are estimated to have been affected by the changes introduced by ATP04, with this resulting in labelling related costs of around €111.3 million
- Given the limited benefits that have been identified from the changes required under ATP02 and ATP04, the costs appear to represent a disproportionate cost burden

9.3.1 Introduction

A review of the ATP process and up-dates to ECHA's guidance finds that the EU has, to date, fully adopted and implemented changes made at the UN level into CLP. This is consistent with the commitments stated in Recital (6) of CLP:

> "This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for C&L, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law".

Many of the revisions carried out to date have been for clarification purposes, definitional purposes or have involved changes in the wording of various hazard and precautionary phrases. In particular, the scope of the assessment to be undertaken concerns the changes made through the 2nd and 4th ATPs.

- The 2nd ATP concerned changes in classification criteria for several endpoints, including the introduction of new sub-categories for respiratory and skin sensitisation, criteria for long-term (chronic) aquatic hazard which may have required the collection of additional data for classification purposes, and a hazard class for hazardous to the ozone layer; and

- The 4th ATP introduced new hazard categories for chemically unstable gases and non-flammable aerosols, and changed labelling requirements for corrosivity to metals.

In procedural terms, these changes were brought in quickly after the revision to the UN GHS took place. Further details of the changes that each of these ATPS introduced and an assessment of their consequences are given below. The relevant evaluation questions are as follows (although not answered in the order presented in the table).

9.3.2 Effectiveness and efficiency – length of transition period

9.3.2.1 Manufacturers, importers and formulators (as downstream users)

The introduction of an ATP under the CLP Regulation is followed by an 18-24 month transition period that enables actors within the supply chain to respond to changes in classification and labelling as required.

A number of industry associations have indicated that it is important that CLP remains aligned with the revisions to the GHS. It is unclear whether these views relate more to a desire to adhere to the commitments that have been made or due to concerns over a loss of global harmonisation benefits. Given the fact that other regions are not adapting their systems at the same pace as the revisions are being made at the UN level, it is hard to argue strongly that there is a significant impact on harmonisation benefits (particularly given that most manufacturers and importers have not yet seemed to experience such benefits).

As part of the targeted data collection exercise, a question was asked as to whether an 18 month transition period is sufficient time to enable an appropriate response to labelling changes. Responses to these questions highlight that an 18 month period leads to efficiency losses for some companies, but not for all. Indeed, one company indicated that: *"There is a constant update of SDS due to changes in CLP. These changes arrive at a very high speed, and very often it is not possible to react in due time before another change has to be made. It is a total mess and the whole CLP strategy should be revised."*

Three quarters of formulators and manufacturers responding to this question indicated that the 18 month transition period is long enough for responding to changes in labelling required as a result of ATPs. Some noted that this period of time refers to a long standing practice within the EU, and that the ATPs should allow suppliers to anticipate the need to make changes.

However, most detergent stakeholders, as well as one quarter of formulators and manufacturers, responded that 18-24 months is insufficient as a transition period. For those indicating that 18-24 months was not sufficient, a series of reasons were highlighted as to why a longer period should be allowed. One of the more detailed comments on this issue is provided in Table 9-3.

Table 9-3: Detailed response to targeted industry consultation

The text of the UN-GHS is continually further developed by the "ECOSOC Sub-Committee of Experts on the GHS" at UNECE. A revised version of the UN-GHS text is published every two years. Resulting changes are incorporated in CLP by way of "Adaptations to technical progress" (ATPs). Furthermore, there are ATPs to update the substance list in Annex VI to the CLP Regulation. In consequence, also the users need to check their product labels and safety data sheets at least in two-year intervals, in order to adapt them to the latest version of CLP (corresponding to the current version of the UN-GHS). But many changes in the UN-GHS are only about purely formal aspects, such as editorial changes of the binding phrases for precautionary statements (e.g. 8th ATP, P502 new: "Refer to manufacturer or supplier for information on recovery or recycling" instead of P502

Table 9-3: Detailed response to targeted industry consultation
old: "Refer to manufacturer/supplier for information on recovery/recycling". However, even such editorial changes generate considerable work and cost for the changeover at the users – without improving safety for the relevant products. Moreover, the linguistic differences between H- and P-phrases within CLP and between CLP and GHS cause implementation problems in practice. These problems are intensified by faulty translations and continuous corrections in the different language versions of the CLP Regulation. Due to such deviations, the labelling of products in the market will not always have exactly the same wording, also with the information necessary for safe handling and use being given in terms of content. Example of the correction of Regulation (EC) No 1272/2008 of 10 April 2015 for the combination phrase "P305 + P351 + P338": "Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen." now reads "Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen." Cost and effort for the changeover could be reduced considerably and without quality loss for product labels and safety data sheets if clearly longer transitional periods were granted for incorporating editorial changes to the UN GHS into CLP. Urgently needed is an acceptance by public authorities of minor text deviations of Hand P-phrases, because the manufacturers cannot put into practice immediately and equally the full application of such continuous adaptations. *Source:* Industry response to targeted consultation and the Open Public Consultation

Following the review of industry stakeholder responses to the targeted consultation questionnaires, a written interview was conducted with the UN GHS Secretariat in order to follow up on some of the key issues raised throughout the study at that point. In response to the comments made by industry regarding editorial changes to pictograms, P and H phrases being made, the Secretariat responded as follows:

Table 9-4: Detailed response to targeted industry consultation
EU stakeholders have commented that there are numerous editorial changes being made to pictograms, P and H phrases, which result in significant costs to industry. Do you have any comments on the importance of the changes being made in this respect? Do you expect that the need for such changes will reduce in the future? We are not sure to which "numerous editorial changes" the question refers to in particular as regards pictograms and H phrases. We haven't identified any significant changes to the pictograms since their adoption. The only change made at the request of the Sub-Committee was a correction to the "hazardous to the environment" symbol aiming at improving its graphic quality and avoiding differences between the symbol used in the GHS and the one prescribed by legally binding instruments implementing its provisions (e.g. CLP or transport regulations). Work to rationalize and improve the hazard and precautionary statements (e.g. eliminate redundancies) started many years ago and still continues within the Sub-Committee. It is worth noting that some of the initiatives for work on this issue emanated from the European Commission (see for instance information document INF.6 (submitted at the 12th session)) and therefore we understand that EU stakeholders were (and still are) supportive of this work. Although we acknowledge the financial impact these changes may have, we consider that industry will be one of the main beneficiaries of the outcome of this work, as it is expected to reduce the number of statements needed as well to address some of the iussues identified as needing improvement. On the importance of the changes being made, we trust Sub-Committee experts and industry representatives will avoid considering changes which are not justified from a cost-benefit point of view. *Source:* UN GHS Secretariat

Factors highlighted by others as impacting the ability of some companies to comply with an 18-24 month period include:

- Large product portfolios, as a large numbers of products may be impacted, making it difficult to meet an 18-24 month time period (see also discussion below on the number of substances affected by the changes under both ATP02 and ATP04);
- Awareness of the upcoming change before publication by following on-going discussions; only becoming aware of the need to make changes after publication may result in 18-24 months being inadequate;
- Slow-moving (speciality) products or products which are sold in packaging which has labels printed directly onto the packaging (e.g. aerosol cans, plastic paint pots, etc.). The 18-24 month transition period can result in stock management problems, as stocks are usually held in labelled packaging, and as soon as a change occurs then those stocks must either be sold as soon as possible or relabelled. This can be a problem for those with slow moving products, as well as those that print labels directly onto the product packaging. In such cases, stocks of labels (which can be costly to print) or of pre-printed containers/packaging may have to be thrown away and replaced with new labels or containers
- Complex supply chains involving several layers; 18-24 months may be sufficient for manufacturers within these supply chains, as well as for first tier formulators, but not for those further downstream; and
- The time taken by providers of the IT tools used to help in updating labels and SDS; some providers can take more than a year to implement all of the changes brought about by an ATP into their tools, with this meaning that companies cannot implement all of the changes required within the remaining period.

Companies also noted that when an ATP brings in new classification categories, such changes may trigger downstream legislation, as well as new labelling (and in some cases reformulation). These impacts have to be taken into account by the supplier in relation to their own operations, but also with respect to the impacts downstream. In some cases, suppliers themselves undertake an "impact analysis" of the products that are affected by an ATP, so that they can communicate this to businesses impacted by the change. Updating SDS, labels, re-labelling current inventories and sending a communication to customers takes time to make sure all people are aligned.

Respondents also noted that the feasibility of the transition period will be dependent on the type of product affected. For example, in the case of standard paint products, an 18-24 month period is sufficiently long enough for responding to labelling changes. However, in the case of biocidal products, an 18-24 month transition period is not deemed sufficient as the re-registration process may take longer. For other products higher up in the supply chain, 18 months may be sufficient for suppliers but not for downstream users (i.e. formulators), who will also have to make label changes; this is especially the case where there are complex supply chains involving products comprised of mixtures of mixtures.

Such respondents therefore suggested a period of 24-36 months (or longer) would be more appropriate, while others indicated that there may be merit in differentiating the transition period depending on whether the change was minor (editorial changes in H and P phrases) or major changes (safety relevant). The suggestion is that minor changes should be phased in over a longer transition period and at a reduced frequency (e.g. every 5 years – so not in line with the UN revision

process). Major changes, however, should be phased in immediately and within the 18-24 month period.

These suggestions would appear to be in line with a desire to ensure and improve both the effectiveness and efficiency of ATPs introducing new classification categories and labelling changes.

9.3.2.2 Member State Authorities

From their perspective, most Member State authorities have indicated that the transition times appear appropriate with respect to both the introduction of minor editorial changes and the introduction of new hazard categories. With respect to the latter types of changes, they are considered important in ensuring the effectiveness of the CLP in terms of identifying new hazards and communicating information on these.

9.3.3 Efficiency - support to duty holders

Member State authorities noted that SMEs may face difficulties in remaining up to date with respect to the overall process and the timing of when changes need to be made. From their perspective, this was considered to be more of an issue of communication than the length of the transition period.

Although national helpdesks may offer reliable information on deadlines/transitional periods, they also recognise that the existence of several overlapping transition times could be a problem, especially for SMEs who may lack the necessary overview. One recommendation for addressing this communication need was for either the Commission or ECHA to produce a consolidated table/document setting out the changes in requirements in a standalone tabular format. Not only should it be easy to compile such a table, but it would also provide a more accessible way of communicating changes to SME companies (particularly those that are not members of an industry association).

Interviews with a small number of companies acting as suppliers of classification and labelling services have indicated that they do not believe the types of changes that have been made to date will have led to significant difficulties for most EU companies, including SMEs. Classification and labelling IT providers within the EU tend to update their systems 3 to 4 times a year. They take such changes into account when making these updates (and changes resulting from ATPs for CLH purposes).

Thus, for users of these services, changes to the wording of hazard and precautionary phrases should be made automatically made to labels and to SDSs; similarly, changes in classifications resulting from the CLH process will be automatically carried through. This does not mean that companies relying on such systems will not face costs in re-labelling (especially, if changes result in the need to redesign a label), only that they should be lower than for those who do not rely on such IT systems.

These service providers did note though that there will be small companies (and potentially many) that do not rely on an IT system to produce their labels. As a result, these companies are likely to face much more significant costs from the need to respond to these ATPs. This was also highlighted by interviews with industry representatives (e.g. the German BDI), who noted that micro and small enterprises who do not rely on sophisticated IT systems struggled to remain up-to-date and compliant with all of the changes that were required.

9.3.4 Costs and benefits from ATP02

Regulation 286/2011 of March 2011 represented the second ATP (ATP02) to CLP and introduced updates to reflect GHS revision 3. ATP02 introduced the following (main) changes:

- For respiratory and skin sensitisation, addition of sub-categories 1A/1B for substances where there are sufficient data to allow sub-categorisation;
- For long-term hazards to the aquatic environment (Chronic 1, 2 and 3), retaining the existing criteria for substances where there are no adequate chronic toxicity data and introducing new classification criteria for substances for which there are adequate chronic toxicity data available (also differentiating on the basis of rapidly versus non-rapidly degrading substances);
- Adding a new hazard class for substances and mixtures hazardous to the ozone layer; and
- Changes to hazard statements and label elements for substances and mixtures.

Regarding the changes in classification, ATP02 will have led to some level of cost impact owing to the need to alter SDS and other information. However, as the change in classifications on, for example, chronic aquatic toxicity allow a lower category/no classification for substances with the appropriate level of information, it can be assumed such changes would be made/required only where there was a net benefit in doing so. Thus, from industry's perspective, any costs might be perceived as being outweighed by the benefits of substances having a lower classification. As such, such changes are (at least) cost neutral.

In contrast, changes in the label elements may have given rise to more significant costs. Although relatively few in number compared with later revisions to GHS, these changes affected a large number of substances (including those subject to changes in classification in the above). The changes to the label elements contained within APT02 are summarised in Table 9-4 below for each of the affected classifications.

9.3.4.1 Changes in labelling elements

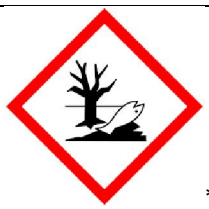
As can be seen from the table, most of the changes relate to slight alterations to the artwork of GHS pictograms 09 and 07. These changes alone would affect 98,993 substances on the current (June 2016) version of the CLI (80% of the total). The (then) new hazardous to the ozone layer class applies to 61 substances on the CLI (0.05% of the total), 37 of which would also be affected by the changes to pictograms. All changes in the table bring the total to 99,017 substances on the current CLI (80% of the total).

Estimated numbers of products re-labelled

ATP02 applied to substances from 1 December 2012 and to mixtures from 1 June 2015. However:

- substances classified, labelled and packaged under the previous arrangements and placed on the market before 1 December 2012 were not required to be relabelled and repackaged in accordance ATP02 until 1 December 2014; and
- mixtures placed on the market before 1 June 2015 were not required to be relabelled and repackaged in accordance with ATP02 until 1 June 2017.

In 2012, the CLI contained information on an estimated[87] 101,400 substances. Applying the numbers and percentages presented above suggests the following numbers of substances were affected by the label changes in ATP02 in 2012:

Table 9-5: Amendments and changes to label elements in ATP02		
Class.	**Status**	**Description**
Aquatic Acute 1	Changed	• New GHS09* pictogram
Aquatic Chronic 1, 2	Changed	• New GHS09* pictogram
Aquatic Chronic 3 and 4	No Changes	• Legal text edited to refer to "long-term aquatic hazard" rather than "chronic aquatic hazard"
Hazardous to the Ozone Layer	Changed	• Table 5.2 label elements Exclamation mark (GHS07) pictogram required • Table 5.2 label elements **Warning** (previously Danger) • Table 5.2 label elements Changed to H420 (was EUH509) with new hazard statement • Table 5.2 label elements Changed **From** "Avoid release to the environment. Dispose of contents/container to …… in accordance with local/regional/national/international regulation (to be specified)" **to** "Refer to manufacturer/supplier for information on recovery/recycling"
Respiratory sensitisation 1 (1A/1B)	No Changes	• No label changes (text edited to account for possibility of 1A/1B division) • Edited to include 1A/1B sub-categories
Skin sensitisation 1 (1A/1B)	Changed	• New GHS07** pictogram required (Legal text also edited to account for possibility of 1A/1B division) • Legal text edited to include 1A/1B sub-categories
Acute toxicity — inhalation 4	Changed	• New GHS07** pictogram
Acute toxicity — oral 4	Changed	• New GHS07** pictogram
Acute toxicity — dermal 4	Changed	• New GHS07** pictogram
Skin irritation 2	Changed	• New GHS07** pictogram
Eye irritation 2	Changed	• New GHS07** pictogram
Specific target organ toxicity — single exposure; respiratory tract irritation 3	Changed	• New GHS07** pictogram
Specific target organ toxicity — single exposure; narcosis 3	Changed	• New GHS07** pictogram
 *Old GHS09		 *New GHS09

[87] Based on data from the CLI applied in work completed by RPA in 2012. From that work 93,169 substances on the CLI had one or more human health or environmental classifications. 92% of substances on the current CLI have one or more human health or environmental classifications which implies the total given.

Table 9-5: Amendments and changes to label elements in ATP02		
Class.	**Status**	**Description**
 **Old GHS07		 **New GHS07

- alterations to the artwork of GHS07 and GHS09 = ~81,000 substances – 80% of substances on the CLI;
- new hazardous to the ozone layer class = ~50 substances – 0.05% of substances on CLI; and
- All changes = ~81,000 substances – 80% of substances on the CLI.

Section 7.3 provided information on the estimated number of substances on the CLI in 2010, based on the number of substances with classifications on the current registration database as well as information from IUCLID. From these data, an estimate has been derived of the numbers of substances (registered and not registered) on the CLI at the time of ATP02.

As the ATP02 requirements coincided with the registration of 100-1000t substances in 2013, by comparing databases over the period, an estimate has been made of the number of 100-1000t substances that changed classification (and hence labels, SDS etc.) owing to the generation of new information. These have been deducted from the total number of substances with classifications to provide an estimate of the total number of substances with a classification on the CLI in 2012 potentially affected by changes to labels/SDS owing to requirements in ATP02 (and not those of REACH).

As noted, an estimated 80% of these substances would have to change labels to make them consistent with the new requirements. Table 9-5 provides the estimated total number of substances on the CLI in 2012 and the number affected by the changes in ATP02.

Table 9-6: Number of substances affected by labelling changes under ATP02 of CLP			
	Estimated number of substances on CLI 2012		Number of substances requiring a change in label (80.2%)
	Total with a classification	Number not changing class. owing to registration 2013	
NONS (Full)	1,035	1,035	830
NONS (intermdiate)	10	10	8
Registered >1000t	1732	1,732	1,389
Registered 100-1000t	719	451	362
Registered 10-100t	226	226	181
Registered 1-10t	198	198	159
Registered Confidential	45	45	36
Registered Intermediate	1304	1,304	1,046
On IUCLID but not yet registered	3,720	3,720	2,984
Implied not registered and not on IUCLID 2005 but on CLI	92,412	92,412	74,133
Total	**101,401**	**101,133**	**81,128**

9.3.4.2 Number of manufacturers' products changing labels

As substances may be manufactured/imported by more than one manufacturer or importer, labelling changes for a substance will apply to all relevant manufacturers and importers. As reported earlier, the analysis of the REACH registration database that we conducted for the DG GROW study *Monitoring the Impact of REACH in Innovation, Competitiveness and SMEs*[88] suggests the average numbers of manufacturers /importers per substance in Table 9-6 for each type of registration.

Table 9-7: Average number of MIs per substance			
	Large MIs	SME MIs	Total
Fully registered (including NONS)	4.90	0.86	5.76
Intermediates (also applied to all other substances on the CLI including <1t substances)	1.39	0.15	1.55

Applying these values to the number of substances for which a change in labelling is required (Table 9-5) provides the total number of manufactured products changing labels to make them compliant with the requirements in ATP02 over the transition period of two years.

However, a proportion of manufacturers would have made changes to labels within this time frame for reasons other than CLP. As part of targeted data collection, industry was asked "*On average, how often would you expect to modify or redesign the labels on the products that you place on the market for reasons other than CLP and REACH (i.e. for marketing reasons or to respond to changes in consumer demand)*". Responses to this question suggest that, overall, almost 70% of products, whether substances or mixtures, would normally retain the same labels for over 24 months but that 30% would normally change their labels within this time frame (for reasons of marketing or changes in consumer demand, etc.).

As a result, overall, the labelling changes under ATP02 are likely to have required an early change in labels in 70% of cases. Applying this percentage, to the number of substances changing labels (Table 9-5) multiplied by the average number of manufacturers and importers per substance provides the total number of manufactured chemical products changing label owing to ATP02 of CLP alone. These figures are given in Table 9-7.

As noted in Section 6.5 on transition costs, the estimated average cost of making a label change is €300 per substance per manufacturer or importer. Applying this figure to the costs of making the changes arising from ATP02 provides the estimated total costs of labelling changes as a result of implementing these revisions within the 24 month transition period. The results are presented in Table 9-8, and suggest that ATP02 of CLP led to costs of almost €95 million to manufacturers and importers of substances.

[88] http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

Table 9-8: Number of chemical products changing label owing to ATP02 of CLP alone			
	Large MIs	SME MIs	Total
NONS (Full)	2,845	502	**3,347**
NONS (intermediate)	8	1	**9**
Registered >1000t	4,761	840	**5,602**
Registered 100-1000t	1,241	219	**1,460**
Registered 10-100t	620	109	**730**
Registered 1-10t	545	96	**641**
Registered Confidential	123	22	**145**
Registered Intermediate	1,018	113	**1,132**
On IUCLID but not yet registered	2,905	323	**3,229**
Implied not registered and not on IUCLID 2005 but on CLI	254,112	44,848	**298,961**
Total	**268,180**	**47,075**	**315,255**

Table 9-9: Costs of chemical products changing label owing to ATP02 of CLP alone			
	Large MIs	SME MIs	Total
NONS (Full)	€ 853,500	€ 150,600	**€ 1,004,100**
NONS (intermediate)	€ 2,400	€ 300	**€ 2,700**
Registered >1000t	€ 1,428,300	€ 252,000	**€ 1,680,600**
Registered 100-1000t	€ 372,300	€ 65,700	**€ 438,000**
Registered 10-100t	€ 186,000	€ 32,700	**€ 219,000**
Registered 1-10t	€ 163,500	€ 28,800	**€ 192,300**
Registered Confidential	€ 36,900	€ 6,600	**€ 43,500**
Registered Intermediate	€ 305,400	€ 33,900	**€ 339,600**
On IUCLID but not yet registered	€ 871,500	€ 96,900	**€ 968,700**
Implied not registered and not on IUCLID 2005 but on CLI	€ 76,233,600	€ 13,454,400	**€ 89,688,300**
Total	**€ 80,453,400**	**€ 14,121,900**	**€ 94,576,800**

9.3.5 Costs and benefits from ATP04

Regulation 487/2013 of May 2013 represented the fourth ATP (ATP04) to CLP and introduced updates to CLP to reflect GHS revision 4. ATP04 contains amendments concerning: new hazard categories for chemically unstable gases and non-flammable aerosols; and further rationalisation and editorial changes to precautionary statements.

The latter amendments will have had the largest impacts in terms of the numbers of substances affected by the changes, the majority of which are editorial. These changes are summarised in a table in Annex 3 to this report, which provides the original and new (ATP04) text of the precautionary statements that apply to each type of classification.

As can be seen from the table given in Annex 3, a large number of classes were affected by these editorial changes. In most cases, revisions to the precautionary statements are relatively minor and there is no substantial change in the message being communicated (and hence no significant benefit from the changes). For others, the changes made could be viewed as potentially having greater

merit in terms of terms of the clarity of communication but the benefit may still not be clear or significant. This latter group have been labelled 'B' in the table.

Another group of editorial changes have a moderate impact on the character length of the phrase and, hence, could be viewed as being more convenient for the manufacturer if provided as an optional alternative phrase as opposed to the compulsory change that they represent. This group has been labelled 'C' in the table (and the amendments referred to are shaded in grey).

Finally, some additions represent more substantive changes. These have been labelled as 'X' in the table and all represent the addition of new hazard categories for chemically unstable gases and non-flammable aerosols. As these affect a very small number of substances, both the costs and the benefits will have been minimal.

The following numbers of substances on the current CLI (June 2016) would be affected by the amendments listed in the table:

- More substantive additions (labelled X in the table) = 12 substances – 0.01% of the total on the CLI (there are no Aerosols 3 on the CLI or on the OECD Echem database);
- The above plus editorial changes of potentially greater merit (but no significant benefits) (labelled B in the table) = 8,064 substances – 6.5% of substances on the CLI; and
- All changes and amendments = 99,929 substances – 81% of substances on the CLI.

9.3.5.1 Estimated numbers of products re-labelled

ATP04 applied to substances from 1 December 2014 and to mixtures from 1 June 2015. However:

- Substances classified, labelled and packaged under the previous arrangements and placed on the market before 1 December 2014 were not required to be relabelled and repackaged in accordance ATP04 until 1 December 2016; and
- Mixtures placed on the market before 1 June 2015 were not required to be relabelled and repackaged in accordance with ATP04 until 1 June 2017.

In 2014, the CLI contained information on an 117,945[89] substances. Applying the numbers and percentages presented above suggests the following numbers of substances were affected by the changes described above in 2014/15:

- More substantive additions (labelled X in the table) = ~10 substances (there were no Aerosols 3 on the CLI or on the OECD Echem database);
- The above plus editorial changes of potentially greater merit (but no significant benefits) (labelled B in the table) = 7,700 substances; and
- All changes and amendments in the table = 95,500 substances.

Table 9-9 provides the estimated total number of substances on the CLI and the number affected by the changes in ATP04 by registration status.

[89] Based on data from the CLI applied in work completed by CSES, RPA and Oekopol (2015).

Table 9-10: Number of substances affected by labelling changes under ATP04 of CLP		
	Estimated number of substances on CLI 2014	Number of substances requiring a change in label (81%)
NONS (Full)	1,035	838
NONS (intermdiate)	10	8
Registered >1000t	1,732	1,402
Registered 100-1000t	1,094	886
Registered 10-100t	467	378
Registered 1-10t	467	378
Registered Confidential	123	100
Registered Intermediate	2,184	1,768
On IUCLID but not yet registered	3,720	3,012
Implied not registered and not on IUCLID 2005 but on CLI	107,113	86,718
Total	**117,945**	**95,488**

9.3.5.2 Number of manufacturers' products changing labels

As noted in relation to ATP02, substances may be manufactured/imported by more than one company and labelling changes for a substance will apply to all manufacturers/importers. Thus, the same approach is used here as for ATP02 (Table 9-7). Applying the different estimates for number of companies per substance to the number of substances for which a change in labelling is required (Table 9-6) provides the total number of manufactured products changing labels to be compliant with the requirements in ATP04 over the transition period of two years. As with ATP02, a proportion of manufacturers would have made changes to labels within this time frame for reasons other than CLP, and for consistency it is assumed that the labelling changes under ATP04 are likely to have required an early change in labels in 70% of cases.

Applying all of the above assumptions to the number of substances changing labels (Table 9-9) yields the total number of manufactured chemical products changing label owing to ATP04 of CLP alone. These results are presented in Table 9-10. Applying the estimate that labelling changes cost €300 per manufacturer or importer per substance (as used for estimation of transition costs) provides the total costs of labelling changes under ATP04 as given in Table 9-11.

It is important to note that the estimates provided in Table 9-10 below and 9-8 for the 2nd ATP relate to substances alone. It has not been possible to estimate the number of mixtures affected due to a lack of data, but the figures are likely to have been significant.

Table 9-11: Number of chemical products changing label owing to ATP04 of CLP alone			
	Large MIs	SME MIs	Total
NONS (Full)	2,872	507	**3,379**
NONS (intermediate)	8	1	**9**
Registered >1000t	4,806	848	**5,654**
Registered 100-1000t	3,037	536	**3,573**
Registered 10-100t	1,296	229	**1,524**
Registered 1-10t	1,296	229	**1,524**
Registered Confidential	343	60	**403**
Registered Intermediate	1,721	192	**1,913**
On IUCLID but not yet registered	2,933	326	**3,259**
Implied not registered and not on IUCLID 2005 but on CLI	297,251	52,462	**349,713**
Total	**315,562**	**55,390**	**370,952**

Table 9-12: Costs of chemical products changing label owing to ATP04 of CLP alone			
	Large MIs	SME MIs	Total
NONS (Full)	€ 861,600	€ 152,100	**€ 1,013,700**
NONS (intermediate)	€ 2,400	€ 300	**€ 2,700**
Registered >1000t	€ 1,441,800	€ 254,400	**€ 1,696,200**
Registered 100-1000t	€ 911,100	€ 160,800	**€ 1,071,900**
Registered 10-100t	€ 388,800	€ 68,700	**€ 457,200**
Registered 1-10t	€ 388,800	€ 68,700	**€ 457,200**
Registered Confidential	€ 102,900	€ 18,000	**€ 120,900**
Registered Intermediate	€ 516,300	€ 57,600	**€ 573,900**
On IUCLID but not yet registered	€ 879,900	€ 97,800	**€ 977,700**
Implied not registered and not on IUCLID 2005 but on CLI	€ 89,175,300	€ 15,738,600	**€ 104,913,900**
Total	**€ 94,668,900**	**€ 16,617,000**	**€ 111,285,300**

9.3.6 Proportionality of the cost burden of ATP02 and ATP04

The total costs of ATP02 and ATP04 combined are provided in Table 9-12, with these being around €63.5 million. Given the limited benefits that have been identified as being associated with these changes, they are considered to reflect a disproportionate cost burden.

This cost burden stems from the need for companies to change the P and H phrases on labels, as well as to update the "hazardous to the environment" pictogram. Actions that could be taken to reduce such a burden in the future include the following:

- Minimising small changes in the wording of phrases to only those that are essential;
- Providing extended periods of time for changes in labelling to be made, so that both substance and mixture manufacturers are able to adopt label text as the change their artwork or revise labels for changes in product ingredients.
- To date, transition periods of 18 to 24 months have been allowed, with these being too short for most products. Consultation found that almost 70% of products, whether substances or mixtures, would normally retain the same labels for over 24 months (and up to much longer periods, e.g. 5-10 years in some cases) with only 30% normally changing

their labels within this time frame (for reasons of marketing, changes in consumer demand, reformulation, etc.).

Table 9-13: Number of chemical products changing label owing to ATP02 and ATP04 of CLP			
	Large MIs	SME MIs	Total
Costs of ATP02	€ 80,453,400	€ 14,121,900	€ 94,576,800
Costs of ATP04	€ 94,668,900	€ 16,617,000	€ 111,285,300
Total	**€ 175,122,300**	**€ 30,738,900**	**€ 205,862,100**
No of companies[1]	**515**	**10,253**	**10,768**
Cost per company (rounded to nearest 100)	**€ 339,900**	**€ 3,000**	**€ 19,100**
Note 1: Numbers of companies based on NACE Codes 19.20, 20.13,20.14,20.53,24.41,20.43, 24.44, 24.45			

It is of note that other countries have not adopted changes introduced at the UN level at the same frequency, with some (such as the US adopting them over a 5 year period).

9.3.7 Transparency and stakeholder involvement in ATP procedures

With respect to transparency, several Member States have indicated that some phases of the ATP process are not transparent enough in their view. Comments specific to non-CLH ATPs include:

- *"…the approach taken for the different types of ATP – whether HCL or non-HCL related – needs to be more consistent, as there can be different approaches used presently depending on whether the focus of the ATP is HCL or non-HCL…";*
- *"ATPs under discussion are almost unknown until they are published"; and*
- *"Procedures for introducing ATPs could be more transparent, and would benefit from a full public consultation within sufficient time before a decision is taken. This would enable broader public consultation and engagements with all the relevant stakeholders*".

The view was expressed though that even if the procedures are transparent, the number of changes being introduced by the ATPs, the frequency of the changes and the fact that 18-24 months are given to comply means that the situation is getting increasingly complex. The process is currently leading to confusion and uncertainty, which is not helped by the length of time it takes to correct obvious mistakes with the ATPS or in the different language versions.

From an industry perspective, the lack of transparency for companies that do not have the resources or sophisticated understanding of the processes can lead to indirect or "hassle" costs; they have to expend additional resources in order to ensure that they are introducing the correct changes in an efficient manner, or to try and keep aware of what is coming in the future so as to avoid stock-management issues, re-labelling or the need to dispose of invalid labels or printed packaging.

The current process was also considered by a Member State authority to lack sufficient input or involvement of physical hazard experts. The suggestion in this respect is that DG Move also be involved in the ATP process, alongside DG GROW and Environment. This would help ensure that all three CLP hazard endpoints are considered equally; indeed, for such involvement to be effective, DG MOVE should be involved in the UN SCEGHS where the decisions are originally taken.

10 The Safeguard Clause and Urgency Procedure

10.1 Introduction

Recital 68 of the CLP Regulation states that:

> *"a safeguard clause should be provided to address situations where a substance or a mixture constitutes a serious risk to human health or the environment, even if, in compliance with this Regulation, it is not classified as hazardous. Should such a situation occur, action at the UN level may be necessary in view of the global nature of trade in substances and mixtures".*

This clause is then provided for in Article 52 of CLP and can be enacted where: "a Member State has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision" (Article 52.1).

Under Article 54(4) of the CLP Regulation, an urgency procedure is provided for and this can be followed when "*the normal time limits for the regulatory procedure with scrutiny cannot be complied with, …"*. This draws on the potential need for such a procedure as foreseen by Decision 1999/468/EC[90] as amended in 2006 by Decision 2006/512/EC as being needed to enable simplified decision making procedures in certain circumstances.

A specific evaluation question was developed with respect to the use of the safeguard clause, but more generally, additional questions related to effectiveness and efficiency, relevance and coherence have been selected for the evaluation of these specific elements of CLP.

Table 10-1: Evaluation questions relevant to the safeguard clause and urgency procedure

Q#	Evaluation Question
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.4.7.	To what extent is the use of the safeguard procedure effectively and consistently implemented across Member States or by the Commission?
2.2.4.	Are the provisions and procedures for hazard/risk identification and assessment efficient?
3.1.1.	Do the original needs still exist or are parts of the chemicals legislative framework now redundant?
	To what extent do the risk assessment procedures and risk management decisions take into

[90] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ: L184/07/1999.

Decision 2006/512/EC amending Decision 99/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ:L200/11/2006.

Table 10-1: Evaluation questions relevant to the safeguard clause and urgency procedure	
Q#	**Evaluation Question**
3.3.1.	account the latest scientific findings?
4.1.2.	To what extent are the legal acts of the chemicals legislative framework coherent in terms of: 4.1.2.1. Hazard identification

10.2 Safeguard procedure

Key findings:

- The only example of the use of the safeguard procedure under CLP is the Netherlands Decree regarding the packaging and labelling of electronic cigarettes and refillable cartridges
- No other Member State authority responding to consultation has considered use of the safeguard procedure
- Member States views on its use are mixed: some consider it an important possibility for emerging risks and others believing that its use leads to a lack of harmonisation across the single market; others note that if CLP is functioning properly, the safeguard procedure should not be required, and that it should not be used to force early implementation of provisions in other legislation.

10.2.1 Extent of use of the safeguard procedure

As part of the targeted data collection, Member State authorities were asked if they have ever considered using the safeguard procedure under CLP. All respondents indicated that they had not.

The exception to this is the Netherlands, which is the only Member State to have made use of the safeguard clause provisions. In 2014, the Netherlands introduced a Decree[91] regarding the packaging and labelling of electronic cigarettes and refillable cartridges or tanks. The Decree, which was brought in to act as a bridging measure while waiting for implementation of the revised Tobacco Products Directive (2014/40/EC) (and to be repealed once this Directive is implemented in 2016), requires that electronic cigarettes and the refills are childproof and protected against leaks, and that refills have childproof fastenings. The decree also sets conditions on the volume of liquid that a refill cartridge can hold, as well as on its nicotine concentration, the need for contents to not be dangerous for human health when in a heated or unheated state, and the presence of certain additives. Several additional labelling and packaging related requirements are set out, including the need for use instructions, and requirements for outer packaging; the latter includes warning statements on the hazards of the product and the need to keep it out of the reach of children.

It is of note that the Dutch Government initially notified the European Commission of its draft Decree under the technical standards Directive (98/34/EC), but following Commission comments brought the measures into place under the Article 52 safeguard clause. The Dutch Government

[91] Decree of 24 November 2014, regarding temporary regulations with regard to the electronic cigarette (Temporary Commodities Act Decree for electronic cigarette), TRIS notification 2014/324/NL.

argued that this measure was needed to ensure that consumers are provided with information on product packaging regarding the dangers of e-cigarette use, the nicotine strength of the cigarettes and correct use.

10.2.2 Effectiveness and efficiency considerations

10.2.2.1 Effectiveness in protecting public health

The overall justification of the Dutch decree was the importance of protecting public health, and in particular small children and those that may become addicted to nicotine. The estimated cost of introducing these measures to industry was around €560,000. No estimates are given on the potential benefits within the Decree.

However, data are available from RAPEX for poisoning incidents from the liquids used in electronic cigarettes[92], and the Electronic Cigarette Industry Trade Association (ECITA) publishes RAPEX alerts for products which are used in electronic cigarettes or the device itself. A lot of these alerts relate to the content of the liquid in which the nicotine content of the liquid is not correctly indicated (lacking any reference to it on the label)[93,94] a lack of safety information on the label, and the lack of child resistant fastenings.[95 96 97 98]

Most incidents have been caused through ingestion of the liquid by small children, small doses of which can cause serious harm to a small child due to the levels of nicotine. Figure 12-2 illustrates the increase in incidents of poisoning in the UK including the primary route of exposure. (Note that these poisoning incidents should be accounted for in the UK data used in Section 7 to estimate benefits of reductions in incidents over time due to CLP and other factors).

Against this background, one can see the importance of the measures brought in by the new Tobacco Products Directive (2014/40/EU), and the assumed benefits underlying the Dutch decree.

[92] The Guardian (2014): E-cigarette poisoning figures soar as vaping habit spreads across UK, available at http://www.theguardian.com/society/2014/apr/14/e-cigarette-poisoning-figures-soar-adults-children

[93] ECITA (2015): Rapex Alert - MAX E-liquid A12/ 0414/ 15, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-max-e-liquid-a12-0414-15

[94] ECITA (2015): Rapex Alert - Dekang A12/ 0419/ 15, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-dekang-a12-0419-15

[95] ECITA (2015): Rapex Alert - euliQuid E-liquid A12/0199/15 Week 6, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-euliquid-e-liquid-a12019915-week-6

[96] ECITA (2015): Rapex Alert - Special smoke A12/0890/14 - Week 24, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-special-smoke-a12089014-week-24

[97] ECITA (2015): Rapex Alert - Special smoke A12/0915/14 - Week 24, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-special-smoke-a12091514-week-24

[98] ECITA (2015): Rapex Alert - Feellife A12/1204/14 - Week 21, available at http://www.ecita.org.uk/rapex-alerts/rapex-alert-feellife-a12120414-week-21

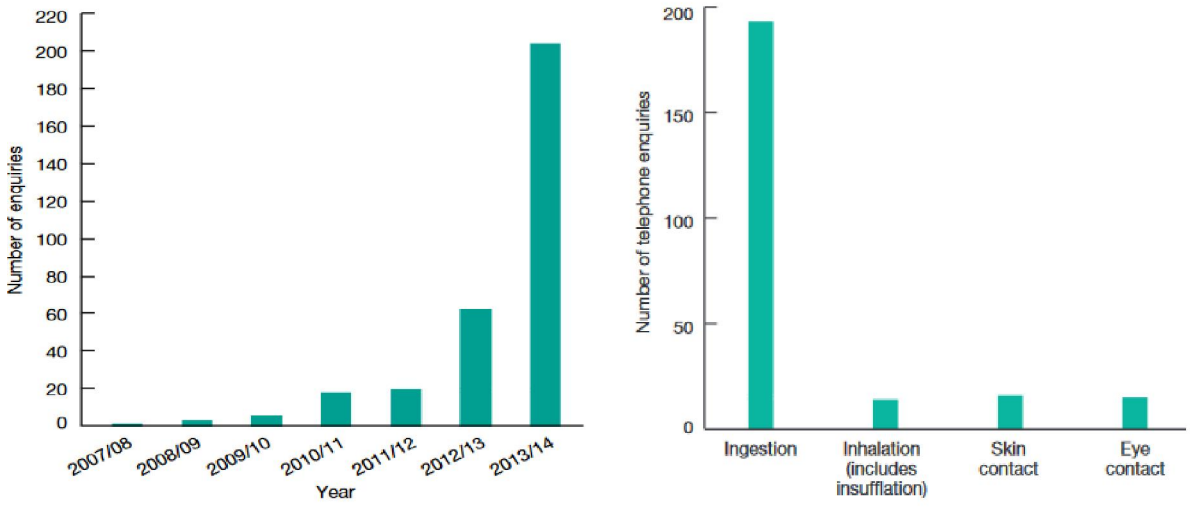


Figure 12-2: Number of enquiries about e-cigarettes to the UK National Poisons Information Service from 2007/08 to 2013/14 and Telephone enquiries on e-cigarettes in 2014/15 by route of exposure

Source: National Poisons Information Service (2014): Report 2013/14, available at http://www.npis.org/NPISAnnualReport2013-14.pdf

10.2.2.2 Procedural effectiveness

With respect to this procedure, we consider effectiveness and efficiency in terms of its role as an element of CLP and its intention as an element of CLP. In this respect, it is important to recognise that one of the conditions of the safeguard clause is that there should be "a serious risk, even if not classified in compliance with the Regulation". Thus, the clause can only be used in exceptional cases, and in such cases may be a very effective and efficient way of addressing such a risk.

Interestingly, Member State views on the safeguard clause are mixed. Some believe that it is important that the clause remains in CLP, so that it can be drawn upon if there is an emerging issue that needs to be addressed quickly or if there are systems already in place and that a Member State does not want to lose in the short term. In this respect, it is seen as an important instrument, particularly in terms of providing a means of protecting consumers from hazardous products. However, some of these Member States also stress that the focus should be on achieving EU harmonised measures. From this perspective, because the clause allows a speedier process for taking action, it is viewed as both effective and efficient with respect to protecting human health and the environment.

Others note that it if CLP is functioning properly, it should not be necessary to use the safeguard procedure (suggesting that the need to use the procedure would result from CLP not effectively delivering its objectives). In particular, these authorities indicate that the safeguard clause should not be used to force early implementation of provisions in other EU legislation. In this respect, they are concerned that granting the Netherlands a temporary measure under the CLP safeguard clause may be seen as setting precedent for the early adoption of other measures already agreed at the EU level by other Member States. This would have impacts for the single market and overall efficiency.

10.2.3 Original needs, scientific findings and coherence

In terms of the relevance and coherence of the safeguard clause, we believe this is most appropriately assessed in terms of:

- Whether the original needs still exist;
- The relevance of the process in terms of enabling risk management decisions to take into account latest scientific findings; and
- The coherence of the clause and its use with other legislation.

Based on the discussion provided above, it is clear that some Member States do believe that the original needs underlying the inclusion of the safeguard clause into CLP continue to exist, even if they may not be called upon except in exceptional circumstances. In particular, the clause may be relevant to enabling Member States and the Commission to take action in response to emerging scientific evidence of a serious risk.

The existence of a safeguard clause in CLP is also coherent with the REACH Regulation and the Biocidal Products Regulation, for example. Article 129 of REACH enables a Member State to take provisional measures (e.g. introduce a restriction) where it has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a mixture or in an article. The steps involved in implementing the procedure under REACH are similar to those under CLP and both refer to Decision 1999/468/EC with respect to decision making. Article 88 of the Biocidal Products Regulation enables use of the safeguard clause to restrict or prohibit the sale of a product, with the process again being similar (although the timing varies slightly.

Table 10-2 provides a summary of the safeguard clauses included in key chemicals legislation. As show by this table, there is good coherence between when and how such actions can be taken under these pieces of legislation.

Table 10-2: Safeguard clause under various European laws					
REACH (1907/2006/EC)	**CLP (1272/2008/EC)**	**Toys Safety Directive (2009/48/EC)**	**Detergents (648/2004/EC)**	**Cosmetics (1223/2009/EC)**	**Biocides (528/2012/EC)**
Article 129: **Safeguard clause** 1. Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a preparation or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. 2. **The Commission shall take a decision in accordance with the procedure referred to in Article 133(3) within 60 days** of receipt of the information from the Member State. This decision shall either: (a) authorise the	**Article 52:** **Safeguard clause** 1. Where a Member State has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision. 2. **Within 60 days of receipt of the information from the Member State**, the Commission shall in accordance with the regulatory procedure referred to in Article 54(2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.	**Article 43:** **Community safeguard procedure** 1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Community legislation, the Commission shall **without delay** enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall **immediately communicate** it to them and the relevant economic operator or operators. 2. If the national measure is considered justified, all Member States shall take	**Article 15:** **Safeguard clause** 1. Where a Member State has justifiable grounds for believing that a specific detergent, although complying with the requirements of this Regulation, constitutes a risk to safety or health of humans or of animals or a risk to the environment, it may temporarily prohibit the placing on the market of that detergent in its territory or make it temporarily subject to special conditions. It shall immediately inform the other Member States and the Commission thereof, giving the reasons for its decision. 2. After consultation of the Member States, or, if appropriate, of the relevant technical or scientific committee of the Commission, a decision shall be taken on the matter **within ninety days** in accordance with the procedure referred to in Article 12(2).	**Article 27:** **Safeguard clause** 1. In the case of products meeting the requirements listed in Article 25(1), where a competent authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted. 2. The competent authority **shall immediately c**ommunicate to the Commission and the competent authorities of the other Member States the measures taken and any supporting data. For the purposes of the first subparagraph, the information exchange system provided for in	**Article 88:** **Safeguard clause** Where, on the basis of new evidence, a Member State has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment, it may take appropriate provisional measures. The Member State shall, **without delay**, inform the Commission and the other Member States accordingly and give reasons for its decision based on the new evidence. The Commission shall, by means of implementing acts, **either permit the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.** Those implementing acts shall be adopted in

Table 10-2: Safeguard clause under various European laws					
REACH (1907/2006/EC)	**CLP (1272/2008/EC)**	**Toys Safety Directive (2009/48/EC)**	**Detergents (648/2004/EC)**	**Cosmetics (1223/2009/EC)**	**Biocides (528/2012/EC)**
provisional measure for a time period defined in the decision; or (b) require the Member State to revoke the provisional measure. 3. If, in the case of a decision as referred to in paragraph 2(a), the provisional measure taken by the Member State consists in a restriction on the placing on the market or use of a substance, the Member State concerned shall initiate a Community restrictions procedure by submitting to the Agency a dossier, in accordance with Annex XV, within three months of the date of the Commission decision. 4. In the case of a decision as referred to in paragraph 2(a), the Commission shall consider whether this Regulation needs to be adapted.	3. In the case of an authorisation of a provisional measure related to classification or labelling of a substance as referred to in paragraph 2, the competent authority of the Member State concerned shall in accordance with the procedure laid down in Article 37 submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision.	the measures necessary to ensure that the non-compliant toy is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw it. 3. Where the national measure is considered to be justified and the non-compliance of the toy is attributed to shortcomings in the harmonised standards referred to in Article 42(5)(b), the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.		Article 12(1) of Directive 2001/95/EC shall be used. Article 12(2), (3) and (4) of Directive 2001/95/EC shall apply. 3. The Commission shall determine, as soon as possible, whether the provisional measures referred to in paragraph 1are justified or not. For that purpose it shall, whenever possible, consult the interested parties, the Member States and the SCCS. 4. Where the provisional measures are justified, Article 31(1) shall apply. 5. Where the provisional measures are not justified the Commission shall inform the Member States thereof and the competent authority concerned shall repeal the provisional measures in question.	accordance with the examination procedure referred to in Article 82(3).
60 days	60 days	Immediately	90 days	Immediately	Defined in the decision

10.3 Urgency procedure

Key findings:

- The CLP urgency procedure was used by Regulation 1297/2014 in relation to liquid laundry consumer detergents in soluble packaging (liquitabs) due to concerns over poisoning incidents with young children
- Extrapolation of data from five Member States reporting on poisoning incidents suggests that the economic costs of poisoning incidents prior to the introduction of the regulation in 2015 could have equalled around €23.4 million, rising to €30.8 million if the industry sector's voluntary initiative (as led by AISE) had not already been implemented
- No robust data on the substantive compliance costs faced by industry are available, although it is understood that research into the design of new packaging and labelling techniques, as well as investment in new packaging technology will have cost in excess of €1 million per company producing liquitabs, and potentially significantly more than this.

10.3.1 Extent of use

Under Article 54(4) of the CLP Regulation, an urgency procedure is provided for and this can be followed when "*the normal time limits for the regulatory procedure with scrutiny cannot be complied with, …".* Commission Regulation (EU) No 1297/2014[99] (adapting Commission Regulation (EC) No 1272/2008 to technical and scientific progress) provides the first example of the use of this procedure, to address packaging and labelling issues arising from liquid laundry consumer detergents in soluble packaging for single use, also known as liquitabs or pods. In this case, urgent action was taken due to concerns over the numbers of incidents across Europe involving young children (with high numbers of incidents involving dogs also being reported in some countries).

The Regulation (EU) No 1297/2014 essentially addresses concerns over the use of soluble packaging and notes that the then existing provisions under the CLP Regulation did not provide sufficient protection. The Regulation adapts Annex II of the CLP regulation so that from 1 June 2015, those who manufacture capsules must ensure that the packaging shall:

- contain an aversive agent in a concentration which is safe, and which elicits oral repulsive behaviour within a maximum time of 6 seconds, in case of accidental oral exposure;
- retain its liquid content for at least 30 seconds when the soluble packaging is placed in water at 20 °C; and
- resist mechanical compressive strength of at least 300 N under standard test conditions.

Furthermore, the capsules shall be contained in an outer packaging, which must display specific warnings and characteristics based on the new rules. Where a mixture used as a consumer laundry detergent in soluble packaging had been classified, labelled and packaged in accordance with the CLP, it had until 1 June 2015 to comply with the new rules. Mixtures used in capsules that had been

[99] Commission Regulation (EU) No 1297/2014 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures accessed at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R1297&from=EN

placed on the market before 1 June 2015 and classified according to Directive 1999/45/EC or the CLP had until 31 December 2015 to conform to be compliant. After this date, products not complying should not have been on the market.

10.3.2 Effectiveness and efficiency of the procedure

10.3.2.1 Urgency procedure and liquid laundry detergent pods

Towards the end of 2012, the Commission became aware that there had been a rise in the number of incidents related to water soluble packaging, specifically laundry detergent products. The number of incidents that involved such products appeared particularly high when compared with conventional laundry detergents and typically involved young children, in part because of their colourful appearance (with children mistaking them for sweets[100] [101]). Children are not the only group of individuals at risk of accidently consuming detergent capsules, with elderly people also at risk (especially elderly people suffering from dementia).[102] Furthermore, the symptoms associated with liquid laundry detergents (caused by ingestion and exposure to the eyes) are also usually more severe compared to traditional products.

In December 2012, the International Association for Soaps, Detergents and Maintenance Products (AISE) introduced a voluntary initiative. The April 2013 Status Report[103] on the voluntary initiative provides a report on the number of incidents of accidental exposure reported in different countries:

- Since 2008, around 500 enquiries per year regarding accidental exposures to liquitabs were made to the National Poisons Information Service (NPIS) in the UK by medical professionals;
- In France, the Lille Poison Control Centre counted over 400 accidental exposures in its regional area between 2001 and 2006;
- In Italy, between 2010 and 2013, there were about 500 reports of accidents to the Milan Poison Control Centre.

Children aged 3-5 years old were involved in at least 80% of these cases (and up to 95%), with 90% of cases relating to ingestion either alone or in combination with other routes of exposure; other potential exposures include skin and eye exposures. The AISE April 2013 Status Report also notes that in about two-thirds of cases accidental ingestion results in nausea or vomiting. Respiratory effects (e.g. chemical pneumonitis) due to ingestion were observed following ingestion in about 5-15% of cases. Of these, about 0.5% led to hospitalisation, with the remainder limited to coughing. In addition, in about 2-4% of cases drowsiness was reported, with one case of severe central nervous system suppression. In the remaining one-third of ingestion cases, there were no symptoms.

[100] Süddeutsche Zeitung (2014): Kinder verwechseln neue Waschmittel mit Süßigkeiten [children mistake washing liquid for sweets], available at http://www.sueddeutsche.de/gesundheit/liquid-caps-kinder-verwechseln-neue-waschmittel-mit-suessigkeiten-1.1927068

[101] Aponet (2014): Kinder: Vergiftungsgefahr durch Waschmittel-Kapseln [Children: danger of poisoning through laundry capsules], available at http://www.aponet.de/aktuelles/ihr-apotheker-informiert/20140401-vergiftungsgefahr-durch-waschmittel-kapseln.html

[102] Süddeutsche Zeitung (2014): Waschmittel im Bonbon-Look: Vergiftungsgefahr auch für Ältere [washing liquid looking like sweets: poising risk also for elderly people], available at http://www.sueddeutsche.de/news/gesundheit/gesundheit-waschmittel-im-bonbon-look-vergiftungsgefahr-auch-fuer-aeltere-dpa.urn-newsml-dpa-com-20090101-140430-99-02723

[103] AISE (2013): AISE product Stewardship Programme for Liquid Laundry Detergent Capsules, Status Report April 10, 2013.

In addition, as part of the voluntary agreement, companies participating in the programme committed to: reducing the visibility of capsules; adopting packaging closures that would impede the ability of small children to open the pack; on-pack communication; consumer communication campaigns; and engagement with Poison Control Centres.

Data reported in a May 2014 AISE Status Report[104] suggest that the voluntary agreement had led to a decrease in the number of cases being reported per liquitab sold in the Italy by more than 40% per million units sold, with reductions also occurring in other countries (although the effect was considered less prominent). The report notes that the decrease in incident rates were not as fast as anticipated and that additional voluntary actions would be taken due to pressure for the EC and Member State authorities via the Detergents Working Group and CARACAL. A December 2014 follow-up report notes that compared to the pre-voluntary agreement baseline, a substantial reduction in the number of exposures per unit product sold can be seen from incident statistics, in the UK, Ireland, Italy and the Czech Republic; overall, it is estimated that a 32% reduction in incidents per million units sold resulted from the industry voluntary initiative. It is understood that this monitoring of accidents is continuing.

In any event, as the market share of these products was increasing and high incident rates persisted, the Commission adopted Commission Regulation 1297/2014 which came into force on the 1st of June 2015. It is of note that AISE formally supported the proposals by the Commission to amend CLP in this manner, including the requirements adopted by the Commission[105]. Member State authorities also indicated their support for the Regulation, although some, such as Ireland, wanted its scope to be expanded to also include dishwashing tablets[106].

10.3.2.2 General views on importance of the added value of the urgency procedure

The ability of the Commission to take action under the urgency procedure is viewed as important by Member State and other stakeholders in providing a mechanism for achieving more rapid risk communication and/or risk management, aimed at protecting human health and the environment, and in particular vulnerable populations. In this respect, it is considered effective. In addition, adaptation of CLP was identified as providing the fastest procedure in the case of liquid laundry detergent pods.

It is understood that consideration was given to amending use of Article 35 of the CLP or to using Article 15 of the Detergents Regulation[107]. Article 15 (*'safeguard clause'*) of the Detergents Regulation was not considered adequate at the time for action at the EU level, as the problem covers a type of laundry detergent and not a specific brand or product within this type. Consideration was also given to use of the General Product Safety Directive and to a restriction proposal under REACH.

[104] AISE (2014): AISE product Stewardship Programme for Liquid Laundry Detergent Capsules, Status Update, May 26, 2014.

[105] AISE (2014): AISE's position in view of the CARACAL discussion on 9 July 2014 to amend CLP Regulation (EC) No 1272/2008 as regards soluble packaging, 30th June 2014.

[106] Health and Safety Authority (2014): IE Comments on Draft legislative proposal.

[107] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=10916&no=2

10.3.3 Benefits and costs of Regulation (EU) No 1297/2014

Clearly, it would be inappropriate to directly base the benefits and costs of there being an urgency procedure within CLP on the one action that has been taken to date, as the provision within the legislation can be drawn again at any point in the future, with such actions having their own benefits and costs. However, it is useful to consider the impacts of implementation linked to the one use of the urgency procedure that has taken place.

10.3.3.1 Benefits from reduced number of poisoning incidents

Given that this Regulation only came into effect in 2015, it is too soon to determine its effectiveness in terms of reducing poisoning incidents amongst children based on Poison Centre or other data. A study was launched in April 2015 to assess the effectiveness of the new measures introduced through Regulation (EC) No 1297/2014.

Interim findings of the study, as reported in CARACAL (19th Meeting, 12 – 13 November 2015), are that exposures to laundry detergent capsules were still being registered by poison centres in all Member States of the European Union under investigation. The age group with the highest risk is still small children below 3 years of age. In detail:

- 738 exposures to LDC were registered by poison control centres covered by the study for August and September 2015;
- Based on a preliminary data evaluation, the dataset seems to indicate that laundry detergent capsules are still the most prominent product group (as opposed to e.g. dishwashing detergents or other products sold in soluble packaging);
- About 75% of all patients suffer from symptoms, with 10% sufffering from symptoms of more than minor severity, mostly from long lasting vomiting; and
- For all poison control centres that submitted records for both months, case numbers declined from August 2015 to September 2015 (information still to be corrected for market share)."

In the absence of the final report of the study being undertaken for DG GROW on the effectiveness of the Regulation, some simple calculations can provide an indication of the potential benefits. The assumptions underlying estimation of the number of incidents are as follows (based on the preliminary dataset – use of the full dataset when published may result in revised figures):

1) Assume that there are 740 incidents across the five Member States involved in monitoring exposures over a period of 2 months, with this translating to around 4,440 per annum (assuming rates remain the same).
2) The five Member States account for 33% of the EU population. Extrapolating out on a per capita basis suggests there would be an additional 9,000 cases across the other EU countries, or roughly 13,450 in total per annum prior to the requirements of the Regulation having to be met.
3) 75% of these, or roughly 10,085 experience minor symptoms, assumed here to be a short period of nausea. 10% or roughly 1,350 suffer from long lasting vomiting or more severe respiratory or eye related effects.

As noted in Section 8, the UK HSE adopts a figure of €280 per annum (£218, converted to 2015 prices) as the notional value for (or willingness to pay to avoid) the pain and suffering associated

with minor cases of ill-health[108] (with higher figures assumed for those requiring treatment or being permanently incapacitated). An alternative set of figures are given by ExternE, with avoidance of one day of respiratory symptoms valued at around €64.50 (2015 prices) per episode.

The WHO Global Burden of Disease studies provide disability weights for a range of different health effects. The 2010 study provides a figure for severe eye impairment, which is adopted here to provide the basis for the valuation of the more severe incidents associated with laundry detergent capsule poisonings. The number of disability adjusted life years (DALYs) lost per case of severe eye impairment is 0.191. If each DALY is valued at €75,000, this equates to an economic cost of €14,325 per case.

To the DALY losses associated with severe eye impairment should be added the cost of hospital treatment. Kapur *et al.* (1999) calculated the cost of poisoning incidents referred to Leeds Teaching University Hospital to be equivalent to €885 per poisoning incident[109] (after conversion to 2015 prices, and from £ to EUR).

Based on these figures, we assume the following economic costs:

- Severe incident: €885 in hospitalisation plus €14,325 for severe eye impairment equates to a total per case cost of 15,210
- Minor incident: €64.50 - €280 for a day of respiratory symptoms.

Table 10-3 provides the resulting estimated economic value of the impacts, together with a sensitivity analysis that assumes that there are 32% more cases than the number reported in August and September 2015. This sensitivity assumption reflects a situation which assumes that the voluntary industry agreement overseen by AISE was not introduced.

Table 10-3: Economic cost of laundry detergent capsule related poisoning incidents per annum

Consequence	Number of cases	Cost per case	Total economic cost
Minor poisoning symptoms	10,085	€ 64.50	€649,090
	10,085	€280.00	€2,823,800
Severe poisoning symptoms	1,350	€15,210	€20,533,500
		Total per annum (high)	**€23,357,300**
Sensitivity – no voluntary initiative (32% more cases)			
		Total per annum (high)	**€30,831,600**

10.3.3.2 Substantive compliance costs

As indicated above, the detergents industry was already voluntarily introducing many of the measures which were subsequently required by Regulation (EU) No 1297/2014. In this respect, the threat of regulation can be assumed to have led to action by industry to reduce exposures to liquid laundry detergent capsules.

No robust data on the substantive compliance costs faced by industry are available, although it is understood that research into the design of new packaging and labelling techniques, as well as

[108] Based on: Davies, N. and Teasdale, P. (1999): The Costs to the British Economy of Work Accidents and Work-Related Ill-Health, HSE.

[109] Kapur, N. et al. (1999) General hospital services for deliberate self-poisoning: an expensive road to nowhere? *Postgrad. Med. J.* **75**: 599-602.

investment in new packaging technology will have cost in excess of €1 million per company producing liquitabs, and potentially significantly more than this.

10.3.4 Original needs, scientific findings and coherence

With respect to the relevance and coherence of the urgency procedure more generally, this is assessed in terms of:

- Whether the original needs still exist;
- The relevance of the process in terms of enabling risk management decisions to take into account latest scientific findings; and
- The coherence of the clause and its use with other legislation.

As for the safeguard clause, the above assessment suggests that there is the need for a procedure that enables a faster process than available under other legislation to respond to emerging evidence on risks stemming from classification, labelling or packaging issues. Thus, it can be easily argued that the original needs still exist. Similarly, it would appear that the process that can be applied for these purposes under the CLP appears to be relevant in terms of enabling new scientific evidence to be taken into account for risk management purposes.

This seems particularly the case given that Regulation (EC) No 1297/2014 applies only to laundry detergent capsules, while water soluble packaging has been developed for a range of other products, including dishwashing products, conditioners, toilet disinfectants, pigments and dyes, etc. As on-going development in novel products and packaging continues, it is clear that there may be other cases where there is a need for urgent action.

With respect to coherence, the clause set out in Article 15 of the Detergents Regulation is more in line with CLP's safeguard clause than with the urgency procedure, as it only enables action at the national level. Article 15 states:

1. *Where a Member State has justifiable grounds for believing that a specific detergent, although complying with the requirements of this Regulation, constitutes a risk to the safety or health of humans or of animals or a risk to the environment, it may take all appropriate provisional measures, commensurate with the nature of the risk, in order to ensure that the detergent concerned no longer presents that risk, is withdrawn from the market or recalled within a reasonable period or its availability is otherwise restricted. It shall immediately inform the other Member States and the Commission thereof, giving the reasons for its decision.*

2. *After consultation of the Member States, or, if appropriate, of the relevant technical or scientific committee of the Commission, a decision shall be taken on the matter within ninety days in accordance with the procedure referred to in Article 12(2).*

Article 12(2) of the Detergents Regulation makes reference to Decision 1999/468/EC as the basis for the decision making procedures.

In this respect, reliance on Article 15 of the Detergents Regulation could have raised inconsistencies in the regulation of these products across the single market, with some Member States taking action and others not, even though the same products were being placed on the market. In addition, if action is required on other products in the future, coherence is better assured through the use of CLP than a more detergents specific measure.

11 Single Market and International Trade

11.1 Introduction

The intention of GHS (and, therefore, CLP) is to create a harmonised system for the classification, labelling and packaging of chemicals which can be easily implemented globally and lead to trade benefits, as well as increasing the protection of human health and the environment. It is widely believed by governments, industry and NGOs alike that such benefits can be achieved but only if and when the system is truly harmonised in its global adoption and implementation. At present, the global disparity is still significant despite many key economies having adopted GHS. The two main sources of this disharmony are the adoption of building blocks and/or hazard classes and the differences in national labelling requirements.

Along with the exploration of these key differences, this chapter examines the way in which the transition from a directive-based system to a regulation-based system has impacted the functioning of the single market (Section 11.2). It also examines the impact of GHS on international trade and the competitiveness and innovation of the European chemicals industry (Section 11.5).

The analysis in this chapter is supported by the work carried out for Case Study 1 ("Comparison of implementation of UN GHS in EU and other key economies and its impact on competitiveness of EU industry").

Analysis conducted in this section is intended to inform the evaluation of CLP in line with the evaluation questions set out in Table 11-1.

Table 11-1: Evaluation questions relevant to the impact of GHS on the functioning of the single market, international trade and competitiveness and innovation

Q #	Evaluation Question
1.1.2.1.	To what extent does the EU legislative framework meet its objectives in relation to the functioning of the single market?
1.1.3.2.	To what extent has the chemicals legislative framework been effective in facilitating international trade of chemicals?
1.1.3.3.	To what extent has the chemicals legislative framework contributed to international competitiveness of the chemicals industry?
1.1.3.4.	To what extent has the chemicals legislative framework contributed to innovation in the chemicals industry?
1.3.8.	To what extent are there synergies between the objectives of protection of human health and the environment and the functioning of the internal market? Are these synergies immediate or do they appear over time?

The findings in this chapter draw on statistical data produced by Cefic (Cefic Chemdata International) and Eurostat for 2016. The interpretation of these data is the study team's.

11.2 Functioning of the single market

Key findings:

- The data presented in this section indicates that despite the introduction of GHS, the differences in take up of building blocks, differences in timings of adoption and the considerable number of NTBs and NTMs still in place for chemical products, the international trade of chemicals continues to thrive.
- The EU chemicals industry imposes the fewest NTMs on its import of chemicals, as well as imposing the fewest labelling-specific NTMs. This further supports that the EU chemicals industry is more competitive on the international market.
- Intra-EU exports are key drivers of the EU chemicals market
- The long term prospects for the EU chemicals industry, in terms of competitiveness, are negatively affected by its dependence on external energy supplies, comparatively high legislative costs, relatively expensive labour, lack of capital spending.

Figure 11-1 below is taken from Cefic's Chemdata International set of charts, in this case providing figures on the end market for EU chemicals sales over time. These data illustrate that the value of chemical sales has almost recovered after falling significantly in 2009. Importantly, given the context of this study, the chart also highlights the increasing role that intra-EU chemical sales are playing compared to domestic sales.

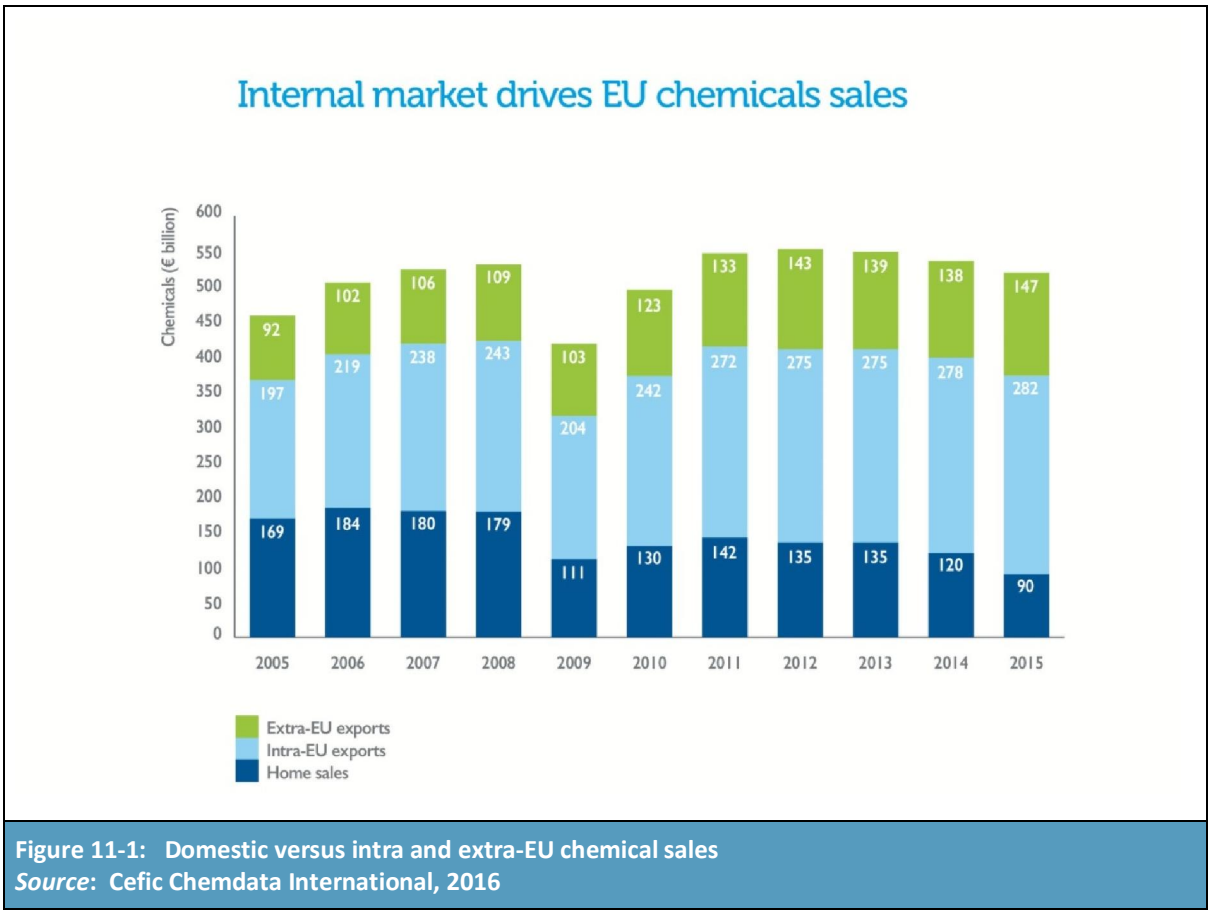


Figure 11-1: Domestic versus intra and extra-EU chemical sales
***Source*: Cefic Chemdata International, 2016**

Since 2009, home country sales have fallen from 37% of total sales to 18% of total sales, with intra-EU exports rising from a figure of 43% to 54% of total sales; in value terms, the level of intra-EU export has increased from €197 billion to €282 billion in the period from 2005 to 2015. The data presented in the figure also highlight the continued importance of the EU as a market for chemicals, even though the trend is for increasing levels of extra-EU exports.

The above trends suggest that the internal market is functioning well with respect to chemicals. Whether this can be attributed to CLP is less certain, given that this time frame also coincides with the introduction of REACH.

Stakeholders from industry as well as those representing environmental protection interests have expressed the belief that the introduction of harmonised communication measures has contributed significantly to the functioning of the single market in an important non-financial way. Workers and consumers who move or travel to different Member States will be familiar with the communication measures and hazard and risk information presented to them. Thus, there are clear synergies with respect to the achievement of the single market in chemicals through the setting of classification and labelling activities, and the achievement of human health and environmental protection.

11.3 Global adoption of GHS

Table 11-2 below shows the key differences in the building blocks which were adopted by key international economies with respect to the trade in chemicals.

Table 11-2: Key differences in building block adoption

Building Blocks	EU	RU	US	CA	CN	JP	BR	AU
Physical Hazard								
Chemically unstable gases, Cat A			■	■				■
Chemically unstable gases, Cat B			■	■				■
Aerosol, Cat 3			■	■				■
Flammable liquids, Cat 4	■							
Health Hazard								
Acute toxicity, Cat 5	■		■	■		■		■
Skin corrosion/irritation, Cat 1	■	■	■		■	■	■	■
Skin corrosion/irritation, Cat 3	■		■	■		■		■
Serious Eye damage/Eye Irritation, Cat 2		■	■	■	■	■	■	■
Serious Eye damage/Eye Irritation, Cat 2A	■							
Serious Eye damage/Eye Irritation, Cat 2B	■							■
Aspiration hazard, Cat 2	■		■	■		■		■
Environmental Hazard								
Acute hazards to aquatic environment, Cat 1			■	■				■
Acute hazards to aquatic environment, Cat 2	■		■	■				■
Acute hazards to aquatic environment, Cat 3	■		■	■				■
Long-term hazards to the aquatic environment, Cat 1			■	■				■
Long-term hazards to the aquatic environment, Cat 2			■	■				■
Long-term hazards to the aquatic environment, Cat 3			■	■				■
Long-term hazards to the aquatic environment, Cat 4			■	■				■
Hazard to the ozone layer			■	■				■

Building block adopted
Building block not adopted

For the most part, the EU, Russia, China and Japan have adopted the same building blocks (though there are some differences in the adoption of the health hazard classes).

As the GHS covers all hazardous chemicals (i.e. chemicals meeting the criteria for classification against a hazard class in the GHS), there are four broad sectors to which it is relevant. Some countries have adopted the GHS across all four sectors, whilst in others the GHS has been adopted for only a few sectors – see Table 11-3. It should be noted that certain consumer products that have specific sectoral legislation (toys, textiles, cosmetics, food, pharmaceuticals, medical devices) are not covered by the GHS at the point of consumption. They will only be covered where workers may be exposed (workplaces) and during transport.

Table 11-3: Scope of the UNGHS and applicable industry sectors

Sector	Comment
Transport	• The UN Recommendations on the Transport of Dangerous Goods - Model Regulations takes precedence • GHS parts expected to be adopted: GHS hazard classification criteria, GHS hazard pictogram
Workplace	• Some authorities may not have jurisdictions over environmental hazards • GHS parts expected to be adopted: GHS hazard classification criteria, GHS label elements
Consumer	• Labels may include the core elements of GHS labels subject to some sector-specific considerations (i.e., instructions for use, expiration date) • Risk-based labelling may be applied • GHS parts expected to be adopted: GHS hazard classification criteria, GHS label elements
Pesticides	• Pesticides labels may include the core elements of GHS labels subject to some sector-specific considerations (i.e. instructions for use, crops, expiration date) • GHS parts to be adopted: GHS hazard classification criteria, GHS label elements, GHS safety data sheets required in workplace

Sector	EU	RU	CA	US	CN	JP	BR	AU
Transport								
Workplace								
Consumer								
Pesticides								

	Building blocks implemented or can be used
	Building blocks not implemented
	Considering implementation

Source: ChemSafetyPro, Introduction to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), accessed at http://www.chemsafetypro.com/UN_GHS_Chemicals_GHS_for_Dummies.html
UNECE, GHS Implementation, accessed at http://www.unece.org/trans/danger/publi/ghs/implementation_e.html
Canadian Centre for Occupational Health and Safety
OSHA fact sheet, Hazard communication standard final rule, accessed at *https://www.osha.gov/dsg/hazcom/HCSFactsheet.html*

11.3.1 Impact on European chemicals industry

Of the companies involved in the import or export of substances and mixtures into/out of the EU, 97 (74%) provided responses to questions concerning the impact that the introduction of CLP has had on their activities. Responses are given in Table 11-4 below. These responses indicate that the ongoing differences in the uptake of GHS building blocks is leading to a lack of savings in costs to exporters, with only 12% noting actual savings due to the introduction of CLP. Responses indicate

though that classification and labelling costs are lower for those countries that have adopted the UN GHS compared to those that have not, for one fifth of the responding companies.

Table 11-4: Importers and exporters views on impacts of CLP implementation (n=97)	
Answer Options	**Percentage of responses**
Classification, labelling and packaging costs vary across the countries my company exports to because of differences in take-up of UN GHS building blocks, categories and sub-categories (please answer Q50)	39.2%
Classification and labelling costs for exports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	12.4%
Classification and labelling costs for imports have decreased due to implementation adoption of CLP and hence greater harmonisation with the UN GHS (please answer Q51)	8.2%
Classification and labelling costs are lower for countries that have adopted the UN GHS than for those that have not adopted the UN GHS	21.6%
There have been no savings in classification and labelling costs due to the more global adoption of the UN GHS system	60.8%

When asked what are the most important factors driving the lack of cost savings, 20% cited differences in the take-up of categories and sub-categories (rather than the take-up of building blocks at 6%). Variations in implementation as set out in various footnotes in the UN's "purple book" were also highlighted as illustrating the types of differences that lead to additional costs compared to a truly harmonised system. These include the variations listed in the following footnotes in the "purple book":

- p.115: There are no Category 5 acute toxicity inhalation numerical values. The OECD Task Force specified doses "equivalent" to the range of 2000-5000 mg/kg bw by oral and dermal route. In some systems, the competent authority may prescribe values.
- p.123: In the event that an ingredient without any useable information is used in a mixture at a concentration >1%, the classification should be based on the ingredients with the known acute toxicity only and additional statements should identify that x% of the mixture consists of ingredients of unknown acute toxicity. The competent authority can decide to specify that the additional statement(s) be communicated on the label or on the SDS or on both, or to leave the choice of where to place the statement to the manufacturer/supplier.
- p.232 (footnote 2 – regarding Acute 2 and Acute 3 aquatic toxicity classification): Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.
- p.236 (footnote 5): Data are preferably to be derived using internationally harmonised test methods (e.g. OECD test guidelines or equivalent) according to the principles of Good Laboratory Practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent.
- p.256 (Table A1.19 – note a): Skin corrosion/irritation cat 3 applies to some authorities.
- p.257-258: For respiratory and skin sensitisation, sub-categories (1A, 1B) may be applied where data are sufficient and where required by a competent authority.

In some cases, these variations were included to enable countries to retain the same level of protection as they had their implementation of GHS (pers. comm, US OSHA, 2016). Other factors include differences in the extent to which other countries are adoption each Revision of GHS (for example, Malaysia is using Revision 3 rather than Revision 4).

More significantly though, 70% identified differences in labelling requirements across nations as being a key driver underlying the costs of classification and labelling activities[110]. Many stakeholders have indicated that labelling requirements differ so much across the regions that have adopted GHS that barriers to the international trade of chemicals have not been reduced, as was intended. This is because these differences in labelling requirements mean that products cannot be easily placed on non-EU markets, as they require re-labelling according to the specific and variable requirements of the markets in which they are placing their products.

Table 11-5 presents data on industry consultees' responses to a question about the adoption of GHS in different regions and how significant this has been for their cost savings. Interestingly, as can be seen from Table 11-5, the smaller number of respondents (n=45) answering these questions identified adoption of GHS in North America and Asia as leading to marginally greater savings than for some of the other regions; however, introduction in other countries has also led to significant savings for a small sub-set of companies. Care is obviously required in interpreting these data given the small number of responses. However, one stakeholder suggested that the early adoption of GHS in the EU (via CLP) made it easier to comply with GHS as implemented in other regions.

Table 11-5: Significance of savings from CLP implementation (n=45)

Answer Options	Rating of significance of savings from low to high				
	1	2	3	4	5
Adoption of the UN GHS in the EU through implementation of the CLP Regulation	62%	9%	13%	4%	9%
Adoption of the UN GHS in North America	31%	24%	9%	7%	9%
Adoption of the UN GHS in China, Japan and other Asian countries	36%	20%	18%	4%	7%
Adoption of the UN GHS by Brazil and other South American countries	49%	16%	7%	9%	0%
Adoption of the UN GHS in other countries (e.g. South Africa, Australia)	49%	7%	11%	4%	9%

Importers providing more detailed information indicated that it has reduced the costs of classification and labelling for importing into the EU by between 5% to 30% for a small set of companies, and for one company by up 90% in terms of any additional classification and labelling that they may face (with this being a distributor); many indicated no savings, however. Interestingly, three importers noted that introduction of CLP has enabled them to sell in more markets within the EU than prior to its introduction, with this applying to between 10% and 20% of mixtures that they place on the EU market.

28 exporting respondents provided information on the reduction in classification and labelling costs that they have realised. Five report no savings, while the remainder report highly varying levels of savings: between 1 and 2%; 10%; 50%; and 100%. These same exporters indicated that CLP alone had not enabled them to increase their export volumes (with the exception of one formulator), or to sell substances or mixtures in key export markets at a more competitive price (again with the exception of one formulator who indicated that they can sell 10% of the mixtures now at more competitive prices).

The results in Table 11-6 confirm the earlier responses regarding limited expectations for benefits from savings in classification and labelling costs associated with substances and indicate that the

[110] See Annex 4 for details of the differences in labelling requirements across the main countries implementing GHS.

same is expected with respect to the export of mixtures (although very large percentages of respondents also indicated "don't know").

Table 11-6: Views on whether CLP will lead to savings in the future in relation to mixtures (n=115)			
Answer Options	**Yes**	**No**	**Don't know**
Classification costs associated with the extra-EU export of mixtures	28%	44%	29%
Classification costs associated with the intra-EU export of mixtures	28%	52%	21%
Costs incurred in re-classifying and labelling imported mixtures	20%	47%	30%
Labelling costs associated with the extra-EU export of mixtures	23%	47%	29%
Labelling costs associated with the intra-EU export of mixtures	18%	55%	24%
Reductions in variable packaging requirements	17%	45%	38%

Many industry stakeholders do believe that GHS will be beneficial but that these benefits can only be realised when the system is truly globally harmonised. For example, stakeholders remarked that, in terms of global harmonisation work, efforts for aligning GHS globally fall far behind the work done to harmonise ADR, IMDG and IATA globally.

11.3.2 Non-tariff measures related to labelling and packaging provisions

Table 11-10 below lists data for 2014 taken from the WITS database relating to the total number of non-tariff measures (NTM) put in place in different importer countries (for which data is available) and the number of these which are linked to the labelling of products and the number which are related to the packaging of chemicals and chemical products. This is based on the UNCTAD Coding System for the classification of non-tariff measures. Classification B31 is entitled "Labelling Requirements" and pertains to measures which regulate the format and information on packages and labels. Requirements may include, amongst others, information on use, safety and security. Classification B33 is entitled "Packaging Requirements" and relates to the measures which regulate the way in which goods are packed and the packaging materials which can be used. Again, the data is given for the NTMs which apply to those product categories listed in Table 11-7:

Table 11-10: Number of NTMs related to labelling (NTM Classification B310)[111]			
Importer	**Total number of NTMs in 2014**	**NTMs related to labelling (B31)**	**NTMs related to packaging (B33)**
EU	157	20	6
Australia	551	63	26
Brazil	263	25	4
Canada	325	30	7
Japan	584	39	15
USA	1046	172	30

NTMs relating to labelling requirements account for between 7% and 16% of all NTMs in 2014 for chemicals and chemical products. This data underlines the point made by many industry stakeholders that differences in labelling requirements can act as a barrier to trade for the chemicals industry.

[111] Data on NTMs not available for China or Russia

These figures suggest that the EU chemicals industry is arguably the most competitive out of its closest competitors, in terms of the number of NTMs[112].

11.4 International trade, competitiveness and innovation

Numerous industry stakeholders suggest that, despite GHS building block adoption not being consistent across countries, the GHS and CLP has helped to reduce technical barriers to international trade within the EU and externally, as classification criteria are more harmonized than previously. These stakeholders see this trend continuing into the future, and anticipate further trade related benefits. However, data collected for Case Study 1 suggests that the number of technical barriers to trade has actually increased over the period from 2004 to 2014.

Data from Cefic (ChemData International, 2013) suggests that the EU chemicals industry continues to perform strongly as the leader of the global chemicals market, experiencing increasingly positive trade balances with its closest competitors (US, China and Japan). With regards to China and Japan, this is surprising given that they are also two of the countries which were identified by consultees where there are in practice significant differences in classification and labelling requirements that result in the lack of a harmonised approach. The Cefic data indicate that the EU had the most favourable trade balance of all regions in 2013. It accounted for 42.5% of all world exports, with the trade balance equating to €62 billion. This is significantly higher than the NAFTA trade balance, estimated at €14 billion, and contrasts significantly to the other regions which are all net importers of chemicals. This suggests that alignment of requirements for classification and labelling at the global level can only be an advantage for EU manufacturers of chemicals.

Figure 11-4 below draws on Eurostat data and shows that the EU holds a positive trade balance for chemical products with seven trading partners over the period. These are (in order of trade balance value in 2015): US; Russia; Turkey; Japan; Brazil; China and Saudi Arabia. The EU holds a negative trade balance for chemical products with India, Singapore and Switzerland.

From this figure, it is evident that the European chemicals industry continued to perform strongly despite the poor global economic conditions in 2008 and 2009 and the burden it faces in terms of energy prices and other EU legislation (i.e. emissions). The pattern of trade balance growth was similar for all those trading partners with whom the EU enjoyed a positive trade balance. The exception is the US with which the EU sees a comparatively sharper rise in the trade balance for chemicals, likely owing to price movements in the energy markets.

[112] The database managers for the UNCTAD TRAINS/WITS database system were contacted with regards to obtaining data from previous years in order to develop a time-series analysis of the NTMSs relating to packaging and labelling. However, we were informed that this data is not held by UNCTAD.

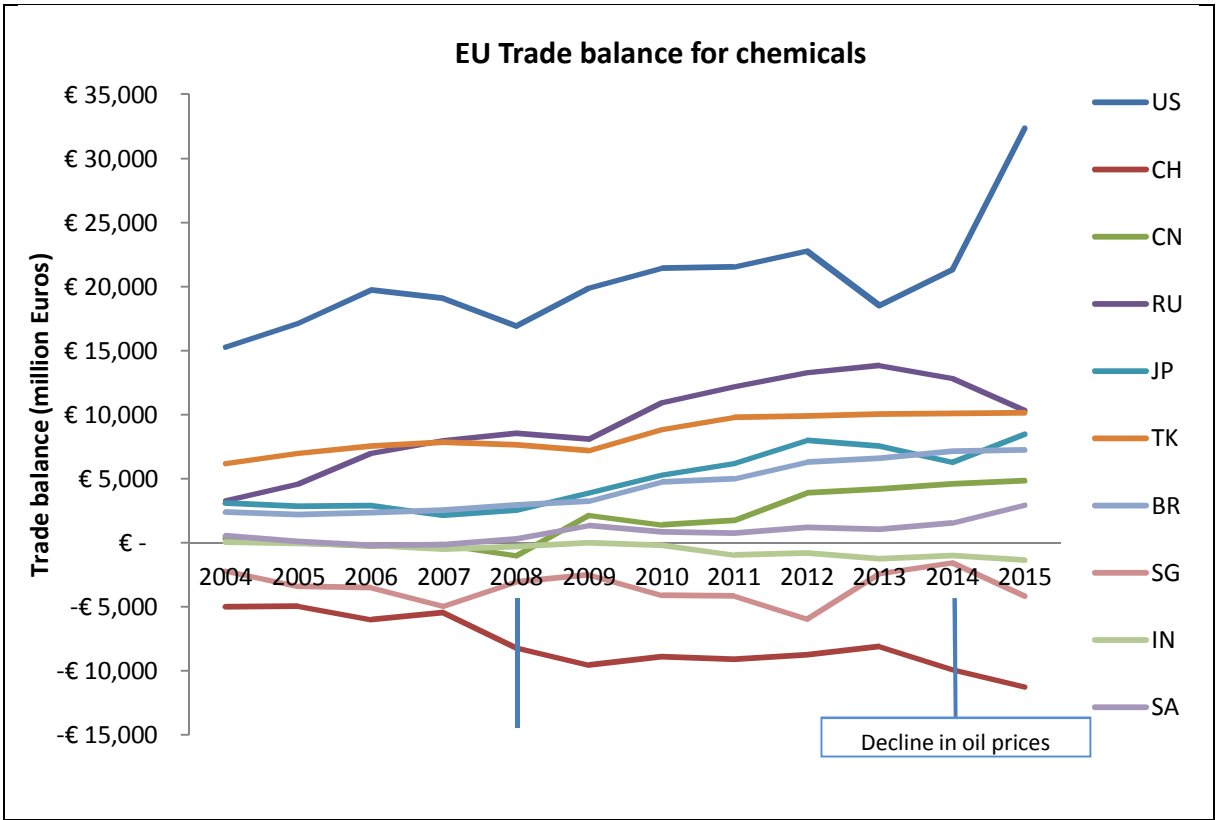


Figure 11-4: EU trade balance for chemicals
Source: Eurostat

The importance of international trade is illustrated in Figure 11-5, which lists the different import and export destinations of the companies responding to the targeted consultation carried out for this study. 170 respondents in total provided information on the countries that they either imported or substances and mixtures from or exported to outside the EU. The relative importance of different countries can be seen from the figure. Exports are important for over 50% of respondents for Turkey, Russia, South and Central America and North America, with China and the rest of Asia of slightly lower (but still significant importance). In terms of imports, China and North America dominate supply sources (45% and 34% respectively).

At the company level, it is clear from the graph that a far larger percentage are exporting substances and/or mixtures than are also importing into the EU. It is also clear that the range of export markets appear to be are important, rather than just one or two to any given company.

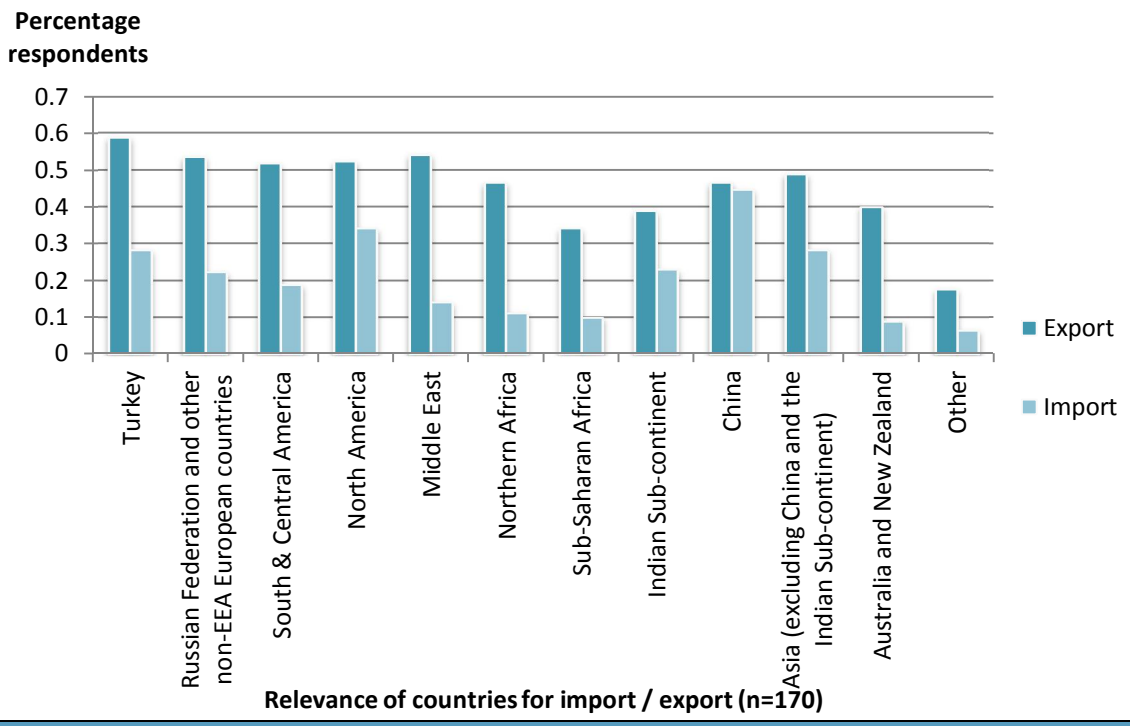


Figure 11-5: Countries traded with – imports and exports

To try and gain a feel for how important imports and exports are to individual respondents, they were asked to indicate what % of their turnover was linked to both intra-EU and extra-EU import and export activities, and for substances and mixtures separately. As anticipated, this question was difficult for many companies to answer, and the total number of responses (reported in Table 11-11) fell to 127.

The figures presented in Table 11-11 exclude importers and exclude substance export for formulators. The numbers entered into each cell are counts of the number of respondents out of a total 127 providing an indication of the importance of exports or imports to their activities (total response counts are less than 127 for any given row due to intra- or extra-EU import or export not being relevant to all respondents). As can be seen from the table, imports and exports generally account for less than 20% by value of a given company's turnover, with there being numerous exceptions where import or export of substances and the export of mixtures accounts for >60% of turnover by value. In this respect, the data suggest that harmonisation of classification and labelling at the global level is of great importance for only a relatively small percentage of companies (i.e. linked to >60% of turnover).

These results support responses to another consultation question regarding whether or not CLP had enabled them to increase their export volumes (with the exception of one formulator), or to sell substances or mixtures in key export markets at a more competitive price (with the exception of one formulator who indicated that they can sell 10% of the mixtures now at more competitive prices). This may suggest that there is a sub-set of companies who are gaining more significantly than others from the implementation of CLP/GHS. Yet it also shows that there remains greater potential for those involved in the chemicals industry to gain from the intended economic benefits of global harmonisation.

Table 11-11: Relative importance of import and export as a percentage of annual turnover (n=127)				
Answer Options	**<20% by value (€)**	**<60% by value (€)**	**>60% by value (€)**	**Response Count**
% turnover related to the export of substances (intra-EU)	34	14	18	66
% turnover related to the import of substances (intra-EU)	49	19	20	88
% turnover related to the export of substances (extra-EU)	34	17	3	54
% turnover related to the import of substances (extra-EU)	52	24	2	78
% turnover related to the export of mixtures (intra-EU)	51	27	17	95
% turnover related to the import of mixtures (intra-EU)	66	15	6	87
% turnover related to the export of mixtures (extra-EU)	53	18	7	78
% turnover related to the import of mixtures (extra-EU)	56	10	1	67

This conclusion is also confirmed by the results presented in Table 11-12, on companies' views with respect to the extent to which the CLP will lead to positive or negative impacts with regard to enhancing trade and competition.

Table 11-12: Views on impacts of CLP with respect to trade and competition (n=101)						
Answer Options	**Large positive impact**	**Low positive impact**	**Neutral/no change**	**Low negative impact**	**Large negative impact**	**Don't know**
Intra-EU trade of chemicals	9%	23%	46%	5%	2%	10%
Extra-EU trade of chemicals	8%	18%	42%	12%	2%	14%
Trade and competition from harmonisation of classification and labelling	22%	30%	31%	6%	4%	6%
Access to markets for SMEs	4%	6%	40%	4%	2%	42%
Trade and competition in terms the costs of substances placed on the EU market	3%	7%	50%	22%	3%	13%

Although most of the respondents indicated that benefits related to intra-EU trade reflected no significant change, there is a subset that believes it has had a small positive effect.

There is also some suggestion that there are positive impacts through greater harmonisation of classification and labelling data for the individual companies and their activities. On the negative side, more respondents indicated that the costs of substances and mixtures in the EU will have increased slightly as a result of CLP implementation.

However, an important point was made that most SMEs are engaged in a local/regional market with only a small proportion of these engaging in trade activities outside of the internal market. Therefore the benefits of an increasingly harmonised global system of chemicals managements are minimal for SMEs. For example, as stated above, one of the greatest advantages of GHS and CLP is that the burden and costs of adapting labelling to meet various international requirements is reduced. However, SMEs not trading internationally do not reap these benefits.

11.4.1 Impact on international trade of chemicals

The data presented in this section indicates that despite the introduction of GHS, the differences in take up of building blocks, differences in timings of adoption and the considerable number of NTBs

and NTMs still in place for chemical products, the international trade of chemicals continues to thrive and that the introduction of GHS has not impacted the competitiveness of the European chemicals industry.

Literature about the European industry suggests that other factors are more important in determining the long-term competitiveness of the industry; these include energy dependence and energy prices as well as a shift in investment away from Europe to Asia and the Middle East. Data from the Cefic Chemdata report support this. For example, in terms of production growth, the EU chemicals industry has yet to see growth rates return to the pre-economic crisis levels:

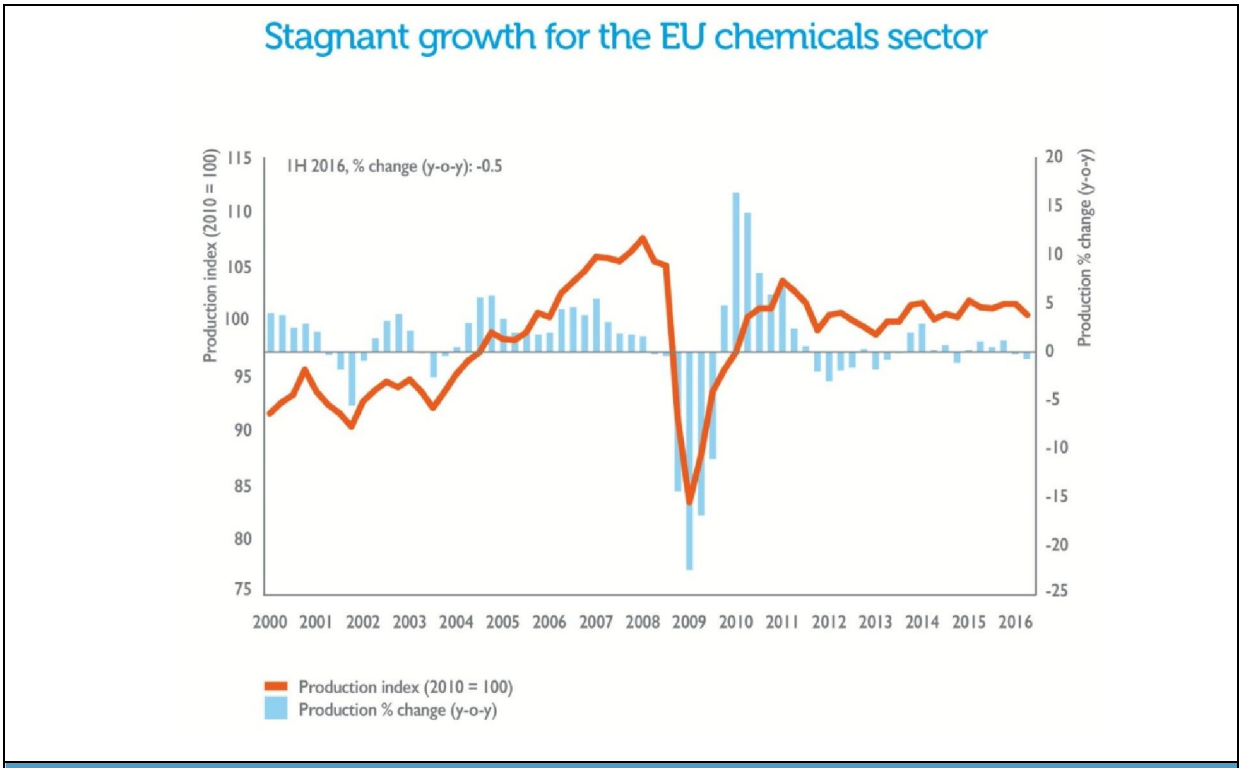


Figure 11-6: EU chemicals production growth
Source : Cefic Chemdata International 2016

Furthermore, the report finds that capacity utilisation in the EU chemical industry has now reached its long-term average (81.5%). This is compounded by the fact that capital spending intensity in the EU chemicals industry is much lower than its counterparts:

Table 11-13: Capital spending intensity (% of sales) (Taken from Cefic Chemdata International 2016)

Country	2005 capital spending	2015 capital spending
EU	3.8	4.0
Brazil	3.0	3.3
China	7.6	6.8
Japan	5.0	4.3
Russia	6.4	8.2
USA	2.7	6.3

In 2015, only Brazil's capital spending intensity was lower than the EU's.

12 Implementation, Monitoring and Enforcement

12.1 Introduction

This Section looks at the way the CLP Regulation is implemented at both Member State level and EU level. We consider the processes undertaken by European agencies and national competent authorities in implementing, monitoring and enforcing the legislative requirements of CLP. The analysis presented below addresses the following evaluation questions.

Table 12-1: Evaluation questions relevant to implementation, monitoring and enforcement of CLP

Question #	Evaluation Question
1.2.1.	Are there unnecessary regulatory burdens?
1.3.1 & 1.3.2	Which factors have the biggest positive impact on the correct functioning of the chemicals legislative framework? To what extent? Which factors have the biggest negative impact on the correct functioning of the chemicals legislative framework? To what extent?
1.4.	To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement)?
1.4.1	Are the main elements of the EU legislative framework for the risk management of chemicals effectively and consistently implemented across all Member States?
1.4.2.	If there is a disparity in the way legislation is implemented, what are the consequences of such a disparity?
1.4.3.	To what extent is enforcement effective and consistent across all Member States? Are the frequency of controls, sanctions and liabilities consistent and comparable in different Member States?
1.4.5.	Are there any measures in place at EU level to support enforcement? Are these tools effective and sufficient?
1.4.6.	Do all actors including regulatory agencies (e.g. ECHA, EFSA) and the Commission consistently implement all aspects of the chemicals legislative framework in accordance with its objectives and intentions?
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?
2.1.1.1.	What are the costs associated with the chemicals legislative framework for regulators at EU and national level?
2.1.3.1.	What are the benefits associated with the chemicals legislative framework for regulators at EU and national level?
2.2.3.	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?
2.2.11.	At Member State level, are there significant differences between Member States as regard the benefits, costs and administrative burdens?

12.2 Expected and realised impacts of CLP

Key Findings

- National helpdesks are a highly valuable resource to industry stakeholders, as are trade associations and external service providers.
- Industry stakeholders have indicated that, despite CLP being easier to understand than the Dangerous Preparations Directive, more guidance is needed in some areas e.g. weight of evidence approach, bridging principles, etc. Many would favour the organisation of more workshops, according to Member States.
- Stakeholders raised over-classification of mixtures and the time allowed to implement the changes being too short, as some of the biggest negative factors with respect to the functioning of CLP.
- Stakeholders also highlighted a lack of coherence between EU Member States and a need for better communication between industry and authorities

12.2.1 Factors having the biggest positive and negative impacts

Interestingly, when asked whether there was one particular aspect of CLP implementation that disproportionately accounts for its benefits, manufacturers, distributors and formulators suggested that CLP is more systematic than the Dangerous Substances Directive and hence more readily understood, while the detergents sector noted that the hierarchy for mixture classification was also a positive introduction compared to the Dangerous Preparations Directive.

Comments from industry also indicated that there are areas where more guidance is needed, e.g. health classification of solid metals, a strategy for classifying alloys (health and environment), bridging principles, weight of evidence and a clearer definition of bioavailability. More generally, some stakeholders noted that the text is far too complicated with extensive use of cross references, and right information is hard to find.

It was indicated that helpdesks are highly appreciated and effective and that it is important to sustain good cooperation between helpdesks, e.g. HelpNet. For their part Member States noted that national REACH/CLP Helpdesk staff are active in increasing awareness and knowledge by replying to queries and providing information and guidance to stakeholders who request it.

Training and conferences were also appreciated but it was suggested that there is a need for a deeper level of training, even though in some cases this would involve more than the resources that companies have. In particular, SMEs were identified by Member State authorities as needing further support from both the Commission and Member States. It was also suggested that is particularly beneficial when guidance is made available centrally (via the Commission or ECHA) because it strengthens harmonisation and reduces work across Member States. However, it is also clear that Member State authorities are providing training themselves for both industry and to further educate professional users and consumers. Over half of the 14 Member State authorities providing responses to the consultation indicated that they either provide educational programmes, are developing such programmes and/or that there is another organisation within their Member State that is developing such a programme.

More detailed responses from companies on how they keep informed of changes in CLP requirements, are set out in Table 12-2 setting for the different sectors. Responses indicate that

most companies rely on a mix of different sources of support in terms of ensuring that they are aware of their obligations and are correctly meeting them. For example, for manufacturers, over 85% indicated that they get information on changes in CLP requirements through their trade association and ECHA's website. Around 60% also indicated that their IT and classification services providers also help keep them informed of changes. These responses are mainly from larger companies, but also include SMEs.

The most surprising finding here is the increased reliance on general chemicals manufacturers, distributers and formulators and the cosmetics sector on external service providers compared to the PPP producers and detergents sector. What is also clear is the importance of ECHA and its website in acting as a resource for industry – only industry associations were relied on to a greater extent. It also appears that different sectors view the level of supporting information provided by national authorities differently, with significant variations across the sectors in drawing on these as sources of information. Companies also indicated that after ECHA, they relied on their trade associations for guidance, with high percentages (over 50%) also attending conferences organised by their trade associations or national authorities.

Table 12-2: Industry approaches to keeping informed of changes in CLP requirements

Answer options	Response Percent (multiple responses possible)				
	Manuf., Distrib. & Formulators (n=91)	Cosmetics companies (n=5)	PPP manufacturers (n=9)	Detergents manufacturers	
				Large (n=7)	SME (n=12)
Through my trade association	89%	100%	89%	86%	92%
Through a trade journal	15%	40%	0%	14%	8%
Through ECHA's website	85%	80%	89%	71%	83%
Through information produced by national authorities	64%	80%	56%	86%	50%
Through social media (e.g. Linked-in)	10%	0%	11%	0%	0%
Through my IT system or classification service provider	62%	60%	33%	14%	42%

Most of these companies also rely on guidance documents made available by national authorities (most common response), ECHA or the Commission and their trade associations. Roughly half have attended some type of conference or other event, with 40% also obtaining other types of support through their trade associations. Taken together, it would appear that there is a range of support mechanisms available for companies.

From a negative perspective, stakeholders raised over-classification of mixtures and the time allowed to implement the changes being too short, as some of the biggest negative factors with respect to the functioning of CLP. Stakeholders also highlighted a lack of coherence between EU Member States and a need for better communication between industry and authorities. Companies also suggested that the classification of active substances should only be made by RMS or ECHA, and not EFSA, which is consistent with Better Regulation and one agency having clear responsibilities.

Other comments concern:

- the disconnect CLP regulation and downstream legislation. Downstream legislation are also often EU directives which need to be transposed at the national level by the Member States;
- the need to better optimise hazard communication to consumers; and
- better links with transport regulations.

12.2.2 Reflection of original intentions in guidance

As part of the consultation, Member States were asked whether the legislation and its original intentions are properly reflected in interpretation and guidance documents. There was good recognition that ECHA had made a big effort in developing guidance, FAQs and other support tools which are of help to authorities, as well as stakeholders. However, one Member State indicated that it is often hard to track the original intentions of the legislation when doubt arises. Also, there are examples of decisions/interpretations being made at a late stage in the CLP implementation process. In practice, this has led to different interpretation approaches by different member states. They highlighted an example as being the interpretation of "placing on the market" under the CLP Regulation (see also Task 2 and a discussion on differences in definitions across EU legislation). Another Member State noted that there will always be deviations (no examples were provided) and it will take time for CLP to be fully implemented in a correct way.

12.3 Consistency

Key Findings

- The point has been made that there are national differences across Member States in terms of the interpretation of mixture classification rules
- Enforcement of CLP is not equal across Member States – this is attributed to differences in regimes, resources, etc.
- ECHA's FORUM is leading to enforcement activities being better coordinated across Member States but Member States still believe there needs to be better communication between competent authorities.

12.3.1 Consistency with wider policies and in national implementation

Consultation asked various stakeholders whether they agreed that CLP is consistent with EU policy and that EU level intervention is required. It also asked whether CLP implementation is consistent at the national level. The responses from industry (manufacturers, importers, distributors and formulators) are given in Table 12-3 below. As can be seen from this table, there is general agreement with the statement that CLP is consistent with wider EU policies for achieving the same general objectives, and that EU level intervention is necessary to achieve these benefits (although there is a greater degree of disagreement with also with this latter statement). However, industry stakeholders are in less agreement that CLP is implemented consistently across Member States. Indeed, the responses are surprisingly negative in this respect, with 17% disagreeing with this statement (although it is clear that the majority feel that it is).

Table 12-3: Views of industry on consistency with wider policies and in implementation (n=83)						
Answer Options	**Strongly agree**	**Agree**	**Neutral**	**Disagree**	**Strongly agree**	**Don't know**
CLP Regulation is consistent with wider EU policies in achieving the same general objectives (increased trade, protection of health and the environment)	11%	63%	17%	5%	0%	3%
EU-level intervention is necessary to achieve these benefits	13%	56%	13%	10%	2%	6%
Implementation of CLP is consistent at the national level across the EU	6%	48%	19%	17%	0%	8%

The responses from the detergents sector are more negative, with 60% of respondents (n=17) disagree with the statement that implementation is consistent at the national level. This response is not surprising; as discussed in Section 4.3, there are concerns within this sector over different interpretations of the mixture classification rules and how they should be applied across Member States. The responses to this question will reflect these experiences. Similarly, negativity from the more general chemicals sectors is also likely to reflect concerns with regard to varying interpretation on issues such as mixture classification, as well as reported differences in national labelling requirements.

Worker representative organisations noted that not all actors (including regulatory agencies / committees, e.g. ECHA, SCOEL, EFSA, CSST and the Commission) consistently implement all aspects of the chemicals legislative framework in accordance with its objectives and intentions. However, the issues raised here are more relevant to the Task 3 research and are reported in further detail there.

From their perspective, Member States noted that the various agencies and the Commission generally implement the framework in a consistent manner but that there are exceptions. Comments include the following:

- Not always. Sometimes by the action (sometimes the "soft law" is used: public consultations, decisions of Committees or guidance resources are used to buffer requirements) and other for failure to act (e.g. the legislation of hazardous waste has inconsistencies that are not solved – EoW, by-products).

- In general yes, but there are always deviations. In general we believe that regarding CLP the relevant agencies try to implement the chemicals legislation in accordance with its objectives and intentions. Difficulties may arise for example when a decision in one piece of legislation depends on a decision in another one (e.g. harmonised classification of pesticides, where decision on the classification is made within the CLP but applied in PPP and biocidal products). These problems should however be resolved by applying better procedures.

- It is sometimes simply not possible to achieve a consistency with all legislative intentions if e. g. a safer substitute for workers has a significantly high environmental impact. Case by case decisions are and will often be needed. The agencies need to weigh all factors in their decisi on and mainly do that.

- Due to the way this question is posed, it is almost impossible to answer with 'yes'. It is our belief that the environment is not properly considered by all actors. One example includes the authorization of the biocide alpha-Cypermethrin, which was already identified as a priority substance under the Water Framework Directive due to environmental risks based on respective Member State monitoring data, resulting from huge differences in the derivation of environmental safe concentrations (i.e., PNEC). Furthermore, until now, with few exceptions, there are no specific provisions for nanomaterials within the substance legislations. As a result, specific environmental risks cannot be described and assessed adequately and appropriate measures to minimize the risks cannot be taken.

12.3.2 Consistency in enforcement

Member States were asked whether, for their part, they felt that the enforcement actions taken across Member States were consistent and comparable. Responses highlight that there are differences due to differences in regimes, resources, etc. These differences were to be expected, but activities are being better coordinated as a result of the work undertaken through ECHA's Forum. Key comments are set out below.

- It is comparable but resources are different among Member States.
- There are no coordination problems, but discrepancies in sanctioning regimes and available resources due exist. On the other hand, coordination with the customs authorities at the EU level is strongly needed.
- As each Member State has different enforcement regimes, this is a difficult issue. However, bodies such as the Forum on Enforcement have brought a higher degree of co-ordination across the Member State.
- The enforcement actions concerning chemical regulation differ very much from Member State to Member State. In the enforcement networks for REACH Annex XII and CLP (FORUM), Biocidal products (CLEEN and BEG) and RoHS (RoHS network), Member States are working towards a more harmonised approach.
- The quality and the frequency of enforcement differs across the different Member States. Partly it has to do with interpretation of legislation, guidance documents and borderline issues (for the Biocidal Products Regulation particularly with medicines and treated articles/biocide products) and partly it has to do with resources. More co-operation is needed.
- The ECHA FORUM is a good tool for discussion regarding enforcement actions and their comparability. Differences can still exist as enforcement is a national issue and resources vary between the Member States.
- It also has to be kept in mind that the Member States have different national legislation with its own specific aspects.

From the above, it is also clear that authorities believe that the responsibility for enforcement should remain at the Member State level, with one authority noting that a Member State is more able to understand what is going on in its market than a centralised mono-cultural office would be.

12.3.3 Regulatory burdens arising from overlaps or inconsistencies

With respect to regulatory burdens, Member State authorities were asked whether there were overlaps or inconsistencies in the chemicals legislative framework which impacted on regulatory burdens for authorities. Almost all authorities indicated that there were no significant overlaps or inconsistencies in implementation, enforcement of monitoring across the legislative framework. The only comments made were that there needs to be more fluid communication between competent authorities, as the time lab between decisions and these being communicated can lead to some overlaps and inconsistencies. Another noted that the legislation for the placing on the market of unpacked detergents is unclear and thus may affect consumer health and safety. Overlaps were also identified between particular product based regulations and CLP with respect to labelling requirements (e.g. food additives, feed related products, storage) and which cause a regulatory burden for authorities.

12.4 Reporting on CLP implementation

12.4.1 ECHA report on the Operation of REACH and CLP 2016

ECHA has published its second five year report on the implementation of REACH and CLP. The report makes more than 50 recommendations and slightly fewer than 20 commitments regarding the implementation of REACH and CLP. Some of the key recommendations and commitments from this report are as follows:

- differences in levels of implementation persist because there is significant variation across Member States relating to their national enforcement strategies and capacities;
- the availability of national helpdesks is one of the resources which enables companies to fulfil their legal obligations and thus leads to greater levels of compliance;
- most REACH instruments for coordinating enforcement work well but there is still a need for more resources to enhance levels of implementation and enforcement; and
- in order to support the functioning of the Single Market, it is necessary that all Member States take part in all Reach Enforcement Projects (REACH EN-FORCE – See 12.5 below), in addition to consistently enforcing ECHA and Commission decisions at the national level.

12.4.2 Country specific reporting on CLP[113]

Country specific reports on the operation of the REACH Regulation have to be submitted to the European Commission on the basis of article 117 (1) of the same Regulation focusing on evaluation and enforcement activities. These reports must be prepared and submitted by the Member States every 5 years and they include the reporting on the progress of the CLP Regulation in their country based on article 46 (2) of the CLP Regulation elaborating "the results of the official controls, and other enforcement measures taken." Further, it states that the results of the CLP reporting will be made available to the Agency [ECHA] who then will submit the results to the European Commission as part of the article 117 reporting obligation.

[113] Commission of the European Union (2015): Member States Reports on the operation of REACH (Art.117), available at http://ec.europa.eu/environment/chemicals/reach/reports_en.htm

The first article 117 (1) reports were published for 2010 and followed a specific set of questions which is the same for all Member States. While many of the questions relate to administrative information, the extensive questionnaire also contains specific questions on REACH and CLP, with a focus on REACH. The 2015 report included more questions on CLP and related enforcement activities. The second set of the 2015 reports from the EU-28 plus 3 EEA countries have now been reviewed and the resultant report published[114]. The report details the administrative measures (competent authorities, staff numbers, staff training, etc.) put in place by the Member State to support and enforce the implementation of REACH and CLP as well as the degree of activities and level of enforcements.

Arguably the most important conclusions from the analysis of these responses is that there is significant variation between countries regarding the numbers of enforcement measures relating to CLP (and REACH), as is seen in Table 12-4 below.

Clearly, there are wide variations from Member State to Member State, though these variations can also be explained by different definitions of "controls" used in each Member State. Within each Member State, CLP enforcement activities were generally applied across all links in the supply chain – manufacturers, importers, distributors and downstream users as illustrated in Table 12-5 below.

Table 12-4: Total number of official controls, such as inspections or investigations, or other enforcement measures carried out by enforcing authorities in which CLP was covered and/or enforced during the reporting period

Country	2010	2011	2012	2013	2014
Austria	3	112	115	132	271
Belgium		34	98	43	114
Bulgaria	16,499	11,042	9,758	7,933	11,113
Croatia				20	20
Cyprus	115	214	282	291	324
Czech Republic		0	17	81	92
Denmark		18	49	59	27
Estonia	2,295	1,724	1,761	2,111	1,537
Finland	9,784	278	298	26	55
France	2,566	822	409	467	262
Germany		2,211	1,338	2,780	2,701
Greece		971	2,213	2,099	1,174
Hungary		1,180		2,254	3,058
Iceland		251	173	63	53
Ireland	1,598	1,535	1,148	1,034	659
Italy			134	136	
Latvia	2,903	1,181	777	866	1,798
Liechtenstein		0	7	2	10
Lithuania		346	367	391	341
Luxembourg		2	1	0	7
Malta		2	3	2	

[114] Milieu (2016): Service contract for technical assistance to review the existing Member State reporting questionnaire under Article 117 REACH, including the evaluation and configuration of an appropriate IT tool for the reporting – Final Report for DG Environment. Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/final_report_2016.pdf

Table 12-4: Total number of official controls, such as inspections or investigations, or other enforcement measures carried out by enforcing authorities in which CLP was covered and/or enforced during the reporting period					
Country	**2010**	**2011**	**2012**	**2013**	**2014**
Netherlands	532	227	457	392	260
Norway		117	48	495	480
Poland		9,975	11,474	11,804	11,881
Portugal			109	86	62
Romania	69	488	509	470	501
Slovakia	767	1,775	947	389	1,412
Slovenia	770	300	300	300	300
Spain	498	828	2,886	3,391	3,322
Sweden		78	155	169	163
UK		16	17	17	17
Source: Mileu (2016) review of 2015 Member State Reports on REACH & CLP					

Table 12-5: Numbers of organisations subject to CLP enforcement activities under CLP in 2014				
Country	**Manufacturers**	**Importers**	**Distributors**	**Downstream Users**
Austria	21	7	140	71
Belgium		4	13	
Bulgaria	527	469	4071	2890
Croatia	0	15	20	25
Cyprus	10	94	521	65
Czech	13	27	53	23
Denmark	1	2	14	6
Estonia	22	51	155	1070
Finland	4	1	27	20
France	6000	77000	449000	1296000
Germany*	>205	>128	>1223	>199
Greece	46	974	79	75
Hungary	82	146	1540	1290
Iceland	0			
Ireland	12	33	240	465
Italy				
Latvia	6	877	1768	1734
Liechtenstein	10	0	0	0
Lithuania	9	31	168	133
Luxembourg	1	4	0	7
Malta				
Netherlands	89	70	70	79
Norway	6	25	202	314
Poland	480	103	8423	20103
Portugal	0	9	4	7
Romania	121	12	72	296
Slovakia	1	1	140	
Slovenia	10	10	100	100
Spain	169	66	542	1923
Sweden	3	3	76	21
UK	0	0	12	0
Source: Milieu (2016) review of 2015 Member State Reports on REACH & CLP (Annex 5) Blank cells represent "no data" *Based on responses from 12 out of 16 Lander in Germany				

The review of the 2015 reports notes that:

> *The majority of EU/EEA countries (26) has implemented an overall strategy for the enforcement of the CLP Regulation. Among the 5 countries that have no enforcement strategy in place, the 3 EU Member States have indicated that they are planning to develop one (Bulgaria, Estonia, Latvia).*

In most countries, this strategy was essentially the same as their REACH enforcement strategy.

Interestingly, no specifc problems with CLP enforcement are identified. Rather, there are several difficulties associated with REACH-related issues and several issues which affect both REACH and CLP enforcement, notably:

- Human and financial resources constraints (specifically Czech Republic, Finland, Latvia, Lithuania, Romania, Slovakia, Spain);
- Finding testing facilities/accredited laboratories (specifically Ireland, Lithuania, Romania); and
- Problems with getting information from long supply chains – especially outside the EU (specifically Austria, Germany, Hungary, Latvia, Slovakia).

The table below gives an overview of the CAs rating of the different resources available to them.

Table 12-6: CA's rating of their financial, technical and human resources (per country)

Rating	Financial resources	Technical resources	Human resources
Very high	1	0	1
High	17	24	8
Medium	19	10	12
Low	8	11	17
Very low	0	0	7

The potential impact of fewer enforcement and implementation activities is that this would most likely lead to a rise in the number of infringements or cases of non-compliance with CLP. The most obvious knock-on effects would be the negative impacts on human health and the environment. Less obvious is the negative impact on the functioning of the Single Market: if implementation of the legislation is more relaxed in one Member States than another, companies in the former may have less incentive to comply with the legislation and potentially, therefore, may incur lower compliance costs. If they choose to do this, they may be at a competitive advantage over companies based in or placing their products on markets in Member States in which the legislation is more stringently enforced.

However, it is not always the case that higher levels of resources leads to greater levels of enforcement-related activity. The table below compares the responses of CAs in different countries to the total number of official controls undertaken relating to CLP (these are the sums of the figures in Table 12-4). It is evident from the table below that the level of resources available significantly impacts enforcement and implementation activities. More interestingly, however, the data presented suggests that the countries who rate their levels of resources highly are not necessarily those who report the highest levels of enforcement-related activity.

Table 12-7: CA's rating of their financial, technical and human resources (per country)				
Country	Financial Resources	Technical Resources	Human Resources	Total number of enforcement-related actions
Austria	Medium	High	Medium	633
Belgium	Medium	High	Low	289
Bulgaria	Medium	Medium	Medium	56,345
Croatia	Low	Medium	Low	40
Cyprus	Medium	High	Low	1,226
Czech Republic	Medium	High	High	190
Denmark	Medium	High	Medium	153
Estonia	Low	Medium	Low	9,428
Finland	Medium	High	Low	10,441
France	Medium	High	Low	4,526
Germany	Medium	High	Medium	9,030
Greece	Very Low	Medium	Low	6,457
Hungary	Low	High	High	6,492
Iceland	Low	Medium	Low	540
Ireland	Low	Medium	Very Low	5,974
Italy	Low	High	Medium	270
Latvia	Low	High	Medium	7,525
Liechtenstein	Medium	High	Medium	19
Lithuania	Low	Medium	Medium	1,445
Luxembourg	Medium	High	Low	10
Malta	Very Low	Medium	Medium	7
Netherlands	Medium	High	Medium	1,868
Norway	Medium	High	Medium	1,140
Poland	Medium	High	High	45,134
Portugal	Very Low	Low	Very Low	257
Romania	Low	Low	Low	2,037
Slovakia	Low	Low	Very Low	5,290
Slovenia	Medium	Medium	Medium	1,970
Spain	Low	Medium	Low	10,925
Sweden	Medium	High	Medium	565
UK	Very High	High	Very High	67
Source: Mileu (2016) review of 2015 Member State Reports on REACH & CLP				

12.5 Broader enforcement activities

12.5.1 CLEEN project e-commerce II

The CLEEN project report[115] on e-commerce looks at trends in online chemicals trade in select European countries. In the case of Germany, it has increased dramatically over the period from 2004 to 2012. Nearly 1,300 illegal offers were detected during the two year inspection period (March 2011 – March 2013); of these, more than half were detected on the auction site "eBay". The

[115] Erdmann et al (2016): Project e-commerce II, Final Report to the Chemical Legislation European Enforcement Network (CLEEN), Germany. Available at: http://www.cleen-europe.eu/projects/ecommerce-ii.html

report also notes that acts of non-compliance with regards to Internet trade of chemicals include: concealing dangerous aspects of chemicals; failure to submit correct SDS to professional users; failing to provide information about the supplier company.

The report identifies the enforcement measures implemented by the authorities in the study countries. In 707 of the 1,289 cases, authorities had the offers removed from the Internet sites, which had the effect of intercepting and blocking the attempted sales. In 579 cases, the seller of the chemical was advised on the legal situation and their conduct. In 170 cases, sellers were instructed to dispose of the chemicals they were attempting to trade.

Authorities cooperated with trade platforms such as "eBay", who provided authorities with the ID of the sellers and bidders, to enable authorities to undertake legal action once the products were identified as being in breach of legislation, if so desired. Items were also removed from sale immediately. Another enforcement measure that was put in place was the implementation of user guidance sheets that appear automatically if a seller attempts to sell a good containing certain dangerous chemicals (Annex IV).

The report also makes recommendations for an EU-wide harmonised and co-ordinated effort for enforcement of online chemicals trade. These include increasing the exchange of information relating to the monitoring of chemicals trade over the Internet between Member States (and European Economic Area countries); harmonising and increasing enforcement via the sharing of knowledge, procedures and methods; and monitoring the online trade of a focused group of dangerous chemicals and chemical products, particularly on Internet auction sites, Internet shops and other such trading platforms.

12.5.2 REACH EN-FORCE

12.5.2.1 REACH EN-FORCE 1

The REACH and CLP enforcement project is organised in the so-called Forum (Forum for Exchange of Information on Enforcement) which "coordinates a network of Member State authorities responsible for enforcement."[116] In the Rules of Procedure of the Forum the scope of legislation which is being inspected by the forum has been summarised as being:

"*In accordance with Article 77(4) of the REACH Regulation, Article 46(3) of the CLP Regulation and Article 18(2) of the PIC Regulation, the Forum shall undertake the following tasks in relation to these three Regulations:*

a) Spreading good practice and highlighting problems at Community level;
b) Proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
c) Coordinating exchange of inspectors;
d) Identifying enforcement strategies, as well as best practice in enforcement;
e) Developing working methods and tools of use to local inspectors;
f) Developing an electronic information exchange procedure;
g) Liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;

[116] ECHA (n.d.): Enforcement Forum, available at http://echa.europa.eu/about-us/who-we-are/enforcement-forum

h) *Examining proposals for restrictions with a view to advising on enforceability (task not being relevant for the CLP and PIC Regulations).*"[117]

Throughout its existence, the Forum has developed the practice to select one specific area of REACH and CLP to be enforced through the REACH-EN-FORCE projects. At the same time as executing one of these specific REACH-EN-FORCE projects, others are being planned. For example, the fourth enforcement project is focusing on child resistant fastenings.[118]

The specific objective of the individual inspection projects differ depending on what issues are being examined. For this analysis only the enforcement projects which specifically addressed the CLP Regulation are elaborated.

12.5.2.2 REACH EN-FORCE 2

The second REACH EN-FORCE project took place from May 2011 to March 2012 in 28[119] Member States and had focused on both REACH and CLP. During this wave of inspections, checks were carried out on compliance with CLP obligations.[120] Compared to the previous enforcement project which focused on substance manufacturers and their role under the REACH, this project focused on downstream users. Inspections covered "*1,181 enterprises of four size categories were reported with checks on approximately 6 900 substances, 4 500 mixtures and the evaluation of 4 500 SDSs*."[121]

With regards to CLP the following two articles have been of interest for the inspectors:

- Article 40 - obligation to notify ECHA (only if the downstream user is also a manufacturer or importer of substances); and
- Article 49 – there is a duty for suppliers to collect and maintain information as required by CLP for at least 10 years after the substance or the mixture was last supplied by that supplier.

It has been said that overall compliance with the obligations arising from REACH and CLP improved compared to the previous enforcement project. However, it also emerged that two thirds of the companies inspected still failed to comply with their obligations. Table 12-8 sets out the measures imposed by authorities in reaction to detected violations of the CLP provisions.

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[117] ECHA (2015): Rules of Procedure for the Forum for Exchange of Information on enforcement, available at http://echa.europa.eu/documents/10162/13577/forum_procedures_rules_en.pdf

[118] European Chemicals Agency (2016): Report on the Operation of REACH and CLP 2016, available at http://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

[119] In 2007 the European Union enlarged from 25 to 27 Member States with the addition of Bulgaria and Romania. In 2016 the European Union has 28 Member States having Croatia join in 2013, available at

http://ec.europa.eu/economy_finance/international/enlargement/index_en.htm

[120] Institute for Environment and Food Safety Vorarlberg (2013): EU Inspection Project "REACH–EN–FORCE 2" Results and Lessons, available at http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Workshops/RIEF-II-18-December-2013/REACH%20Enforcemement%202%20%28E.%20Anwander%20-%20Institue%20Environment%20Food%20Safety%20-%20Austria%29.pdf

[121] European Chemicals Agency (2013): Forum REACH-EN-FORCE 2 Project Report Obligation of downstream users-formulators of mixtures, available at http://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

Table 12-8: Measures imposed by authorities in reaction to detected violations of CLP provisions																	
	n[122]		No measures	Enjoinments		Other measures		Advice verbal/written		Fines		Orders		Criminal complaints		Request to other MS	
Infringement category		#[123]	%[124]	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Non-compliance over all	789	38	5	38	5	92	12	548	69	8	1	167	21	4	1	18	2
Failure to notify to C&L inventory[125]	32	2	6	4	13	1	3	19	59	2	6	12	38		0	1	3
– Required SDSs missing – Deficient information in SDS – Information obligation acc. Art 32 REACH not met – No access to relevant information for workers – Insufficient archiving infrastructure/ – instruments – Other defects	623	35	6	20	3	52	8	422	58	5	1	116	19	3	0	10	2

[122] *n*: sample size

[123] #: cases reported

[124] %: percentage of the total number of cases in the infringement category

[125] Includes only MIOR-companies with no further offenses related to the pre-registration status of managed substances

12.5.2.3 REACH EN-FORCE 4

Under the fourth enforcement project a pilot project on child resistant fastenings was carried out. The pilot project was implemented in the second half of 2015, after the deadline for mixtures expired. It has taken into account that "when assessing compliance, the aim was to get a general picture of the enforceability of child resistant fastenings and related obligations, regardless of whether the obligation is based on Directive 99/45/EC (Dangerous Preparations Directive) or the CLP Regulation."[126]

The pilot project was undertaken in 15 Member States and EEA counties and in total 797 products were inspected for their compliance with article 35 (2) CLP regarding child resistant fastenings (CRFs). Non-compliance was identified in 230 of these products (for some products, there were multiple deficiencies). These instances of non-compliance were:

- 136 products did not comply with CRF provisions;
- 77 products didn't meet TWD (tactile warnings of danger) requirements;
- Classification and labelling was incorrect in 66 cases; and

In 32 cases, CRF on packaging was judged by inspectors to be inadequately secure. 411 legal actions and enforcement measures were taken by inspectors relating to these cases of non-compliance. Most of the actions taken were verbal or written advice or administrative orders. In the cases where the security of the packaging was compromised, inspectors either prohibited the product being placed on the market or the products were withdrawn from the market, if already placed.

Recommendations from this project regarding the implementation and enforcement of the CRF provision in CLP included:

- In order to address the challenges to those in the supply chain, ECHA guidance on complying with the CRF and TWD requirements is needed;
- Inspectors need guidance, particularly regarding the interpretation of certain standards and provisions within the legislation;
- The Forum recommends that national authorities promote awareness within their country regarding the requirements of CRF and TWD; and
- More detailed information is required either in Annex II of CLP or in a form of guidance as the relevant standard relating to CRF and TWD requirements is often not available to industry, according to this report.

12.5.2.4 REACH EN-FORCE 5

In the meeting minutes of the Forum deciding on future enforcement projects it was decided by a majority vote to investigate extended SDS and Risk Management Measures for the REF-5 project. The WG also proposed some topics for pilot projects to be executed during 2016-2017. These proposals included E-commerce and Article 48 of CLP, and the labelling of unpacked mixtures and detergents in soluble packaging."

[126] ECHA (2016): Report: Forum Pilot Project on Child-resistant fastenings, available at http://echa.europa.eu/documents/10162/13577/forum_pilot_project_crf_en.pdf

12.5.3 RAPEX

The EU's Rapid Exchange System for information on dangerous non-food products (RAPEX) was established in 2003 and submissions by Member States had increased to nearly 2,500 notifications in 2014.[127] In simple terms this information exchange system can be described as a database of products which need to be withdrawn from the internal market because of their dangerous properties. In 2013, there have been a total of 2,364 of notifications of the 31 participating countries (EU28 and Norway, Iceland and Liechtenstein), with the most frequent notified product categories being the following:

- 25% Clothing, textiles and fashion items;
- 25% Toys;
- 9% Electrical appliances and equipment;
- 7% Motor vehicles;
- 4% Cosmetics

Although these submissions relate mostly to consumer products and not directly to chemicals, the presence of substances that are restricted under REACH is often the reason for notification. However, a search of RAPEX database product recalls for chemical substances themselves can also be found with some relating to the labelling and packaging requirements of CLP. For example, in the case of valve oil for musical instruments, a recall has been issued on the basis of lacking labelling information: *"The product lacks the required labelling, child-resistant fastening and tactile warning of danger. The precautionary statements on the label are insufficient. The product does not comply with the Regulation on the classification, labelling and packaging of substances and mixtures (CLP)."*[128]

Another such product recall which has been classified as serious because of lack of compliance with CLP can be seen in the following case in which the risk was described as: "*The product lacks the required safety cap, while it can contain up to 30% by weight of dichloromethane (according to the safety data sheet). The absence of a child-resistant fastening could lead children to accidentally swallow some of the product. The product does not comply with the Regulation on the classification, labelling and packaging of substances and mixtures (CLP).*"[129]

The notifications by Member States include an example of a poisoning case involving a product which is a rust-removing and descaling agent containing nitric acid. The product was imported from Turkey in packaging which was not compliant with CLP; the same product is sold on the German market but in this case it is fully compliant with the CLP Regulation. The product did not have a child resistant fastening and a child consumed a small quantity of the household cleaner. This incident

[127] ECHA (n.d.): RAPEX – keeping European consumers safe from chemical risks, available at http://newsletter.echa.europa.eu/home/-/newsletter/entry/3_15_rapex-keeping-european-consumers-safe-from-chemical-risks

[128] European Commission (2016): The Rapid Alert System for Non-Food Products (RAPEX): Notification Reference: A11/0009/16, available at http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/index.cfm?event=main.notification&search_term=A11/0009/16&exclude_search_term=0&search_year=2016

[129] European Commission (2016): The Rapid Alert System for Non-Food Products (RAPEX): Notification Reference: A12/0237/16, available at http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/index.cfm?event=main.notification&search_term=A12/0237/16&exclude_search_term=0&search_year=2016

resulted in the child being treated for 12 days in intensive care before having numerous follow-up appointments to treat the gastrointestinal wounds.[130]

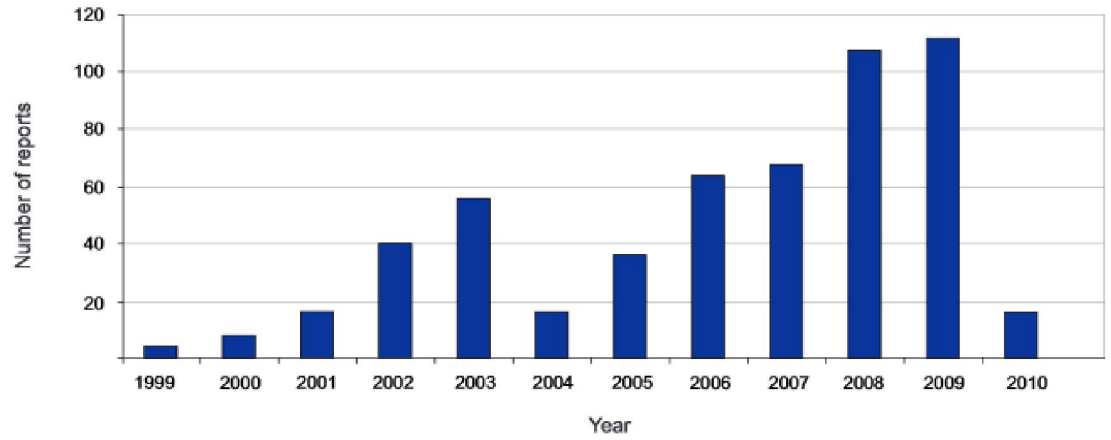

Figure 12-1: Cases of poisoning by Por Çöz by year of accident
***Source*:** Bundesinstitut für Risikobewertung (2010): Cases of Poisoning Reported by Physicians in 2010, available at http://www.bfr.bund.de/cm/364/cases-of-poisoning-reported-by-physicians-2010.pdf

This example clearly shows the benefits of the CRF requirements for such products (note that action in this case was taken under these requirements as set out in the Dangerous Substances Directive rather than CLP). The product was banned from sale within Germany, and the need for such action can be seen by statistics pulled together by German Authorities after the incident to collect data on other reported cases involving the same household cleaner; this illustrates the ongoing importance of national enforcement activities and the why CLP's packaging continue to be important.

12.6 Costs of implementation, monitoring and enforcement

Key Findings

- The average annual costs to ECHA associated with implementing CLP are estimated to be over €2.57 million.
- The total cost to ECHA of implementing CLP over the period 2010 to 2016 is over €22.8 million, equivalent to 17% of the total REACH and CLP budget.
- The total annual costs related to CLP of monitoring, enforcement and adjudication across EU €32,459,600.

12.6.1 Costs to ECHA

Data are taken from the publicly-available ECHA budgets[131] (Budget 2011 to Budget 2016) to estimate the costs to ECHA associated with implementing CLP. In these budgets, payment

[130] Bundesinstitut für Risikobewertung (2010): Cases of Poisoning Reported by Physicians in 2010, available at http://www.bfr.bund.de/cm/364/cases-of-poisoning-reported-by-physicians-2010.pdf

[131] http://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2016

appropriations are allocated to REACH and CLP together. Therefore we have drawn out the data for the cost categories which we believe are relevant to CLP and have made assumptions about the percentage of the budget allocated to each of these categories that would be spent on CLP-related activities. For example, we have assumed that 100% of the budget allocated to line 3006 of the budget, 'Classification and labelling', is related to CLP whereas we have assumed that only 20% of the budget allocated to line 3011, 'Committees and Forum', would be attributable to CLP. Where possible, we have endeavoured to take the most up-to-date data available, to provide as accurate an estimation of the costs as possible. However, for the years 2015 and 2016, final data is not available and so the figures for these years are the best estimates of projected expenditure for these years. The average annual costs to ECHA associated with implementing CLP are estimated to be over **€2.57 million**. This figure constitutes the cost of providing guidance, running helpdesks, overseeing committees and forums, etc.[132]. The total cost to ECHA of implementing CLP over the period 2010 to 2016 is over **€22.8 million**, equivalent to 17% of the total REACH and CLP budget.

Table 12-9: ECHA Budget for CLP

Reference in ECHA budget	Operational Activity	% of total budget for activity estimated as attributable to CLP	Total budget between 2010 and 2016	Cost estimated as attributable to CLP
3006	Classification and labelling	100%	€796,198	€796,198
3007	Advice and assistance through guidance and helpdesk	40%	€2,165,835	€866,334
3008	Scientific IT tools	5%	€76,496,410	€3,824,821
3009	Scientific and technical advice to EU institutions and bodies	10%	€1,206,007	€120,601
3011	Committees and Forum	20%	€12,824,617	€2,564,923
3012	Board of Appeal	20%	€560,886	€112,177
3013	Communications including translations	40%	€35,330,895	€14,132,358
3801	Cooperation with international organisations for IT programmes	10%	€4,216,291	€421,629
Total across period			**€133,597,139**	**€22,839,041**

12.6.2 Regulatory burdens - costs to Member States

The estimated costs to Member States of enforcement activities take into account three factors: cost of training inspectors, cost of on-site inspections, and cost of running poison centres. The cost assumptions for the first two factors are based on a 2011 report commissioned by DG Environment which looked at the inspection requirements for REACH and CLP[133]. The costs of running poison centres are detailed in chapter 6.

12.6.2.1 Cost of Training Inspectors

The Enforcement Forum oversees an annual two-day training event for inspectors from each Member State with the intention to provide inspectors with the resources and information required to enable them to carry out inspections in an effective and efficient way. The expectation is that the

Detailed descriptions of the cost categories can be found within the original ECHA budget.

[132] See Annex 5 for the raw data used to calculate the average annual costs to ECHA of implementing CLP.

[133] http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study6.pdf

inspectors attending the training event will then pass on the materials and methods which they have learnt to fellow inspectors in their Member State. We assume that the cost of training one inspector is equivalent to two working days plus travel and accommodation expenses of attending the workshop. We therefore calculate the cost of training one inspector as follows.

Table 12-10: Costs of training inspectors	
Cost assumptions for training one inspector	
Two working days	€600 (based on 7.5 hours per day multiplied by an hourly rate of €40, as has been the case in our other calculations).
Travel and accommodation expenses	€200
Total cost of one inspector attending ECHA's annual training event	**€800**

The average number of inspectors who are trained on REACH and CLP per year in the EU is 2,087[134]. Therefore, the total cost per annum of training inspectors across the EU-28 is **€1,669,600**.

12.6.2.2 Frequency of On-site Inspections

As reported above, the number of inspections which took place as part of the REACH-EN-FORCE-2 (REF 2) project was 1,181 over an 11 month period between 2011 and 2012. Table 12-11 indicates the number of reported inspections for each Member State.

Table 12-11: Countries participating in REACH-EN-FORCE-2 Project and reported inspections	
Country	**Number of submitted inspection reports**
Austria	20
Belgium	41
Bulgaria	31
Cyprus	13
Czech Republic	17
Denmark	20
Estonia	20
Finland	14
France	97
Germany	228
Greece	41
Hungary	22
Iceland	5
Ireland	22
Italy	43
Latvia	24
Liechtenstein	3
Lithuania	26
Malta	7
Netherlands	48
Norway	24
Poland	90
Portugal	43
Romania	10
Slovakia	39

[134] European Commission (2015). Measuring Enforcement. Indicators at EU level. Available at: http://echa.europa.eu/documents/10162/13577/f22_pres_17_1_com_enforcement_en.pdf

Table 12-11: Countries participating in REACH-EN-FORCE-2 Project and reported inspections	
Country	**Number of submitted inspection reports**
Slovenia	9
Spain	161
Sweden	43
United Kingdom	20
Total	**1,181**
Source: Forum REACH-EN-FORCE 2 Project Report (2013)[104]	

However, as we are only concerned with Member States, we will exclude Liechtenstein and Norway from our calculations. This leaves us with 1,154 reported inspections. Germany and Spain report a much higher number of inspections compared to other Member States (228 and 161, respectively) whereas Iceland, Malta and Slovenia report comparatively fewer inspections. The report attributes this disparity in the number of enforcement actions performed to differences in several factors such as economic conditions, resources available and size of the country. Moreover, the size of the chemicals industry in each of these countries will also be a significant factor in explaining the variance in the number of reported inspections across Member States.

We can use the number of inspections reported over this 11 month period to extrapolate to give the number of inspections over a 12 month period, which will help to calculate the annual costs of inspections. Dividing 1,154 by 11 gives a monthly figure of just under 105 inspections; multiplying this by 12 gives the average annual number of inspections across the 28 Member States as **1,259**.

However, in our cost analysis, it will be important to take into account that only a certain percentage of the costs of carrying out enforcement-related inspections will be attributable to CLP. In the report, it is stated that the REACH EN-FORCE 2 project focused on only two articles of the CLP Regulation, compared to the eight articles of the REACH Regulation which are under the scope of the REF 2 project. On this basis, our calculations of the total enforcement costs based on the data taken from this report will assume that 20% of the total costs are the costs associated with enforcing CLP. This figure is in line with the estimated percentage of costs to ECHA of implementing REACH and CLP which are deemed attributable to CLP (17%).

12.6.2.3 Costs of On-site Inspections

A study undertaken for DG Environment[135] provides estimates for the costs of conducting on-site inspections, as well as desk-based inspections. As stated in the report, it is difficult to make a generalisation about the duration, and hence the cost, of an inspection: in the report, six countries are used to form the case study. Across these six countries, the average duration of an on-site inspection varies from 1.5 days to 6 days. The average duration across those reported in the study is 2.93 days for an on-site inspection, therefore this is the number we employ when calculating the cost of an on-site visit.

The report calculates the cost of an inspection as the duration of the inspection multiplied by the daily tariff. We follow the same procedure and assume a daily tariff of €300 (based on an hourly tariff of €40 and a working day assumed to be 7.5 hours). Multiplying by 2.93 gives the average cost of an on-site inspection as €879. Following the estimates and assumptions made about the annual number of inspections carried out in relation to the enforcement of REACH and CLP, the annual cost of on-site inspections pertaining to these pieces of legislation is estimated to be €1.1 million.

[135] http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study6.pdf

Assuming CLP-related enforcement activities only account for 20% of this total, it is estimated that the annual cost of CLP-related on-site inspections is just over **€220,000**.

12.6.3 Total Costs of Implementation, monitoring and enforcement

Table 12-12 below summarises the costs incurred in the EU relating to monitoring, enforcement and adjudication with respect to the CLP Regulation, including the costs of running poison centres (as discussed in Section 8).

Table 12-12: Total costs of monitoring, enforcement and adjudication across EU	
Cost Element	**Annual Cost**
Costs to ECHA	€2,570,000
Costs of Training Inspectors	€1,669,600
Costs of On-site Inspections	€220,000
Costs of Poison Centres	€28,000,000
Total	**€32,459,600**

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Annex 1 Child Resistant Closures

A1.1 Introduction

The general requirements relating to physical packaging are set out under Article 32 and 35 of CLP. Article 35(1) specifies that packages must be:

- Well designed and constructed.
- Compatible with the contents.
- Such that fastenings will not loosen and meet stresses and strains of normal handling, and shall be capable of repeated closure with contents escaping.

If packages are to be supplied to the general public, Article 32(2) requires that they:

- do not have shape or design likely to attract or arouse the active curiosity of children or mislead consumers; and
- do not have a presentation or design used for human or animal foodstuffs, medicinal, or cosmetic products which would mislead consumers.

Article 35(2) then goes on to require that packaging supplied to the general public shall, in certain circumstances, feature a child resistant fastening (CRF, also commonly known as a child resistant closure - CRC), and/or a tactile warning of danger (TWD). A child resistant closure (CRC) is a particular type of closure that is required to be present on the receptacle immediately containing certain hazardous chemicals, when they are supplied to the general public. Its function is to act as a last line of defense against the possibility that a child may accidentally ingest the contents. A Tactile Warning of Danger (TWD) is a device required to be present on the immediate receptacle of certain hazardous chemicals, and the intention of which is to alert visually handicapped general public users of the fact that the receptacle contains a dangerous product.

These provisions are not new, having been a feature of the former 67/548/EEC Dangerous Substances Directive and 1999/45/EC Dangerous Preparations Directive system. The Dangerous Preparations Directive is being fully replaced by CLP, with effect from 1 June 2015. In addition, there are two exceptions to these requirements: they do not apply to transportable gas receptacles; and aerosols and containers fitted with a sealed spray attachment and containing substance or mixtures classified within aspiration toxicity cat 1 need not be fitted with a TWD, unless they are also classified for one or more of the above listed hazard types.

A1.2 Requirements under the Dangerous Substances Directive/ Dangerous Preparations Directive compared to CLP

A1.2.1 Legislative requirements

The need to modify packaging for CRC and TWDs in moving from the Dangerous Substances Directive/Dangerous Preparations Directive to CLP will have had a number of implications:

- The need to replace cartons and pouches with plastic containers that can carry a CRC, and the need to modify some of the existing plastic containers to include CRC;

- The need to modify the equipment used in packing/filling lines;
- The need to modify existing moulds for plastic packaging to incorporate tactile warnings of danger;
- Potential implications for transport and storage due to changes in packaging; and
- Potential costs under the Packaging Waste Directive in relation to changes in 'producer responsibilities'.

Under Annex IV to the Dangerous Preparations Directive 1999/45/EC, containers containing substances or preparations with specific labelling requirements or which contain methanol or dichloromethane had to be fitted with child resistant closures and/or tactile warnings as set out in Table 3.1. Such provisions applied regardless of the size of the container concerned. It should be noted that preparations were only to be labelled as highly toxic (T+), toxic (T), corrosive (C), or harmful (Xn), where the substance/s that assigned these hazard classifications were present in concentrations greater than the limit concentrations as set out in Annex I to Directive 67/548/EEC or Part B of Annex II to Directive 1999/45/EC.

Table A1-1: A Summary of the Criteria for Triggering Provisions for Child Resistant Closures and/or Tactile Warnings Under the Dangerous Preparations Directive 1999/45/EC

Criteria	Child-Resistant Closures	Tactile Warnings
Very toxic (T+)	✓	✓
Toxic (T)	✓	✓
Corrosive (C)	✓	✓
Harmful (Xn)		✓
Aspiration hazard (Xn, R65) *Not aerosols or if in container with sealed spray attachment*	✓	
Methanol (concentration limit ≥ 3%)	✓	
Dichloromethane (concentration limit ≥ 1%)	✓	
Extremely flammable (F+: gases, liquids or solids) *Not extremely flammable" aerosols*		✓
Highly flammable (F: gases, liquids or solids) *Not highly flammable aerosols*		✓

Under CLP, containers containing substances or mixtures (preparations) with specific labelling requirements must be fitted with child resistant fastenings and/or tactile warnings as set out in Table A1-2. Again, these provisions apply whatever the size of the container concerned. The provisions requiring the fitting of CRCs and/or TWDs are triggered by the hazard classification of the substance or preparation concerned, in contrast to Directive 1999/45/EC where the provisions were triggered by the hazard label affixed to the packaging containing the substance or preparation. Thus, all products classified as corrosive under CLP (including those previously classified as irritant) require CRCs and TWDs.

Table A1-2: A Summary of the Criteria for Triggering the Provisions for Child Resistant Fastenings s and/or Tactile Warnings Under CLP		
Hazard Class	**Child-Resistant Fastenings**	**Tactile Warnings**
Acutely toxic (category 1 to 3)	✓	✓
Acutely toxic (category 4)		✓
STOT single exposure (category 1)	✓	✓
STOT single exposure (category 2)		✓
STOT repeated exposure (category 1)	✓	✓
STOT repeated exposure (category 2)		✓
Skin corrosive (category 1A, 1b and 1C)	✓	✓
Reparatory sensitisation (category 1)		✓
Aspiration hazard (category 1) *Not aerosols or if in container with sealed spray attachment*	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
Flammable liquids (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
Flammable solids (category 1 and 2) *Not "extremely flammable" or "flammable" aerosols"*		✓
* Note that the TWD provisions do not apply to aerosols which are only classified and labelled as extremely flammable or flammable aerosols. *Source: ECHA (2011): Guidance on Labelling and Packaging in accordance with Regulation (EC) No 127, Helsinki.*		

A1.2.2 AISE estimates of products requiring CRCs or TWDs

Previous work for AISE found that from 15% to 55% of a manufacturer's products falling within the detergents and cleaning products sector included CRCs or TWDs under the Dangerous Preparations Directive (depending on the manufacturer and product types). It then predicted that between 80% and 100% (and even up to 100%) of certain products may require CRCs and TWDs under CLP for the majority of companies within the detergents and cleaning products sector due to changes in classification thresholds and the increased number of relevant classification categories, although there were also lower estimates. Estimates were based on the then draft legislation which corresponded to Table A1-2 above with the key inclusion of eye damage cat 1.

The potential to reformulate was identified but there was concern over the impact this would have on product efficacy. The implications were therefore that new packaging would have to be designed, together with a move to plastic containers for certain categories of products. This would also result in the need for modifications to packaging lines. Furthermore, some of the existing CRCs are not compliant with the norms (e.g. sprays) such that packaging development may have to occur.

A1.2.3 Costs of CRCs and TWDs

The costs of the CRCs themselves are relatively low, at just a few cents per cap, but they have to be applied to all containers of all products falling into a relevant classification. As well as the CRC, packaging needed to be changed so that it is appropriate to carry a CRC, with this meaning that the packaging lines also have had to be modified. The costs of changing packaging from cardboard skillets/cartons to plastic containers are estimated at around €60 per 1000 pieces, based on data from a number of manufacturers. These are on-going compliance costs that will be realised annually. The requirement for TWDs involves the redesign of bottle mould cavities for products sold in plastic bottles or development of new moulds for products currently sold in cardboard skillets/cartons or pouches.

The modifications required to packaging lines vary according to the packaging previously used. Cost estimates of moving from cardboard/cartons or pouches to plastic bags range from around €2 – €2.5 million per product line for a larger manufacturer. The costs of moving from plastic bottles without CRCs to those with CRCs are calculated at €150,000 per pack size, with this cost applying to each pack size per product line. Assuming, an average of three pack sizes per product line (which is reasonable for the most affected types of products) gives costs per product line of €450,000 for moving from plastic bottles without CRCs to those with CRCs. These costs are one-off compliance costs.

The AISE study used two case studies to calculate costs: one was based on a large company (with turnover of around one billion euros and operations across the several sites in the EU) and a small/medium company (with turnover of <€50 million – assumed here to be €25 million). The calculations were based on specific information provided by companies within the detergents and cleaning product sector. Three different cost estimates covering a 10 year period were developed:

- Costs associated with a change in packaging required due to the need to provide a CRC, with these including the additional running costs associated with, for example, slower filling of plastic containers, compared with cardboard containers;
- The costs of including the CRCs themselves; and
- Costs for changes in packaging lines when the new packaging and/or CRCs are used.

Figure A1-1 provides an overview of the approach used to estimate the costs of providing CRCs for the AISE study and repeated for this study.

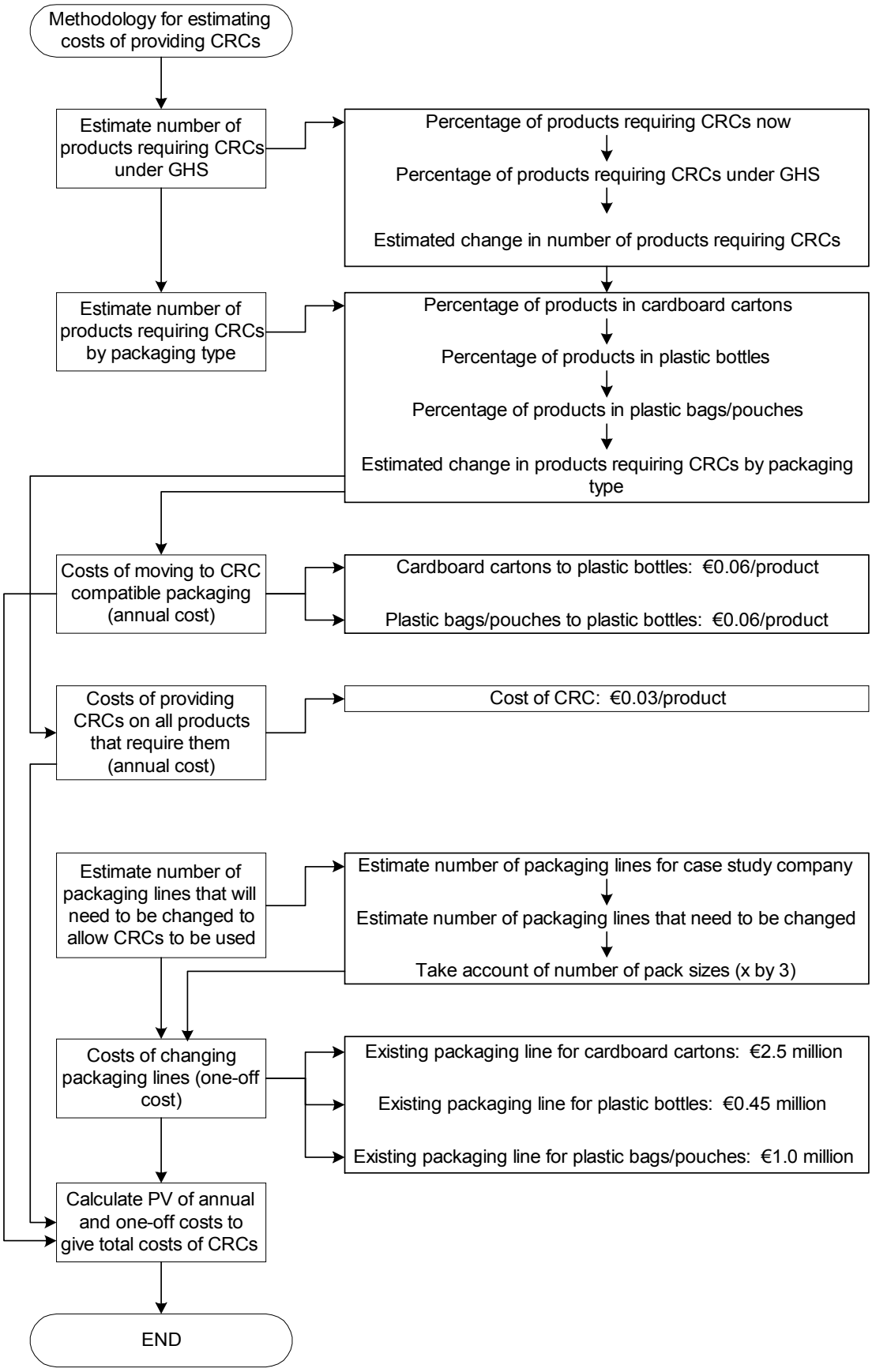

Figure A1-1: Overview of the Methodology Used to Estimate the Costs of CRCs

The Figure shows that there are three key estimates that have to be developed before costs can be calculated. These are:

1. An estimate of the number of products requiring CRCs under GHS: this was estimated by considering the difference between the percentage of products that require CRCs now and the percentage of products that would require CRCs under CLP;

2. An estimate of number of products requiring CRCs by packaging type: many of the costs vary according to the packaging that is currently used for different product types. The number of products affected per product type is estimated by considering what percentage of products are provided in cardboard cartons, plastic bottles and plastic bags/pouches and how this would have to change such that CRCs can be used; and

3. An estimate of the number of packaging lines that would need to be changed to allow CRCs to be used: following the change of packaging and inclusion of CRCs, it would then be necessary to change the packaging lines so that the new products can be manufactured. The number of packaging lines affected is estimated by calculating the number of packaging lines that would have to change, taking into account the number of product lines and pack sizes for which the packaging type will change or for which the existing packaging includes CRCs.

These estimates are then multiplied by the appropriate costs to give overall estimates of the costs of the changes that will have to be made to meet the requirements of GHS.

A1.3 Large Company Case Study

A1.3.1 Introduction

The large company case study was developed to reflect a multinational company, operating at several sites across the EU, with annual sales of around €1.3 billion. It was assumed to produce more than 1 billion products per year, of which 45% are fabric washing products, 24% are hard surface cleaners and 19% are bleaches. The company also produces hand dish washing and automatic dish washing products (6%) and maintenance products (6%). The case study company is assumed to represent a 'typical' company based on the questionnaire responses from several large companies.

Table A1-3 sets out the assumptions that were made in the study as to the number of products that would change classification within a large manufacturer's product portfolio. It is important to note that the main classification criterion assumed to drive costs was the inclusion of serious eye damage cat 1 (Dangerous Preparations Directive classification R41) into the categories requiring CRCs, although skin corrosive (cat 1A, 1B and 1C) was also important in some cases. As the serious eye damage category was not included in the final CLP Regulation as requiring CRCs, the figures estimated for AISE are no longer valid. Indeed, this decision not to include serious eye damage cat 1 will have led to significant savings in the costs of implementing CLP.

Table A1-3: Change in Percentage of Products Identified as Requiring a CRC Now and in the Future			
Product Type	% Requiring CRCs Now		Source
	Under DSD/DPD	Assumed to under GHS	
Soaps	0%	0%	Based on changes for other products – no data specific to soaps
Fabric washing – washing powder/tablets	3%	83%	Based on change in products classified as R41 from questionnaires (for fabric washing generally rather than sub-categories)
Fabric washing – washing liquid	3%	83%	
Fabric washing – softener	3%	83%	
Fabric washing – stain remover/spotter	3%	83%	
Hand dish washing	0%	100%	Based on change in products classified as R41 from questionnaires
Automatic dish washing	85%	100%	
Hard surface cleaning	0%	100%	
Maintenance products	50%	50%	Based on change in products classified as R41 from questionnaires before and after – suggests no change
Bleaches	30%	100%	Based on change in products classified as R41 from questionnaires (increased to 30% to account for some bleach products already having CRCs)
Note: The current classifications were in some cases based on the AISE expert system rather than the DPD calculation method. The % assumed to be classified under the GHS were derived using the GHS calculation methods and/or the tables of equivalence. DSD: Dangerous Substances Directive. DPD: Dangerous Preparations Directive. *Source*: RPA (2007)			

A1.3.2 Impacts of Changes in Packaging Type and CRCs

The packaging type used by manufacturers for each product type was then considered, as there are price differences for including CRCs on products that are packaged in cardboard cartons or plastic bags/pouches than in plastic bottles. Table A1-4 provides a summary of the assumptions on the percentage of each product type that was supplied pre CLP in cardboard cartons, plastic bottles or plastic bags/pouches, together with estimates of the number of products per packaging type based on data provided by large companies.

The costs of moving from cardboard cartons to plastic bottles and from plastic bags/pouches to plastic bottles were based on estimates provided by AISE members:

- moving from cardboard cartons to plastic bottles: €60 to €650 per 1,000 pieces, with the analysis based on €350 per 1,000 pieces (or €0.35 per product unit); and
- moving from plastic bags/pouches to plastic bottles: €60 to €230 per 1,000 pieces, with the analysis based on €60 per 1,000 pieces (or €0.06 per product unit).

Based on these figures, the annual compliance costs of new packaging were estimated, taking into account the savings from not having to purchase the old packaging. Table A1-5 provides the resulting estimates, by product type, of moving to alternative packaging compatible with CRCs.

Table A1-4: Percentage of Products Provided in Different Kinds of Packaging – large manufacturer						
Product Type	% products by packaging type			No. units by packaging Type		
	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches
Soaps	100%	-	-	-	-	-
Fabric washing – washing powder/tablets	70%	-	30%	180 million	-	76 million
Fabric washing – washing liquid	-	75%	25%	-	27 million	9 million
Fabric washing – softener	-	100%	-	-	36 million	-
Fabric washing – stain remover/spotter	-	80%	20%	-	29 million	7.2 million
Hand dish washing	-	100%	-	-	40 million	-
Automatic dish washing	80%	20%	-	3.6 million	0.9 million	-
Hard surface cleaning	-	100%	-	-	250 million	-
Maintenance products	-	100%	-	-	-	-
Bleaches	-	100%	-	-	140 million	-
Source: RPA (2008): Estimates based on products available for purchase in supermarkets, etc. and data provided by large manufacturers within the sector						

Table A1-5: Costs of Moving to CRC Compatible Packaging and Including CRCs on individual containers				
Product Type	Packaging Type			Costs of including CRC per product type
	Cardboard cartons	Plastic bottles	Plastic bags/ pouches	
Soaps	-	-	-	€0 (not included in case study)*
Fabric washing – washing powder/tablets	€11 million	-	€4.5 million	€7.6 million
Fabric washing – washing liquid	-	-	€0.5 million	€1.1 million
Fabric washing – softener	-	-	-	€1.1 million
Fabric washing – stain remover/spotter	-	-	€0.4 million	€1.1 million
Hand dish washing	-	-	-	€1.2 million
Automatic dish washing	€220,000	-	-	€0.1 million
Hard surface cleaning	-	-	-	€7.5 million
Maintenance products	-	-	-	€0 (no change in products classified as corrosive)
Bleaches	-	-	-	€4.2 million
* No soap production by large companies responding to questionnaire *Source*: RPA (2008): Based on data from large companies on number of products manufactured and guesstimates on type of packaging used, multiplied by costs relevant to each packaging type. Also based on additional number of products that would be classified as corrosive under GHS multiplied by cost of providing CRC (to two significant figures)				

These are annual compliance costs[136], and assume only cardboard cartons and plastic bags/pouches were not compatible with CRCs.

Added to these are the costs of providing CRCs on every container, which are estimated at €0.03 per product unit. This cost applies to all products that did not include a CRC under the Dangerous Preparations Directive; when multiplied by the number of units produced per annum, it provides an indication of the annual compliance costs that are additional to the costs of changing packaging. The costs by product type are also provided in Table A1-5 above. These figures include the increased costs of running the packaging lines, arising from the longer time it takes to fill the containers.

A1.3.3 Impacts on Packaging Lines

Changes also had to be made to packaging lines so that that they could be used to fill the new containers. These changes include development costs, costs of new moulds and new installations. Calculation of these costs as part of the AISE work required estimation of the number of packaging lines for a large case study company. Based on data submitted by a range of companies, the assumption was made that 30 million products are filled per packaging line per year for all product types. The estimate is based a realistic production rate, assuming 1 product per second on a packaging line operating 24 hours per day for 300 days per year[137]. The number of packaging lines assumed to be affected by the increased number of products classified as corrosive, and taking into account that each is used on average to produce three different pack sizes, are given in Table A1-6.

The costs of the changes that need to be made to each packaging line to accommodate the new containers are also given in Table A1-6. These were estimated to be as follows:

- moving from cardboard to plastic bottles: €2.5 million per packaging line;
- moving from plastic bottles with no CRCs to those with CRCs: €450,000 per packaging line; and
- moving from plastic bags/pouches to plastic bottles: €1.0 million per packaging line.

These are one-off costs that would have to be incurred before any new packages with CRCs could be filled.

Table A1-6: Number of packaging lines affected and costs of changing lines taking into account different pack sizes

Product Type	Packaging Type					
	No. of packaging lines			Cost of changing lines		
	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches
Soaps	-	-	-	-	-	-
Fabric washing – washing powder/tablets	18	-	8	€44million	-	€7.6 million

[136] Note, this assumes that there is no plan to repackage any of the products over the next 10 years.

[137] This gives an estimate of 25.9 million products per year, but is rounded to the nearest 10 million to reflect uncertainty, resulting in an estimate of 30 million.

Table A1-6: Number of packaging lines affected and costs of changing lines taking into account different pack sizes						
Product Type	Packaging Type					
	No. of packaging lines			Cost of changing lines		
	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches	Cardboard Cartons	Plastic Bottles	Plastic Bags/ Pouches
Fabric washing – washing liquid	-	3	1	-	€1.2 million	€0.9 million
Fabric washing – softener	-	4	-	-	€1.6 million	-
Fabric washing – stain remover/spotter	-	3	1	-	€1.3 million	€0.7 million
Hand dish washing	-	4	-	-	€1.8 million	-
Automatic dish washing	<1	<1	-	€0.9 million	€0.04 million	-
Hard surface cleaning	-	25	-	-	€11 million	-
Maintenance products	-	-	-	-	-	-
Bleaches	-	14	-	-	€6.3 million	-
Source: RPA (2008): Based on responses to questionnaires for large companies for typical number of products, divided by 30 million to reflect estimated packaging rate and multiplied by % of products that would be classified as corrosive under GHS, multiplied by three to account for three different pack sizes						

A1.3.4 Summary of Predicted, Pre-CLP Costs for Large Company (CRCs)

The above discussion and tables set out the assumptions, approaches and cost estimates used to predict the costs associated with the additional requirements for CRCs – pre-CLP - for a large company due to GHS implementation. Table A1-7 presents a summary of the total costs (summed across all product and packaging types). It also identifies which of the costs are annual and which are one-off. It is important to note that these cost estimates assume that eye damage cat 1 (and 2A) were included in CLP as triggering the need for CRCs and TWDs. Present value costs were developed assuming a notional ten year period and 4% discount rate, and are the costs for a single large manufacturer.

Table A1-7: Summary of compliance costs for a large company from the requirements for CRCs under CLP – assuming inclusion of eye damage cat 1 (to two significant figures)		
Cost Type	Annual Costs	One-Off Costs
Costs of moving to CRC compatible packaging	€16 million	-
Costs of CRCs	€24 million	-
Changes to packaging lines	-	€78 million
Cost Type	**PV Costs**	
Costs of moving to CRC compatible packaging	€138 million	
Costs of CRCs	€201 million	
Changes to packaging lines	€78 million	
Total (discounted over 10 years at 4%; year 0 being 2015)	€417 million	

The large company was assumed to have estimated sales of €1.3 billion per year which, discounted over 10 years at 4%, gives €11 billion. Thus, the costs presented in Table A1-7 represent 4% of the total annual sales over the next 10 years. The costs are greater in year 0 (assuming the packaging lines are changed and the annual costs are also incurred) such that they represent around 9% of the annual sales value for year 0 for a large company. Dividing these PV costs by total annual production over the 10 year period, gives a per unit increase in costs of around €0.06 (over the estimated 77% of all products that would require CRCs).

A1.4 Small company case study

The case study prepared for a small company made a series of similar assumptions adjusted for differences in product portfolios. The small/medium sized company was assumed to have a turnover of around €25 million (assumed to be equal to annual sales), producing around 40 million products per year, of which 55% are fabric washing products, 15% are hard surface cleaners, 12% are bleaches and 10% are automatic dish washing products. The company also produces hand dish washing products (6%) and soap (2%).

Table A1-8 sets out the assumptions used for the change in number of products classified as corrosive, the typical product price and the number of products (units) that were predicted as requiring CRCs under the draft legislative proposals. The number of products was estimated based on annual sales estimated at €25 million and a typical price per product (estimated).

Table A1-8: Change in Percentage of Products Identified as Requiring a CRC Now and in the Future

Product Type	% Requiring CRCs		Typical Product Price	Number of Products Requiring CRCs
	Now	Under GHS		
Soaps	0%	30%	€0.30	500,000
Fabric washing – washing powder/tablets	11%	30%	€2	480,000
Fabric washing – washing liquid	11%	30%	€1	620,000
Fabric washing – softener	11%	30%	€0.50	2.1 million
Fabric washing – stain remover/spotter	11%	30%	€1	0*
Hand dish washing	11%	30%	€0.30	960,000
Automatic dish washing	11%	30%	€1.30	350,000
Hard surface cleaning	13%	30%	€1.20	520,000
Maintenance products	0%	30%	€2.50	0 *
Bleaches	0%	30%	€0.30	3.0 million

A1.4.1 Summary of Predicted, Pre-CLP Costs for a SME Company (CRCs)

Assumptions were also made on the percentage of each product type that is supplied in cardboard cartons, plastic bottles or plastic bags/pouches. These assumptions are the same as those used for the large company case study, and are not repeated here. Similarly, the costs of moving from cardboard to plastic bottles and from plastic bags/pouches to plastic bottles are the same as assumed for the large company case study.

In terms of modifications to packaging lines, the costs are provided per pack size and it is assumed that one pack size is produced per packaging line. This gives costs for the SME as follows:

- moving from cardboard to plastic bottles: €700,000 per packaging line;
- moving from plastic bottles with no CRCs to those with CRCs: €130,000 per packaging line; and
- moving from plastic bags/pouches to plastic bottles: €280,000 per packaging line.

Table A1-9 presents a summary of the total present value costs (summed across all product and packaging types) based on a notional 10 year period and discounted at 4%.

Table A1-9: Summary of Costs for a Small/Medium Sized Company from the Requirements for CRCs (to two significant figures)		
Cost Type	**Annual Costs**	**One-Off Costs**
Costs of moving to CRC compatible packaging	€85,000	-
Costs of CRCs	€260,000	-
Changes to packaging lines	-	€2.4 million
	PV Costs	
Costs of moving to CRC compatible packaging	€720,000	
Costs of CRCs	€2.2 million	
Changes to packaging lines	€2.4 million	
Total (discounted over 10 years at 4%)	€5.3 million	

Table A1-9 shows that the total estimated costs for a small/medium sized company from the requirement for CRCs is €5.3 million (PV over 10 years). The small/medium sized company has estimated sales of €25 million per year which, discounted over 10 years at 4%, gives €210 million. Thus, the costs represent around 2.5% of the total annual sales over the next 10 years. Dividing these PV costs by total annual production over the 10 year period, gives a per unit increase in costs of around €0.07 (over the 22% of all products produced by the small/medium company that would require CRCs).

A1.5 Adjusted costs based on targeted consultation findings

A1.5.1 Aggregation of pre-CLP estimated costs across AISE Members

The cost estimates from the large and small/medium sized company case studies were used to predict the estimated costs across all of AISE, based on the percentage of companies within AISE that are small/medium (640, or 64%) and those that are large (360, or 36%), out of the total number of members of ca 1,000[138]. The percentage of sales per company out of the total annual sales in 2006 (then €24 billion for household products) was used to reflect the proportion of sales represented by small/medium and large companies. This percentage was 0.1% for the small/medium company (based on sales of €25 million) and 6% for the large company (based on sales of €1.3 billion).

[138] Taken from the AISE Annual Report for 2006 and the value for annual sales relates to household products. Note that this number of large companies is inconsistent with the number (71) quoted in Eurostat for NACE 20.41, with this assumed to be because many of the larger manufacturers will produce a wide range of products and be classed under other NACE codes.

It was assumed that 30% of sales from SMEs and 50% of sales from large companies would incur the above costs, based on the percentage of companies that are manufacturing household products and the proportion of these products that would require CRCs and, hence, for which costs would be incurred.

Total costs for each sector are estimated by dividing the costs from the small/medium and large company case studies (€5.3 million and €420 million, respectively) by the percent of AISE sales by company, multiplying by the percentage of companies within that sector (i.e. 64% for small/medium and 36% for large) and multiplying by the percentage of sales that would incur costs (i.e. 30% for SMEs and 50% for large companies). The results are overall PV costs of (discounted over 10 years at 4%; with year 0 being 2015):

- Costs to all small/medium companies in AISE: €1.0 billion;
- Costs to all large companies in AISE: €1.3 billion; and
- Overall costs to AISE from need to include CRCs on products classified as corrosive: €2.3 billion.

The total predicted costs of €2.3 billion represented 1.1% of annual sales for the year 2006.

A1.5.2 Revised estimates for the detergents and cleaning products sector

Data was collected through the targeted data collection to identify the percentage of products that changed classification under the CLP, as well as the percentage of products with changed packaging requirements due to changes in classification. Figure A1-2 below sets out the responses in relation to changes in packaging, with A1-3 and A1-4 providing data for CRCs and TWDs respectively and the detergents sector.

Although the number of respondents is low, as can be seen from these figures, there were mixed experiences regarding the number of products that required a change in packaging at the company level. In particular, it would appear that the actual impacts of CLP in relation to CRCs and TWDs for the detergents and cleaning products sector are much lower than originally anticipated, due in part to the changes in final requirements. One respondent indicated that because they already used CRCs on most of the products that became classified as skin corrosion cat 1, they did not face significant additional costs. However, it is also understood that at the regional level impacts were significant; for example, a national association indicated that "Greece is a strong bleach market (sodium hypochlorite based) and this results in a large no. of products bearing CRCs/TWDs".

In terms of the costs of the new CRC and TWD requirements, most respondents (16 in total – 6 large and 10 SME companies) indicated that the costs were at the lower end of the scale, e.g. below €200,000 per annum, as indicated in Figure A1-5.

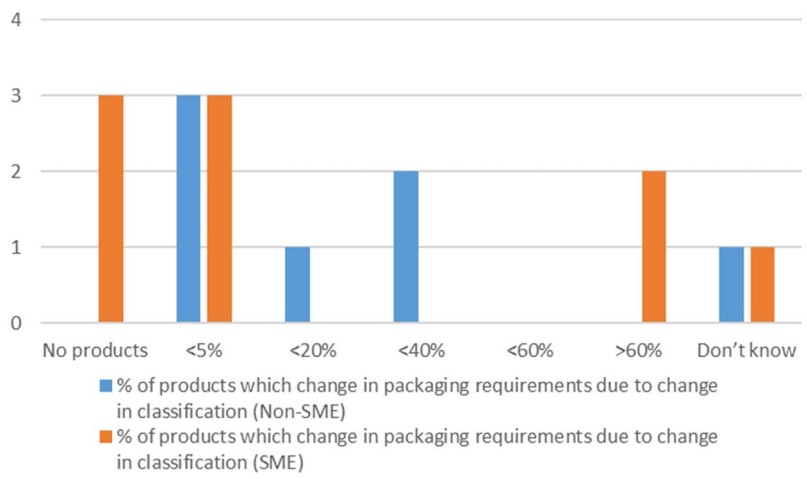

Figure A1-2: Percentage of products with a change in packaging requirements due to a change in classification under CLP – detergents sector

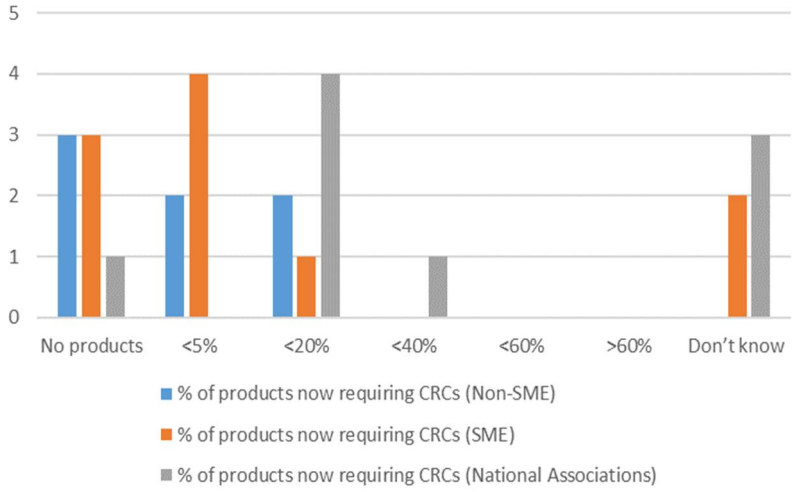

Figure A1-3: Percentage of products for which change resulted in the need for child resistant closures (CRC)

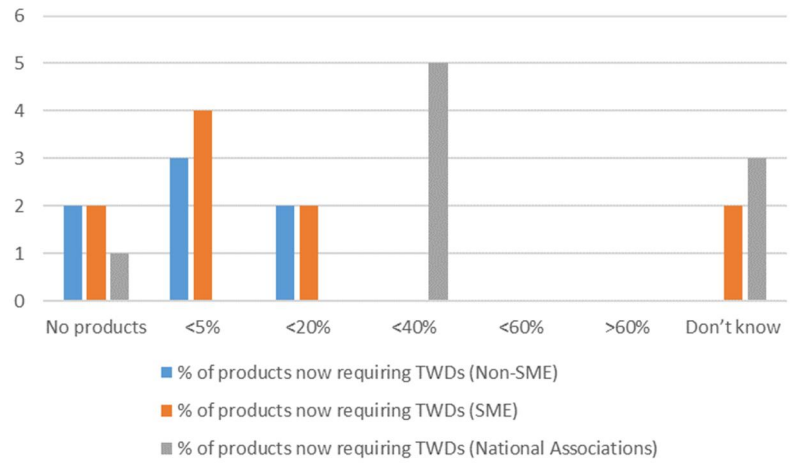

Figure A1-4: Percentage of products for which change resulted in the need for tactile warnings of danger

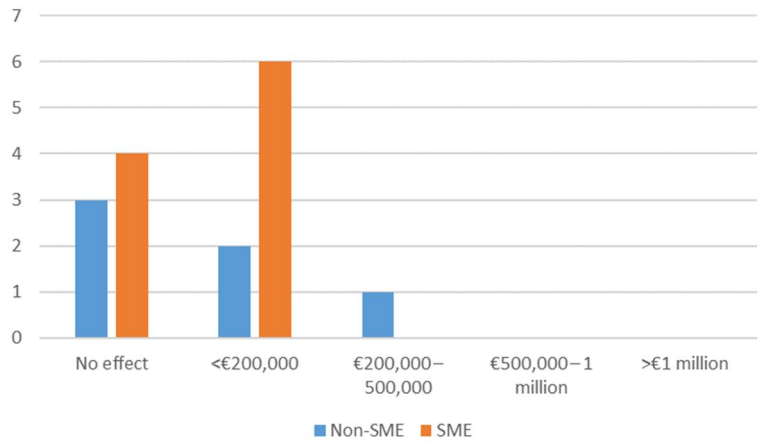

Figure A1-5: Additional cost of packaging and/or due to CRC and/or TWD requirements

Using the cost figures provided in Figure 1-5 provides us with an alternative approach to calculating the costs to the sector. Taking an assumed annual increase in costs of €100,000 per SME and €200,000 per large company, and combining these figures with the number of companies in the sector, an upper bound figure for the costs of the new CLP requirements can be generated.

Based on data available from AISE, the total value of the household products sector for 2014 is estimated at €28.3 billion. AISE itself has over 900 companies as members supplying both household and professional cleaning and maintenance products. For the purposes of this assessment it is assumed that in total there are around 1000 companies producing detergents and cleaning products for sale on the EU market. Roughly 65% (640) of these companies are SMEs, with the remaining 35% (360) being large companies. Not all products would be affected by the need for CRCs, with the requirements only applying to products supplied to the general public. To account for this factor, we apply the same adjustment as used in the original analysis:

- 30% of SMEs (192) produce household products and would have been affected;
- 50% of large companies (180) produce household products and would have been affected.

On this basis, the total estimated present value costs (@ 4% over 10 years) of additional CRC requirements under the CLP for detergent and cleaning household products are estimated at:

- SMEs: €162 million (€846,000 per company affected);
- Large companies: €304 million (€1.687 million per company affected); and
- Total: €466 million across all affected companies.

A1.5.3 Difference in costs

The difference in costs between the pre-CLP draft legislation estimates and the post-CLP implementation estimates is calculated as follows for the household detergents and cleaning products sector:

- Pre-CLP draft legislation estimate: €2.3 billion
- Post CLP implementation estimate: €466 million
- Difference: €1.83 billion (on-going costs of €55.2 million/yr)

As noted above, this difference is due in part to the fact that the final regulation did not include requirements for CRCs to be placed on products classified for series eye damage cat 1. (or for some of the other endpoints originally considered in the draft 27 June 2007 proposal for the regulation). This was the main factor driving the cost analysis produced in 2007 and highlights the economic importance of the modifications made to the legal text when implementing it in practice.

All respondents to the detergents sector targeted consultation indicated that the change in classification that led to the need for changes in packaging was skin corrosivity cat 1. One respondent further noted that: "For skin corrosivity validated in-vitro methods exist, but these are over-predicting for acidic cleaners and to a lesser extent also for alkaline cleaners, leading to many more products being classified for skin corrosivity (cat 1) and hence requiring CRCs and TWDs". Another noted that the increased numbers of warning required significant changes to labelling, but also that some lines became unviable due to the numbers of warnings that would have had to have been placed on the products. Another noted that child Impeding Fasteners (CIFs) could replace CRCs in domestic hypochlorite bleaches (up to 5% w/w sod. hypochlorite), since their extended use for many decades clearly indicate that they do not possess corrosive potential for consumers.

Annex 2 List of National Appointed Receiving Bodies and Poison Centres

MS	Appointed receiving body		Poison centre	
	Name	Founded	Name	Founded
Austria	Umweltbundesamt	§§ 25 para. 8 to 10 chemicals Directive 1999.	Vergiftungsinformationszentrale	No information available
Belgium	Centre Antipoisons Belge	1963	Antigif centrum, centre antipoisons	Founded in 1963
Bulgaria	Клиникапо Токсикология	No information available	No information available	No information available
Croatia	Hrvatski Zavod Za Toksikologiju I Antidoping (HZTA)	No information available	Croatian Institute for Toxicology (CIT)	Founded in 1997
Cyprus	Τμήμα Επιθεώρησης Εργασίας	No information available	**Poison Control Center** for Cyprus	No number was previously provided for this service so it is safe to assume it is new in the last few years.
Czech Republic	Ministerstvo Zdravotnictví	356 LAW dated September 23, 2003 on chemical substances and chemical preparations and amending some laws	Toxikologického informačního střediska (TIS)	TIS in operation since 1963
Denmark	Arbejdstilsynet	No information available	No information available	No information available
Estonia	Terviseametist	No information available	Terviseameti mürgistusteabekeskuse infoliin	Did not exist prior to CLP. Have seen a dramatic effect from PC.
Finland	Turvallisuus- Ja Kemikaalivirasto (Tukes)	Responsible for registering from 2011	Turvallisuus- Ja Kemikaalivirasto (Tukes)	No information available
France	Institut National De Recherche Et De Sécurité (INRS)	Founded in 1947. Computer system set up by 2002, where if requested information from manufacturers was mandatory.	CAPTV (network of 9 poison centres)	CAPTV was founded in 2001, Poison centres were founded in 1996
Germany	Bundesinstitut Für Risikobewertung	Formed in 2002	9 poison centres	Giz- nord was founded in 1996
Greece	Χημείου Του Κράτους	2002	The Greek National Poison Information Centre	1975
Hungary	Országos Kémiai Biztonsági Intézet	1998	ETTSZ Egészségügyi Toxikológiai Tájékoztató Szolgálat	No information available

Iceland	Eitrunarmiðstöð	No information available	Eitrunarmiðstöð	1994
Ireland	National Poisons Information Centre	2001	National Poisons Information Centre (NPIC)	1966
Italy	Istituto Superiore Di Sanità, ISS	Existed prior to CLP 2000 Legislative Decree 25 February 2000 n. 174,	Centro Antiveleni (network of 9 poison centres)	Existed prior to CLP. Gemelli has operated since 171, and has been a regional reference centre since 1995
Latvia	Latvijas Vides, Ģeoloģijas Un Meteoroloģijas Centrs	Just moved onto electronic submission	No information available	No information available
Lithuania	Aplinkos Apsaugos Agentūra	No information available	No information available	No information available
Luxembourg	Centre Antipoisons Belge	No information available	(since 2015 they are covered by Belgium)	No information available
Netherlands	Product Notifaction Portal Nationaal Vergiftigingen Informatie Centrum (NVIC)	National Poisons Information Centre of the National Institute for Public Health and Environmental information in 1995, NVIC after 2011	National Poisons Information Service	1995
Poland	Biuro Do Spraw Substancji Chemicznych	No information available	No information available	No information available
Portugal	Centro De Informação Antivenenos	2002	Centro De Informação Antivenenos	2002
Romania	Institutul National De Sanatate Publica	No information available	Institutul National De Sanatate Publica	1982
Slovakia	Národné Toxikologické Informačné Centrum	Registration since 2010? - keeping a database on the composition of chemical products imported or produced in Slovakia in accordance with Slovak Act No 67/ 2010	Národné Toxikologické Informačné Centrum	Founded in 1968 as the toxicological information centre, in march 2006 it gained a status of National Toxicological Information Centre.
Slovenia	Urad Republike Slovenije Za Kemikalije		Not available to public http://www.ktf.si/?page_id=171894	1973 LjubljanaUniversityMedicalCenter
Spain	Servicio De Información Toxicológica (SIT)	Database active since 1991, substances must have been registered from 85	Servicio De Información Toxicológica (SIT)	1971
Sweden	Giftinformationscentralen	1960	Giftinformationscentralen	1960
Switzerland	Anmeldestelle Chemikalien	Registration of biocides in 2005	Tox info suisse	1966
UK	National Poisons Information Service	1963	National Poisons Information Service	1963

Annex 3 Supporting Information to Calculation of Costs of ATPs

A3.1 Frequency of and costs of label changes

Companies were asked to indicate how often they would expect to modify or redesign the labels on the products that they place on the market for reasons other than CLP and REACH (i.e. for marketing reasons or to respond to changes in consumer demand). Responses are given in Table A3-1.

Table A3-1: Frequency of modifying or redesigning labels for reasons other than CLP or REACH (n=96, manufacturers, formulators and importers)					
Answer Options	< 6 months	6 months-18 months	18 months-36 months	36 months-60 months	>5 years
Substances	8%	21%	23%	25%	21%
Mixtures	9%	18%	33%	23%	11%

As can be seen from Table A3-1, there is a fairly even distribution across the companies with respect to the frequency at which they change their product labels for substances for reasons other than regulatory compliance with CLP and REACH (in other words the frequency at which they change labels for marketing reasons or to respond to changes in consumer demand); although for mixtures, the highest percentage would normally change labels at between 18 to 36 months. Those that change labels the least often tend to be producers of substances sold to industrial users and more durable consumer goods (such as aerosols). Overall, these figures highlight that almost 70% of products, whether substances or mixtures, would normally retain the same labels for over 18 months, highlighting why short transition times under CLP for adapting labels for minor editorial reasons (i.e. small changes in the wording of a H or P statement) can pose significant additional costs. As will be recalled, over 30% of substance manufacturers, importers and distributors indicated that their product portfolio includes more than 250 substances, while over 30% of respondents also offer over 1500 mixtures per annum.

The impact assessment supporting the adoption of GHS (and hence implementation of CLP) and further work carried out for AISE expected the average cost of re-designing and modifying labels to be compliant with CLP to be around €300 per formulation, based on experiences under the Dangerous Preparations Directive. This level of cost was confirmed by the majority of respondents to the targeted data collection, with 62% and 54% indicating costs of less than €500 per substance or mixture respectively, with the majority of these indicating costs of less than €250. Further significant percentages indicated costs between €500 and €1000. The weighted average cost is €388 for substances and €475 for mixtures. Note that these higher cost figures tended to be provided by SMEs.

Table A3-2: Average cost of re-designing and modifying labels (n=99)							
Answer Options	≤€100	€100-€250	€250-€500	€500-€1000	€1000-€2500	≥€2500	Don't know
Substances	7%	25%	29%	11%	4%	4%	16%
Mixtures	6%	11%	36%	24%	7%	1%	8%

As can be seen from Table A3-3, most companies reported having to change large percentages of their product labels due to changes in CLP introduced by the ATPs. Note that these figures do not distinguish between CLH-driven changes and editorial changes, although the latter are expected to have been the main factor.

Table A3-3: Percentage of portfolio requiring re-labelling due to Adaptations to Technical Progress (ATPs) under CLP				
Answer Options	Percentage of respondents			
	Manufacturers (n=63)	Formulators (n=45)	Distributors (n=9)	Importers (n=14)
<10%	33.3%	11.1%	42.9%	21.4%
<20%	10.4%	28.9%	0.0%	7.1%
<40%	12.5%	15.6%	14.3%	14.3%
<60%	10.4%	4.4%	14.3%	35.7%
>60%	18.8%	22.2%	0.0%	0.0%
None	0.0%	0.0%	0.0%	0.0%
Don't know	14.6%	17.8%	28.6%	21.4%

Despite the high numbers presented in Table A3-3, when asked whether the 18 month transition period was long enough to undertake labelling changes, 79% of manufacturers and 88% of distributors indicated that it was (n=71 in total), but only 61% of formulators (n=43) and 64% of importers did (n=12).

A3.2 Changes introduced by ATP04

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
Chemically unstable gases A B	Changed	• Added to P202: "Do not handle until all safety precautions have been read and understood"	**X**
Aerosols 1 and 2	Changed	**New wording:** • **From** "Pressurized container: Do not pierce" **to** "Do not pierce **or burn, even after use**". **Legal text alterations (not affecting labels etc.):** • Legal text changes so that no longer only flammable aerosols.	**B**
Aerosols 3	Changed	**The following added:** • Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. • Do not pierce or burn, even after use • Protect from sunlight • Do not expose to temperatures exceeding 50 °C/122 °F. • Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.	**X**
Unstable explosives	Changed	**The following added:** • Wear protective gloves/protective clothing/eye protection/face protection.	**X**
Explosives Divisions 1.1, 1.2, 1.3, 1.4, 1.5	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking."	
Flammable gases 1, 2	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking."	
Flammable liquids 1, 2, 3	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** "**Remove**/Take off immediately all contaminated clothing" **to** "Take off immediately all contaminated clothing" • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use **… to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
Flammable solids 1, 2	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Self-reactive substances and mixtures Types A, B, C, D, E, F	Changed	**New wording and requirements:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media— if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **Legal text alterations (not affecting labels etc.):** • Legal text changes from "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify incompatible materials." **to** "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify **other** incompatible materials."	
Pyrophoric liquids 1	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Pyrophoric solids 1	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces,	

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
		sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Organic peroxides Types A, B, C, D, E, F	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." **Legal text alterations (not affecting labels etc.):** • Legal text changes from "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify incompatible materials." **to** "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify **other** incompatible materials."	
Oxidising Gases 1	Changed	**New wording:** • **From** "Keep **reduction** valves free from grease and oil." **to** "Keep valves **and fittings** free from oil and grease" **Legal text alterations (not affecting labels etc.):** • Legal text changes from "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify incompatible materials." **to** "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify **other** incompatible materials."	**B**
Oxidising liquids 1	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Oxidising liquids 2, 3	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier	

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
		to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **Legal text alterations (not affecting labels etc.):** • Legal text changes from "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify incompatible materials." **to** "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify **other** incompatible materials."	
Oxidising solids 1	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • Following requirement removed: "… Manufacturer/supplier to specify incompatible materials"	
Oxidising solids 2, 3	Changed	**New wording:** • **From** "Keep away from heat/ sparks/open flames/hot surfaces. — No smoking" **to** "Keep away from heat, hot surfaces, sparks, open flames **and other ignition sources**. No smoking." • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **Legal text alterations (not affecting labels etc.):** • Legal text changes from "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify incompatible materials." **to** "Keep/Store away from clothing/…/combustible materials….Manufacturer/supplier to specify **other** incompatible materials."	
Substances and	Changed	**New wording:**	**C**

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
mixtures which, in contact with water, emit flammable gases 1, 2		• **From** "Keep away **from any possible** contact with water, **because of violent reaction and possible flash fire**" **to** "Do not allow contact with water" • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media— if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Substances and mixtures which, in contact with water, emit flammable gases 3	Changed	**New wording:** • **From** " Use … for extinction…. Manufacturer/supplier to specify appropriate media — if water increases risk." **to** "Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk." • **From** "In case of fire: Use … for extinction…. Manufacturer/supplier to specify appropriate media. — if water increases risk." **to** "In case of fire: Use … **to extinguish**…. Manufacturer/supplier to specify appropriate media. — if water increases risk."	
Respiratory sensitisation 1 (1A/1B)	Changed	**New wording:** • **From** "**If breathing is difficult**, remove victim to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "IF INHALED: **If breathing is difficult, remove victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing" **Legal text alterations (not affecting labels etc.):** • Legal text edited to include 1A/1B sub-categories	**C**
Skin sensitisation 1 (1A/1B)	No Change	**Legal text alterations (not affecting labels etc.):** • Legal text edited to include 1A/1B sub-categories	
Germ cell mutagenicity 1A, 1B, 2	Changed	**New wording:** • **From** "**Use personal protective equipment as required**." to Wear protective gloves/protective clothing/eye protection/face protection."	**B**
Carcinogenicity 1A, 1B, 2	Changed	**New wording:** • **From** "**Use personal protective equipment as required**." to Wear protective gloves/protective clothing/eye protection/face protection."	**B**
Reproductive toxicity 1A, 1B, 2	Changed	**New wording:** • **From** "**Use personal protective equipment as required**." to Wear protective gloves/protective clothing/eye protection/face protection."	**B**

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
Acute toxicity — inhalation 1, 2	Changed	**New wording:** • **From** "Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "IF INHALED: Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing"	**C**
Acute toxicity — inhalation 3	Changed	**New wording:** • **From** "Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "IF INHALED: Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing"	**C**
Acute toxicity — inhalation 4	Changed	**New wording:** • **From** "Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "IF INHALED: Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing"	**C**
Acute toxicity — dermal 1, 2	Changed	**New wording:** • Changes from P322 "specific **measures**" to P321 "Specific **Treatment**" • **From** "Wash with plenty of **soap and** water." **to** "Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**" • **From** "**Remove**/Take off immediately all contaminated clothing" **to** "Take off immediately all contaminated clothing" • **From** "Take off contaminated clothing and wash before reuse." **to** "(P362) Take off contaminated clothing. (P364) And wash **it** before reuse." • **From** "IF ON SKIN: Gently wash with plenty of **soap and** water." **to** "IF ON SKIN: Wash with plenty of Water/ **……Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**."	
Acute toxicity — dermal 3	Changed	**New wording:** • Changes from P322 "specific measures" to P321 "Specific **Treatment**" • **From** "Wash with plenty of **soap and** water." **to** "Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**" • **From** "**Remove**/Take off immediately all contaminated clothing" **to** "Take off immediately all contaminated clothing" • **From** " Take off contaminated clothing and wash before	

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
		reuse." **to** "(P362) Take off contaminated clothing. (P364) And wash **it** before reuse." • **From** "IF ON SKIN: Wash with plenty of **soap and** water" **to** "IF ON SKIN: Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**."	
Acute toxicity — dermal 4	Changed	**New wording:** • Changes from P322 "specific measures" to P321 "Specific **Treatment**" • **From** "Wash with plenty of **soap and** water." **to** "Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**" • **From** " Take off contaminated clothing and wash before reuse." **to** "(P362) Take off contaminated clothing. (P364) And wash **it** before reuse." • **From** "IF ON SKIN: Wash with plenty of **soap and** water" **to** "IF ON SKIN: Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**."	
Skin corrosion 1A, 1B, 1C	Changed	**New wording:** • **From** "Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "**Remove**/Take off immediately all contaminated clothing" **to** "Take off immediately all contaminated clothing" • **From** "IF INHALED: Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing"	**C**
Skin irritation 2	Changed	**New wording:** • **From** "Wash with plenty of **soap and** water." **to** "Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**" • **From** " Take off contaminated clothing and wash before reuse." **to** "(P362) Take off contaminated clothing. (P364) And wash **it** before reuse." • **From** "IF ON SKIN: Wash with plenty of **soap and** water" **to** "IF ON SKIN: Wash with plenty of water/……**Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate**."	
Specific target organ toxicity, single exposure 1	Changed	**New wording:** • Changes from P307 "IF exposed" to P308 IF exposed **or concerned**"; • **From** "IF exposed or concerned: Get medical advice/attention" **to** "IF exposed or concerned: **Call a POISON CENTER/doctor/……Manufacturer/supplier to specify the appropriate source of emergency medical advice**"	

Table A3-4: Amendments and alterations to P statements in ATP04			
Class.	**Status**	**Description**	
Specific target organ toxicity, single exposure 2	Changed	**New wording:** • Changes from P309 "IF exposed or if you feel unwell" to P308 "IF exposed **or concerned**"	
Specific target organ toxicity — single exposure; respiratory tract irritation 3 and narcosis 3	Changed	**New wording:** • **From** "Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing" **to** "Remove person to fresh air and keep comfortable for breathing." • **From** "IF INHALED: Remove **victim** to fresh air and keep **at rest in a position** comfortable for breathing." **to** "IF INHALED: Remove person to fresh air and keep comfortable for breathing"	

Annex 4 Global Differences in Labelling Requirements

A4.1 Mandatory Label Content

All countries implementing GHS are required to include the following elements on their labels:

- Product identifier
- Signal word
- Pictograms
- Hazard statements
- Precautionary statements
- Supplier identification

However, there are additional elements under CLP that were taken from the previous legislation and must be included in the supplemental information section. These elements are not always included on labels for imports into Europe; in some cases the information is listed in the SDS as additional information. Another difference in labelling requirements in the EU is that CLP states that a maximum of six precautionary statements can be printed on the label, unless more are required to "reflect the nature and the severity of the hazards." Yet many other countries do not stipulate a maximum number of precautionary statements and often labels in these countries will have a long list of them. A problem then occurs when these countries have to cut this list of statements down to six ready for import into Europe: which statements should be excluded and included on the EU labels is a decision usually made at the manufacturers' discretion. This is a potential source of inconsistent hazard communication which may hinder the downstream user's understanding of the risks of the chemicals.

China imposes an additional format requirement for its labels: a black border must be placed around the label inside which the following must be present:

- The percentage/percentage range of ingredients which contribute to the hazards of a mixture, usually for up to five components
- An emergency telephone number of a company located in China
- A reminder to the user to "Please refer to the Safety Data Sheet"

In Japan there are additional labelling requirements which are quite complex as they pertain to other pieces of national legislation[139], including:

- Poisonous and Deleterious Substances Control Law
- Fire Service Law
- Chemical Substances Control Law
- High Pressure Gas Control Law
- Explosives Control Law
- Ship Safety Law
- Civil Aeronautics Law

[139] https://www.chemicalsafetyconsulting.com/sites/www.chemicalsafetyconsulting.com/files/global-ghs-labeling_csc.pdf

Those exporting to Japan must take care to list the hazardous ingredients in compliance with these other laws as well as following the specific labelling requirements of these other laws.

In GHS guidance, it is stipulated that if the skull and crossbones pictogram is used, the exclamation mark pictogram needn't be displayed on the label and so only a maximum of three pictograms would appear on a label. However, under US OSHA, this stipulation is not made and so it could be the case that four pictograms appear on one label. Furthermore, OSHA allows for both the GHS physical hazard pictogram and the Department of Transportation (DOT) diamond transport label of the same class to appear on the same label, though this is not generally supported by 1.4.10.5.1. of the UN GHS standard.

A4.2 Label Dimensions

Different countries implement minimum label sizes for their chemical products. These are outlined in Table A4-1 below:

Table A4-1: Differences in label size requirements

Country/Region	Package capacity	Label size (mm)	Pictogram size(mm)
EU	<= 3L	52 x 74 if possible	10 x 10 min, 16 x 16 if possible
	>3 to <=50L	74 x 105 min	23 x 23 min
	>50 to <=500L	105 x 148 min	32 x 32 min
	>500L	148 x 210 min	46 x 46 min
China	<=0.1L	Use simplified label	Visible from a distance, even in mist conditions
	>0.1 to <=3L	50 x 75 min	
	>3 to <=50L	75 x 100 min	
	>50 to <=500L	100 x 150 min	
	>500L to <=1,000L	150 x 200 min	
	>1,000L	200 x 300 min	
Japan		No minimum label sizes defined	No minimum pictogram sizes defined
US		No minimum label sizes defined under HCS but DOT diamond transport label size requirement is referenced	No minimum pictogram sizes defined

Source: Chemical Safety Consulting (2013)

There is considerable disparity across the different regions in terms of their packaging and labelling size requirements. For example, Japan and the US do not have specific minimum size requirements whereas the EU stipulates specific dimensions for different package capacity in terms of label size and pictogram size. China has two extra dimension requirements for label size compared to the EU, one for packaging capacity <3L and one for >1,000L. Comparing the dimensions listed for the package capacity bands shows small but important differences in the label size requirements. For example, for the packaging capacity band ">3 to <=50L", the EU sets minimum dimensions of 74 x 104mm. China sets a minimum of 75 x 100mm. Even though these are given as minimums, thus allowing some leeway, it still represents an arguably unnecessary burden to companies trading with either or both of these countries, especially as one label isn't smaller than the other for both height and width.

Annex 5 Data Used to Estimate Costs to ECHA of Implementing CLP

Table A5-1: Data used to estimate the costs to ECHA of implementing CLP								
Reference in ECHA budget (attributable to CLP)	**Operational Activity**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
3006 (100%)	Classification and labelling	€ 50,150	€ 20,058	€ 162,500	€ 36,200	€ 44,145	€ 50,000	€ 40,000
3007 (40%)	Advice and assistance through guidance and helpdesk	€ 387,683	€ 329,169	€ 234,360	€ 167,300	€ 132,427	€ 181,300	€ 160,700
3008 (5%)	Scientific IT tools	€ 10,044,009	€ 11,954,079	€ 8,579,450	€ 9,536,800	€ 7,595,005	€13,808,000	€11,903,200
3009 (10%)	Scientific and technical advice to EU institutions and bodies	N.A.	€ 25,023	€ 330,500	€ 103,500	€ 118,983	€ 282,000	€ 260,000
3011 (20%)	Committees and Forum	€ 1,645,700	€ 1,370,733	€ 1,370,920	€ 1,443,000	€ 947,078	€ 1,821,500	€ 2,505,900
3012 (20%)	Board of Appeal	€ 73,200	€ 32,801	€ 80,000	€ 59,000	€ 24,821	€ 115,500	€ 98,500
3013 (40%)	Communications including Translations	€ 4,852,000	€ 5,383,953	€ 4,959,080	€ 2,961,900	€ 2,254,649	€ 2,641,200	€ 3,057,000
3801 (10%)	Cooperation with international organisations for IT programmes	€ 556,560	€ 698,845	€ 622,440	€ 520,330	€ 385,635	€ 341,000	€ 779,000

These are payment appropriation figures taken from the ECHA budget 2016. The data relate to implementation of the processes under REACH but which will also apply to CLP. Therefore, whilst these provide useful estimates for the costs to ECHA of enforcing, implementing and monitoring CLP, it is not possible to isolate the costs solely attributable to CLP. Therefore, in our estimation of enforcement costs, assumptions are made in relation to the percentage of these costs which are attributable to CLP. These are given in parentheses below the reference in the first column.

Annex 6 Cost Sensitivity Analysis

A6.1 Transition costs

Estimation of the total costs of classification, labelling, SDS and reformulation for mixtures are dependant on estimates of the percentage of mixtures containing hazardous substances and the percentage of these that are classified mixtures. In addition, all unit costs applied to numbers of substances, mixtures and manufacturers can be expected to have an error of around ± 30%. Both of these sets of uncertainty will have an effect on the overall costs.

To identify how great the combined error is we have undertaken a sensitivity analysis for these factors. Table A6-1 overleaf provides alternative total cost estimates for the lower and upper bound scenarios for numbers of mixtures subject to transitional costs of classification, labelling, SDS and reformulation. These suggest that:

- for the lower bound estimate of direct costs, costs may be 0.1 billion lower than the €1.4 billion estimate provided in the main report; and
- for the upper bound estimate of direct costs, costs may be 0.1 billion higher than the €1.6 billion estimate provided in the main report.

Table A6-1: Sensitivity of total cost estimates to key assumptions on numbers of hazardous mixtures for classification								
	Lower bound (2 million mixtures)	Upper bound (2.5 million mixtures)	Lower bound (2 million mixtures)	Upper bound (2.5 million mixtures)	Lower bound (2 million mixtures)	Upper bound (2.5 million mixtures)	Lower bound (2 million mixtures)	Upper bound (2.5 million mixtures)
	As reported in main report		Varying mixtures with hazardous substances		Varying mixtures with classification		Varying both factors	
Mixtures	2,000,000	2,500,000	2,000,000	2,500,000	2,000,000	2,500,000	2,000,000	2,500,000
Mixtures containing hazardous substances	47%	47%	40%	47%	47%	47%	40%	47%
Percentage of these that are classified mixtures	30%	30%	30%	30%	25%	35%	25%	35%
Reformulating	3%	5%	3%	5%	3%	5%	3%	5%
Substances (based on 99,266 classified substances)								
Classification	€ 226,600,000	€ 226,600,000	€ 226,600,000	€ 226,600,000	€ 226,600,000	€ 226,600,000	€ 226,600,000	€ 226,600,000
Labelling	€ 153,900,000	€ 153,900,000	€ 153,900,000	€ 153,900,000	€ 153,900,000	€ 153,900,000	€ 153,900,000	€ 153,900,000
SDS	€ 141,700,000	€ 141,700,000	€ 141,700,000	€ 141,700,000	€ 141,700,000	€ 141,700,000	€ 141,700,000	€ 141,700,000
Updating IT systems	€ 11,900,000	€ 11,900,000	€ 11,900,000	€ 11,900,000	€ 11,900,000	€ 11,900,000	€ 11,900,000	€ 11,900,000
Staff training	€ 92,300,000	€ 92,300,000	€ 92,300,000	€ 92,300,000	€ 92,300,000	€ 92,300,000	€ 92,300,000	€ 92,300,000
Reformulation	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**	**€ 626,400,000**
Mixtures								
Classification	€ 300,800,000	€ 376,000,000	€ 256,000,000	€ 376,000,000	€ 300,800,000	€ 376,000,000	€ 256,000,000	€ 376,000,000
Labelling	€ 107,200,000	€ 134,000,000	€ 91,200,000	€ 134,000,000	€ 89,300,000	€ 156,300,000	€ 76,000,000	€ 156,300,000
SDS	€ 112,800,000	€ 141,000,000	€ 96,000,000	€ 141,000,000	€ 94,000,000	€ 164,500,000	€ 80,000,000	€ 164,500,000
Updating IT systems	€ 42,700,000	€ 42,700,000	€ 42,700,000	€ 42,700,000	€ 42,700,000	€ 42,700,000	€ 42,700,000	€ 42,700,000
Staff training	€ 163,300,000	€ 163,300,000	€ 163,300,000	€ 163,300,000	€ 163,300,000	€ 163,300,000	€ 163,300,000	€ 163,300,000
Reformulation	€ 67,700,000	€ 141,000,000	€ 57,600,000	€ 141,000,000	€ 56,400,000	€ 164,500,000	€ 48,000,000	€ 164,500,000
Total	**€ 794,500,000**	**€ 998,000,000**	**€ 706,800,000**	**€ 998,000,000**	**€ 746,500,000**	**€ 1,067,300,000**	**€ 666,000,000**	**€ 1,067,300,000**
Grand total (substances and upper bound mixtures) € billions)	**1.4**	**1.6**	**1.3**	**1.6**	**1.4**	**1.7**	**1.3**	**1.7**

As noted above, for all cost estimation a potential error of ±30% is also possible. Applying this to the above totals provides the error associated with this, which can then be combined with the uncertainty error described above to provide the overall error for the totals provided in the main report.

This is summarised in Table A6-2 below which uses the + and – error to derive lowest and highest total estimates for both sets of estimates. The final ± error values for the estimates provided in the final report are equal to the difference between these lowest and highest estimates and the respective value in the report. The sensitivity analysis suggests that:

- For the lower bound estimate total direct costs are €1.4 billion (+0.4 or – 0.5 billion i.e. a range of €0.9 to 1.8 billion); and
- For the higher bound estimate total direct costs are €1.6 billion (+0.6 or – 0.5 billion i.e. a range of €1.1 to 2.2 billion).

Thus, in each case the lower and upper bound estimates provided in the report are, broadly, mid-point estimates for each of the scenarios (lower and upper bound numbers of mixtures).

Table A6-2: Derivation of overall error values for direct transition costs (all values in € billions)		
	Lower bound (2 million mixtures)	**Upper bound (2.5 million mixtures)**
Reported estimates	€ 1.4	€ 1.6
Mixtures error	Minus € 0.1	Plus € 0.1
Other costs error (±30%)	€ 0.4	€ 0.5
Lowest estimate	€ 0.9	€ 1.1
Highest estimate	€ 1.8	€ 2.2
Negative error	€ 0.5	€ 0.5
Positive error	€ 0.4	€ 0.6
Result	**€1.4 billion (€+0.4 or – 0.5 billion)**	**€1.6 billion (€+0.6 or – 0.5 billion)**

A6.2 Ongoing costs

Estimates of the ongoing costs are not sensitive to assumptions on the numbers of hazardous mixtures because all costs are calculated with reference to the number of companies based on Eurostat data for 2012/13 (for NACE codes 19.2, 20.1, 20.2, 20.3, 20.5, 24.1, and 24.4). However, as with the transition costs, a ±30% error factor is possible for these costs.

The table below provides expected error around the central estimate of the ongoing annual costs. For the total annual costs this suggests an error of €0.4 billion meaning that ongoing costs are in the range of €0.92 to €1.71 billion with a central estimate (as reported) of €1.31 billion.

Table A6-3: Sensitivity/error values for estimates of ongoing costs			
	SME	**Large**	**Total**
Total annual costs	€ 1.05	€ 0.26	**€ 1.31**
Error 30%	30%	30%	**30%**
Error (€ billions)	€ 0.3	€ 0.1	**€ 0.4**
Lower estimate	€ 0.74	€ 0.18	**€ 0.92**
Upper estimate	€ 1.37	€ 0.34	**€ 1.71**

Annex III: Evaluating the horizontal links between EU legislation on hazard identification and communication (Task 2 Report)

Table of Contents

1 Introduction to Task 2

1.1 Scope of the evaluation

The evaluation carried out under Task 2 focuses on the 'horizontal' links between the CLP Regulation[1] and other relevant EU legislation (as opposed to the downstream or 'vertical' links that are the subject of Task 3). For the purposes of this study, horizontal links are defined as links to other legislation that has a similar scope to the CLP Regulation in terms of the following: 1) Setting criteria for identifying hazardous properties (that are not present in the CLP Regulation and hence are additional); examples include criteria for Persistence, Bioaccumulation and Toxicity (PBT), very Persistent and very Bioaccumulative (vPvB), endocrine disruptors, and allergens; and 2) Requiring the communication of hazard information and/or the setting of particular packaging or labelling requirements; examples include the labelling of allergens and preservatives (as well as all other ingredients) under the Cosmetic Products Regulation[2], and the provision of hazard information in Safety Data Sheets (SDS) under the REACH Regulation[3]. Note that REACH is only within the scope of this evaluation in relation to the provision of hazard information.

The Task 2 work has been divided into two broad sub-tasks:

- Sub-task 2a has involved:
    - the mapping of the CLP Regulation and other relevant legislation or provisions in legislation that have the purpose of identifying the properties of concern of chemicals, the communication of hazards or other properties of concern, as well as setting packaging requirements for chemicals,
    - assessing these links for coherence, inconsistencies, unnecessary duplication or overlap and legal gaps,
    - identifying the way these different pieces of EU legislation are adapted to scientific and technical progress or market developments, and
    - related case study work;
- Sub-task 2b involved:
    - compilation of existing information on the overall awareness of companies (including SMEs) of hazard communication obligations in the CLP Regulation and other relevant EU legislation,

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[2] Regulation (EC) No 1223/2009 of the European parliament and of the Council of 30 November 2009 on cosmetic products

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

- assessing the relevance, effectiveness, efficiency, coherence and EU added value of communication governed by the CLP Regulation and other legislation towards downstream companies, workers and consumers, and
- related case study work.

The information needed to undertake the evaluation has been collected through a combination of desk-based research, interviews, targeted data collection and analysis of the responses to the open public consultation. Both of the sub-tasks are also supported by case studies, as follows[4]:

- Case Study 3: Lack of consistency in parallel hazard assessments under different legislation
- Case Study 4: Relevance and coherence as regards the introduction of new test methods within chemicals legislation
- Case Study 5: Coherence of classifications, definitions and the labelling requirements for detergents
- Case Study 6: Inconsistencies in assessment procedures for PBT and vPvB as properties of concern
- Case Study 7: SME awareness of ATPs and changes in classification and of labelling and packaging requirements
- Case Study 8 (and also informing Case Study 11 under Task 3): Awareness of Chemical Safety Assessment and labelling requirements for Toys
- Case Study 9: Consumers' comprehension of and relevance of safety information on product labels.

The evaluation questions are set out in the Evaluation Summary report. They were mapped across the two sub-tasks listed above, to identify those that should be answered, at least in part, through the Task 2 evaluation. In order to report against both the sub-tasks and the evaluation questions, a set of themes has been developed to act as the basis for reporting. Each of these themes provides reporting in relation to one of the sub-tasks (in whole or in part) and against one or more specific evaluation questions.

The evidence base that has been used to support this evaluation includes a combination of sources: literature review and legal analysis, interviews, targeted consultation, and results from the SME Panel Survey and the Open Public Survey. Note that interviews carried out with national experts, industry experts, non-governmental organisations (NGOs), academics and practitioners inform both the case study work, as well as the more general evaluation.

1.2 Organisation of Task 2 reporting

In order to provide a context for reporting on the Task 2 evaluation, Section 2 of this report provides the output of the mapping of the chemicals related legislation that has been identified as having horizontal linkages (as defined above) to the CLP Regulation.

This overview is then followed by a discussion of the evaluation findings, which have been organised under the following 'themes':

- Section 3: Differences in definitions
- Section 4: Identification of properties of concern

[4] Note that case studies 1 and 2 fall under Task 1; while case studies 11 to 13 fall under Task 3.

- Section 5: Test methods and GLP
- Section 6: Processes and procedure
- Section 7: Hazard communication
- Section 8: Packaging
- Section 9: Overarching evaluation findings

2 Mapping of Relevant Horizontal Legislation

2.1 Overview of the mapping exercise

The starting point for mapping the horizontal links between the CLP Regulation and other EU chemical related acts was to develop a 'master list' of the various acts which are concerned with preventing harm to human or animal health or to the environment from certain substances and mixtures. To this end, the consultants mainly drew upon two sources:

- Firstly, the indicative list of legislation in the fitness check roadmap[5]; and
- Secondly, the legislation identified for the study "Technical assistance related to the scope of the REACH Regulation and other relevant EU legislation to assess overlaps", Commission Services, March 2012[6].

From these sources, the consultants compiled a master list of over 145 potentially relevant pieces of legislation. A thorough screening of this list was carried out, followed by a mapping of legislation, which identified where various pieces of legislation specify properties of concern, outline requirements for communicating properties of concern and/or set packaging requirements for chemicals. These are summarised in the tables provided in the remainder of this section.

2.2 Mapping of legislation identifying properties of concern

Table 2-1 below lists those acts which were identified as having, as part of their purpose, the identification of properties of concern other than by reference to the CLP Regulation.[7] The acts are organised into categories related to their primary objectives.[8]

A number of the acts with horizontal links contain lists of substances and mixtures deemed safe (or unsafe) for certain purposes, such as the legislation on cosmetic products and detergents. As a rule, only those acts that set their own specific scientific criteria, or that require a scientific evaluation to identify a property of concern other than a CLP hazard, have been listed. For example, the Plant Protection Products Regulation and Biocidal Products Regulation also provide for determining which active substances are approved for use in such products.

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5 European Commission (2016): Fitness Check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. Available at: http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_grow_050_refit_chemicals_outside_reach_en.pdf

6 This second set of legislation is broader than the 41 pieces of legislation identified in the non-exhaustive list given in the Roadmap.

7 Legislation on foodstuff, feedstuff and medicinal products (except food contact materials and contaminants in food and feed) is outside the scope of the fitness check exercise. Nevertheless, any legislation with horizontal links to the CLP Regulation is included for the purpose of this mapping exercise.

8 Where pieces of legislation fall within the scope of several categories, they were only assigned to one, e.g. the Biocidal Products Regulation and the Plant Protection Products Regulation apply to both consumer as well as professional products. They have been assigned to the category of professional products only.

Table 2-1: Identification of properties of concern	
EU act	**Properties of concern other than CLP hazards**
Framework legislation	
Regulation (EC) No 1907/2006 - the REACH Regulation	Annex XIII sets criteria for the identification, screening and assessment of persistent, bioaccumulative and toxic substances and very persistent and very bioaccumulative substances in the registration process. PBT and vPvB are given priority in the evaluation process to ensure compliance of the registration dossiers. The REACH Regulation does refer to substance having endocrine disrupting properties in article 57 as a substance that may be included in Annex XIV but does not set scientific criteria for identifying endocrine disrupting properties.
Consumer products	
Regulation (EC) No 1223/2009 on cosmetic products	The CLP Regulation does not apply to cosmetic products but to substances that are used as ingredients in cosmetic products. The CR has two systems for identifying substances with properties of concern. The first system (Art. 14) is based on prior evaluation of a chemical which may result in it being listed in one of five annexes. Annex II lists prohibited substances and Annex III lists substances subject to restrictions. In contrast to Annexes II and III, Annexes IV to VI are positive lists. A chemical must be listed in the relevant annex in order to be used as a colorant, preservative or UV filter in a cosmetic product. In addition, the Cosmetic Products Regulation relates to nanomaterials and provides a definition. Regarding substances with endocrine-disrupting properties it mandates the Commission to review the Regulation when Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015. The Cosmetic Products Regulation does not, however, set its own criteria for the identification of properties of concern. It does not refer to allergens as such, either. Rather specific substances that are likely to cause allergic reactions have been listed in the Annexes. The second system (Art. 15) is linked to the CLP Regulation, as described below in Task 3a.
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	Refers to the addictiveness, toxicity or the CMR properties of the tobacco product. Manufacturers must report if ingredients are classified under the CLP Regulation.
Regulation (EC) 648/2004 on detergents	The Regulation refers to a lack of biodegradability as a property of concern and provides testing requirements for this.
Professional and consumer products	
Regulation (EC) No 1107/2009 on plant protection products	The Plant Protection Products Regulation covers both professional and consumer products. It sets out the two step approval process for plant protection products: approval of active substances, safeners and synergists, and authorisation of the plant protection product. As part of the approval, the Plant Protection Products Regulation relies partly on the CLP classification. Approval criteria and corresponding properties of concern for approval of active substances, safeners and synergists include: impact on human health (CMR, endocrine disruptor), fate and behaviour in the environment (POP, persistence, bioaccumulation, potential for long-range environmental transport, PBT, vPvB), ecotoxicology (risk characterisation looking i.e. at endocrine properties), fate and behaviour concerning groundwater. An active substance may be approved as a candidate for substitution for a period not exceeding 7 years if it meets any of

Table 2-1: Identification of properties of concern	
EU act	**Properties of concern other than CLP hazards**
	the conditions of Point 4 of Annex II. An active substance may be approved for a period not exceeding 15 years if it is considered low-risk. Incentives may be given for the placing on the market of low-risk plant protection products.
Regulation (EU) No 528/2012 biocidal products (with the Regulation also applying to products sold to consumers)	The Biocidal Products Regulation covers both professional and consumer products. It aims at identifying properties of concern relying partly on the CLP Regulation but also covering other properties of concern, notably endocrine-disrupting properties, PBT or vPvB, and POPs. These are considered as part of the approval of active substances process (for approval, candidate for substitution and restriction on use by the general public). A simplified procedure of authorisation applies to products not containing 'substances of concern' and containing specific active substances, defined by reference to the Dangerous Substances Directive (Directive 67/548/EEC) and the Dangerous Preparations Directive (Directive 1999/45/EC) and the CLP Regulation but also POPs and vPvB.
Regulation (EC) No 2003/2003 relating to fertilisers	A fertiliser type may be included on the Fertilisers Regulation's Annex I positive list only if it does not adversely affect human, animal, or plant health, or the environment under normal conditions of use. Other 'properties of concern' relates to unintentional cadmium content and other contaminants that potentially pose a risk to human and animal health. The Dangerous Substances Directive is referenced only with respect to chelating & complexing agents, but the CLP Regulation is applicable to all fertilisers.
Directive 2001/82/EC on the Community code relating to veterinary medicinal products	Directive 2001/82/EC on the Community code relating to veterinary medicinal products does not refer directly to other specific other properties of concern. However, it does require providing specific information for the environmental risk assessment of veterinary medicinal products. This would include reviewing PBT and vPvB properties as per the Committee for Medicinal Products for Veterinary Use Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products.
Directive 2001/83/EC on the Community code relating to medicinal products for human use	The same remark applies in relation to Directive 2001/83/EC on the Community code relating to medicinal products for human use. Although there is no guidelines specific to PBT and vPvB substances, the 'Guideline on the environmental risk assessment of medicinal products for human use' takes into consideration PBT and vPvB properties.
Directive 2014/28/EU on the making available on the market and supervision of explosives for civil uses (recast)	Directive 2014/28/EU applies to explosives within the meaning of Class 1 of the UN Recommendations. The Directive sets out properties which must be considered when demonstrating that explosives meet essential safety requirements, with these including physical and chemical stability, temperature and water resistance amongst others.
Environmental Protection	
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	Substances posing significant risks to, or via, the aquatic environment. These are considered priority substances and priority hazardous substances, where the latter are priority substances that are PBT or give rise to an equivalent level of concern. Article 16 of the Directive sets out the process for identifying priority substances and priority hazardous substances, to inform proposals from the Commission. In this process, the Commission takes into account the selection of substances of concern undertaken in the relevant Community legislation regarding hazardous substances or relevant international agreements.

Table 2-1: Identification of properties of concern	
EU act	**Properties of concern other than CLP hazards**
Directive 2008/105/EC on environmental quality standards in the field of water policy as amended by Directive 2013/39/EU	Substances posing significant risks to, or via, the aquatic environment (priority substances and priority hazardous substances).
Commission Decision 2015/495/EC establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC	Substances that may pose significant risks at EU level to, or via, the aquatic environment.
Health & Safety of Workers	
Directive 98/24/EC chemical agents at work Directive 2000/39/EC, Directive 2006/15/EC, and Directive 2009/161/EU setting up lists of occupational emission limits	The CAD applies to any chemical agent that meets the criteria for classification as hazardous within any physical and/or health hazard classes laid down in the CLP Regulation, whether or not that chemical agent is classified under that Regulation. It also covers any chemical not related to CLP classification that may, because of its physico-chemical, chemical or toxicological properties and the way it is used or present in the workplace, present a risk to the safety and health of workers, including any chemical agent that is assigned an occupational exposure limit value. As part of the assessment to set up limit values, the Scientific Committee on Occupational Emission Values (SCOEL) considers the substance hazards.
Directive 2004/37/EC carcinogens or mutagens at work	Carcinogens and mutagens are defined by reference to CLP classification but also in the case of carcinogens to a substance, mixture or process referred to in Annex I to the Directive as well as a substance or mixture released by a process referred to in that Annex. Annex I includes specific processes and types of work involving exposure to specific substances or effects (e.g. dust). The Annex I can be revised on the basis of a procedure similar to the one under the Chemical Agents Directive (see above)

Consequently, the table does not include legislation that applies either to only pre-defined substances or that applies to 'hazardous' substances without defining what is meant by 'hazardous'. For instance, Regulation on food additives (Regulation (EC) No 1333/2008)[9] has not been included here.

This is because it requires labelling for aspartame in table-top sweeteners but, since this is a pre-defined substance, it is not considered a 'property of concern'. Other examples of such legislation include Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)[10], some OSH Directives (e.g. Directive 92/57/EC and 92/91/EC) and also some New Approach Directives[11].

2.3 Mapping legislation for communicating properties of concern and setting packaging requirements

The next step in the mapping exercise was the mapping of the CLP Regulation and other EU acts which contain provisions for communicating properties of concern, including substances or mixtures classified as hazardous, or which set packaging requirements.

Table 2-2 below summarises the results of this mapping exercise.[12] The second column in the table shows where labelling of hazards in accordance with the CLP Regulation is required. It also shows where additional requirements are set out in the horizontal legislation. Be aware that, as opposed to Table 2-1, which presents legislation identifying properties of concern other than CLP hazards, Table 2-2 contains also labelling requirements that refer to pre-defined substances, e.g. the Batteries Directive (Directive 2006/66/EC)[13] that requires labelling of batteries with the name of the metal contained, or the Cosmetic Products Regulation that requires a warning on products that contain formaldehyde above a certain threshold.

For certain products aimed at consumers, such as cosmetics or toys, the requirements are often quite extensive. In addition to specifications concerning the name and address of the manufacturer or importer, they may also include requirements aimed more directly at communication of properties of concern, such as lists of ingredients, instructions for use, precautions and warnings.

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[9] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

[10] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment

[11] New Approach Directives define "essential requirements" related to health, safety and environmental issues. Products must meet these requirements in order to be placed on the European market. One way of demonstrating compliance with the essential health and safety requirements is through compliance with harmonized European standards. In the case of the Machinery Directive, for example, 13 European standards are applicable and relevant for the reduction of risk to health from hazardous substances emitted by machinery. However, the standards are not obligatory and compliance can be demonstrated also by other means ensuring a similar level of safety.

[12] Legislation on foodstuff, feedstuff and medicinal products (except food contact materials and contaminants in food and feed) is outside the scope of the fitness check exercise. Nevertheless, any legislation with horizontal links to the CLP Regulation is included for the purpose of this mapping exercise.

[13] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
Framework legislation		
Regulation (EC) 1907/2006 -- the REACH Regulation	Pursuant to Article 31, the supplier of a substance must provide the recipient of the substance with a safety data sheet compiled in accordance with Annex II: (a) where a substance or mixture meets the criteria for classification as hazardous in accordance with the CLP Regulation or (b) where a substance is PBT or vPvB; or (c) where a substance is included in the candidate list referred to Article 59(1) for reasons other than those referred to in points (a) and (b). A safety data sheet must also be provided when a mixture does not meet the criteria for classification as hazardous but contains: - At least one substance posing human health or environmental hazards - At least one substance that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is PBT vPvB or has been included for reasons other than those referred to in point (a) in the above-mentioned candidate list - A substance for which there is Community workplace exposure limits.	n/a
Consumer products		
Regulation (EC) No 1223/2009 on cosmetic products	Labelling requirements: • Article 3 (b): Among others, the labelling must ensure that the cosmetic product is safe for human health when used under normal or reasonably foreseeable conditions. • Pursuant to Article 14 in conjunction with Annex III, hair colorants containing certain substances must be labelled with a warning of the possible allergic reactions caused by those substances. • Article 15(2) 3rd sentence: In case of CMR substances being used in the cosmetic product, "*Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure*." • Article 19(1) sentence 10: All ingredients present in the form of nanomaterials must be clearly indicated in the list of ingredients. The names of such ingredients must be followed by the word 'nano' in brackets. • Annex V Preamble Point 2: All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde'	n/a

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	where the concentration of formaldehyde in the finished product exceeds 0.05 %. Other communication requirements: • Article 3 (b) and (c): Among others, the labelling and instructions for use must ensure that the cosmetic product is safe for human health when used under normal or reasonably foreseeable conditions. • Article 13(1)(f): Notification to the Commission of presence of substances in the form of nanomaterials and their identification and reasonably foreseeable exposure conditions. • Article 16(3): More notification requirements on nanomaterials used in cosmetics products. The information notified to the Commission must contain at least the following: - (a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI; - (b) the specification of the nanomaterial including size of particles, physical and chemical properties; - (c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year; - (d) the toxicological profile of the nanomaterial; - (f) the reasonably foreseeable exposure conditions; - (e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products; Article 13(1)(g): Notification to the Commission of the name and the CAS or EC number of substances classified as CMR of category 1A or 1B, under Part 3 of Annex VI to the CLP Regulation	
Directive 2009/48/EC on the safety of toys	• Article 4 Obligations of manufacturers: identification of the product, name and contact detail of manufacturer. • Article 6 Obligation of importers: contact details of importers. • Annex II safety requirements: names of allergenic fragrances must be listed on an affixed label or on the packaging. • Annex II safety requirements: toys that are themselves substances or mixtures must comply also with (…)the CLP Regulation, as applicable, relating to the classification, packaging and labelling of certain substances and mixture. • Article 11: warnings: safety warnings as per annex V. • Article 16: CE marking.	n/a

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	Annex V: Warnings: Where appropriate for safe use, minimum or maximum age/weight of user, need of adult supervision, instruction for assembly of the toy, precautions for use. Regarding chemical toys, i.e. "*toys intended for the direct handling of chemical substances and mixtures and used in a manner appropriate to a given age-group and under the supervision of an adult*" (definition in Article 3 of the Directive): Annex VB4: without prejudice to CLP requirements, the instructions of toys containing inherently dangerous substances or mixtures shall bear a warning of the dangerous nature of these substances or mixtures and an indication of the precautions to be taken, the first aid in case of accidents and age limits. In addition, on the packaging "*Not suitable for children under … years. For use under adult supervision*."	
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	The list of ingredients that the manufacturers and importers of tobacco products must submit to their competent authorities must indicate inter alia the classification of the ingredients under the CLP Regulation. It must also indicate toxicological data and refer to any addictive effects. Manufacturers and importers submitting a notification of a novel tobacco product shall also provide the competent authorities with: (a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions; Manufacturers and importers of electronic cigarettes and refill containers must submit a notification to the competent authorities of the Member States, including toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect. Chapter 2 sets labelling requirements on tobacco products, including the display of health warnings related to the toxicity, addictiveness and harmfulness of the product. Unit packets of electronic cigarettes and refill containers include a leaflet with information on addictiveness and toxicity, and carry a health warning 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.	Article 14: appearance and content of unit packages
Regulation (EC) 648/2004 on detergents	Article 11 Labelling Without prejudice to CLP requirements, packaging of detergents must bear: identification of the product, contact details of manufacturer, precautions of use, list of constituents and their concentration (Preservation agents and allergenic fragrance in accordance with Directive 76/768/EEC), dosage instructions)	n/a
Council Directive 75/324/EEC on aerosol dispensers	Where an aerosol dispenser contains flammable components but the aerosol dispenser is not considered as 'flammable' or 'extremely flammable', the quantity of flammable material contained in the aerosol	The Annex contains packaging requirements for metal

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	dispenser must be stated on the label. Furthermore, the Directive requires without prejudice to the CLP Regulation that the label must contain certain hazard statements and certain precautionary statements. The Directive also contains traceability requirements (Art. 8(1)).	aerosol dispensers, glass aerosols dispensers, and unprotected glass containers regarding capacity, coating and filing.
Regulation (EU) No 1169/2011 on the provision of food information to consumers	The Regulation contains a labelling requirement for engineered nanomaterials. They must be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.	n/a
Regulation (EC) 1333/2008 on food additives	Chapter IV: Labelling Article 22: Food additives not intended for sale to the final consumer: contact details of manufacturer Article 23: Food additives intended for sale to the final consumer: identification of product, warnings concerning table-top sweeteners containing aspartame.	n/a
Professional and consumer products		
Regulation (EC) No 1107/2009 on plant protection products	The Plant Protection Products Regulation sets labelling requirements additional to those applicable pursuant to the CLP Regulation. The additional requirements are quite extensive. In addition to standard phrases for special risks to human or animal health or to the environment and standard phrases for safety precautions for the protection of human or animal health or of the environment, the label should include a number of information, in particular the name and amount of each active substance, net quantity, batch number, the type of action of the product, the type of preparation, the authorised uses, and directions for safe disposal of the product and its packaging. Pursuant to the CLP Regulation, the label must also include the additional phrase EUH401 — 'To avoid risks to human health and the environment, comply with the instructions for use'. These labelling requirements are set by the Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products. In addition, pursuant to Article 49, the label and documents accompanying the treated seeds shall include the name of the PPP with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for by the CLP (although the legislation refers to the Dangerous Preparations Directive) and risk mitigation measures set out in the authorisation for that product where appropriate (Art.49(4)). Update: Member States may provide that authorisation holders shall classify or update the label without	The Dangerous Preparations Directive requirements apply to packaging of PPP, including to packaging of PPP and adjuvants that would not fall under the scope of the Dangerous Preparations Directive (Art.64(3)); however, MS and companies interpret this as referring to CLP. The authorisation can include requirements as to the packaging size and material (Art. 31(4)(j). Plant protection products and adjuvants that may be mistaken for food, drink or feed shall be packaged in such

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	undue delay following any change to the classification and labelling of the PPP in accordance with the Dangerous Preparations Directive. In such cases, they shall immediately inform the competent authority thereof (Art. 31(2), second paragraph). Finally, the Plant Protection Products Regulation offers Member States the possibility to impose additional phrases if it considers those necessary. In this case, the Member State notifies the other Member States and the Commission, including the reasons for the requirements. The Member State may require the use of the additional phrase(s) pending their inclusion in Regulation 547/2011 (Art. 65(3)).	a way as to minimise the likelihood of such a mistake being made […] and shall contain components to discourage or prevent their consumption (Art.64(1) and (2)).
Regulation (EU) No 528/2012 biocidal products	The Biocidal Products Regulation sets labelling requirements additional to those applicable pursuant to the CLP Regulation (Art.69). The additional requirements are quite extensive and specify certain information that must be included clearly and indelibly on the label of a biocidal product. In particular, the label should include the name and amount of each active substance, any nanomaterials in the product, the authorisation number and details of the authorisation holder, the type of formulation, its batch number and expiry date, the uses for which the biocidal product is authorised and directions for use, any likely direct or indirect adverse side effects, directions for safe disposal and net quantity, batch number, instructions regarding application of the product, any restrictions on use, and details of any specific danger to the environment. No inconsistencies, overlaps or gaps were identified. In relation to the placing on the market of treated articles, when the conditions of the Art 58(3) or (4) are met, the label should include a statement that the treated article incorporates biocidal products, the biocidal property, without prejudice to Article 24 of the CLP Regulation, the name of all active substances contained in the biocidal products, the name of all nanomaterials contained in the biocidal products, instructions for use (Art.58)	Biocidal products must be classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, and with the CLP Regulation (Article 69(1)). Products which may be mistaken for food are to be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children (Article 69(1)). Where necessary because of

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
		the size or the function of the biocidal product, certain information may be indicated on the packaging or on an accompanying leaflet integral to the packaging (Article 69(3)).
Professional products		
Regulation (EC) No 2003/2003 relating to fertilisers	"*Without prejudice to other Community rules*", pursuant to Article 9 the packages, labels and accompanying documents of EC fertilisers must bear the different markings, i.e. the words EC FERTILISER, the designation of the type of fertiliser, the marking 'blend' where applicable, additional marking for certain types of fertilisers, indication of nutrients (in addition specific requirements for micro-nutrients, directions for use for some fertilisers, quantity, and name and address of the manufacturer).	Article 10 provides where and how the above-mentioned markings must be applied to the packaging/accompanying documents.
Directive 2014/28/EU on the making available on the market and supervision of explosives for civil uses (recast)	Obligation on manufacturers/exporters/distributors to provide instructions and safety information. The Directive also sets identification and traceability requirements applicable to products placed on the market. These obligations are implemented through Directive 2008/43/EC, which set up a system for the identification and traceability of explosives for civil uses.	The identification should be placed on the explosives and/or packaging.
Directive 2001/82/EC on the Community code relating to veterinary medicinal products	Title V on Labelling and package insert : traceability of the product, end-use, expiry date, particulars, therapeutic indications, contra-indications etc.	n/a
Directive 2001/83/EC on the Community code relating to medicinal products for human use	Title V on Labelling and package leaflet: traceability, identification of product, end-use, characteristics and dosage, method of administration, expiry date, therapeutic indications, instructions for use, adverse reactions, expiry date etc.	n/a
Directive 98/79/EC on in vitro diagnostic medical devices	Annex I (Essential requirements) Part B, Point 8.3: In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use.	n/a

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	
Directive 2014/68/EU on Pressure Equipment	Annex I on Essential Safety Requirements, 3.3: identification of the product, maximum/minimum allowable limits, information necessary for safe installation, operation or use, maintenance and inspections, warnings etc. Article 6(6) Obligations of manufacturers: name and contact details of the manufacturer Article 8(3) Obligations of importers: name and contact details of importers Article 19: CE marking	n/a
Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products	When a construction product is covered by a harmonised standard or conforms to a European Technical Assessment, the manufacturer must draw up a declaration of performance. This is to be accompanied by information on the content of hazardous substances in the construction product (SDS). This applies to substances referred to in Articles 31 and 33 of the REACH Regulation, which include substances which meet the criteria for classification as hazardous under the CLP Regulation, or a mixture which meets the criteria for classification as dangerous under the Dangerous Preparations Directive.	n/a
Environmental Protection		
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	n/a	n/a
Directive 2008/105/EC on environmental quality standards in the field of water policy as amended by Directive 2013/39/EU	n/a	n/a
Decision 2015/495/EC establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC	n/a	n/a
Directive 2008/98 on waste	According to Article 19, hazardous waste must be labelled in accordance with the international and Community standards in force. The Directive does not set additional labelling requirements. When transported, hazardous waste must be accompanied by an identification document as per Annex	According to Article 19, hazardous waste must be packaged in accordance with

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	IB of Regulation 1013/2006 on shipments of waste	the international and Community standards in force. The Directive does not set additional labelling requirements.
Directive 2000/53/EC on end-of life vehicles	Producers must provide dismantling information for each type of new vehicle put on the market within six months after the vehicle is put on the market. This information must identify, as far as it is needed by treatment facilities in order to comply with the provisions of this Directive, the different vehicle components and materials, and the location of all hazardous substances in the vehicles (Article 8). 'Hazardous substances' are defined by reference to the CLP Regulation (Article 2).	n/a
Directive 2006/66/EC on batteries & accumulators	Article 21: Labelling : symbol for separate collection, capacity, appropriate use, chemical symbol of metal contained (Hg, Cd or Pb)	n/a
Regulation (EC) No 1013/2006 shipments of waste	To 'hazardous waste' the procedure of prior written notification and consent applies.	n/a
Directive 2008/68/EC on inland transport of dangerous goods	Labelling requirements from ▪ Annexes A and B to the ADR ▪ RID ▪ Annexed Regulations to the AND Member States can adopt more stringent provisions or request derogations.	n/a
Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (recast)	Chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to the CLP Regulation, Plant Protection Products Regulation or Biocidal Products Regulation or any other relevant Union legislation. This requirement applies unless those provisions would conflict with any specific requirements of the importing Parties or other countries. (Art.17(1))	See communication provisions.
Occupational health & safety		
Directive 98/24/EC chemical agents at work	n/a	n/a
Directive 2004/37/EC carcinogens or mutagens at work	n/a	n/a
Directive 92/58/EEC on H & S signs at work	Areas, rooms or enclosures used for the storage of significant quantities of hazardous substances or mixtures must be indicated by a suitable warning sign taken from Section 3.2 of Annex II, or marked as	

Table 2-2: Legislation on communicating properties of concern and packaging requirements		
EU Act	**Communication provisions**	**Packaging provisions**
	provided in Section 1 of Annex III, unless the labelling of the individual packages or containers is adequate for this purpose. Section 1 of Annex III covers containers used at work for chemical substances or mixtures classified as hazardous (physical or health hazard class) under the CLP Regulation and containers used for the storage of such hazardous substances or mixtures, together with the visible pipes containing or transporting such hazardous substances and mixtures. These must be labelled with CLP hazard pictograms. These may be replaced by warning signs set out in Annex II, using the same pictograms or symbols. If there is no equivalent warning sign in Annex II, the relevant CLP hazard pictogram must be used, The labels must be supplemented by additional information, such as the name and/or formula of the hazardous substance or mixture and the details of the hazard The warning signs in Section 3.2 of Annex II include e.g. signs for flammable, explosive, toxic or corrosive material. These signs may be used instead of the CLP pictograms to indicate the presence of hazardous substances. CLP pictograms will also be used if an equivalent sign does not exist in Section 3.2 of Annex II. The relevant question for coherence is whether the signs are different from the CLP pictograms and, if yes, whether there are any reasons for maintaining the different signs. There are some minor differences with the GHS pictograms used in the CLP Regulation, although possibly not significant for understanding.	

A number of acts (e.g. veterinary medicines, toys) include traceability requirements. While these are not aimed at the communication of a hazard, they are a type of risk management measure in that products identified as posing a risk to human or animal health and/or the environment that are already on the market can be traced and removed, if necessary.

Column three notes where the packaging requirements set forth in the CLP Regulation apply. It also identifies where the legislation has outlined additional packaging requirements.

2.4 Focus of the evaluation

For the purposes of Task 2, it was deemed necessary to focus on specific legislation with horizontal links to the CLP Regulation. This is considered an appropriate approach given the need to focus on the key issues that arise with regard to the linkages between the CLP Regulation and other legislation within the chemicals legislative framework. Thus, specific legislation was selected for further analysis based on information obtained from initial research and consultation regarding potential issues that have been highlighted (in relation to effectiveness, efficiency, coherence, relevance and/or EU added value). Legislation was also selected on the basis of how changes are made with regards to adaptations to technical progress (ATPs) under the CLP Regulation.

It was therefore agreed that this task would focus on the following legislation:

- The REACH Regulation (Regulation (EC) No 1907/2006) (limited to Annex XIII on PBTs and vPvBs);
- Plant Protection Products Regulation (Regulation (EC) No 1107/2009)[14];
- Biocidal Products Regulation (Regulation (EU) No 528/2012);
- Cosmetic Products Regulation (Regulation (EC) No 1223/2009);
- Detergents Regulation (Regulation (EC) No 648/2004)[15];
- Toy Safety Directive (Directive 2009/48/EC)[16];
- The Water Framework Directive (Directive 2000/60/EC)[17];
- Fertilisers Regulation (Regulation (EC) No 2003/2003)[18]; and
- OSH legislation (in particular the Chemical Agents and Carcinogens and Mutagens Directives (Directive 2004/37/EC)).

Although the focus has been on the above legislation, issues raised during interviews or through consultation on other pieces of legislation with a horizontal link to the CLP Regulation are also highlighted as appropriate.

[14] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[15] Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents

[16] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys

[17] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

[18] Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers

3 Coherence of Definitions

3.1 Introduction

Initial consultation identified issues pertaining to the consistency of definitions across the chemicals-related legislation. This included a lack of definitions in some cases and the use of the same term to mean different things in the different pieces of legislation. Although only a small number of such definitional issues have been identified, they may lead to confusion or (in the worst case) a lack of compliance. They may also lead to increased costs to industry, for example, in having to spend time trying to understand the legislation or even in seeking legal clarification.

The issues identified from the legal analysis and consultation are set out below, with the relevant evaluation questions given in Table 3-1.

Table 3-1: Evaluation questions to be addressed relating to a lack of definitions

Q #	Evaluation Question
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.1.2.3	Are the information requirements on chemicals (including on e.g. chemical content, hazard, risk, use) and the availability of this information sufficiently clear to allow their harmonised application throughout the single market?
1.1.3	Does the EU legislative framework for the risk management of chemicals meet the primary objective of enhancing competitiveness and innovation?
4.2.2	What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

3.2 Lack of definitions

Key findings

- The Cosmetic Products Regulation does not include the term allergen, although specific fragrance allergens have been identified as requiring labelling and a longer list have been identified by SCCS. Until there is agreement on a revised list in Annex II of the Regulation, there is the potential for an uneven playing field within the market.
- The Regulation on the Provision of Food Information to Consumers lacks a specific definition as to what constitutes an allergen but there is no evidence of this having given rise to significant impacts.

The two key pieces of legislation which have been identified as suffering from a lack of definitions are as follows (further information is provided in Section 7.2):

1) Labelling of certain substances that "*may cause allergenic reactions*" is required under the Cosmetic Products Regulation (Regulation (EC) No 1223/2009); but what constitutes an allergen is not specifically defined in the Cosmetic Products Regulation;

2) Under Regulation (EU) No 1169/2011 on the Provision of Food Information to Consumers, information on the presence of certain substances, listed in Annex II, that may cause

allergies or intolerances should be included on the label; in this case broad groups of allergens are identified but the term allergen is not specifically defined.

An allergen may or may not also be a respiratory or skin sensitiser. Many are natural (e.g. natural fragrances) while others are man-made. The lack of clear definitions is considered by stakeholders (such as ANEC, health and environmental NGOs, some Member State authorities and a number of citizen respondents to the Open Public Consultation) to be likely to be leading to a lack of harmonised application of the requirements across the single market, by both companies and by Member States.

No evidence of a lack of harmonised application was presented to the consultants in relation to the Cosmetic Products Regulation, although it is understood that there are proposals to amend Annex III of the Regulation to address a lack of mandatory labelling of fragrance allergens. Issues regarding the labelling of fragrance allergens in particular have been the subject of an opinion[19] of the Scientific Committee on Consumer Safety (SCCS), which recommended that the presence of any of 127 fragrance allergens should be indicated on cosmetic product labels, with 11 key ingredients restricted to 0.01% in the final product. In addition, the SCCS also indicated that substances that are known to be transformed, through air oxidation and/or bioactivation (prehaptens and prohaptens), into allergens should be treated as being equivalent to those allergens. In response to this opinion, industry is working with the Commission and other stakeholders under the framework of the IDEA project (International Dialogue for the Evaluation of Allergens) to agree a transparent framework for assessing fragrance sensitisers globally. In 2014 the Commission launched a consultation on fragrance allergens, with the aim of addressing the lack of labelling as well as proposing changes to the Regulation, which have been drafted.[20] It is understood that due to reorganisation of responsibilities within the Commission, these proposals have not progressed.

Regulation (EU) No 1169/2011 on the Provision of Food Information to Consumers sets out a list of 14 allergens that are recognised as the most common ingredients or processing aids causing food allergies and intolerances. These allergens are defined in terms of groups of products, and there is the potential for businesses to interpret what is covered by some of the individual allergens headings differently. However, no evidence of a lack of harmonised application has been identified from research.

3.3 Legal definitions

Key findings:

- Variations in the definition of 'placing on the market' between the CLP Regulation and the Explosives Directive and Pyrotechnic Articles Directives have led to confusion, increasing the costs faced by operators and potentially affecting the performance of the legislation.
- The legal concept of a 'treated article' under the Biocidal Products Regulation (Regulation (EU) No 528/2012) has led to some confusion for industry, and in particular smaller

[19] SCCS (2012): Opinion on fragrance allergens in cosmetic products. Available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

[20] European Commission (n.d.): Public consultation on fragrance allergens in the framework of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products. Available at: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/ca/consultation_cosmetic-products_fragrance-allergens_201402_en.htm

formulators, due to the fact that some mixtures under the CLP Regulation may become treated articles under the Biocidal Products Regulation. The extent to which this is leading to additional costs for industry, operators failing to meet their obligations or the failure for the Regulation to be effective in protecting human health or the environment is not known.

Stakeholders have highlighted differences in the definitions included under different pieces of legislation, which it appears can create problems in some cases. Identified examples relate to the terms 'placing on the market' and 'articles', which appear to be defined differently in different pieces of legislation (as summarised in the sections that follow).

3.3.1 Placing on the market

A range of different definitions as to what is meant by the term 'placing on the market' is used across the different pieces of legislation, as illustrated in Table 3-2.

Table 3-2: Definition of placing on the market	
CLP Regulation ((EC) No 1272/2008)	*'placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market'*
Explosives Directive ((EU) No 2014/28)	*'placing on the market' means the first making available of an explosive on the Union market'*
Pyrotechnic Articles Directive ((EU) No 2013/29)	*'placing on the market' means the first making available of a pyrotechnic article on the Union market'*
Biocidal Products Regulation Directive ((EU) No 528/2012)	*'placing on the market' means the first making available on the market of a biocidal product or of a treated article'*
Detergents Regulation ((EC) No 648/2004)	*'placing on the market' means the first making available on the Union market. Import into the Union customs territory shall be deemed to be placing on the market.*
Plant Protection Products ((EC) No 1107/2009)	*'placing on the market' means the holding for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation'.*

A Member State authority raised concerns over the differences in the definitions for the CLP Regulation compared to the Explosives Directive (2014/28/EU)[21] and the Pyrotechnic Articles Directive (2013/29/EU)[22]. The authority notes that this appears to result in some confusion as regards who has the obligation to label (as the obligation relates to *first* making available). From the Member State's perspective, it is important that the definitions and concepts are applied

[21] Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast)

[22] Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast)

consistently across legislation within the existing legislative framework and when new legislation is introduced (see also Section 7.2). In this respect it is of note that the definition in other chemicals legislation, such as in the Biocidal Products Regulation[23], is similar to that in the Explosives Directive and Pyrotechnic Articles Directives. No issues regarding potential confusion were raised with regard to the Biocidal Products Regulation, potentially due to the need for products to be authorised for use and the process supporting this including classification and labelling activities that rely on the involvement of Member State authorities.

Interviews with the pyrotechnics and explosives industries have also indicated that there is some confusion in this respect, with this leading to legal uncertainty and a failure of some operators to correctly fulfil legal obligations (with this raised in relation to pyrotechnics in particular). This will not only have given rise to costs for industry of ensuring their legal position, but also potential hassle costs when dealing with other operators within the supply chain. It is not clear how significant this issue is (although it was noted by more than one company). As noted by the Commission Services, the definitions adopted in both of these sets of product legislation are aligned to the harmonised definition that is used in the New Legislative Framework, so is the more broadly used definition. In this regard, it is not expected that this difference in definitions will have impacted on the functioning of the legislation.

Stakeholders from the detergents sector also identified differences in the definition of 'placing on the market' between the CLP Regulation and the Detergents Regulation as an issue. From their perspective, this lack of consistency leads to some confusion. Discussions with relevant stakeholders as part of Case Study 5 (relating to coherence of classification, definitions and labelling requirements for detergents) indicate that different Member States have interpreted the term 'placing on the market' differently with regards detergents. The issue was raised by Member States and industry with the Commission in the run up to the 2015 deadline for meeting the CLP Regulation's requirements. Although the issue has now been addressed, both Member State authorities interviewed for the case study, as well as industry, noted that this gave rise to uncertainty for industry and led to extensive discussions at the Member State level between authorities and industry, resulting in considerable effort which could have been avoided if the difference in definition had been dealt with more efficiently from a process perspective.

It is also of note that the definition under the Plant Protection Products Regulation also varies from those used in the other legislation. In this case, the definition is much broader and includes the concept of 'making available on the market' which is defined in its own right in some of the other legislation, e.g. under the Biocidal Products Regulation. Nevertheless, stakeholders consulted for the purposes of this study have not identified any problems that have arisen as a result of this particular deviation in definitions.

3.3.2 Articles

Differences in the definition of an 'article' have also been identified. Under the CLP Regulation, an article is defined as follows:

> *"'article' means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'."*

[23] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

This definition is consistent with the definition of an article under the REACH Regulation, but has been identified as leading to confusion with the concept of a treated article under the Biocidal Products Regulation:

> *treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.*

The legal concept of a treated article under the Biocidal Products Regulation is different from the legal concept of an article, as defined in the REACH Regulation or the CLP Regulation. In this case, a treated article covers not only articles but also mixtures that contain biocidal products. The Commission has clarified that the decision to create the legal concept of a 'treated article' was expressly made so as to include under the same term all of the articles and mixtures treated or incorporating a biocide.

In addition, Article 3(1)(a) of the Biocidal Products Regulation states that:

> *A treated article that has a primary biocidal function shall be considered a biocidal product*.

As a result, paints which include a biocidal in-can preservative (which most waterborne paints are likely to include) are mixtures under the CLP Regulation (and the REACH Regulation) but become 'treated articles' under the Biocidal Products Regulation; in some cases, they may also be biocidal products (e.g. wood preservative mixtures, as the objective of the paint is to have a biocidal function). This has been identified by EU and national industry associations as leading to confusion for some stakeholders, and in particular was raised as an issue for some smaller formulators.

The legal text of the Biocidal Products Regulation itself recognises the need for clear borderlines due to the fact that treated articles as defined under the Biocidal Products Regulation are also regulated by other Union legislation. This is the list of product-types with indicative sets of descriptions, which are set out in the Regulation. Nevertheless, there may be merit in providing further clarification for the avoidance of confusion and to ensure that operators understand their legal obligations. Both are important to ensuring the effectiveness and efficiency of the legislation in meeting its single market and human health and environmental protection goals.

3.3.3 Manufacturers

Differences have also been identified with regard to the definition of manufacturers between the CLP Regulation and the Detergents Regulation (Regulation (EC) No 648/2004). Under the CLP Regulation, a manufacturer is defined as:

- *'manufacturer' means any natural or legal person established within the Community who manufactures a substance within the Community.*

However, under the Detergents Regulation a manufacturer is defined as:

- *'Manufacturer' means the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof, shall be deemed to be a manufacturer. A distributor who does not change the characteristics, labelling or packaging of a detergent, or of a surfactant for a detergent, shall not be deemed to be a manufacturer, except where he acts as an importer.*

Therefore, under the Detergents Regulation the definition of a manufacturer is much broader (and more inclusive) compared to the definition included in the CLP Regulation because manufacturers, importers and packagers are all classified as manufacturers (and subject to the relevant requirements) under the Detergents Regulation, whereas manufacturers and importers are considered separately under the CLP Regulation. Whilst this difference could be considered as an inconsistency, discussions with stakeholders have not identified any significant impacts.

4 Identification of Properties of Concern

4.1 Introduction

The different chemical legislative acts listed in Table 2-1 identify different properties of concern. The properties of concern taken from the CLP Regulation, in addition to those in the CLP Regulation or via other definitions that are relevant to each of the pieces of legislation are set out below in Table 4-1. Table entries that read 'CLP' indicate that the legislation relates directly to CLP classifications for hazard identification. 'Other' entries indicate that hazard identification takes into account additional considerations to CLP classifications and may also rely on data other than that generated by the CLP Regulation. Entries that read 'Other' indicate the legislation does not specify what data should be used for identifying properties of concern. Entries that read NR indicate the property is not relevant to or not referenced in that legislation. For the column on 'negative lists', only those legislation to which these are relevant are ticked.

Table 4-1: Identification of properties of concern						
EU act	**Properties of concern other than CLP hazards**					
Framework legislation	**PBT**	**vPvB**	**ED**	**C,M,R**	**Allergens**	**Negative list(s)**
Regulation (EC) No 1907/2006 - REACH Regulation	Other	Other	Other	CLP	CLP	✓
Consumer products						
Regulation (EC) No 1223/2009 on cosmetic products	NR	NR	Other	CLP	Other	✓
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	NR	NR	NR	Other	NR	
Regulation (EC) 648/2004 on detergents	Other	NR	NR	CLP	CLP	✓
Directive 2009/48/EC on the safety of toys	NR	NR	NR	CLP	CLP	✓
Professional and consumer products						
Regulation (EC) No 1107/2009 on plant protection products	Other	Other	Other	CLP	CLP	✓
Regulation (EU) No 528/2012 biocidal products (with the Regulation also applying to products sold to consumers)	Other	Other	Other	CLP	CLP	✓
Regulation (EC) No 2003/2003 relating to fertilisers	NR	NR	NR	NR	NR	
Directive 2001/82/EC on the Community code relating to veterinary medicinal products	Other	Other	NR	NR	NR	
Directive 2001/83/EC on the Community code relating to medicinal products for human use	Other	Other	NR	NR	NR	
Environmental Protection						
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	Other	Other	Other	Other	NR	✓
Directive 2008/105/EC on environmental quality standards in the field of water policy as amended by Directive 2013/39/EU	Other	Other	Other	Other	NR	✓
Commission Decision 2015/495/EC establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC	NR	NR	NR	NR	NR	✓

Table 4-1: Identification of properties of concern						
EU act	**Properties of concern other than CLP hazards**					
Health & Safety of Workers						
Directive 98/24/EC chemical agents at work Directive 2000/39/EC, Directive 2006/15/EC, and Directive 2009/161/EU setting up lists of occupational emission limits	NR	NR	NR	CLP	CLP	
Directive 2004/37/EC carcinogens or mutagens at work	NR	NR	NR	CLP (C, M)	NR	

The remainder of this section looks at the effectiveness, efficiency and coherence of the different chemicals legislation identified in Table 4-1 above with respect to the identification and assessment of properties of concern (i.e. health or environmental hazards). The evaluation questions considered under this heading are set out below. The findings of Case Study 6 are also relevant to this part of the evaluation.

Table 4-2: Evaluation questions to be addressed relating to hazard identification	
Q #	**Evaluation Question**
1.1.1.2.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the combination effects of chemicals (simultaneous exposure to chemicals)?
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?
2.2.4.9.	To what extent are substances assessed on an individual basis and to what extent are similar substances assessed together? What differences are there in the efficiency of these approaches?
2.2.4.10.	To what extent is it efficient to assess substances which are structurally related, used for the same purpose or otherwise similar assessed individually or together?
2.2.4.11.	To what extent do the current provisions provide for assessments of chemical groups and if so are they applied? What are the pros and cons of these approaches e.g. effectiveness, efficiency, relevance.
4.1.2.	To what extent are the legal acts of the chemicals legislative framework coherent in terms of hazard identification?
4.1.3.	To what extent are the legislative provisions referring to various hazards (e.g. CMRs, PBTs, vPvBs, POPs, endocrine disruptors) coherent?
4.1.4.	To what extent are the criteria for identification of hazards coherent (e.g. PBT and vPvB criteria)?
4.2.9.	Are there any inconsistencies as regards quality requirements for data?
4.2.8.	Is there any inconsistency as regards format for data provisions? If yes, are they justified?

4.2 Variations in criteria for identified properties of concern

Key findings:

- Some differences exist regarding the numeric criteria that establish whether or not a substance meets PBT or vPvB criteria. However, these are in general coherent, with most legislation drawing on the criteria set out in the REACH Regulation. The key differences are the criteria set under the Plant Protection Products Regulation; in particular, the ability to use weight of evidence approaches under all other legislation is likely to account for any differences.
- The CLP Regulation lacks any criteria or labelling provisions for PBT/vPvB properties, although their potential inclusion in the CLP Regulation is mentioned in the recitals of the Regulation. This is considered to be a gap in relation to hazard communication, as users will not have all of the information needed to ensure safe use and disposal (as not all PBTs will be classified as acute/chronic aquatic toxic).
- After significant delays, the Commission has published draft criteria for the identification of endocrine disruptors in the context of the EU legislation on plant protection products and biocidal products. Criteria are still lacking for application under other legislation. The potential for criteria to be non-harmonised across the legislation raises significant concerns over coherence and costs.
- The CLP Regulation sets out clear criteria for the classification of CMRs; other legislation, including Plant Protection Products Regulation, Biocidal Products Regulation and Toy Safety Directive all refer to the CLP Regulation for classification for these properties, however the Young Workers Directive does not define carcinogenic properties or refer to the CLP Regulation.
- Allergies are estimated to impact around 20% of the EU population. Although chemicals will only be one contributing factor, there are differences in the number of allergens that are regulated under different pieces of legislation; although this may be appropriate given the different scopes of the legislation, the reason for the differences is not clear.

As can be seen from Table 4-1, the main additional properties that are identified under the chemicals legislation that has horizontal linkages to the CLP Regulation are:

- Persistence, Bioaccumulation and Toxicity – PBT;
- very Persistent, very Bioaccumulative – vPvB;
- Endocrine Disruption – ED;
- Carcinogenicity, Mutagenicity and Reprotoxic – CMR; and
- Allergenic properties.

In addition to these properties, some of the chemicals legislation identifies negative lists of substances, which may be based on a combination of hazardous properties as defined by the CLP Regulation and other properties (e.g. an assessment of PBT characteristics and endocrine disrupting properties in relation to water quality policy). These are not considered further here as they are substance specific rather than regulating in relation to a hazardous property.

4.2.1 PBT and vPvB

There are clear links between CLP classification information and the data needed to classify a substance as a PBT or vPvB. For example:

- Persistent Organic Pollutants (POP) and vPvB substances will normally meet the criteria for classification as at least Aquatic Chronic 4 under the CLP Regulation;
- PBT substances may be classified as T due to either Aquatic Acute 1 and Aquatic Chronic 1 classification or with reference to a human health classification such as Carcinogen 1A; and
- The aquatic chronic classification will be influenced by the potential for rapid degradation and/or bioaccumulation (in cases where a surrogate approach is applied).

The CLP Regulation currently does not include a hazard class for PBT/vPvB properties and, hence, lacks any respective criteria or any labelling provisions. Recital 75 of the CLP Regulation provides for the possibility to include provisions on PBTs/vPvBs into the Regulation and Article 53(2) tasks the Member State and the Commission with promoting the harmonisation of the criteria for classification and labelling of PBTs/vPvBs at the level of the UN Globally Harmonized System (GHS). The EU delegation in the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals submitted a respective proposal to consider harmonisation of the PBT/vPvB criteria[24] to the meeting in December 2009, however, it is understood that the issue has not yet been discussed again in the sub-committee. The lack of labelling requirements in particular under the CLP Regulation for PBT properties is considered to reduce the effectiveness of the Regulation in hazard communication terms with respect to industrial chemicals, although it is also recognised that the CLP Regulation would no longer conform to GHS.

Across the other chemicals legislation, PBT is the most common additional 'property' to the CLP hazards, with vPvB being the second most common. As indicated in Case Study 6, several pieces of legislation include criteria and procedures to identify PBT and vPvB substances[25]. Also, within the scope of the Water Framework Directive[26], PBTs/vPvBs may be identified as priority hazardous substances.

Due to the different contexts and the timing of adoption of the legislation that includes references to PBT and vPvB properties, differences exist regarding the criteria that establish whether or not a substance is a PBT or vPvB. These are discussed in more detail in Case Study 6, but can be summarised as follows:

- The REACH Regulation sets out numeric criteria for identifying PBTs/vPvBs in Annex XIII, but also allows use of a weight of evidence (WoE) approach;
- The Biocidal Products Regulation refers to the REACH Regulation Annex XIII and is therefore coherent in terms of the criteria used;
- The Plant Protection Products Regulation includes its own criteria for the identification of a PBT/vPvB, which are identical to those of REACH Annex XIII before its revision. The key difference arising from this is that the Plant Protection Products Regulation does not include the use of a WoE approach; in addition, metabolites and degradation products are not considered in the PBT/vPvB identification[27] but should be taken into account in the overall approval decision of an active substance;

[24] UN/SCEGHS/18/INF.4

[25] The EU Regulation on Persistent Organic Pollutants implements the provision of the Stockholm Convention but does not include any criteria for the identification of POPs but directly refers to the annexes of the Convention.

[26] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

[27] European Commission, DG Sanco (2012), 'DG Sanco Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides"', Brussels, 25.09.2012. Available at:

- The Medicinal Products Directive (Directive 2001/83/EC) does not explicitly include a PBT/vPvB assessment but draft guidelines for the environmental risk assessment do, and refer to REACH Annex XIII; and
- The Water Framework Directive (Directive 2000/60/EC) sets no clear cut-off criteria for PBT or vPvB as the basis for identifying priority hazardous substances, but draws on REACH Annex XIII.

The Commission Services and stakeholders also discussed the various PBT criteria and their implementation in detail at a workshop in December 2014[28]. They concluded that there are some differences in the numeric PBT criteria, which could give rise to different PBT conclusions. The most frequently named differences are:

- The temperature for persistence testing, which is 20°C for Plant Protection Products Regulation (in accordance with the OECD simulation test 308) and 12°C under the Biocidal Products Regulation [29];
- The use of other information than the bioconcentration factor (BCF) to assess the bioaccumulation potential; and
- The possibility to use data from terrestrial organisms and birds under the REACH Regulation.

However, many of the stakeholders at the workshop were of the opinion that any differences in PBT conclusions across the legislation would mainly originate from the use of other evidence based on a WoE approach, in particular when many different and/or contradicting test results are available.

In conclusion, the legal basis of the PBT criteria and partly also the used guidance documents are regarded as harmonised under the REACH Regulation, the Biocidal Products Regulation, the medicinal products directives and the Water Framework Directive. However, differences in conclusions could occur in particular for medicinal products, because of the differences in assessment triggers and the existence of different assessment procedures and committees. Only under the Plant Protection Products Regulation does a different legal basis exist, different guidance documents are being used and a different procedure is used in implementation. There is no evidence that these differences have led to problems of inconsistency between the Plant Protection Products Regulation and the REACH Regulation to date; no substance has been refused approval yet

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http://ec.europa.eu/food/plant/docs/pesticides_ppp_app-proc_guide_fate_evidence_identify-pop-pbt-vpvb-props.pdf

[28] European Commission (2015): Workshop - Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations Brussels, 17 December 2014. Available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_type=250&lang=en&item_id=7978

[29] The applicability and relevance of results from the OECD simulation test 308 is currently discussed by several scientists. The results from the test are found as not sufficiently certain and robust, due to the difficulties in distinguishing between actual elimination of substances and transfer between compartments. Furthermore the test results were found to depend on the geometry of the test. It is recommended to invest further research in developing standardised tests (at lower costs) to derive persistency values; c.f. among others: Honti, M. and Fenner, K. (2015), 'Deriving Persistence Indicators from Regulatory Water-Sediment Studies – Opportunities and Limitations in OECD 308 Data', in: Environ. Sci. Technol., 2015, 49 (10), pp 5879–5886 and Honti *et al.* (2016), 'Bridging across OECD 308 and 309 Data in Search of a Robust Biotransformation Indicator', in: Environ. Sci. Technol., 2016, 50 (13), pp 6865–6872

under the Plant Protection Products Regulation which would not also have been identified as a PBT under the REACH Regulation.

4.2.1.1 Other legislation

The Detergents Regulation stipulates that surfactants used in detergents must be fully biodegradable, with biodegradation criteria applying to all types of surfactants (anionic, non-ionic, cationic and amphoteric). This criterion is specific to the Regulation and based on 'ultimate biodegradation' into carbon dioxide, water and mineral salts within 28 days.

Interestingly, the Stockholm Convention on Persistent Organic Pollutants has criteria that correspond to REACH Annex XIII cut-offs for vP and vB, which means that POPs under this Convention will be a sub-set of those identified under the REACH Regulation. In contrast, the criteria that apply under the OSPAR Convention are stricter than those that apply under the REACH Regulation. There are also differences between the REACH criteria and those that apply in other countries, such as the US, Canada and Australia (see Case Study 6).

4.2.2 Endocrine Disruption

Endocrine disruptors are only referred to once in the CLP Regulation, and this is in relation to the use of WoE approaches for reproductive toxicity. In this respect, it is important to recognise that endocrine disruption is a mode of action rather than a property *per se*; as a result, some endocrine disruptors will be covered by CLP classifications for reproductive toxicity.

As indicated in Section 3 of the Task 1 report, it has been argued that endocrine disrupting criteria could be incorporated into the CLP Regulation (as well as PBT, vPvB etc.), however, it is also recognised that this would create an inconsistency between GHS and the CLP Regulation. GHS, at present and like the CLP Regulation, only makes reference to endocrine disruptors in relation to WoE approaches for reproductive toxicity.

With respect to the identification of endocrine disruption as a property of concern under the various pieces of horizontal legislation, a communication was issued by the Commission on the identification of endocrine disruptors on the 15th June 2016. The draft Commission acts (see COM(2016) 350 Final[30]) set out the scientific criteria for the determination of endocrine disruptors in the context of the EU legislation on plant protection products and biocidal products. In the specific areas of biocides and plant protection products the Biocidal Products Regulation and Plant Protection Products Regulation determine the regulatory consequences for endocrine disruptors. The legislation also requires the Commission to determine how the criteria for endocrine disruptors should be defined, by drawing up acts "*specifying scientific criteria for the determination of endocrine-disrupting properties*"[31]. The Commission has focussed its attention to developing criteria for endocrine disruptors for these two areas, with this resulting in two draft measures[32], which will

[30] European Commission (2016): Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products, COM(2016) 350 final. Available at: http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf

[31] Article 5(3) of the Biocidal Products Regulation.

[32] Draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012 and Draft Commission Regulation setting

be the subject of the established procedures with Member States and other EU institutions, before final adoption by the Commission. The communication is specifically focused on plant protection products and biocidal products, and indicates that the Commission is reviewing endocrine disruptors in the context of the Cosmetic Products Regulation, the REACH Regulation and water quality legislation; these reviews are ongoing and that the Commission will present information on these later this year.

Prior to the publication of this communication and the development of draft measures for biocidal products and plant protection products, a number of Member States and respondents to the consultation highlighted the need for a definition to establish the properties for classifying a substance as an endocrine disruptor, noting that progress within the Commission was slow. Due to the timing of the publication of this communication, the consultants were not able to ask respondents for their views on the communication in the interviews or as part of consultation and it may take a while for their views on this matter to be formed in any case. It should be noted that there is a feedback mechanism (in the form of public consultation) to allow the Commission to obtain views from stakeholders on the proposed draft legal acts, which were then taken into account in their development.

Under the REACH Regulation, Article 138(7) indicates that:

> *By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals.*

Article 57(f) does not define what an endocrine disrupter is; it indicates that substances with endocrine disrupting properties will be included in REACH Annex XIV in accordance with the procedure laid down in Article 58 - Inclusion of substances in Annex XIV. Article 57(f) states:

> *f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.*

Under the Cosmetic Products Regulation, a definition for what constitutes an endocrine disruptor is also missing. Article 15 indicates that the Commission has the mandate to review the Regulation when Community or internationally agreed criteria for identifying substances with endocrine disrupting properties are available, or at the latest on 11 January 2015. This Regulatory review has not taken place although the Commission indicated in its recent (15 June 2016) communication that a definition with respect to cosmetics is currently under consideration.

The Biocidal Products Regulation sets out exclusion criteria for active substances in Article 5(1)(d) which have endocrine disrupting properties. This links to the classification of substances under the

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out specific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009.

CLP Regulation and to any substances identified under the REACH Regulation as having endocrine-disrupting properties:

> *active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.*

Paragraph 3 states that pending delegated acts adopted by the Commission which specify scientific criteria for determination of endocrine-disrupting properties:

> *…active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.*
>
> *Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.*

The endocrine disruptors Roadmap[33] is focused on the setting of criteria for the Plant Protection Products Regulation and the Biocidal Products Regulation, but acknowledges that other legislation also includes specific provisions governing endocrine disruptors. It also identifies the differences in wording across the legislation. Following the development of this roadmap, in June 2016 an impact assessment on defining criteria for identifying endocrine disruptors in the context of the implementation of the Plant Protection Products Regulation and Biocidal Products Regulation was published[34].

The differences across legislation are important and, in this context, the fact that the CLP Regulation does not include a definition of endocrine disruptors is not considered to be a significant weakness. Such an inclusion, if also agreed at the UN GHS level, might have advantages in that it would ensure harmonisation across legislation and avoid the potential for confusion and any 'hassle costs' for industry and other stakeholders associated with the existence of multiple regulatory definitions and criteria. However, such benefits would need to be off-set by the benefits of allowing varying criteria across the legislation (e.g. varying criteria for pesticides and biocides from those applied in relation to water policy or cosmetics). At this point in time, no judgement can be made in the absence of proposed criteria across all of the relevant legislation. Delays in establishing the appropriate criteria for endocrine disrupting chemicals will have impacted on the functioning of the legislation and its ability to ensure that endocrine disrupting chemicals are identified correctly.

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[33] European Commission (2014): Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and the Biocidal Products Regulation, Roadmap published June 2014. Available at: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

[34] European Commission (2016): Commission Staff Working Document Impact Assessment – Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and the Biocidal Products Regulation. Available at: http://ec.europa.eu/health/endocrine_disruptors/impact_assessment/index_en.htm

4.2.3 CMR properties

The CLP Regulation sets out clear criteria for the classification of Carcinogens, Mutagens and Reproductive Toxins (CMRs), and the Plant Protection Products Regulation, the Biocidal Products Regulation and Toy Safety Directive all refer to the CLP Regulation for classification against these properties. However, this is not the case for all pieces of legislation. Key exceptions are the Directive 2014/40/EU on Manufacture, the Carcinogens and Mutagens Directive (Directive 2004/37/EC)[35], the Chemical Agents Directive (Directive 98/24/EC)[36], and the Pregnant Workers Directive (Directive 92/85/EEC)[37] and the Young Workers Directive (Directive 94/33/EC)[38].

With respect to OSH legislation, only the Carcinogens and Mutagens Directive (Directive 2004/37/EC) sets out definitions for what constitutes a carcinogen or a mutagen. These are defined in Article 2 of the Carcinogens and Mutagens Directive as:

a) *'carcinogen' means:*
   (i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council;
   (ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;

b) *'mutagen' means:*
   a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008.

Thus, the definition of a mutagen draws only on the CLP Regulation, while the definition of a carcinogen is broader as has been specifically developed so as to include process generated chemical agents that have carcinogenic properties. These are hazardous substances created during manufacturing processes that have been identified as having carcinogenic properties but that are not classified under the CLP Regulation because they are not placed on the market. This includes chemical agents such as exhaust fumes and wood dust.

This approach is similar to that in the Chemical Agents Directive, in the sense that it also includes those substances/mixtures/processes that would not perhaps under any circumstances be classified under the CLP Regulation but that workers might still be exposed to in the workplace. In this respect, it should also be noted that the Pregnant Workers Directive and Young Workers Directive both make reference to chemicals that are hazardous; in the case of the Young Workers Directive,

[35] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

[36] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

[37] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

[38] Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work

Member States must prohibit the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. However, these properties are not further defined in the Directive and there is no link to the CLP Regulation. Previous studies[39] have suggested that this may lead to confusion for employers and workers.

4.2.4 Allergens

As noted in Section 3.2, the Scientific Committee on Consumer Safety (SCCS) is responsible for identifying fragrance allergens that either require banning, labelling (with these then also requiring labelling under the Detergents Regulation) or should be restricted in cosmetics. There are currently 26 fragrance allergens that require labelling under the Cosmetic Products Regulation.

The SCCS in its 2012 opinion[40] identified additional fragrance allergens which should be labelled in cosmetic products. The SCCS 2012 opinion is awaiting implementation as the question of labelling additional fragrance allergens needs profound analysis of different options. Moreover, under the Toy Safety Directive, cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements of the Cosmetic Products Regulation. In addition, the Toy Safety Directive also has its own independent list of fragrance allergens for other toys.

The Cosmetic Products Regulation does not include a specific definition of allergens, so no comparison of the criteria used to trigger requirements can be readily carried out. It has therefore not been possible to determine whether or not the legislation is coherent despite the variations in the numbers regulated under the different pieces of legislation.

However, there is a question of whether there is a need for such coherence. The mechanisms of exposure to an allergen in cosmetics and in toys are different and thus it could be considered appropriate that the risk assessment and management are separate. As the SCCS opinion is given in the context of cosmetics, the conclusion cannot not be automatically applicable to other sectors. Therefore, it is justified that the Toy Safety Directive has a separate list of allergens (with the exception of cosmetic toys).

4.3 Data quality and consistency of hazard assessments

Key findings:

- PBT data requirements are essentially harmonised and the consistency of conclusions are high, although there are differences in screening triggers and some criteria.
- There are some differences in the data required under the different legislation for assessing endocrine disruption, but there is no evidence that this has a significant impact on the level of protection to human health or the environment. However, greater harmonisation may reduce costs to companies and increase the efficiency of data familiarisation for authorities.

[39] RPA *et al.* (2011): Analysis and Evaluation of the Health, Social, Economic and Environmental Impact of a Possible Amendment of Certain EC Directives on Health and Safety at Work as a Result of the Adoption of Regulation (EC) No 1272/2008 (Contract Number: VC/2010/0446), Final Report prepared for DG Employment, December.

[40] Opinion of 26-27 June 2012 on fragrance allergens in cosmetic products, SCCS/1459/11.

- IARC and SCOEL are not constrained by the types of data used to assess carcinogenicity as are ECHA, with this being one reason for differences in hazard assessments for REACH purposes and for OEL setting purposes.

The CLP Regulation is coherent with the other legislation in principle, as it defines criteria for hazard identification and sets rules for 'translating' information from test results into a classification. As long as the standard tests are conducted and used, the Regulations 'fit' with each other. As soon as alternative methods are applied for data generation, the coherence of the system is no longer ensured, either because the endpoints addressed by alternative methods are different or the results cannot be expressed in a similar manner to the classification thresholds.

Member States and industry stakeholders have indicated that it is clear what types of data need to be provided under the different pieces of legislation and, in general, how their quality will be assessed (i.e. against what scientific standards). However, there may be differences in deciding on the relevance and validity of data under different legislation.

4.3.1 PBT and vPvB Identification

As noted above, the legal basis of the PBT criteria and, to a large extent, guidance documents are regarded as harmonised under the REACH Regulation, the Biocidal Products Regulation, the Medicinal Products Directive and the Water Framework Directive, while the Plant Protection Products Regulation has its own definition, set of procedures and guidance documents. As a result, data requirements are essentially the same across most of the legislation and the consistency of conclusions is high. A few inconsistencies have been identified, however, with these discussed in Case Study 6; in most cases, these arise due to the timing of the decision making on PBTness. It should be highlighted that exclusively under the Plant Protection Products Regulation substances identified as PBT or vPvB are banned with no risk assessment considerations and no possibility for derogations. Under the Biocidal Products Regulation, substances identified as PBT or vPvB are banned unless the derogations set in Article 5(2) apply, e.g. in case of negligible risk or of a disproportionate negative impact on society when compared to the risk to human health, animal health or the environment arising from the use of the substance.

PBT/vPvB identification under the REACH Regulation may be a two-step process consisting of an initial screening and, if necessary, a comparison of substance properties to the criteria. Different data may be used for screening and the definitive assessment.

Table 2-2 gives an overview of the standard information requirements under the REACH Regulation, Plant Protection Products Regulation and Biocidal Products Regulation that are needed to compare with the PBT threshold values, which allows concluding if a PBT assessment is normally possible. It should be noted for the standard REACH information requirements that a) if the registrants have any indication of PBTness, e.g. from the screening assessment, further information on the related property is to be generated in order to allow a conclusion, regardless of the registration tonnage, and b) authorities may request any (additional) information when doing a substance evaluation, independent of the registered tonnage.

Table 4-3: Availability of data for PBT/vPvB assessment in different legal frameworks			
Legislation	**P-criterion: simulation study required?**	**B-criterion: Bioconcentration test required?**	**T-criterion: classification possible, data required?**
REACH Regulation (Regulation (EC) No 1907/2006)	Further degradation testing for the "*relevant compartment*", i.e. that exposed depending on CSA outcome CSA[41] WoE is to be used in all assessment situations (including screening)	BCF as standard requirement in Annex IX[42]	**CMR**: available information and test proposals from Annex IX **STOT**: indications from Annex VIII (repeated dose toxicity) **Aquatic toxicity**: long term testing required from Annex IX
Plant Protection Products Regulation (Regulation (EC) 1107/2009)	Soil, water, water sediment system if not readily degradable	BCF Required if LogKow > 3	Yes
Biocidal Products Regulation (Regulation (EU) No 528/2012)	Water, soil and water-sediment, if not readily biodegradable	BCF Required if LogKow > 3	Yes

Table 2-2 shows that the standard data requirements and for PBT/vPvB assessment are different under the three regulations. For the P-criterion, the Plant Protection Products Regulation and Biocidal Products Regulation require data from simulation testing for any substance seeking approval, whereas under the REACH Regulation this is only required if there are indications of PBTness. The same applies for information on the T-criterion, where the Plant Protection Products Regulation and the Biocidal Products Regulation require submission of information on toxicity and long-term aquatic toxicity, while under the REACH Regulation this information is only required as part of the information set for substances above 100 t/a. Consequently, whether or not the information basis to conclude on a PBT/vPvB under the REACH Regulation depends on the decision making of the registrant (or the information request posed by an assessing authority), whereas the information available under the Plant Protection Products Regulation and the Biocidal Products Regulation should be similar (but might be extended differently based on further requests by authorities).

Indications that a substance fulfils P or B trigger further information collection under all legislation. The screening criteria / triggers for further information collection partly differ for the B criterion across legislation: log Kow > 3 for the Biocidal Products Regulation and the Plant Protection Products Regulation (and the REACH standard information requirement); log Kow of 4 under the Veterinary

[41] Annex VIII of the REACH Regulation: "*Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.*"

[42] The information needs not be generated, if the there are indications of a low bioaccumulation potential, e.g. indicated by a log Kow ≤ 3, is unlikely to cross biological membranes or if exposure is unlikely.

Medicinal Products Directive (Directive 2001/82/EC)[43] and log Kow under the HMPD and REACH (screening criterion).

In addition, under the REACH Regulation, any available data including e.g. (Q)SARs, information from non-standardised testing and monitoring data may be used. If the screening assessment identifies a substance as "potential PBT/vPvB", further information should be gathered to make a definitive assessment. If the numeric criteria of REACH Annex XIII are not met and/or a direct comparison is not possible, a PBT/vPvB could still be identified using weight of evidence and include further information, such as monitoring data[44].

Although the Biocidal Products Regulation draws on the REACH criteria, it defines information requirements for substance approval in its Annex II. Due to the timelines of the Biocidal Products Regulation (and its review programme), it may not always be possible to obtain all necessary data within a substance approval procedure to finally conclude on the PBTness of a substance. If data are requested but cannot be taken into account in the assessment, the Biocidal Products Committee (BPC) may define a substance as "potential PBT/vPvB", confirm the data request to the applicant and initiate reassessment of the substance upon receipt of this information. If data are not submitted in time, the BPC may also conclude on non-approval due to failure to meet the information requests.[45]

For the Medicinal Products Directive[46], the environmental assessment starts with exposure estimation. If the exposure level remains below the "action limit", the environmental risk assessment can be terminated, except if the $LogK_{ow}$ exceeds 4.5. In this case, a PBT assessment is to be performed based on Annex XIII of the REACH Regulation. For veterinary medicinal products, the PBT assessment is required, if the $LogK_{ow}$ exceeds a value of 4.

The identification of priority hazardous substances priority hazardous substance under the Water Framework Directive is based on "all available information", which includes several information sources, such as existing (regulatory) lists and risk assessments, data on hazardous properties, as well as modelled or measured data on environmental concentrations. The information evaluated is based on expert judgement.

With respect to data quality and availability, the legislation identifies the quality requirements for the data that should be used in PBT assessments, although there is agreement that there is no objective means of assessing data quality, relevance, reliability and validity. However, information from the PBT expert group on their experience with the data availability for PBT assessment indicates the following challenges:

- Substances are technically difficult to test and therefore information is (and might remain) missing;

[43] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

[44] Cana R. (2016): 'PBTs and vPvBs: different procedures under REACH', in: Chemical Watch, March 2016. Available at: https://chemicalwatch.com/45725/pbts-and-vpvbs-different-procedures-under-reach

[45] European Commission, DG ENV (2015): 'Data requirements for the evaluation of the exclusion and substitution criteria under the Biocidal Products Regulation', CA-March15-Doc.5.3 - Final

[46] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

- The interpretation of test results might need additional information, which is not available and/or collected with initial testing; if there are timelines for decision making, additional information may not be generated in time;
- Read-across and Quantitative Structure Activity Relationships ((Q)SARs) are not well documented and therefore difficult to check, this slows down the assessment or triggers the need for new / additional information;
- Available data are not always taken into account (not found, evaluated as not reliable, relevant or valid, not conforming to Good Laboratory Practice (GLP) etc.).

Additional comments received in from NGOs and industry stakeholders from the targeted consultation regarding the quality of data for use in PBT assessments include:

- Under the Plant Protection Products Regulation and the Biocidal Products Regulation substances are re-evaluated every 10 to 15 years. These extended periods for review means that there may be delays in taking account of new scientific findings and data in approval decisions;
- A discussion on use of screening data and read-across approaches for making definitive conclusions on PBTness is needed, regarding both the positive and the negative PBT identification; and
- The GLP requirement within the legislation prevents the use of some scientific studies which are conducted by academia and which do not use GLP. This may impact on the extent to which new data relevant to assessing PBT properties is taken into account.

The above point with respect to requirements for data to be conducted in accordance with GLP is addressed further in Section 5 below. In addition, while it is the case that new data are only considered as part of re-evaluations under the Plant Protection Products Regulation and the Biocidal Products Regulation, these reviews are carried out systematically. The same cannot be said for the other hazard assessment systems that exist under other legislation such as the REACH Regulation, where evaluations are undertaken once a substance enters onto the Community Rolling Action Plan; there is no associated systematic review procedure. For example, information in the EU Pesticides database[47] indicates that there are 54 active substances that are candidates for substitution due to their meeting two of the three criteria for being PBTs. There are a further 56 CMR substances that will require re-assessment within the next 5 years.

The NORMAN network (a network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances)[48] suggests that more harmonisation is needed, among the different regulatory frameworks, as regards the derivation of human health and environmental protection values for substances. They recommend that a formal consultation procedure (among the authorities responsible for the different chemicals legislation) should be established for the derivation of common safety thresholds (e.g. $PNEC_{freshwater}$)[49] as a basis for a more comparable assessment of the risks of chemicals. In this context, post-authorisation

[47] http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

[48] NORMAN (2016): Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances. Available at: http://www.norman-network.net/

[49] This proposal for the common derivation of safety thresholds would appear to contradict the principle that no safe thresholds can be derived for PBT/vPvB and that according to the precautionary principle, emissions should be minimised in general.

monitoring could offer assurance that the use of authorised active substances is indeed not posing an unacceptable risk to the environment.

4.3.2 Endocrine disruptors

In its Annex II (Part A), the REACH Regulation sets out the requirements that a supplier shall fulfil for the compilation of a safety data sheet (SDS) in accordance with Article 31. In section 12.6 of the SDS, *Other Adverse effects*, information on any other adverse effects on the environment shall be included where available; this includes endocrine-disrupting potential.

Annex IX and Annex X of the REACH Regulation set out the standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more (Annex IV) and 1000 tonnes or more (Annex X). Both of the Annexes establish the standard information required for all substances manufactured or imported in accordance with Article 12(1)(d) and Article 12(1)(e). This includes information on an extended one-generation reproductive toxicity study basic test design (cohorts 1A and 1B without extension to include a F2 generation). If there is an indication that a substance exhibits one or more relevant modes of action related to endocrine disruption from available *in vivo* studies or non-animal approaches, an extended one-generation reproductive toxicity study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41.

ECHA's guidance document '*Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.7b: Endpoint specific guidance'*, is designed to be used by users when complying with their obligations under the REACH Regulation and it contains some more information about endocrine disrupting properties and information sources. Within the guidance document[50] an endocrine disrupter definition is set out:

> *According to a widely accepted consensus reached at an international workshop in Weybridge, UK, in 1996 (which was later also adopted by OECD expert groups) "an endocrine disruptor is an exogenous agent that causes adverse health effects in an intact organism, or its progeny, consequent to changes in endocrine function."*
>
> *"Endocrine disruption" is not a toxicological endpoint per se but a functional change of the endocrine system which may involve a variety of molecular mechanisms and which may result in adverse health effects in an organism or its progeny. This guidance document distinguishes between the identification of an endocrine mode of action and the characterisation of sub-lethal chronic and adverse effects on development and reproduction, which may also arise from other mechanisms of toxicity; the causal link between an endocrine mode of action and an adverse effect should be established to meet the Weybridge/OECD definition of an endocrine disruptor.*

Annex II of the Biocidal Products Regulation sets out the information requirements for active substances, including information on endocrine disruption. If there is any evidence from *in vitro*, repeat dose or reproduction toxicity studies that the active substance may have endocrine disrupting properties, then additional information or specific studies shall be required to:

[50] ECHA (2016): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance. Available at: https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf

- Elucidate the mode/mechanism of action;
- Provide sufficient evidence for relevant adverse effects.

For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.

Thus there are differences in the data that is required under the different legislation. However, there is no evidence that this has a significant impact on the level of protection provided to human health or the environment under the legislation. Industry has indicated that it would be more cost-effective for all legislation to require the same test information to enable the same data to be used. There may also be efficiencies for competent authorities if the same data were to be used across legislation, as this would reduce the need for authorities to familiarise themselves with different data sets for the same substance.

4.3.3 CMRs

Most of the legislation draws on CLP classifications for CMR properties (e.g. the Toy Safety Directive applies CLP classifications for CMRs to "articles" (as most toys are articles).

In terms of the data that may be used under other legislation for the identification of CMRs, this may well include information other than that which would be used as the basis for a CLP classification for these properties, particularly for process generated substances. EU scientific committees, such as the Scientific Committee on Occupational Exposure Limits (SCOEL), as well as international expert bodies, such as the International Agency for Research on Cancer (IARC), can be expected to draw on a range of information for such purposes, and add their own expert interpretation of that data; they will not therefore be constrained by the types of data used as the basis for CLP classifications.

This does not necessarily mean that the data will be of lower or higher quality, only that different types of data may be taken into account in the hazard assessment process. Indeed, it has been argued that because SCOEL is an expert committee it is able to draw on and interpret a broader set of data than only that which would form a REACH dataset, for example, as used by the RAC in setting a dose-response function for REACH Authorisation or Restriction purposes.

4.3.4 Allergens

As the Toy Safety Directive draws on CLP classifications, the same issues as highlighted above for PBTs will apply, e.g. with regard to the availability of test data, its reliability and interpretation.

As noted in Section 3, the Cosmetic Products Regulation does not specifically refer to allergens within the text of the regulation, although in relation to CMR substances it draws on classifications under the CLP Regulation. The Scientific Committee for Consumer Safety is responsible for the identification of allergens that are to be banned, restricted or labelled for under the legislation. As this is again an expert body, it is assumed that they will take all relevant data into account in the hazard assessment process and not necessarily just the types of data that are used for classification under the CLP Regulation.

Interestingly, the list of 26 fragrance allergens that are designated as allergens requiring labelling under the Cosmetic Products Regulation, also require labelling under the Detergents Regulation and

are likely to require labelling under the Medicinal Products Regulation[51]. There is therefore a high level of coherence across these three pieces of legislation as they currently stand in terms of the information acting as the basis for the hazard assessment aspects.

4.4 High level of protection and efficiency in hazard identification

Key findings:

- Member State and NGO stakeholders argue that further classification criteria should be considered for inclusion in the CLP Regulation, including endocrine disruption, neurotoxicity and immunotoxicity, and terrestrial toxicity.
- Draft criteria for endocrine disruption under the Plant Protection Products Regulation and the Biocidal Products Regulation have been published by the European Commission. Although interim criteria have been in place, the absence of these, as well as for application under the REACH Regulation and the Cosmetic Products Regulation, has been a gap within the legislative framework.
- A Commission workshop concluded that the current PBT criteria that are being applied under the legislation may not identify substances which are bioaccumulative and/or toxic in non-aquatic compartments.
- There is a view by some in industry that CMR classifications may be overly conservative and precautionary, although other industry representatives do not agree with this conclusion, and indicate that the current system performs well.

4.4.1 PBT and vPvB

The issue of effectiveness more generally was also discussed at the Commission's Workshop on PBT assessment regarding effectiveness, with key points being as follows:

- The current PBT criteria may fail to identify substances that are bioaccumulative and/or toxic in non-aquatic compartments. P and T criteria for non-aquatic compartments would have to be developed; and
- Many PBTs / vPvBs could not be identified via a 1:1 comparison with the PBT criteria but were identified based on "other evidence". This indicates the need for case-by-case assessments and for more extensive data than required under the REACH Regulation, the Plant Protection Products Regulation and the Biocidal Products Regulation.

Proposals put forward by stakeholders during the Workshop include:

- Widening the possibilities to identify persistence (e.g. "overall persistence" considering physical-chemical property data and environmental fate under "real life conditions");
- Adaptation of B-criteria to better reflect terrestrial bioaccumulation and bioaccumulation which is not based on lipid partitioning;
- Extending toxicity criteria to endocrine disruption, neurotoxicity and immunotoxicity.

[51] European Medicines Agency (2016): Information in the package leaflet for fragrances containing allergens in the context of the revision of the guideline on 'Excipients in the label and package leaflet of the medicinal products for human use' (CPMP/463/00 Rev. 1), Draft.

It is understood though that ECHA's guidance on PBT-assessment is currently under discussion and that a range of scientific issues are being considered as part of this (see also Case Study 6). Thus, in terms of ensuring the effectiveness of the relevant pieces of chemicals legislation with regard to PBT and vPvB identification, the need to take further action has already been identified. In this respect, initiatives are being taken to address weaknesses in the current approaches, with the aim of improving the effectiveness of the legislation in protecting the environment.

All stakeholder groups are of the opinion that PBT/vPvB identification is subject to political interests, due to the risk management implications. This is also likely to be the case for endocrine disruptors, carcinogens, mutagens, reproductive toxins (CMRs) and allergens, as political interests are likely to try and influence decisions by highlighting issues with respect to the reliability or validity of data, data interpretation, appropriateness or not of test methods, etc. Some of this might be addressed through improved and clearer guidance.

For example, the ability to use a WoE approach under the REACH Regulation to assess the PBTness of a substance is particularly unclear. Some believe that it decreases the predictability of the PBT assessment and could lead to inconsistent PBT conclusions because of the expert judgement involved. Industry has proposed to develop a consistent EU-wide weight of evidence methodology (clear and transparent), including scoring methods to allow identification of the (most) reliable and relevant data, which is of sufficient quality for use in the assessment. If developed, such a methodology should allow consideration of non-default PBT criteria and the use of all scientific studies available, with GLP data being prioritised. Non-GLP data, including monitoring data, should be considered if conducted according to scientific standards.

In terms of the relevant efficiency questions regarding grouping of substances for assessment purposes, the PBT case study (Case Study 6) found that structurally related and similar substances are sometimes assessed together (e.g. short chain chlorinated paraffins (SCCPs) or Perflourooctanoic acid (PFOA) precursors). This is regarded as efficient and may even be inevitable, e.g. for substances which cannot be manufactured as individual substances (source: stakeholder input). For substances of very high concern (SVHC) identification under the REACH Regulation, group assessments are obviously possible and accepted (candidate list). For active substance approvals under the Biocidal Products Regulation and the Plant Protection Products Regulation, usually only one individual substance is assessed and the question does not normally occur.

4.4.2 Endocrine Disruptors

On behalf of the WHO, the IPCS has established the following definition[52] of an endocrine disruptor:

> *"An exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."*

Although this definition may be commonly agreed to, and has acted as a working definition with the EU since 1999, the scientific criteria which are to be used for the identification of endocrine disruptors under EU legislation still remain the subject of debate, as indicated in the earlier sub-sections. At this point in time, it is too early to assess the effectiveness and efficiency of the recently

[52] IPCS (2002): Global Assessment of the State-of-the-Science of Endocrine Disruptors, on behalf of the WHO, ILO and UNEP, WHO/IPCS/EDC/02.2. Available at: http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

published draft endocrine disruptor criteria for biocidal and plant protection products as they still have not been adopted and have not entered into force.

The delay in the Commission bringing forward its draft proposals for the criteria will have impacted on the ability of the relevant legislation (the Plant Protection Products Regulation, the Biocidal Products Regulation, the REACH Regulation, the Cosmetic Products Regulation) to identify correctly endocrine disrupting chemicals, although interim criteria have been in place in relation to the Plant Protection Products Regulation and the Biocidal Products Regulation since 2013. The criteria put forward by the Commission are based on the WHO definition and do not include consideration of potency. In addition, the draft legal act presented under the Plant Protection Products Regulation amends the possible derogations, taking into account latest scientific knowledge, best available evidence and information on exposure and corresponding risk. Overall, the hazard-based approach under the Plant Protection Products Regulation and the Biocidal Products Regulation is maintained (see also the Task 3 report).

The draft criteria will be voted on by Member States in relation to the Plant Protection Products Regulation and will be discussed by Member State experts in relation to the Biocidal Products Regulation. It is anticipated that the draft legal texts presented in June 2016 may be changed during the decision making with Member State experts and before they go to both the Parliament and the Council. In the meantime, the interim criteria still apply under both the Plant Protection Products Regulation and the Biocidal Products Regulation.

The Commission's impact assessment highlights the difficulty in quantifying the impacts of the proposed criteria noting that there was a lack of reliable and sound data to assess impacts. It also stated that: *"… The preliminary assessment of the evidence concluded that it would not be possible to quantify impacts, as data would neither be of sufficient quality nor reflect reality due to the high level of uncertainties and assumptions made. In addition, some approaches to estimate impacts would - as a consequence of the variable data availability in the different areas – create a strong imbalance between the assessments of the areas."*[53] A multi-criteria analysis was applied because quantifiable estimates of costs or benefits are not available for all areas. It is of note though that Option 2 in the Impact Assessment (which is the option on which the Commission's proposal is based) would result in an estimated 26 active substances in plant protection products and 5 active substances in biocidal products being identified as endocrine disruptors (out of a screening of 347 plant protection and 98 biocidal products active substances).

These issues are discussed further in the Task 3 report, but it is important to note that the end criteria are of concern to the agricultural sector. Results of a recent study by steward redqueen (2016), for example, identifies a number of active substances at risk due to the automatic bans on approval linked to classification as a PBT/vPvB, mutagenic or as an endocrine disruptor, with potentially significant impacts on agricultural production.

It is of note that the US, Canada, Japan and China appear to advocate similar risk-based approaches to regulation. As a result, third countries, including the US and Canada, have already warned[54] that a

[53] European Commission (2016): Impact Assessment – Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation, Main report, Staff Working Document, SWD(2016) 211 final, Part 1.16, 15 June. Available at: http://ec.europa.eu/health/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

[54] U.S. Government (2015): European Commission's Public Consultation on Defining Criteria for Identifying Endocrine Disruptors (EDs) in the Context of the Implementation of the Plant Protection Product

decision based solely on hazard rather than case-by-case risk assessment would have serious implications for trade, in particular of agricultural and agri-food products; as a result, it has been suggested by some industry commentators that the EU criteria may trigger World Trade Organisation objections, as they may act as non-tariff barriers to trade.

4.4.3 CMRs

As noted above, all of the key legislation has a horizontal link to the CLP Regulation for the identification of CMR substances, and the criteria used for this identification are globally agreed. In this respect, the hazard identification processes is considered effective and efficient from a hazard assessment perspective. Formal assessment of CMRs for regulatory purposes is based on the Harmonised Classification and Labelling processes under the CLP Regulation which is discussed under Task 1 in terms of its effectiveness and efficiency.

Of relevance here is the issue of whether the application of these criteria is being carried out in a manner such that the original intentions of the legislation are being properly reflected. In general, based on the evidence gathered for this evaluation, the answer to this question would be yes.

At the more detailed substance by substance assessment level, however, multiple industry respondents to the targeted consultation (both associations and individual companies) have suggested that some substances are now being classified as CMR Category 1B by the Risk Assessment Committee (RAC) for REACH purposes on a precautionary basis rather than on a robust, transparent WoE approach. They have suggested that new harmonised classifications are often overly conservative and do not always follow the EU guidelines. In addition, they also suggested that the overly conservative classifications are often in contradiction with other EU goals, e.g. increase trade and resource efficiency (especially where the classification could have an impact on the recyclability of materials, see also Case Study 2 on metals classification and the lead metal example).

To establish whether or not there is a consistent bias would require that one examined in very close detail a large number of cases, including an examination of the underlying data and of the decisions. Such an exercise is clearly not feasible within the constraints of this evaluation. However, professional toxicologists (consultants and academics) have indicated that there have been cases where (individually) they have been surprised by the outcome of a harmonised classification. These specialists also cited cases which would go in both directions – sometimes more severe than expected and in other cases less severe than expected. A key factor noted by some of these specialists is the fact that the data for some industrial chemicals is lacking, with this impacting on RAC's discussions. Other industry observers of the process have also noted that, in their view, the Committee deliberates all available information in a mature and systematic manner; and that there are probably as many Carc. Cat 1B proposals that are finally classified as Cat 2, as there are Cat 2 proposals that finally classified as Cat 1B.[55]

Regulation and Biocidal Products Regulation. Available at: http://www.usda-eu.org/wp-content/uploads/2015/01/United-States-Submission-Endocrine-Disrupters-2015-01-20.pdf

[55] Research by Oltmanns *et al.* (2014) analysed the effect of REACH on classification for human health endpoints by comparing information from REACH registration dossiers with legally binding, harmonised classifications for 142 high production volume chemicals. Oltmanns *et al.* (2014): The impact of REACH on classification for human health hazards, Regulatory Toxicology and Pharmacology, 70, pp 474-481.

It is of note that research has found in general that REACH has resulted in more severe classifications for a range of studies. For example, Oltmanns *et al.* (2014) analysed the effect of REACH on classification for human health endpoints by comparing information from REACH registration dossiers with legally binding, harmonised classifications for 142 high production volume chemicals. The study notes that: "*Of 20 substances lacking a harmonised classification, 12 chemicals were classified in REACH registration dossiers. More importantly, 37 substances with harmonised classifications for human health endpoints had stricter classifications in registration dossiers and 29 of these were classified for at least one additional endpoint not covered by the harmonised classification…. one third of these additional endpoints emerged from experimental studies performed to fulfil information requirements under REACH, while two thirds resulted from a new assessment of pre-REACH studies*."

From an effectiveness perspective, one might argue that adopting a more precautionary approach to classification is more appropriate than adopting a less precautionary approach, in terms of protecting human health and the environment. However, care must be taken in making such an argument given the role that formal hazard identification for CMR properties has in downstream legislation. Of particular concern is the potential for such classifications to lead to substitution decisions involving a transfer to another chemical of similar or higher hazard but which has not yet gone through the harmonised classification process, i.e. a regrettable substitution[56]. This not only leads to an inefficient use of resources by industry but also fails to deliver the desired health and environmental benefits. The potential for regrettable substitution is real, and indeed may have taken place in response to the REACH authorisation process.

In the survey on substitution and assessment of alternatives recently carried out by RPA in the context of the study to support the Non-Toxic Environment Strategy of the European Commission, around 40% of industry stakeholders consulted estimated that over 50% of the substitutions implemented have been with substances that are part of the same functional or structurally similar group. Abelkop *et al.* (2014)[57] note that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure. However, robust comparative risk analyses need a high level of information and can be resource and time intensive. Lofstedt (2014)[58] argues that substitutes may not serve the same economic utility as the original chemical, thereby generating other types of risks to human health and the environment. For example, the substitution of lead from solders in EEE with lead-free solders had the consequence of creating failures to the board of the components and of operating at higher temperatures, with higher energy consumption. Moreover, EC (2012) notes that lead free

[56] A regrettable substitution is the "*replacement of a toxic substance with one that has unknown – if not greater – toxic effects*". Washington State Department of Ecology (2015): 'Green chemistry: what is a regrettable substitution?'. Available at: http://www.ecy.wa.gov/GreenChemistry/faq.html

[57] Abelkop A. D. K. and Graham J. D. (2014): Comment – Principles and tools of chemical regulation: a comment on 'the substitution principle in chemical regulation: a constructive critique', Journal of Risk Research, 17(5), pp. 581-586. Available at: https://spea.indiana.edu/doc/research/working-groups/PrinciplesToolsChemicalRegulation.pdf

[58] Lofstedt R. (2014): The substitution principle in chemical regulation: a constructive critique, Journal of Risk Research, 17(5), pp. 543-564. Available at: http://www.tandfonline.com/doi/abs/10.1080/13669877.2013.841733

solders may need an increased amount of rosin added to the flux, with rosin fumes identified as a cause of occupational asthma.

Thus, adopting a precautionary approach to classification may not be effective in protecting human health or the environment, with perverse outcomes resulting from substitution decisions. This also means that such actions result in inefficiencies, in that resources are diverted away from investment in other activities, such as innovation, towards the substitution.

Differences in the approaches adopted by RAC and SCOEL were also highlighted as leading to inconsistencies in exposure limits; these are particularly noticeable when one compares the exposure-response relationships developed by RAC for SVHC substances going through Authorisation to the exposure-response relationships defined by SCOEL and that act as the basis for proposals on Binding Occupational Exposure Limit Values (BOELVs).

In terms of the identification of CMR substances, again group assessments are possible, and indeed this is the case under both the REACH Regulation and the Carcinogens and Mutagens Directive (e.g. with respect to chromates, group approaches have been taken by both RAC and SCOEL; RAC's exposure response function and SCOEL's proposed BOELV are both applicable to multiple substances (and mixtures) which have hexavalent chromium as a constituent. Clearly, where it is possible to group substances for assessment purposes, this is more efficient for regulators and should also be more efficient for industry and non-industry stakeholders (in terms of their relative roles in the process). It may also help ensure that substitution from one substance within a group to another within the same group does not take place. For example, Article 2 of the 1991 Geneva Protocol concerning the control of emissions of Volatile Organic Compounds (VOCs) or their trans-boundary fluxes requires that "*in implementing the present Protocol, and in particular any product substitution measures, Parties shall take appropriate steps to ensure that toxic and carcinogenic VOCs, and those that harm the stratospheric ozone layer, are not substituted for other VOCs*".

4.4.4 Allergens

Allergens are an important issue within the chemicals framework as an estimated 1-3% of the EU population has a skin allergy to fragrances, with the SCCS reporting that around 16% of eczema patients in the EU being sensitised to fragrance ingredients. Similarly, a significant percentage of the population may suffer from food allergies, with 1-2% of the adult population and 5-8% of children in the UK for example having a food allergy and around 10 dying each year from allergic reactions. Overall, the prevalence of allergies in children varies from 1.7% in Greece to 4% in Italy and Spain, to over 5% in France, UK, Netherlands and Germany[59]. An estimated 150 million plus people have allergies in Europe, with it being the most common chronic disease in the EU at a prevalence of greater than 20% of the population[60]. This figure is estimated by the European Academy of Allergy and Clinical Immunology to rise to around 40% of the population having an allergic predisposition in

[59] EAACI (2011): Allergy statistics from the EAACI: 17 million Europeans allergic to food; allergies in children doubled in the last 10 years, The European Academy of Allergy and Clinical Immunology (EAACI). Available at: http://www.foodsmatter.com/allergy_intolerance/miscellaneous/research/allergy_statistics.02.11.html

[60] EAACI (2016): European Union Activities. The European Academy of Allergy and Clinical Immunology (EAACI). Available at: http://www.eaaci.org/outreach/eu-activities/eu-activities.html

Europe by 2040. In the UK alone, an estimated £900 million per annum was spent on primary care related to allergens in 2004[61].

A range of factors have been identified as possible causes (increased diagnosis, increased allergen exposure, excessive cleanliness, sedentary lifestyle, etc.), and it is therefore not possible to link changes in chemicals regulation to trends in the incidence of allergies. However, it is clear that providing consumers with information on the presence of known allergens is important given the potential for reducing disease cases and associated health care costs.

Against this background, the effectiveness and efficiency of the hazard identification processes for allergens cannot be readily assessed. It is clear that the SCCS has identified more fragrance allergens than are currently regulated in terms of labelling or other requirements, with this suggesting that there may be significant gaps within the legislative framework that should be addressed.

In addition, it is clear that the inclusion of fragrances within different products is increasingly being used by the major producers as a means of market differentiation. Internet searches highlight the fact that different global companies are responding to growing consumer demand for greater transparency on products by publishing both lists of fragrances that are used and of those that are excluded.

4.5 Legislative coherence

Key findings:

- There are differences in the number of fragrance allergens that require labelling under the different legislation, as highlighted in the previous sections.
- There are overlaps between the Detergents Regulation and the CLP Regulation with regards to the listing of allergenic substances, which is leading to 'double-labelling'.
- A common set of criteria – applicable across all relevant legislation – for endocrine disruptors is currently lacking, which could lead to uncertainty and inconsistency and the potential for varying implementation across Member States.
- Some hazard classes are not covered in certain pieces of legislation to which they may be relevant; for example, biocidal substances may be present in finger paints for children but the Toys Directive does not cover environmental hazards, and pharmaceutical regulations do not cover environmental hazards.
- ECHA and EFSA may reach different classifications for the same substance. Although this has only occurred a few times, it leads to uncertainty and confusion within supply chains.

4.5.1 Coherence across horizontal legislation

As can be seen from Table 4-1 presented at the start of this section, in general, when looking across the different legislation, there appears to be good coherence in what properties are taken into account in the different pieces of legislation, and in whether or not the legislation draws on the CLP Regulation for the purposes of hazard assessment. This would also be the general conclusion from

[61] House of Commons Health Committee (2004): The provision of allergy services. Sixth report of session 2003–04. London: TSO. Available at: http://www.bsaci.org/pdf/HoL_6th_report_vol1.pdf

interviews and consultation activities. For example, the targeted consultation asked whether it was appropriate for different properties to be considered (POP, PBT, vPvB, endocrine disruption) in legislation that had a different focus or whether this results in inconsistencies and/or overlaps. Similarly, the Open Public Consultation asked participants to identify any key issues with respect to gaps, overlaps and inconsistencies. Key issues identified by NGOs, civil society and industry consultees include:

- Differences in classification system approaches exist under the CLP Regulation and waste legislation, with this potentially reflecting inconsistencies;
- Inconsistencies with regard to the treatment of fragrance allergens, this includes overlaps between the Detergents Regulation and the CLP Regulation in relation to fragrance allergens;
- The lack of common horizontal criteria for endocrine disruptors; and
- Different treatment of certain hazardous properties across the legislative framework, with PBT properties highlighted by some stakeholders as being of concern in this regard.

As indicated by Table 4-1 in Section 4.1 to this report, there are also areas where there appear to be missing linkages, with the key areas being in relation to the Cosmetic Products Regulation and the Tobacco Directive[62]. These are discussed further below.

4.5.2 Classification under the Waste Framework Directive

As detailed in Case Study 13, the core element of the EU legislative framework with regard to waste is the Waste Framework Directive (Directive 2008/98/EC)[63] which defines:

> […] "*the legislative framework on the handling of waste in the Community. It defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste, notably an obligation for an establishment or undertaking carrying out waste management operations to have a permit or to be registered and an obligation for the Member States to draw up waste management plans. It also establishes major principles such as an obligation to handle waste in a way that does not have a negative impact on the environment or human health, an encouragement to apply the waste hierarchy and, in accordance with the polluter-pays principle, a requirement that the costs of disposing of waste must be borne by the holder of waste, by previous holders or by the producers of the product from which the waste came".* (Recital 1)

As per this definition, waste is distinguished from a status that is non-waste. Criteria for having the waste status or leaving the waste status are defined by the Waste Framework Directive. With regard to chemical substances, both Article 1 (3) of the CLP Regulation and Article 2 (2) of the REACH Regulation clarify that they relate to placing substances and mixtures on the market; the definitions of 'substance', 'mixture' or 'article' as laid down in Article 2 of the CLP Regulation do not apply to waste.

[62] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC

[63] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

The definition of waste and the definitions of substance, mixture and article have some significant impacts on the two classification approaches. While the main objective of classification under the CLP Regulation is to inform the user of chemical substances and mixtures, the main task of waste classification is to ensure that waste is handled in a way that ensures that it has no negative impact on the environment or human health and to avoid inappropriate waste management.

Prior to the CLP Regulation, the classification of waste was linked to the system that existed under the Dangerous Substances Directive (Directive 67/548/EEC)[64] and the Dangerous Preparations Directive (Directive 1999/45/EC)[65] via the so called H-criteria defined in Annex III of the Waste Framework Directive. In order to align the transition of the chemicals legislation towards the CLP Regulation, this Annex of the Waste Framework Directive was also changed in 2014 with Commission Regulation 1357/2014[66]. The general scope of Annex III was not changed, but some of the now called HP-criteria[67] for the classification of waste were fully aligned with the classification system for the respective classification criteria of Annex I of the CLP Regulation while others differ significantly. In addition, the classification of hazardous waste is also regulated via Article 7 of the Waste Framework Directive, which sets out further requirements for the classification of wastes including the so-called "List of Waste" (LoW) that establishes further rules for the classification of waste. The LoW is implemented by Commission Decision 2104/955/EU[68].

The existence of such differences in classification has been raised as an issue by some consultees, however, they are not considered to represent a significant legislative issue. The main aim of the waste legislation is not to provide detailed information on the substance contained in waste. Rather, the aim is to ensure that waste streams can be handled in a way that neither negative effects for human health or the environment originate from the treatment. This is supported by other principles, such as the dilution of hazardous substances by mixing them with non-hazardous waste. As long as waste ends up in energy recovery, incineration or landfill, the differentiation between hazardous and non-hazardous in combination with the six digit waste code that also provides information on the composition of the waste information seem sufficient to decide on the adequate treatment.

4.5.3 Fragrance Allergens – Toys, Cosmetics and Detergents

As highlighted in earlier sections, different numbers of fragrance allergens are being regulated under the different legislation. This may be due to the specific reference to the CLP Regulation in the Toy Safety Directive and the lack of a specific definition in relation to cosmetic products and for food

[64] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

[65] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

[66] Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L365, 19.12.2014, p. 70

[67] The name was changed from H-criteria towards **H**azardous **P**roperties-criteria to avoid confusions with the hazard statements (H-statements) under the CLP Regulation.

[68] Commission Decision of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council (Text with EEA relevance), (OJ L 370, 30.12.2014, p. 44–86)

information, that allows more discretion in identifying relevant fragrance allergens (i.e. do not need to be classified as sensitisers under the CLP Regulation to be identified as an allergen). This inconsistency may or may not be significant as discussed above in Section 4.4.4; however, in light of the prevalence of allergies within the EU population, it is an issue that may require further consideration.

There are also inconsistencies and overlaps between the Detergents Regulation and the CLP Regulation regarding the listing of allergenic substances. The CLP Regulation sets out the hazard classification criteria and requirements for respiratory and skin sensitisation in Article 3.4. Substances require classification if there are positive results of sensitisation; mixtures require classification against the rules set out in Table 3.4, which indicate that classification is required when concentrations range from ≥0.1% to ≥1.0%. Moreover, the CLP Regulation requires labelling (EUH 208) of mixtures with sensitisers above the concentration limit for elicitation, i.e. 0.01% for respiratory or skin sensitisation Category 1A. The Detergents Regulation indicates that allergenic fragrances that appear in Cosmetic Directives in Annex III, Part 1 of Directive 76/768/EEC and Directive 2003/15/EC, as a result of its amendment by Directive 2003/15/EC, as well as allergenic fragrances subsequently added thereto[69], that exceed concentrations of 0.01% by weight require labelling.

If allergens exceed concentrations of 0.01% in detergent products then they must be labelled under the Detergents Regulation; in addition, if these allergens are also skin sensitisers and if they individually or in combination with other skin sensitisers in the mixture exceed concentrations of either 0.1% or 1.0% (depending on the type of sensitiser), then they also need to be included on the label under the CLP Regulation. This leads to a problem of double-labelling.

The Toy Safety Directive also includes lists of substance allergenic fragrances that toys should not contain and that if contained above 100 mg/kg require labelling on the toy, on an affixed label, on the packaging or in an accompanying leaflet. Not all substances that appear to require labelling under the Detergents Regulation require labelling under the Toy Safety Directive and vice versa.

4.5.4 Lack of horizontal criteria for endocrine disruption

Several stakeholders across all groups have argued for the need for a consistent set of criteria to apply horizontally across all legislation for endocrine disruptors. A few Member State authorities have suggested that criteria for endocrine disruptors should be included in Annex I to the CLP Regulation; this would in effect then create a consistent set of criteria for classification purposes (and would reflect the fact that information about biodegradation is already used in the CLP Regulation during the classification of chronic hazards for the environment).

Industry stakeholders have also indicated that there needs to be a common definition for endocrine disruptors and that criteria should be consistent across legislation, to reduce uncertainty and inconsistency, and the potential for varying implementation across Member States. One would also expect a harmonised set of criteria to reduce costs for industry with respect to submission of data under the different legislative frameworks. Depending on the number of substances that fall under the final criteria that are adopted, such cost savings could be considerable. However, in the absence of draft criteria proposed for the REACH Regulation and the Cosmetic Products Regulation, it is also

[69] The Cosmetics Directives have been replaced by the Cosmetic Products Regulation in force since 11 July 2013.

not clear whether a single horizontal set of criteria would have greater or lesser impacts on substance availability under the different legislation.

It is of note that the European Parliament also adopted a resolution[70] which calls on the Commission to adopt horizontal criteria for endocrine disruptors.

4.5.5 Missing links and inconsistent treatment of hazards across the legislative framework

NGOs have raised the issue of inconsistent treatment of substances and mixtures across the legislative framework, where use is authorised or allowed under one regime but not another. The comment reflects the fact that different hazardous properties are taken into account under the different legislation, as highlighted in Table 4-1. In addition, this potential for inconsistencies due to legislation referring to properties that are not classified under the CLP Regulation was also raised as a significant issue by Member State authorities. They note that for coherence reasons key properties of concern, such as PBT and vPvB, that are not covered under the CLP Regulation should be incorporated into the Regulation by adding new hazard criteria.

The comment by the NGOs referred to treatment of PBTs. In particular, the comment reflected the fact that PBTs are regulated under the Plant Protection Products Regulation and the Biocidal Products Regulation, but that there is no consideration of such properties under the Cosmetic Products Regulation, which does not require classification for environmental properties. As a result, a substance can be used within cosmetics which gives rise to risks to the environment, with emissions potentially at significant levels. This issue has been raised in Task 1 more generally (rather than specific to PBTs) as a significant gap within the legislative framework, and further details are provided in Section 7.2. Indeed, a range of cosmetic ingredients, ranging from Siloxanes, Triclosan, synthetic fragrances, UV filters[71] etc., have been identified as having significant impacts on the environment (see also Section 7.4.2 on cosmetics labelling).

Triclosan was highlighted by an NGO as an example of the incoherence in how substances are treated under legislation. Triclosan is restricted in soaps and shampoos used by medical professionals but can be used in consumer products, e.g. soaps and toothpaste. It is banned from use under the Biocidal Products Regulation but, due to differences between the Biocidal Products Regulation and the Cosmetic Products Regulation, there are no restrictions on its use under the latter. The NGO also suggests that biocidal substances may also be present in finger paints for children as the Toy Safety Directive does not cover environmental hazards; they further note that the pharmaceutical regulations do not cover environmental hazards.

Member State authorities also noted that the Water Framework Directive is not aligned with the CLP Regulation in terms of what constitutes a hazardous substance. CLP classification for environmental hazards is not directly linked to the identification of priority substances under the Water Framework Directive (as not all priority substances are 'hazardous'), however, it will draw on similar data as identification of priority substances and environmental quality standards (EQS) is based on requirements under the Water Framework Directive and takes account of the findings under the REACH Regulation. Thus, this difference in terminology is not considered to be a significant problem

[70] European Parliament (2015): Resolution – horizontal criteria for endocrine disruptors. Available at: http://www.endseurope.com/docs/150126a.pdf

[71] Sobek, A., *et al* (2013): In the shadow of the Cosmetic Directive —Inconsistencies in EU environmental hazard classification requirements for UV-filters. Science of the Total Environment 461-462, 706–71.

for either duty holders or regulators. (One authority also suggested though that closer coordination between chemical standards set under the Water Framework Directive and the development of BREF (BAT) documents under the Industrial Emissions Directive would also be beneficial).

Responses to the Open Public Consultation by the German Chemicals Industry Association (VCI)[72] also identify a discrepancy in how the Biocidal Products Regulation in principle excludes the approval of an active substance if it meets certain classification criteria (CMR, endocrine disrupting properties, PBT, vPvB, respiratory sensitisers or two out of three PBT criteria) or it is thus classified and how this is independent of the concentration of the substance within a product. In contrast, they highlight CLP and mixture classification which identifies certain hazards by taking into account concentrations, limits are laid down, and potential hazards are communicated by way of pictograms, signal words and H- and P-statements. The VCI suggest that the Biocidal Products Regulation requirements go much further than the CLP Regulation and that this constitutes an unequal treatment of substances intended for biocidal uses, as compared with the same or comparable substances that just fall under CLP requirements.

4.5.6 Plant protection products

Formulators specialising in plant protection products were asked questions related to consistency in the classification of products. Written comments included:

- The Member States react differently and this can mean that there is random implementation of classifications across EU Member States. Considerable internal resources are needed to handle these discrepancies which may lead to the need for additional vertebrate studies. This can lead to a competitive disadvantage in some Member States;
- EFSA has indicated that they may make a classification proposal even when there is already a harmonised RAC classification, making the harmonised classification system obsolete from the formulator's point of view.

Respondents also noted that plant protection products (rather than the active substances) can have different classifications (resulting in different labels) in different Member States, with nine out of ten respondents indicating that this situation had occurred in relation to their products. This suggests that there are inconsistencies arising from the fact that plant protection products are self-classified under the CLP Regulation, with these self-classifications then either agreed or not in Member States other than where the approval was granted. This issue raises concern for plant protection product producers and it causes confusion within the supply chain (when the same product has different classifications in different countries); it also creates additional costs for industry. From this perspective, and given the number of respondents highlighting this as an issue, this is considered to be a significant issue.

4.5.7 Other issues

Industry stakeholders responding to the targeted consultation noted that specific guidance on the use of WoE approaches should be developed to ensure that they are consistently applied through all chemicals legislation, to ensure a degree of predictability and stability for industry (and to enable investment in existing and new substances). From the information collected, it is not clear to what extent the approaches applied in practice vary across the key legislation or across Member States. Specific examples were not provided. As a result, it is not clear to what extent the lack of specific

[72] Verband der Chemischen Industrie e.V. website available at: https://www.vci.de/startseite.jsp

guidance leads to significant impacts on industry in terms of investment in existing and new substances, especially as the evidence will generally be reviewed by a scientific committee as part of regulatory processes. However, the availability of such guidance may make responding to regulatory requirements more efficient, and there could be significant benefits in this respect. It may also be of value to NGOs and other stakeholders in providing a consistent basis for commenting purposes.

More generally, one Member State authority suggested that to ensure a high degree of protection for the environment, the biodegradability requirements of surfactants according to the Regulation (EC) No 648/2004 on detergents should be extended to all surfactants which are able to enter the aquatic environment[73]. It is also suggested that it is not clear why surfactants in cosmetics, animal shampoos or contact lens care solutions are excluded from such biodegradability requirements. Consultation with the animal skin care products association (ASPE) indicates that they do not view their members' products as being similar to detergents, but on a par with cosmetic products (and indeed, they would argue that they should fall under this regulation) as ingredients in animal-focused products can be almost exactly the same as those in traditional cosmetic products. Indeed, in December 2015, Member State representatives supported the view that pet shampoos do not fall under the Detergents Regulation (Regulation (EC) No 648/2004). Without further detailed information on the volume of surfactants in these other products, it is not possible to assess how significant this difference in requirements is in terms of ensuring protection of the environment.

Several NGO and Member State stakeholders identified the need for the CLP Regulation to include criteria for 'classification' of nanomaterials, even though being a nanomaterial is not a hazard property. In response to the OPC, the comment was made that overall the EU legislative framework does not address nanoforms, with the exception being the Biocidal Products Regulation and the Plant Protection Products Regulation. However, nanomaterials are subject to all chemicals legislation, similarly to other chemicals. Nevertheless, some NGOs consider transparency on nanomaterials to be lacking and indicate that enforcement agencies are not able to identify them for an adequate hazard or risk assessment. They also suggested that the lack of a harmonised definition leads to legal uncertainties.

4.6 Gaps in identification and assessment of properties of concern

Key findings:

- Lack of clear hazard criteria under the General Product Safety Directive, which leads to significant impacts on the effectiveness and efficiency in the regulation of consumer products for chemical hazards.
- Concern has been raised over the extent to which the hazards associated with combination effects are identified under the current legislative requirements. The issue has been examined and priorities set for further research, with the potential significance of the issue with respect to environmental effects in particular identified.
- There is currently no consideration of ecotoxicological properties comparable to PBT under the Waste Framework Directive, leading to the potential for waste to be managed in a

[73] Such an approach could have enormous implications for other sectors. For example, a large number of surfactants are used in the offshore oil and gas industry (e.g. scale and corrosion inhibitors, demulsifiers), which are regulated under OSPAR as well as the REACH Regulation, and not all of these are likely to meet the surfactants requirements for detergents. This is likely to be the same case for a number of other sectors, all of which will have different emissions and usage profiles compared to detergents.

manner which does not minimise ecological impacts; this issue is being addressed by the Commission.

In general, and taking into account the discussion provided above, there do not appear to be large numbers of gaps within the legislative framework. However, gaps which are significant have been identified. The most significant of these are:

- The lack of hazard criteria under the General Product Safety Directive[74];
- The issue of combination effects and multiple exposures; and
- A failure for PBT and vPvB properties to be taken into account in waste classification.

4.6.1 General Product Safety Directive

A range of stakeholders, including authorities, the Commission services and NGOs, have identified a gap with respect to the identification of substances having properties of concern and which are used in a range of consumer products, such as textiles, furniture, carpets and construction materials.

The General Product Safety Directive (Directive 2001/95/EC) will apply to such products in the absence of other specific EU regulations concerning safety. The General Product Safety Directive is meant to complement the provisions of sector legislation, which do not cover certain matters such as producers' obligations and the authorities' powers and tasks (for example, it does not cover medical devices, cosmetics or pharmaceuticals, while the safety obligations do not apply to toys). The Directive places a general safety requirement for any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them.

The Directive does not, however, contain any information or criteria for hazard identification, physical and chemical properties, exposure controls, personal protection, toxicological information, ecological information or transport information. This can be seen as a major gap within the horizontal legislative framework for consumer products, as manufacturers of products are effectively not given clear indications of what types of chemical hazards should be considered when ensuring that their products are safe. The result is that substances which can give rise to human health hazards may be being used in a range of different consumer products, with significant exposures for vulnerable populations such as children.

This is clearly a significant issue and represents a significant gap within the overall legislative framework. As it currently stands, the only means of addressing the risks in consumer products is through the REACH Regulation, via the Restriction, Authorisation or the Article 68(2) fast track Restriction procedure. The first two procedures take time and are essentially substance specific (or apply to a small number of related substances). The fast track procedure clearly provides a mechanism for addressing such issues more quickly, with the example being its application to CMR substances in textiles consumer articles. However, there have been protests against this approach by EU industry on the basis that it is not evidence (risk) based and contradicts the principles of

[74] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

'Better Regulation'. In contrast, NGOs such as ChemSec have supported the approach and called for it to be applied to further sets of substances[75].

On balance, it would clearly be more efficient and effective if producers of consumer articles were forced to consider chemical hazard issues earlier on, to avoid innovation being based on substances with high hazard properties and to reduce the need for costly reformulation and technical processing changes from the start. It would also reduce the overall costs of regulation, in terms of reducing the need for the implementation of the fast track procedure, Restriction or Authorisation.

In addition, a member of the public responding to the OPC highlighted their personal experiences of having allergic reactions to chemical substances. The respondent highlighted everyday difficulties from exposures to printing ink and clothing arising from a lack of labelling of substance properties in consumer products. The individual suggested that substances which are potentially allergens should be labelled in a way similar to how gluten free products are labelled, so that individuals who are particularly sensitive can avoid exposures. Again, this could be considered to represent a gap in labelling requirements under the General Product Safety Directive.

4.6.2 Combination effects and multiple exposures

The issue of exposures to multiple chemicals from multiple sources and from 'non-intentionally added substances' was raised by respondents to the Open Public Consultation, as well as in response to the targeted consultation and as part of case study interviews. In general the view is that the combined effects of chemicals are not sufficiently taken into account within the legislative framework. This issue with respect to the need for greater consideration of combined effects and multiple exposures in risk assessment is addressed in more detail in the Task 3 report. However, some mention is relevant here given that the issues relate to both hazard identification and risk assessment.

Firstly, it is important to note that the issue of combination effects and multiple exposures has been recognised at the EU level. In 2012, the European Commission published a communication on "*The combination effects of chemicals – Chemical mixtures*".[76] This communication was prepared in response to a request from the Parliament for the Commission to consider the extent to which the existing legislation *"adequately addresses risks from exposure to multiple chemicals from different sources and pathways, and on this basis to consider appropriate modifications, guidelines and assessment methods".*

The communication is based on the opinions of the relevant Scientific Committees as well as research commissioned specifically to inform the communication[77]. It accepts that there is a gap with respect to EU legislation on the assessment of chemical mixtures with unknown compositions, compared to what is required for mixtures of known compositions (e.g. cosmetic products, plant protection products, etc.), with this point also noted by respondents to the Open Public

[75] ChemicalWatch (2016): Fast tracking CMR restrictions sets 'dangerous precedent'. Available at: https://chemicalwatch.com/45962/fast-tracking-cmr-restrictions-sets-dangerous-precedent

[76] European Commission (2012): Communication from the Commission to the Council: The combination effects of chemicals – Chemical mixtures, COM(2012) 252 final, Brussels, 31.5.2012.

[77] Kortenkamp *et al.* (2009): State of the Art Report on Mixture Toxicity; study contract No. 070307/2007/485103/ETU/D.1. Available at: http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf

Consultation. For example, it notes that: "*There are very few examples of EU legislation specifically requiring the assessment or testing of whole mixtures. However, the requirement set down in the Water Framework Directive for water bodies to achieve good ecological status as well as good chemical status entails a focus not only on the concentrations of individual chemicals but also on their effects in combination.*"

The communication concludes that the current EU legislation does not provide for a comprehensive and integrated assessment of cumulative effects of different chemicals taking into account different routes of exposure. In the case where a mixture of concern is identified and where such a mixture contains chemical substances regulated under different pieces of EU legislation, no mechanism currently exists for promoting an integrated and co-ordinated assessment across the different pieces of legislation. It also concludes that, in the case of chemicals with independent modes of action, the establishment of 'safe levels' based on the assessment of individual substances appears, in relation to human health, to provide a sufficient safeguard against possible negative effects from mixtures/combinations. However, where chemicals have similar modes of action there is a potential for cumulative effects when such chemicals are present together in a mixture (even when the concentration of each substance is below its 'safe level') and then, the concentration/dose addition approach is preferred in order to assure an adequate level of protection. The communication notes that, in relation to the effects on wild species and ecosystems, the situation is less clear and the possibility of combination/mixture effects should be considered both in the case of independently acting chemicals as well as for chemicals with similar modes of action.

The communication also concludes that while methodologies for the identification of chemical mixtures of potential concern as well as for the assessment of chemical mixtures are available, there are extensive knowledge and data gaps (mainly related to the mode of action and exposure data) that limit the extent to which mixtures can be properly assessed. However, information being collected in the context of EU legislation, in particular the REACH Regulation, will contribute to reducing current uncertainties. It is also noted that, notwithstanding the knowledge and data gaps, it is possible to assess mixture toxicity in a more systematic manner in the context of EU legislation. When information regarding the mode of action and dose/response is not available, or inconclusive, a default assumption of dose/concentration addition provides a higher level of protection but may also overestimate negative effects. This limitation and the additional costs it might imply shall be taken into account in the case where possible management measures are being considered.

The communication highlights the significance of the problem and the areas where action is needed, and also sets priorities based on the recommendations of the main Scientific Committees. The good progress that has been achieved in setting these recommendations needs to be maintained as part of the on-going development of chemicals policy.

In this respect, there are two additional areas identified by responses to the Open Public Consultation that should be considered. Firstly, there may be a need for greater hazard assessment of non-intentionally added substances (NIAS), which stem from chemical impurities, reaction and degradation products. NGOs raise this issue with respect to plant protection products, arguing that these can be at levels far higher than pesticide residues. However, such impurities, reaction and degradation products are also relevant in other regulatory contexts and, indeed, have driven risk management in the past (e.g. Nonylphenols and Brominated flame retardants).

With respect to occupational health and safety, there is a duty for employers to consider combined effects, e.g. under the Chemical Agents Directive, but both industry respondents and authorities indicated that it is not very clear at present how this should be done, or how this duty should be enforced. For example, as commented to the Open Public Consultation (with several respondents providing similar comments):

"There is a problem with the combined effects of chemicals. The SDSs and exposure scenarios offer risk management measures only for separate substances or mixtures. These measures could be contradictory to the options the employer has decided to put in practice based on the Chemicals Agents directive when there are two or more chemical agents causing exposure. The vulnerable groups are also a grey area in the risk management."

The gap or inconsistencies in information on the hazard identification, risk assessment and enforcement of potential combined effects (which may not be solely chemical, but chemical and other hazardous agent) indicates that there may be significant occupational health impacts that are currently not being adequately controlled. Given the high costs of occupational diseases in the EU, with estimates suggesting that there are 187,500 fatal work-related deaths in the EU 28 in 2011 and 192,500 in 2014[78], then further guidance on these aspects may be warranted.

[78] Takala, J (2014): Economic Cost of Work-related Injuries and Ill-health in Singapore and Application Elsewhere, EU Presidency Conferences, Athens, 16-17 June.

5 Test Methods and GLP

5.1 Introduction

Hazard assessment in relation to human health and environmental hazards traditionally relies on endpoint information from animal testing. There are several points of criticism related to the use of animal test data from a scientific perspective (e.g. poor reproducibility, ability to predict risks from life-long low dose exposures), from an economic point of view (time and resource intensive) and not least an ethical point of view (protection of animal health and welfare).

In addition, all EU legislation[79] that requires the provision of substance property data, which may be generated via testing, includes provisions to prevent or reduce animal testing through the use of alternative methods.

A large number of endpoint data from animal tests are now available on hazardous and non-hazardous substances. These data are used to develop hazard prediction models, grouping and read-across approaches, as well as to validate any non-animal test methods for generating hazard data, including in vitro test systems. Research has progressed to create extensive knowledge in the fields of mechanistic toxicology[80], toxicokinetics and toxicodynamics of substances. In order to be useful in the regulatory context, the results from non-animal approaches need to allow classification according to the CLP Regulation as well as the derivation of safe exposure levels for risk assessment (DNELs, PNECs, occupational exposure limit values, acceptable daily intakes etc.). While an equivalent level of protection from non-animal data could only be achieved if classification would include sub-categorisation, which is not always possible based on *in vitro* data for eye corrosion/irritation, for the purpose of risk assessment, European Commission experts' note, for some endpoints (e.g. irritation) qualitative data would be sufficient.

Questions for the evaluation include whether or not data from alternative methods can be used to fulfil data requirements under different legislation and whether or not the requirement to apply GLP in generating new information via alternative methods are coherent and do not hinder the use of non-animal methods. In addition, it is important to understand whether new scientific methods for testing, as alternatives to animal tests, can be adapted so as to correspond to the CLP classification criteria or vice versa, if the CLP classification criteria fit to the results from non-animal test methods. Additional questions include whether there are new test methods that could help identify combination effects so that these effects can be taken into account in classifying mixtures.

The evaluation questions examined in the remainder of this section are set out below. In addition, the evaluation draws on the findings of Case Study 4 on test methods. This case study considers what opportunities and barriers exist to the use of non-animal test methods within the current regulatory context, whether the existing quality requirements can be met by non-animal test methods.

[79] In the case study, the following legislation is considered: the REACH Regulation, Biocidal Products Regulation, Plant Protection Products Regulation, and Cosmetic Products Regulation.

[80] e.g. Adverse Outcome Pathway Knowledge Base, available at: http://aopkb.org/

Note that the generation of information to determine physical-chemical hazards is not assessed in detail here, as it is not relevant to the horizontal linkages examined under this task. Any issues identified during the consultation on the CLP Regulation are discussed under Task 1.

Table 5-1: Evaluation questions to be addressed relating to test methods and data quality	
Q #	**Evaluation Question**
1.1.1.2.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the combination effects of chemicals (simultaneous exposure to chemicals)?
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?
1.1.1.6.	Are testing methods adequate to identify all hazards to human health and the environment?
1.1.1.8.	Is the scientific data on which the regulatory decisions are based of good quality, complete and reliable? Are quality requirements (e.g. GLP) appropriate?
2.2.4.	Are the provisions and procedures for hazard/risk identification and assessment efficient?
3.1.2.	Have new needs emerged in relation to the risk management of chemicals? If yes, what are they?
3.1.6.	Does the chemicals legislative framework ensure that the scientific and technical development is taken into account on a regular basis (e.g. through periodic review of the legislation)?
3.1.7.	Is there a mechanism to ensure that the hazard identification and risk assessment are based on the latest state-of-the-art method and sufficient to identify all risks for health and environment?
4.1.2.	To what extent are the legal acts of the chemicals legislative framework coherent in terms of hazard identification?
4.2.9.	Are there any inconsistencies as regards quality requirements for data?
4.2.8.	Is there any inconsistency as regards format for data provisions? If yes, are they justified?

5.2 Adequacy and availability of test methods

Key findings:

- Where available, alternatives to animal testing can generally be used to fulfil data requirements.
- There were divided opinions on the benefits and drawbacks of requiring GLP in testing
- Alternatives to animal testing are increasingly being used.
- (Q)SARs and read-across frequently lack sufficient documentation and justification, further guidance documents may be beneficial.
- GLP can be applied to all non-clinical safety tests conducted for regulatory purposes, including in vitro testing; no corresponding “good practice” exists for the use of read-across and WoE.
- There is a need for quality requirements to be applied to *in silico* methods.
- Coherence issues have been identified with regards to references to GLP requirements in product-specific legislation, which may result in different interpretations regarding the extent of the required compliance with the GLP principles.
- There is a high level of coherence in data requirements and the use of data in all legislation, except the Cosmetic Products Regulation, which prohibits all animal testing for the purpose of fulfilling this legislation.
- It is suggested that there may be a need to update test methods and develop new tests for specific criteria, including endocrine disruption, transformation process, immunotoxicants etc.

5.2.1 Coherence in data requirements

The CLP Regulation does not require but allows, under certain conditions, data generation (Article 8) for classification purposes. All available information should be considered for the classification of substances (Article 5) and mixtures (Article 6). The information sources may include epidemiological data, information generated according to REACH Annex XI, new scientific information and information from recognised chemical programmes. In other words, the source of the data is not limited; it could be testing or non-testing data, new or old, from any source. However, new tests can only be performed if all other means of generating information have been exhausted (Article 8).

New toxicological and ecotoxicological tests for the purpose of classification and labelling should be conducted using GLP and according to the Test Methods Regulation (Regulation (EU) No 440/2008)[81] or internationally recognised / validated scientific principles or methods. Article 7 of the CLP Regulation prohibits testing on humans and non-human primates and states that animal testing can only be performed if no alternative methods can be used, which provide reliable data of sufficient quality. In relation to physic-chemical properties, tests carried out to other relevant recognised standards (i.e. ISO 17025) can also be accepted.

For classification of substances and mixtures, hazard data are to be compared with the classification triggers. If individual data are insufficient for classification or a direct comparison of the available data with the classification triggers is not possible, a WoE approach may be taken (Art. 9 and Annex I, Section I). Accordingly, non-animal test data can principally be used for classification of substances and mixtures, if it is adequate, reliable and scientifically valid.

The definitions of many toxicological and ecotoxicological hazard classes, as well as the related classification trigger values, refer to information from animal testing. For example, the CLP Regulation (Annex I, Part III, 3.1.1.1) defines acute toxicity as:

> *"[…]those adverse effects occurring following oral or dermal administration of a single dose of a substance or a mixture, or multiple doses […]."*

The trigger values are expressed as LD50 or LC50. Consequently, both the hazard definition and the trigger values are based on animal data. Several other hazard classes are defined similarly.

For all endpoints, existing data should be assessed before new tests are undertaken. However, in the specific provisions for classification in the CLP Regulation's annexes, information on the use of non-animal test data is explicitly included for the endpoint serious eye damage / eye irritation: before animal tests are applied, existing information and hazard predictions should be used; this may or may not involve application of a WoE approach. Explanations for all other endpoints do not include such provisions.

The following table, drawn from Case Study 4, provides an overview of the requirements for data generation and use under the CLP Regulation compared to the current systems under the REACH Regulation, the CLP Regulation, the Cosmetic Products Regulation, the Plant Protection Products Regulation and the Biocidal Products Regulation.

[81] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Table 5-2: Summary of provisions on the use of non-standard data / new testing methods			
Legislation	**Provisions related to animal testing**	**Requirements for data generation**	**Data for hazard assessment**
The CLP Regulation (Regulation (EC) No 1272/2008)	Avoid animal tests if other methods generate adequate information (Q)SARs, read-across, grouping and WoE possible, if "adequate for classification" Endpoint definitions and trigger values refer to animal test data	None	Data comparable to the trigger values to decide on the classification
REACH Regulation (Regulation (EC) No 1907/2006)	Animal testing should be the last resort, waiving based on hazard or exposure data possible (Column 2; Annex XI). Annexes IX and X animal tests must be approved by ECHA (after public consultation). Data to be used in a WoE approach. Annex XI: guidance and rules for the use of non-standard data	Substances registered above 1 t/a; the higher the tonnage the more data	Classification PNEC DNELs
Cosmetic Products Regulation (Regulation (EC) No 1223/2009)	Prohibition of placing on the market of cosmetic products and/or ingredients for which animal tests have been performed for the purposes of this regulation	Annex 1: "full toxicological profile"	Margin of Safety (MoS)
Plant Protection Products Regulation (Regulation (EC) No 1107/2009)	Approval requires toxicological and eco-toxicological information, specified in a separate regulation Steps taken to avoid animal testing are to be described in the dossier	Core and additional data for substance appro-val	Classification ADI, AOEL and ARfD; PNEC
Biocidal Products Regulation (Regulation (EU) No 528/2012)	Animal testing should be the last resort. Annex II specifies information requirements alluding to the test methods and species to be used	Core and additional data for substance approval	AEL; PNEC
Notes: ADI = Acceptable Daily Intake. AEL = Acceptable Exposure Level. AOEL = Acceptable Operator Exposure Level. ARfD = Acute Reference Dose. PNEC = Predicted No-Effect Concentration. WoE = Weight of Evidence.			

In addition to the requirements set out in Table 5-2, all legislation requires new testing to be performed according to internationally accepted methods, e.g. OECD guidelines as listed in the Test Methods Regulation, conduction of tests according to GLP and documentation of the methods used. Deviations are generally possible, if justification is provided, internationally accepted methods are used and appropriate documentation is given. In addition, although the use of various methods is accepted to fulfil the data requirements for registration or substance approval, the classification triggers as well as the methods for deriving safe exposure levels for risk assessment are based on the use of animal test data and/or the related outcomes (e.g. LD50, LC50 values).

There is therefore currently a high level of coherence in data requirements and the use of data, with the exception of the Cosmetic Products Regulation. Under the regulation, testing of finished cosmetic products and cosmetics ingredients using animal tests is prohibited, and the marketing of finished cosmetic products and ingredients which were tested on animals for the purpose of this regulation is prohibited within the EU. These prohibitions apply to tests that are specifically aimed

at consumer safety (i.e. human health, rather than risks to the environment), and only to those ingredients that are specific to cosmetics. The Cosmetic Products Regulation therefore establishes very different data generation requirements, requiring all new data for cosmetics-only ingredients to be developed using alternative methods. This prohibition on the use of animal tests represents an area of incoherence between this regulation and the other legislation. In particular, ingredients that are used in cosmetics, but also in other applications, may still require data from animal testing under the REACH Regulation. This is a key complaint of the animal rights organisations, and also raises concern for manufacturers of chemicals. In this respect, there is strong support from both sets of stakeholders to reduce the use of animals in the regulatory testing of chemicals.

5.2.2 New needs and scientific and technical developments

In 2014, the Joint Research Centre (JRC) of the European Commission compiled a state-of-the-art review on alternative methods for regulatory toxicology[82]. The report shows that a number of non-standard methods are available for most of the human health endpoints[83] for classification. However, many of these have limited applicability domains, do not provide quantitative information or are associated with high levels of uncertainty, e.g. due to lack of scientific validation. It was recently decided to adapt the Annex VII of the REACH Regulation to include *in vitro* methods for three endpoints:

- Skin corrosion/irritation (Annex VII, 8.1);
- Serious eye damage/eye irritation (Annex VII, 8.2); and
- Skin sensitisation (Annex VII, 8.3).

According to stakeholders, the more complex hazard classes, such as reproductive toxicity or chronic toxicity, cannot be assessed using only *in vitro* tests, because respective methods are not available. Nevertheless, existing (non-validated) tests may contribute information to an overall assessment of a hazard class.

There are, however, a multitude of research projects ongoing in the area of developing new *in vitro* testing methods, (Q)SAR models and adverse outcome pathways. Whereas most of them relate to the development of one, specific method, some larger initiatives adopt a broader perspective. These include (see also Case Study 4 for more details):

1) The development of mode-of-action frameworks and related *in chemico*, *in silico* and *in vitro* methods to predict hazards;
2) The development of scientific methods and tools for the prediction of repeated dose toxicity;
3) The development of new *in vitro* assays, use of computational methods and software development as well as the use of data on the interaction of substances with biological functions for the development, further improvement and/or validation of hazard prediction models and tools.

[82] European Commission, Joint Research Centre (2014): 'Alternative methods for regulatory toxicology – a state-of-the-art review', 2014. Available at: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/alternative-methods-regulatory-toxicology-state-art-review

[83] The report covers the following endpoints: skin irritation and corrosion; serious eye damage and eye irritation; skin sensitisation; acute systemic toxicity; repeat dose toxicity; genotoxicity and mutagenicity; carcinogenicity; reproductive toxicity (including effects on development and fertility); endocrine disruption relevant to human health; and toxicokinetics.

With respect to other needs, most Member State authorities agreed that the current testing methods for determining the hazard classification of substances are adequate to identifying hazards to human health and the environment. However, it was also noted by authorities that existing test methods are generally not designed to test mixtures; as a result, although the CLP Regulation allows the use of test data for mixtures to be included in the hazard evaluation, these data may be difficult to interpret. Authorities also indicated that some methods do not adequately identify certain hazards, e.g. irritation, sensitisation, endocrine disruptors (in relation to legislation other than the CLP Regulation).

Other comments by Member State authorities include:

- The Test Methods Regulation should be reviewed in light of most test methods for physical hazards being obsolete since the CLP Regulation refers to the test methods of the UN Manual of Tests and Criteria. The current situation is a bit misleading and may lead to double testing for the same physical hazard;

- Cyanoacrylates cause many allergies but that they are not classified as allergens; it is not clear whether this is due to the test method or to application of the criteria for classification (and whether they lead to under-classification in this case);

- There is a need for further test development for:
  - PBT properties
  - nanomaterials
  - endocrine disruption
  - environmental effects other than for water ecosystems, such as terrestrial toxicity
  - environmental fate and behaviour - especially degradation and transformation processes
  - immunotoxicants and gene expression.

One Member State authority noted that, though they will always be supportive of continual development where needed, it should be recognised that there are many types of hazard and it may be unreasonable, and indeed unnecessary, to seek to develop test methods for all of them. For example, alternative methods for identification of non-genotoxic carcinogens are lacking, existing data from (animal) testing on reprotoxicity, carcinogenicity or STOT tests can be used in a WoE approach.

Another Member State authority also indicated that there is national discretion for testing wastes for their environmental hazard, leading to variation across the EU and that some Member States ask for up to 10 tests using a range of organisms. They suggest that there is an opportunity to consider standardisation of approaches, and/or whether some of the methods could be incorporated into standard testing relevant for CLP purposes.

NGOs noted that there is a need to update existing test methods; they suggested that most of the existing test methods are decades old and therefore fail to take into consideration many new scientific insights, such as vulnerable windows in development or epigenetics. The NORMAN network highlighted the example of veterinary drugs that cause reproductive effects in fish populations in the second generation. These effects are not observed in the commonly applied first generation test methods although they are expected to cover chronic effects. With this in mind, a continuous integration of new testing methods into regulations considering new scientific results is recommended. The European Environmental Bureau suggested that tests should be introduced for

additional endpoints such as immunotoxicity, neurotoxicity, endocrine disruption, persistence and that test methods should be updated to avoid non-genotoxic carcinogens going undetected.

5.2.3 Effectiveness: data quality, adequacy and availability

The effectiveness of the current provisions can be expressed in terms of the flexibility that exists under the current requirements, the ability to reliably characterise relevant hazards, the ability to use alternative hazard information and assessment methods for classification and risk assessment, and the degree to which the different methods provide for a high level of protection of human health and the environment. These issues are examined further below.

5.2.3.1 Test methods

The legal texts define the requirements concerning the quality of information for classification and hazard assessment. Guidance documents further explain how the legal requirements should be interpreted. All legal acts specify that new tests should follow internationally accepted standards, with exemptions requiring justification, and be conducted according to GLP. Annex XI of the REACH Regulation includes criteria for the acceptance of alternative data.

The availability of data in general depends on the legal framework with the CLP Regulation not requiring the generation of new information but consideration of all available data. Alternative methods can be used to fill data gaps and support existing data sets, thereby reducing the level of uncertainty. This overall approach has been implicitly or explicitly stated as accepted and useful by all consulted stakeholders. As noted earlier, under all relevant legislation, new tests are to be performed following accepted test methods and standards and implementing good laboratory practices.

ECHA indicated that for alternative test methods, the classification criteria in the CLP Regulation are in general based on data from *in-vivo* studies. Although use of non-testing approaches, such as (Q)SARs (Quantitative Structure Activity Relationships) and *in-vitro* methods, is allowed, the current classification criteria can make them difficult to apply. In order to address this concern, work within the OECD has been initiated with the main aim of examining whether new classification criteria, based on alternative approaches, should be developed in the GHS. This work would also consider the current development of new alternative test methods. This OECD initiative is a necessary step towards a further adaptation of the classification system into the technical progress.

The development of test guidelines is carried out at the OECD level and they are then subsequently adopted in the EU, e.g. in the EU Test Methods Regulation (Regulation (EU) No 440/2008) is generally accepted as an appropriate procedure, because it ensures international harmonisation and acceptance of data. Although the OECD guidelines are subject to updates, it seems not always to be ensured that scientific progress is sufficiently (quickly) taken into account. An analysis of the time of adoption and the date of the last revision of the OECD testing guidelines for human health effects shows that the updating process is not systematic (different time periods for updates for different guidelines) and that there are indeed some test guidelines which are very old. The majority of testing guidelines for health effects is between 0 and 10 years old, counting the 'age' from the date of the last review of the guidelines (see also Case Study 4). One of the issues is that industry and other organisations are dependent on the willingness of OECD country representatives to submit a new method to the OECD Technical Guidelines Programme for assessment and validation.

Responses to the targeted consultation by health and environmental NGOs highlighted the need for the test methods that are accepted as evidence in the classification process to include the latest and

most sensitive test methods, as well as data from peer-reviewed science in the public domain, even though such methods may not yet be accepted at the OECD level or the data may not have been generated in accordance with GLP[84]. The need for tests to cover 'new' endocrine disrupting mechanisms was also identified.

There have also been suggestions that an alternative to the Klimisch reliability assessment method should be used more often; for example, Moermond *et al.* (2016)[85] indicates that a CRED ring test found the CRED evaluation method to be more accurate, applicable, consistent, and transparent than Klimisch. At the workshop carried out in April 2016 to support the Fitness Check, stakeholders proposed to use the CRED system to assess the quality of ecotoxicity data. The system has been discussed in the scientific context (e.g. SETAC) and is being used already in the context of the Water Framework Directive. Academic stakeholders also support increased use of CRED method. For example, the NORMAN network suggested that it should be generally applied by the research community (i.e. all relevant metadata on studies should be reported) and that authorities should include these studies in their assessments too.

The paper by Beronius *et al.* (2014)[86] (see also Section 4.6), submitted in response to the OPC, suggests that health risk assessment of endocrine disrupting chemicals relies on the efficient integration of academic research to fill information gaps. However, the use of non-standard academic research studies in regulatory risk assessment has often been hampered because of limitations in study design or reporting.

A report by the JRC (Bopp et. al., 2015[87]) reinforces the view that new test methods and approaches could generally support the identification of mixture effects; however further guidance on their use is needed to facilitate a more widespread application.

ECHA also indicated that alternative methods to animal testing are used quite a lot (estimations raise the percentage to about 50%), but less so for CLH. There have been very few cases of the use of alternative methods from an environmental point of view in CLH dossiers (in particular on the use of ((Q)SARs). While read-across is the most commonly used approach, ECHA cannot know what methods the companies have used for their self-classifications, especially for mixtures. ECHA also suggests that it is of interest that the majority of read-across in REACH registrations was made against negative substances, i.e. in order to prove that the registered substance was not hazardous. It should be remembered that read-across can also be made against hazardous substances in order to identify hazardous properties for the test substance. This is not very commonly practiced under REACH although it is used under the CLP Regulation (see also Task 1 though, where some sectors have faced issues with regard to authorities' acceptance of read-across approaches). At the moment, there are limitations to the scope of alternative methods with regard to classification and

[84] See for example: Buonsante *et al.* (2014): Risk assessment's insensitive toxicity testing may cause it to fail, Environmental Research. Available at: https://www.researchgate.net/publication/266249085

[85] Moermond *et al.* (2016): CRED: Criteria for reporting and evaluating ecotoxicity data. Environmental Toxicology and Chemistry, Vol. 35, No. 5, pp. 1297–1309.

[86] Beronius *et al.* (2014): Bridging the gap between academic research and regulatory health risk assessment of Endocrine Disrupting Chemicals, Current Opinion in Pharmacology, 19, 99–104.

[87] Bopp *et al.* (2015): 'Scientific methodologies for the assessment of combined effects of chemicals – a survey and literature review'. JRC Technical Reports. Available at: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC97522/jrc_tech_rep_sci%20meth%20for%20mix_final.pdf

labelling and hazard/risk assessment. For example, systemic toxicity cannot be evaluated by *in vitro* data and (Q)SARs may not be reliable as well.

Finally, ECHA noted that if testing requirements change under the REACH Regulation, the CLP Regulation would not be significantly affected, provided that the changes are well founded, as is mostly the case. It should be remembered that the REACH Regulation, through registration, is supposed to provide information for classification and labelling, so if any decisions are taken regarding changes in testing requirements, they should be scientifically based and take CLP into account. For example, for skin sensitisation, it was made clear that alternative methods should be sufficient for classification purposes as well.

5.2.3.2 Good Laboratory Practice

Data quality

Directive on the Harmonization of the Principles of Good Laboratory Practice (Directive 2004/10/EC)[88] and Directive on the Inspection and Verification of Good Laboratory Practice (Directive 2004/9/EC)[89] specify quality management and documentation standards for laboratories. Implementation of GLP ensures the reconstructability of a study that has been conducted for regulatory purposes. The GLP Directive does not address the scientific quality of actual studies, however.

At the April workshop, opinions were divided on the benefits and drawbacks from requiring GLP in testing[90]. While some participants said that GLP is "outdated" because all laboratories work up to high management and documentation standards (compared to 10 years ago), others strongly supported the existence of the requirement as a general quality assurance mechanism, in particular regarding the study documentation. In addition, its removal may result in labs no longer adhering to GLP requirements, given that they increase the work associated with testing.

Several stakeholders indicated though that they do not see a relationship between the use of GLP and the scientific quality of testing results at all. Drawbacks related to GLP stated as being higher laboratory costs, the potential shortage of laboratories which could provide testing services, in particular in relation to new testing methods, and a fear that studies from academia and independent institutions, which are of high scientific quality but not conducted according to GLP, are not considered[91]. With respect to GLP increasing laboratory costs significantly, no data is readily

[88] Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

[89] Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)

[90] The requirement for GLP for physical chemical hazards was unanimously considered as creating unnecessary burdens without improving the information quality. As physical chemical endpoints do not involve new testing approaches, this is not further discussed here.

[91] It could not be checked in this case study to what extent non-GLP studies, which are scientifically valid and relevant are disregarded when fulfilling data requirements, classifying and/or conducting risk assessments. The fears were mainly raised by NGO representatives, who expect a bias in industry conducted studies. This could not be fully levelled out by authorities, in particular under the REACH Regulation, where only dossier evaluation and substance evaluation include a data quality control. Several stakeholders commented that non-GLP data can and is used at least in all procedures involving authorities.

available to establish whether or not GLP adds significant costs. Discussions with two laboratories suggest that testing costs are likely to be between 10% and 30% higher when conducted according to GLP compared to non-GLP approaches (further details provided in Case Study 4). ECHA has expressed concern itself as to whether or not there is adequate testing capacity, in particular in relation to the extended one-generation reproductive toxicity study. Research on the issue has been undertaken for ECHA to identify the global capacity of labs that could undertake the work to GLP requirements, with this suggesting that there is likely to be sufficient capacity[92].

Responses to the targeted consultation suggest that views are mixed with regard to the role of GLP. NGOs believe that restricting data to only that developed in line with GLP prevents the use of existing data from sources other than testing by the substance manufacturer (the REACH Regulation, the Plant Protection Products Regulation, the Biocidal Products Regulation). This is regarded as inappropriate and hindering the use of (independent) available data, if it is not submitted by the applicants directly. One NGO further argued that the test requirements should be expanded, test methods updated and that presently too few chemicals undergo testing for effects on developmental neurotoxicity and immunotoxicity.

Similarly, there was agreement from most respondents (industry, NGOs, Member State authorities, workers representatives, academics, etc.) that:

- The RAC should base its decisions on all available scientific evidence, not just data developed in line with GLP; and
- The RAC should take only scientific evidence into account when developing their opinion on a new harmonised classification.

Where views varied, it was with respect to the extent to which all available scientific evidence should be taken into account, based on the view that data that does not meet GLP or ISO 17025 quality requirements should be given much less credibility and priority within the classification process.

When Member States were asked whether GLP should be a minimum requirement for new studies and existing studies, a range of responses were provided. With respect to existing data, it was recognised that a lot of the existing data that is being used is not GLP compliant and setting GLP as a minimum requirement in such cases would create difficulties (again in particular in relation to physical hazard testing).

With respect to new data, it was generally recognised that it is essential to ensure a minimum of scientific data reliability. Some Member State authorities suggested that ISO 17025 is sufficient for these purposes, especially for physical hazard testing, and thus that GLP is not necessary for future studies where ISO requirements are met. Others indicated that all information should be used and suggested that university and epidemiology data etc. should be taken into account to a greater extent. The CRED method was suggested by one Member State authority as an alternative to Klimisch due to the application of more objective criteria. However, one Member State authority expressed the view that accepting non-GLP data for new animal studies would give rise to a risk of increasing the amount of animal testing required, as the studies may have to be repeated under GLP to be regarded as trustworthy. Overall, ten Member State authorities expressed the view that the

[92] RPA (2015): Analysis of capacities and capabilities of laboratories to conduct OECD TG 443 extended one-generation reproductive toxicity study, Final Report, Contract No. ECHA/2015/145, November. Available at: https://echa.europa.eu/documents/10162/13630/echa_sr26_eogrts_en.pdf

RAC should base its decisions on all available scientific evidence, or just that developed in line with GLP, while three did not agree with this position or were neutral. Two of the ten authorities commented that the data should be evaluated for reliability, however.

In response to the OPC, the Royal Society for Chemistry noted that quality control is a fundamental requirement for the production of scientific data in general, including that related to safety for chemicals. They suggest that GLP guidelines for toxicological testing are merely the codification of the good practice that all professional scientists should be following – including academics and researchers – and similarly, ISO & CEN standards should be followed in other areas such as analytical science.

Coherence issues

A number of potential issues with regard to the coherence of GLP requirements in product specific legislation have been identified by the Commission. It has not been possible for the consultants to verify these within the resources available, however, for completeness these issues are detailed below.

- Directive 2004/9/EC (regarding the inspection and verification of GLP) requires EU Member States to implement GLP compliance monitoring programmes and provides guidance on procedures for inspections and information exchange, whereas Directive 2004/10/EC (on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of GLP and the verification of their applications for tests on chemical substances) outlines the principles of GLP. The requirements regarding the application of the principles of GLP are specified in various pieces of EU legislation (i.e. in the sectors of chemicals, biocides and pesticides, food and feedstuff, medicinal products, cosmetics and detergents). These product-specific legislative texts provide, in varying detail, the requirements related to GLP compliance. In practice, this diversity might result in different interpretations regarding the extent of the required compliance with the principles[93]. For example, in Directive 2004/9/EC, Article 1(2) refers to "in accordance with the principles", Article 2(2) refers to "*conformity with GLP*" and Annex I uses the wording "*adherence to GLP principles*". Other legislation uses different terminology, for example, Article 13 of the REACH Regulation uses "in compliance with the principles of good laboratory practice". Thus, this variation may lead to confusion as the wording may be interpreted as having different meanings under different legislation. For instance, some stakeholders have suggested that conducting a test "*in accordance with the principles*" only requires a test to follow the principles without being subject to inspections, while "in compliance with Directive 2004/10/EC" requires the test facility to be in a compliance monitoring programme. The EU GLP Working Group published a Questions and Answers document concerning the implementation of Directives 2004/9/EC and 2004/10/EC on GLP[94] underlining that all of these variations in wordings constitute a claim to GLP, thereby requiring the test facility to be part of a compliance monitoring programme. However, in order to avoid confusion or misinterpretation of the requirements a greater level of coherence in legal wording is suggested for future requirements.

[93] As indicated in a meeting of the EU GLP Working Group, 17-18 March 2016.

[94] European Commission (2016): Questions and Answers document concerning the implementation of Directives 2004/9/EC and 2004/10/EC on GLP. Available at: http://ec.europa.eu/DocsRoom/documents/8576/attachments/1/translations/en/renditions/native

- In certain pieces of legislation, reference is made to international standards that are equivalent to GLP requirements. Article 13(4) of the REACH Regulation indicates that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of GLP provided for in Directive on the Harmonization of the Principles of Good Laboratory Practice (Directive 2004/10/EC) or other international standards recognised as being equivalent by the Commission or Agency. However, no other international standards have been recognised to be equivalent to GLP (as indicated in ECHA's Q&A ID number 0117). Thus, the interpretation of the provision within the REACH Regulation may be questioned and potentially lead to confusion.

- In the case of the CLP Regulation, a specific case has been identified concerning the quality requirement in Article 8(5), which states that "*where new tests for physical hazards are carried out for the purposes of this Regulation, they shall be carried out, at least from 1 January 2014, in compliance with a relevant recognised quality system or by laboratories complying with a relevant recognised standard*". Discussions in the CARACAL expert group about the exact interpretation of this requirement[95] (strictly relating to GLP or ISO 17025 or other standards) have not yet yielded a conclusion. It is suggested that the lack of clarity in the legal text makes it difficult to enforce this quality requirement.

Other issues

In addition to the coherence issues identified above, other issues relating to GLP have been identified with further details provided below.

- There is considered to be a lack of recognition of EU agencies in the GLP Directives. The EU GLP Directives were adopted prior to establishment of EU agencies as GLP receiving authorities; thus no procedures are foreseen for ECHA, the European Medicines Agency or the European Food Safety Agency to request study audits. Article 6(1) of the Directive on the Inspection and Verification of Good Laboratory Practice (Directive 2004/9/EC) allows Member States to request a study audit, but does not mention EU agencies. However, in the meantime, ECHA/EMA/EFSA have become important receivers of GLP data and will therefore need to be able to verify the GLP status of submitted data. In practice, ECHA/EMA/EFSA work together with national GLP authorities, but legal provisions are not yet in place with regards to the involvement of EU agencies.

- Issues have also been identified with regard to the use of data from OECD and Mutual Acceptance of Data (MAD) countries. The GLP Directives do not foresee the submission of data from non-OECD/MAD countries, such as China and Taiwan, which becomes increasingly relevant. In principle, data from these countries *a priori* cannot be considered GLP compliant.

- The GLP Directives specifically refer to "tests on chemical products", but the exact scope of "chemical products" can be argued; for instance with regard to biological pharmaceuticals or medical devices. Thus, it can be questioned whether the legal scope in the GLP Directives is still up-to-date/fully relevant.

[95] As discussed in the 19th meeting of Competent Authorities for REACH and CLP (CARACAL), 12-13 November 2015 and the 20th meeting of Competent Authorities for REACH and CLP (CARACAL), 8-9 March 2016.

5.2.3.3 Alternative hazard information

According to ECHA's report on alternatives to animal testing[96], an increase in the use of *in vitro* tests is being observed from an analysis of available registration dossiers. Grouping and read-across are the most widely used approaches, in particular for higher tier endpoints; this is then followed by WoE, (Q)SARs and, where available (eye and skin irritation and skin corrosion), *in vitro* methods. ECHA states that registrants use these methods even though they are in an early implementation stage (particularly skin sensitisation).

ECHA's evaluation report[97] provides little detail on the extent to which alternative data has been provided in sufficiently high quality. Their observations and recommendations indicate that the quality of documentation and partly the justification of read-across / grouping and (Q)SARs are frequently not regarded as sufficient. Registrants hardly ever use mechanistic data and related tests in their registration dossiers. ECHA interprets this as a sign that these methods are not sufficiently well developed and little experience exists on how to interpret and use this data as supporting evidence.[98] Guidance documents and scientific publications state that New Assessment methods (NAMs) are generally useful to support a better understanding of (the mechanisms of) effects and hence, inter alia, to gather information on the relevance of effects for humans. Some stakeholders commented that this is a useful approach for using this type of data.

ECHA states that non-acceptance of read-across in REACH registrations is frequently due to a lack of supporting information, of scientific plausibility, or insufficient description of substance identity. ECHA's RAAF guidance[99] explains the use of read-across and grouping and includes a description of methods, documentation requirements and practical examples. The use of alternative methods is stated as acceptable, if the hazard predictions are reliable and useable for classification and risk assessment. Several publications exist aimed at facilitating the use of alternative methods, e.g. through elaborating how to evaluate the methods and document results[100]. The RAAF aims to structure argumentation and provide more clarity on the level of confidence and hence usefulness of the information for classification and risk assessment.[98]

ECHA's guidance document[101] on the reporting of data from in-vitro methods specifies that only data from validated and pre-validated methods can be used for classification and risk assessment. In addition, this type of data can contribute to elucidating the effect mechanisms and hence support other evidence.

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[96] ECHA (2014): 'The use of alternatives to testing on animals for REACH - Second report under Article 117(3) of the REACH Regulation', Helsinki, 2014. Available at: https://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2014_en.pdf

[97] ECHA (2016): 'Evaluation under REACH: progress report 2015', Helsinki, 2016. Available at: https://echa.europa.eu/documents/10162/13628/evaluation_report_2015_en.pdf

[98] Fedtke N. (n.d.): Presentation on ,Critical aspects in the assessment of adaptations based on read-across: The role of supporting evidence' held at the ECHA Read-across Workshop in April 2016, ECHA. Available at: https://echa.europa.eu/documents/10162/22301701/plenary1904_fedtke_en.pdf

[99] ECHA (2015): 'Read-Across Assessment Framework (RAAF)', Helsinki, 2015. Available at: https://echa.europa.eu/documents/10162/13628/raaf_en.pdf

[100] C.f. e.g. Schultz et.al. (2015): A strategy for structuring and reporting a read-across prediction of toxicity', in Regulatory Toxicology and Pharmacology, 72 (2015) 586-601.

[101] ECHA (2012): 'How to report *in vitro* data Practical Guide', Helsinki, September 2012. Available at: https://echa.europa.eu/documents/10162/13655/pg_report_in_vitro_data_en.pdf

The degree to which non-animal test methods are used to fulfil information requirements, conduct risk assessment and classify substances was not discussed at the stakeholder workshop. The respondents to the stakeholder questionnaires did not have an overview in this regard and therefore could not comment.

With regard to the quality of *in vitro* tests, most stakeholders support that information from validated methods should be accepted and that data from non-validated methods should be accepted on a case by case basis. A specialist in the field commented that there is currently a deadlock surrounding their use, because industry states that authorities have too little experience in interpreting such data and would therefore tend not to accept it. They would therefore prefer using accepted (animal) test methods, thereby preventing that more experience is gained on the side of regulators. According to this stakeholder, the deadlock should be resolved by industry submitting *in vitro* data and investing in discussions with regulators on its acceptance. Efforts to pre-define interpretation logics of (a combination) of test were regarded as cumbersome and ineffective by the same stakeholder.

The effectiveness of the ban on animal testing under the Cosmetic Products Regulation was questioned by some stakeholders (NGO, other). One point of criticism regards the possibility to use animal test data conducted to comply with other legislation which, stakeholders pointed out, undermines the goal of preventing animal testing. It could be argued that this reflects incoherence within the legislation, however, the overall goal of EU legislation is not to prevent animal testing but to minimise it.[102] Testing on animals for cosmetics is not seen as necessary (because cosmetics are arguably just a luxury product), while testing for occupational health purposes for example is seen as important.

Another point of criticism relates to the (frequent) occupational occurrence of sensitising effects of cosmetic products. One stakeholder suggests that this might be prevented in relation to products, if animal tests had been conducted and respective hazards been identified, according to one stakeholder. As it is not possible to verify whether this stakeholder was referring to new or older products (which would have been tested on animals), it is not possible to determine whether or not this is a valid criticism.

The use of *in vitro* methods would increase, in particular by SMEs, if respective integrated approaches for testing and assessment existed. This was underlined at an ECHA Workshop for the endpoint skin sensitisation, where respective methods exist but guidance on the sequence of applying them and interpreting their results is missing.[103]

Endocrine disruption is an example of a hazard, which is currently mainly identified via *in vitro* methods using animal or human cells. Here, the hazard assessment and identification is directly based on non-animal test methods, which (some) stakeholders considered efficient and appropriate with a view to the complexity of the "endpoint".

In practical implementation, (Q)SARs and read-across/grouping under the REACH Regulation frequently lack sufficient documentation and justification. Some stakeholders, in particular from the

[102] See for example: European Commission (2016): Legislation for the protection of animals used for scientific purposes. Available at: http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm

[103] C.f. Philip Lightowlers, 'Experts discuss testing approaches for skin sensitisation', in Chemical Watch, April 2015, viewed May 2nd. Available at: https://chemicalwatch.com/23653/experts-discuss-testing-approaches-for-skin-sensitisation

civil society organisations, feared that the data are of insufficient quality and prevent new test data from being generated and which might lead to a different hazard conclusion. Furthermore, the data may not be regarded as "sufficient for classification".

5.2.4 Guidance documents

Guidance documents exist for the use of alternative data for classification and hazard assessment. However, due to the diversity of methods and uses and according to stakeholder feedback, terms that are particularly relevant for alternative testing methods because little experience on regulatory acceptance exists, are not fully defined. One example is the term 'sufficient for classification'. According to one stakeholder comment, the term could be interpreted differently and therefore, some uncertainty is created regarding the potential regulatory acceptance. The development of more guidance, in particular related to the use and interpretation of *in vitro* test methods, including at international level, was specified as an important support activity to increase the (efficient) use of these tests.

Stakeholders at the April workshop, as well as those responding to the consultation, generally described the requirements for data generation as clear and understandable, including the related guidance documents. However, as part of the test methods case study (Case Study 4) stakeholders indicated that the aim of avoiding animal testing is not sufficiently reflected in the CLP Regulation guidance documents, as information on alternative methods is not readily available and there is uncertainty about regulatory acceptance of *in vitro* data for e.g. sensitisation.

One Member State authority also indicated that despite OECD 236 being adopted in July 2013, further guidance is needed to take account of the growing database and that this is needed to help achieve the replacement of OECD 203. When ECHA were asked whether the FET test (also known as OECD 236, an alternative to OECD 203 – aquatic fish toxicity test) has been used they indicated that it has not been used in a CLH dossier so far. ECHA indicated that it apparently has its limitations; specifically, it cannot cover all substance groups, such as for example large molecules which cannot penetrate the membrane and affect the embryo. Furthermore, the metabolism of the embryo is not yet fully known and this makes it difficult to extrapolate to a fully grown organism. These are findings from an ECHA project, which were presented to the Member State Committee[104].

5.2.5 High level of protection

5.2.5.1 Effectiveness of the current system

In responding to the targeted consultation, most Member State authorities agreed that the current testing methods for determining the hazard classification of substances/mixtures are adequate to identifying hazards to human health and the environment. However, it was noted that existing test methods are generally not designed to test mixtures. As a result, although the CLP Regulation allows the use of test data for mixtures to be included in the hazard evaluation, these data may be difficult to interpret. As discussed in Section 5.2.2, Member States also highlighted a range of areas where there is a need for further test and method development in order to ensure the effectiveness of the current system.

[104] ECHA (2016): Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity (FET) Test Guidance (OECD 236) to fulfil the information requirements and addressing concerns under REACH. Available at: https://echa.europa.eu/documents/10162/13639/fet_report_en.pdf

In addition, based on the literature review and the opinions of most stakeholders, no negative impact on the level of protection would be expected if there was an increase in the use of the existing and validated non-animal test methods. Some stakeholders state that *in vitro* (and other) methods that are (also) based on human data and/or human cells are even more reliable than animal tests.

It is recognised that the degree of uncertainty surrounding hazard predictions differs across the various methods. Several stakeholders emphasised that the results from animal studies show a high variability, which causes uncertainty. Any alternative tests developed and validated based on animal test data would therefore integrate this degree of uncertainty plus that introduced by the method itself. Due to the high variability of animal tests, as well as uncertainties on the relevance of effects identified in animals for human health[105], some stakeholders questioned the usefulness of testing overall, thereby addressing animal-tests and non-animal methods alike.

Furthermore, several stakeholders stated that *in vitro* tests may not provide the same extent of information as a corresponding animal test. An example is given by skin sensitisation *in vitro* tests, which do not allow sub-categorisation in direct comparison with CLP criteria (although this may be possible using WoE approaches). Therefore, the need to develop and validate new *in vitro* test methods needs to be balanced against the risk of decreasing the level of protection delivered by the legislation.

One stakeholder was concerned that non-animal test methods, in particular (Q)SARs and read-across, would lead to an increase in the use of 'expert judgement'. This could open opportunities to manipulate the outcome of assessments, which in turn could lead to a decrease in the level of protection. This concern relates to the interpretation of test results rather than the methods as such. The need for expert judgement is obvious for all complex endpoints where WoE approaches are implemented; however the more methods that are used, the greater the number of different competences that are needed.

Another stakeholder commented that alternative methods, which do not allow sub-categorisation (e.g. skin sensitisation), would lead to a decreased level of protection because less information is communicated and can be considered by chemicals users. As indicated by ECHA, the main problem is that many mixtures would not be classified. Then there is of course no information communicated but the sentence is a bit misleading.

5.2.5.2 Barriers to the Use of Alternative Methods

It is unclear how the performance of alternative methods can be evaluated in cases where no 1:1 replacement of an animal test method is possible. All stakeholders have little experience with the use of alternative hazard data, in particular for classification and hazard assessment purposes and where the information 'format' does not correspond to the classification triggers and/or starting values for risk assessment. In addition, there is a high degree of uncertainty about the regulatory acceptance of non-animal test data, including e.g. the interpretation of terms such as 'sufficient for classification'. Authorities are uncertain how to interpret non-animal test data and fear accepting false negative results. There is a perception of the lack of interpretation methods for non-animal test results in legislation / guidance.

[105] The predictability of the test for ecotoxic effects was not discussed by most stakeholders.

There is also variability in the approaches of authorities in terms of their acceptance or non-acceptance of non-animal test data under the different legislation and even for the same legislation, which causes uncertainty on the use of respective methods. Reasons for differences are considered to include differences in legal interpretations and the experience of the assessors. Authorities are not trained (enough) to identify options to use alternative methods and, therefore, can provide little support to industry on their use.

It is more difficult to get regulatory acceptance of data from non-validated (new testing) methods[106] and there is a high degree of uncertainty about the regulatory acceptance of non-animal test data[107], even if based on validated methods. In addition, some company representatives stated that acceptance of alternative methods, in particular 'waiving' based on WoE or read-across, outside the EU is much lower than inside the EU. This would require conducting additional animal tests for approval or authorisation procedures in other countries.

The current classification triggers and the provisions to use data from new testing methods lack alignment and consistency (c.f. section **Error! Reference source not found. Error! Reference source not found.**) in some cases. This is a barrier to the use of all alternative data that are not provided in the required 'format' (e.g. NOAELs or LD50 values).

5.2.5.3 Approaches to increase the Use of Non-Animal Test Data

Stakeholders see the following opportunities to increase the use of non-animal test data:

- Investment in the development of non-animal test methods, better accessible and resourced validation process, e.g. at OECD level, including acceleration of efforts;
- Changes in classification criteria to allow comparison of non-animal test results with the classification criteria (c.f. Section **Error! Reference source not found.** and **Error! Reference source not found.** as well as Annex 3 and Annex 4);
- Development of guidance on the interpretation of test results for *in vitro* methods (at the level of the OECD). More and better guidance on how the use of non-animal methods and respective data can be identified as "adequate for classification" and how sufficient documentation can be provided to support acceptance;
- Increased enforcement of the prevention and reduction of animal testing at Member State level and in ECHA;
- Capacity building in industry and for authorities to ensure a better understanding of new testing methods, including their limitations and advantages regarding human health; and
- A checklist or reporting format for new testing methods to assess their quality, including completeness and reliability of data.[108]

[106] According to authority stakeholders the use of data from non-validated (*in vitro*) methods as contributing information, e.g. to identify modes of action, is well received by regulators.

[107] No analysis could be made of rejections of alternative data for regulatory purposes to verify this statement. ECHA clearly states that the quality of justifications for (Q)SARs, grouping and read-across is not sufficient and it is likely that this data is rejected, if evaluated under the REACH Regulation. ECHA does not specify the quality and related acceptance of data from *in silico* or *in vitro* methods. We did not identify any corresponding reports on the acceptance / acceptability of new testing information under e.g. the Plant Protection Products Regulation or Cosmetic Products Regulation.

[108] Note: the OECD already provides templates, e.g.: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2014)35&doclanguage=en

One authority stakeholder emphasised that development of new methods and hazard assessment approaches strongly needs to take the regulatory context into account, e.g. the need for sub-categorisation with hazard classes, in order to be compatible with the overall framework. The EPAA network concluded similarly[109] and recommended, in order to increase regulatory acceptance of alternative approaches to animal testing:

- Early involvement of and close collaboration between all relevant stakeholders and across all sectors, in particular scientists developing new methods and users of alternative approaches as well as regulators in the process of planning, developing and validating and implementing alternative approaches;
- International harmonisation of legal requirements, including rules and criteria for interpreting and accepting negative and positive results;
- Consideration of whether the validation of methods could be streamlined (case-by-case);
- Investments in training and education, creation of additional incentives for the use of non-testing methods.

[109] Ramirez *et al.* (2015): Knowledge sharing to facilitate regulatory decision-making in regard to alternatives to animal testing: Report of an EPAA workshop, Regulatory Toxicology and Pharmacology. 2015 Oct; 73(1):210-26. doi: 10.1016/j.yrtph.2015.07.007

6 Processes and Procedures

6.1 Introduction

A key element of Task 2 is examining the consistency of the processes and procedures under the different legislation and the degree to which these could lead to varying outcomes, which includes adaptations to technical progress. Adaptations to technical progress (ATPs) for the CLP Regulation were discussed under Task 1 (see Section 9.3 of the Task 1 report). Also of relevance is the way in which other chemicals legislation takes into account scientific and technical developments, as well as new information, through ATPs. A legal analysis was required of ATPs under Task 2, and is reported on below, together with the findings from the case study work.

The evaluation questions relevant to this section are set out in Table 6-1.

Table 6-1: Evaluation questions to be addressed relating to parallel procedures

Q #	Evaluation Question
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?
2.1.6.	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
2.2.1.0	How easy is it to launch, initiate and complete the necessary procedures to identify and assess hazards of chemicals?
2.2.4.1	Are the procedures fast enough to identify new hazards/risks?
2.2.4.2	Is the level of evidence required to identify hazard and risks appropriate?
2.2.4.3	Is the burden of proof properly allocated?
2.2.4.4.	To what extent are the stakeholders able to contribute to the procedure for hazard identification?
2.2.4.5.	Are the procedures and timelines sufficiently clear and reliable?
2.2.4.7.	Are procedures able to achieve consistent and efficient conclusions?
2.2.4.8	Are procedures for hazard/risk identification and assessment implemented in the least burdensome manner?
2.4.4.8.	Are procedures for hazard/risk identification and assessment implemented in the least burdensome manner?
3.1.6.	Does the chemicals legislative framework ensure that the scientific and technical development is taken into account on a regular basis (e.g. through periodic review of the legislation)?
3.1.7.	Is there a mechanism to ensure that the hazard identification and risk assessment are based on the latest state-of-the-art method and sufficient to identify all risks for health and environment?
4.2.7.	Are there any inconsistencies (e.g. resulting from multiple committees) as regards hazards and risk assessments performed under the chemical legislative framework?
4.2.10.	Are there any inconsistencies in allocation of burden of proof?

6.2 Inconsistencies in hazard assessments

Key findings

- Different conclusions on classification of an active substance have been reached under the Plant Protection Products Regulation and separately under the CLP Regulation.
- Disagreement between authorities regarding the proposed classification of an active substance used in PPPs can have significant impacts for industry and downstream users.

Inconsistencies from multiple committees are possible and there are activities to harmonize assessment work, e.g. between ECHA's Biocides Committee and the European Commission's Standing Committee on the Food Chain and Animal Health (SCFCAH) (in the case of the Plant Protection Products Regulation) (COM Workshop on PBT assessment, e.g. presentations by Streck and Peltola)[110].

However, as part of the parallel hazard assessment case study (Case Study 3), stakeholders indicated that there was an issue with regards to the classification of substances/mixtures under the Plant Protection Products Regulation compared to the CLP Regulation. It was intended that all active substances under the Plant Protection Products Regulation and the Biocidal Products Regulation would be subject to harmonised classification and labelling. Article 36(2) of the CLP Regulation states that a substance that is an active substance shall normally be subject to harmonised classification and labelling. However, as there is no legal requirement under the Plant Protection Products Regulation or set deadlines for Member States to submit proposals for harmonised classification under the CLP Regulation, many active substances for which approval is sought under the Regulation are not yet subject to harmonised classification (in contrast there is such a requirement under the Biocidal Products Regulation).

In the absence of a harmonised classification, companies must self-classify and therefore propose a classification of the substance as part of their dossier for approval, or renewal of approval, of the active substance under the Plant Protection Products Regulation or the Biocidal Products Regulation. During the procedure for approval of the active substance, the applicant, the Rapporteur Member State (RMS) and the relevant authority (i.e. EFSA or ECHA) may reach different opinions on the classification of the substance. Where a proposal for harmonised classification is made, this is usually only submitted at the same time or after an application for approval of the active substance has been submitted under the Plant Protection Products Regulation. This can result in classification of the active substance being considered by two different bodies under different procedures and timescales.

As part of the parallel hazard assessment case study (Case Study 3), a number of examples were identified where different conclusions on classification of an active substance had been reached under the Plant Protection Products Regulation and separately under the CLP Regulation. These differences were highlighted for Amitrole, Isoproturon and Flutianil. These cases are discussed in more detail in Case Study 3 examining the parallel hazard assessment procedures, with key findings summarised in the box below. As part of targeted consultation, Plant Protection Product (PPP)

[110] Workshop - Assessment of Persistent, Bioaccumulative and Toxic (PBT) substances in different EU legislations Brussels, 17 December 2014; available at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_type=250&lang=en&item_id=7978

stakeholders were asked whether there had been cases where EFSA and ECHA's RAC have disagreed on the (harmonised) classification of an active substance used in one of their products. There were ten responses to this question with six replying 'yes' and the remainder indicating 'no'. Examples of cases where different classifications were given include for Terbutylazine, penthiopyrad, calciumcarbid and copper compounds. It has not been possible to clearly establish whether some endpoints are likely to be more prone to differences in assessment, based on the information provided.

Case Study 3 findings – different conclusions in parallel hazard assessments

In the cases of Amitrole and Isoproturon, an application was submitted to renew the approval of both substances under the Plant Protection Products Regulation. EFSA proposed a different classification to that put forward by the RMS. In both cases, the approval as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expired on 30 June 2016 and therefore a decision was required to be taken by the Commission on the renewal of the approval of the active substance by that date. The Commission issued Implementing Regulations (EU) 2016/871 and (EU) 2016/872 on 1 June 2016 concerning the non-approval of the active substances Amitrole and Isoproturon respectively. In both cases, the approval of the active substance was not renewed due to a number of risks identified by EFSA, based on which, it was concluded that it was not established with respect to one or more representative uses that the approval criteria provided for in Article 4 of the Plant Protection Products Regulation would be met.

In the case of Flutianil, an application for approval of the new active substance under the Plant Protection Products Regulation was received by the UK as RMS on 23 February 2011. Following its initial evaluation of the dossier in the Draft Assessment Report (DAR), the RMS sent this to EFSA for a peer review in June 2013. The conclusions of the EFSA peer review (published 6 August 2015) suggested classification as carcinogen category 2 and reproductive toxicant category 2. However, the RMS remained of the opinion that classification regarding carcinogenicity was not appropriate. The DAR stated that the weight of evidence was insufficient to conclude that the test substance is carcinogenic for classification purposes and did not support classification for reproductive toxicity. The CLH dossier for Flutianil was submitted by the UK on 23 February 2015, following which the RAC published its opinion on harmonised classification on 10 March 2016. RAC is also of the opinion that Flutianil does not warrant classification as having carcinogenicity. Although the procedures did not run in parallel, this will be one of the first cases where ECHA and EFSA may have to produce a joint opinion for the Commission, explaining their views and why they have reached different conclusions on classification.

Although Flutianil is the only example to date where ECHA and EFSA need to collaborate to resolve the differences in conclusions on classification, the potential impacts of such differences should not be underestimated, nor the possibility of this issue arising again. Responses to targeted consultation by plant protection products and biocidal products manufacturers highlights the difficulties they are currently facing in getting Member State authorities to act as rapporteurs for active substances through the ECHA CLH process. This means that classification decisions may not be available from the RAC prior to the need for such a classification for active substance approval.

This is an important issue. A review of the EU pesticides database provides an indication of the number of substances on which decisions may need to be taken in the near future. Table 6-2 indicates that under the Plant Protection Products Regulation, there are potentially 56 substances which may require re-assessment within the next five years. One could expect that if the Commission adopts a non-approval decision based on a classification proposal by EFSA, which is later overturned in a CLH-decision based on a RAC opinion, then the non-approval decision will be challenged by manufacturers. It should also be noted that the differing legal position for industrial and plant protection substances would result in considerable uncertainty within supply chains for the industrial chemical industry.

Table 6-2: Plant Protection Products Regulation: substances currently approved but requiring re-approval within the next five years	
CLP classification	**Number of substances**
Substances currently approved but requiring re-assessment within the next five years	
Carc. 1B	none
Carc. 2	27 approved
Muta. 1B	none
Muta. 2	2 approved
Repr. 1A	none
Repr. 1B	5 approved
Repr. 2	22 approved
Source: European Commission (2016): EU Pesticides database. Available at http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN on 27th June 2016	

In response to the targeted consultation, companies within the PPPs sector also identified cases where RMS and EFSA did not agree on the proposed classification of an active substance (8 out of 11 respondents). It is clear from the responses received that disagreement between authorities regarding the proposed classification of an active substance used in PPPs can have impacts for industry and downstream users. The uncertainty that this can lead to can have significant impacts, and it if was clear from the start what the harmonised classification of a substances was, then stakeholders may not go through the expense of trying to renew their approval.

A number of respondents highlighted business impacts as resources are required to contend with these discrepancies, the potential need for additional vertebrate studies (resulting in additional costs) and potential delay or non-renewal in active substance approval. However, this situation can also cause confusion within the supply chain regarding the hazards associated with PPPs. Further discussion regarding the implications of differences in PPP classifications is provided in Section 7.2.7.

6.3 Scientific and technical developments

Key findings

- Under the legislation reviewed (the Cosmetic Products Regulation, Detergents Regulation, Biocidal Products Regulation, Plant Protection Products Regulation and Fertilisers Regulation), there is no stipulated frequency for undertaking a review of the requirements/procedures.
- In general, the mechanisms to ensure assessments are based on state-of-the-art methods under the Cosmetic Products Regulation, Detergents Regulation, Biocidal Products Regulation, Plant Protection Products Regulation are considered appropriate. However, in the case of the Fertilisers Regulation, the lack of specific data requirements and a risk assessment process is not deemed sufficient to ensure risk assessment is based on the latest state-of-the-art methods.
- Fertilisers Regulation – the length of the process for adding new products to the list of approved fertilisers reduces its responsiveness and flexibility in relation to market developments, and appears to have led some firms to decide not to move into the introduction of a new product or to focus only on national markets.
- Plant Protection Products Regulation and the CLP Regulation – there are clear procedural steps and timelines as set out under in the CLP Regulation and the Plant Protection Products

Regulation, for the CLH and active substance approval process respectively. In order to avoid divergence of opinions between these two processes, and thus ensure the effectiveness of each procedure, ECHA and EFSA have taken steps to align the timing and coordination of both procedures, and further measures are ongoing. However, ECHA and EFSA may still reach different conclusions on the classification of active substances, which can create issues within the supply chain (as discussed in Section 6.4).

6.3.1 Accounting for scientific and technical developments through reviews

A legal analysis of the Cosmetic Products Regulation, Detergents Regulation, Biocidal Products Regulation, Plant Protection Products Regulation and Fertilisers Regulation took place to identify whether the regulations take into account scientific and technical developments[111]. No significant issues were identified from this review in terms of the existence of mechanism to adapt new developments, with the exception of the Fertilisers Regulation, as discussed below.

The legal analysis of the Cosmetic Products Regulation indicated that there is no fixed frequency for the review of the Regulation. The Cosmetic Products Regulation is reviewed when the Commission decides to take action through discussions with the Scientific Committee on Consumer Safety (SCCS) and following the issuing of an opinion with regard to the potential need for legislative action. In practice, this is happening several times a year. If CMRs 1A and 1B are authorised in cosmetics (under the conditions laid out in Article 15(2)), the Commission must mandate the SCCS to re-evaluate those substances as soon as safety concerns arise, and at least every five years.

The legal analysis of the Detergents Regulation also indicated that there is no fixed frequency for the review of the Regulation. The Commission is empowered to adopt delegated acts to amend the Annexes to technical progress (including test methods, labelling requirements and ingredient data sheets), introduce provisions on solvent-based detergents, and introduce individual risk-based concentration limits for fragrance allergens when new evidence comes to light. The Commission can review (via implementing acts) derogations granted to detergent containing surfactants which failed the biodegradability test, when new information justifying a significant revision of the technical file that was included in the application for derogation becomes available.

With respect to the Biocidal Products Regulation, there is no fixed frequency for the review of the Regulation itself, but decisions under the Regulation (approval of active substances and authorisation of biocidal products) are regularly reviewed. Active substances are approved for a fixed duration not exceeding ten years, after which approval must be renewed. The renewed approval cannot exceed 15 years. Similarly, an authorisation for a biocidal product can only be granted for ten years. In addition, the Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions for approval are no longer met. Similarly, the Competent Authority of a Member State may at any time cancel or amend an authorisation where it considers the conditions for authorisation are not satisfied.

A legal analysis of the Plant Protection Products Regulation indicated that there is no fixed frequency for the review of the Regulation itself, but decisions under the Regulation (approval of active substances and authorisation of plant protection products) are regularly reviewed. Active

[111] The same question in relation to the CLP Regulation is examined in the Task 1 report.

substances are approved for a fixed duration not exceeding ten years, after which approval must be renewed. The renewed approval cannot exceed 15 years. The duration of the authorisation to place a plant protection product on the market is laid down in the authorisation. Approvals of substances and plant protection products can however be reviewed at any time in light of new scientific information. Guidance is updated to take into account the latest scientific information. Furthermore, at each renewal, the hazards of the substance have to be re-assessed according to the latest data available and latest guidance.

A legal analysis of the Fertilisers Regulation indicated that there is no periodic review mechanism. The adaptation process is only triggered where operators submit an application (backed by a Member State rapporteur) for the inclusion of a new product into Annex I. Alternatively, the mechanism could in theory be triggered by a Member State invoking the Safeguard Clause that allows them to restrict the market access of a product in their national territory, due to concerns about the safety of the product. So far, this latter mechanism appears to not have been used for this purpose.

6.3.2 Mechanisms to ensure assessments are based on state-of-the-art

A legal analysis of the Cosmetic Products Regulation, Detergents Regulation, Biocidal Products Regulation, Plant Protection Products Regulation and Fertilisers Regulation was undertaken to identify whether the regulations consider state-of-the-art methods in their assessments.

A legal analysis of the Cosmetic Product Regulation indicated that the definition of nanomaterials provided in Article 2 must be adapted to technical and scientific progress and to definitions subsequently agreed at international level. Paragraph 4 of Article 15 also states that "*when community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regards to substances with endocrine-disrupting properties*".

A legal analysis of the Detergents Regulation indicated that the Commission is empowered to adopt delegated acts to amend the Annexes concerning test methods and complementary risk assessment for surfactants in detergents, GLP and animal protection, and test and analytical methods applying to control procedures for detergents on the market carried out by Member States.

A legal analysis of the Biocidal Products Regulation indicated that the Commission is empowered to adopt delegated acts to adapt to scientific and technical progress the information requirements for the preparation of application dossiers for active substances and biocidal products (Annexes II and III) and the rules for adaptations of data requirements (Annex IV).

The Commission is also empowered to adopt delegated acts to adapt the definition of nanomaterials to technical and scientific progress via delegated acts, taking into account Recommendation 2011/696/EU.

A legal analysis of the Plant Protection Products Regulation indicated that the data requirements for application dossiers (both for active substances and for PPPs) can be reviewed through comitology (with data requirements updated in 2013), as well as the uniform principles for evaluation and

authorisation of PPPs at national level, which are set out in Regulation No 546/2011[112]. In addition, new risk assessment guidance has been adopted.

A legal analysis of the Fertilisers Regulation indicated that there seems to be a mechanism for hazard identification and that it is largely dependent on the REACH Regulation and the CLP Regulation. Although the Regulation independently requires that fertilisers, under normal conditions of use, do not adversely affect human, animal, or plant health or the environment (and this is a condition taken into account in the approval process for individual products), there is a lack of specificity in the data requirements of the process. Arguably, this is not sufficient to ensure risk assessment on the basis of the latest state-of-the-art methods.

Research undertaken also indicates that there is not currently an official approach specifically outlined in the Fertilisers Regulation for undertaking an assessment of the risks associated with the use of a fertiliser. The lack of a defined risk assessment approach and associated data requirements within the Fertilisers Regulation means that it is currently difficult to formulate coherent conclusions about the validity of the existing type-approvals. This creates an issue from the perspective of the regulator because there is no efficient and coherent approach to removing a substance from the approved list. Hence, the inclusion of a specified procedure for assessing the risks of fertiliser use along with the necessary data requirements within the Fertilisers Regulation would be of help in this case (see the Task 3 Report for further details).

6.3.3 Ease of launching, initiating and completing procedures

As part of the research undertaken into the Fertilisers Regulation it was identified that the process of adding new products to the list of approved fertilisers takes typically 4-5 years and in some cases, where new categories of products are added, a total of 7 years (Evaluation of Regulation (EC) 2003/2003 relating to Fertilisers (CSES, 2010)[113]). It seems that the length of the process reduces its responsiveness and flexibility in relation to market developments, and appears to have led some firms to decide not to move into the introduction of a new product, or to focus only on national markets. The main reasons for the length of the approval period are, according to the Evaluation Report, the slow procedure for the determination of the candidate fertiliser type and the lengthy discussions in the working group meetings where the review and decisions on the relevant technical files are taken.

With respect to the procedure for applying for approval of an active substance under the Plant Protection Products Regulation and consideration of proposals for harmonised classification under the CLP Regulation, the criteria to be applied to the classification of a substance are set out in the CLP Regulation. Whilst there is only one set of rules which is applied to the same set of data in each case, different conclusions on classification can still arise from different interpretations of the data. This creates difficulties in the implementation of the Plant Protection Products Regulation, in particular where it concerns classification that would meet the cut-off criteria in Article 4 of the Plant

[112] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) no 1107/2009 of the European Parliament and the Council as regards uniform principles for the evaluation and authorisation of plant protection products

[113] CSES (2010): Framework Service Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations – Interim, final and ex-post evaluations of policies, programmes and other activities – Evaluation of Regulation (EC) 2003/2003 relating to Fertilisers. Centre for Strategy & Evaluation Services. Report accessed from the European Commission website. Available at: http://ec.europa.eu/smart-Regulation/evaluation/search/download.do?documentId=4416

Protection Products Regulation. There are clear procedural steps and timelines set out in the CLP Regulation and the Plant Protection Products Regulation, however, for the harmonised classification and labelling and active substance approval process respectively. In order to avoid divergence of opinions between these two processes, and thus ensure the effectiveness of each procedure, ECHA and EFSA have taken steps to align the timing and coordination of both procedures. Further measures are also ongoing, such as the development of a common template for both submissions.

To date, there have been no examples of where ECHA and EFSA have reached different conclusions on classification and where this has had to be resolved. Flutianil will therefore be the first case where a resolution will have to be found (see Case Study 3). Article 30 of Regulation (EC) No 178/2002[114] sets out procedures for EFSA with respect to divergences in scientific opinions issued by other bodies carrying out similar tasks. The article requires that EFSA cooperates with other Scientific Committees or Community Agencies with a view to resolving such divergences or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data (this also applies to cases where there is substantive divergence in the views of EFSA and a Member State)

As noted above, it is now likely that ECHA and EFSA will be required to produce a joint opinion stating that each authority's opinion is based on the same evidence, explaining their views and why they have different interpretations on classification. While ECHA and EFSA are now required to work together to resolve the conflict or to submit a joint document to the Commission, there are no set procedures or timescales.

In terms of the significance of this issue, it clearly is not a problem that has arisen on a repeated basis yet, however, there are other cases which may need consideration. As part of targeted consultation, PPP stakeholders were asked to identify any issues with regard to the level of evidence considered. One respondent noted:

- *The classification of the active substance XXXXX is harmonised within the EU as H302, H400 and H410. EFSA proposes additionally H351 and H361, which defines it as an Endocrine Disruptor under the plant protection regulation as determined by the interim cut-off criteria. Several Member States follow the proposal of EFSA, although a CLH dossier is not submitted to ECHA for the RAC process. The impact for our Company is that we have lost several products in some EU countries, which accept EFSA´s proposal for classification although a harmonised classification already exists for this substance*.

It is difficult at this stage to determine the significance of this issue overall, and it is clear that ECHA and EFSA are jointly working to reduce the probability that such an issue could arise in the future. However, the potential impacts in such individual cases may be significant. The existence of a classification proposal from EFSA for a plant protection active substance which differs from the harmonised classification will cause confusion within the market. It will lead to increased 'hassle' costs for both manufacturers and their downstream supply chain, in understanding the regulatory status of the substance. It also sends confusing messages to workers and other stakeholders.

[114] Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures and matters in food safety.

6.4 Quality, levels of evidence and burden of proof

Key findings

- Some stakeholders question the relevance of animal testing to identifying hazards for human health. As non-animal test methods are usually developed based on animal test data and verified against that data, they may have the same bias. Hence, non-animal test methods would only provide an advantage, if they more closely relate to human health evidence.
- Stakeholders also indicate that clear and commonly agreed rules for the interpretation of *in vitro* test results or results from other methods are missing.
- Fertilisers Regulation – there is a lack of fixed rules and data requirements when it comes to demonstrating the safety and effectiveness of a fertiliser.
- In general, the burden of proof is considered to be appropriately allocated. However, in the case of the Fertilisers Regulation the lack of clear rules and data requirements concerning the safety and efficiency of a substance or mixture arguably increases the burden for the operator to prove the safety of a product before approval for use (and inclusion in Annex I of the regulation) and for the regulator (albeit to a lesser extent) to prove a product is not safe for use as a fertiliser after inclusion in Annex I of the regulation.

The outcomes of parallel procedures for hazard identification and assessment will depend, at least in part, on the degree to which the procedures vary in terms of the quality, level of evidence required and potentially on what party the burden of proof is placed. It may also depend on the extent to which stakeholders are able to contribute to the process. In addition, in the case of the Plant Protection Products Regulation, the assessment is carried out each time the active substance is renewed. As new data may become available or there may be changes in how data are interpreted, this may also be a reason for discrepancies in the hazard assessment.

6.4.1 Appropriateness of level of evidence

In the parallel hazard assessment case study (Case Study 3), no information emerged that suggests that the level of evidence required across the legislation is not appropriate.

As part of the application process under the Plant Protection Products Regulation, following receipt of a DAR from the RMS, EFSA will start a public consultation process (60 days for submission of written comments). Where appropriate, EFSA will organise a consultation of experts. As part of the steps taken to streamline both procedures, ECHA and EFSA have identified the need to coordinate both consultations by launching these at the same time and encouraging consistent commenting under both consultations through allowing parties to comment in parallel to the two reports (source: 13th Meeting of CARACAL Doc.CA/47/2013).

In terms of the parallel hazard assessments, following public consultation on the CLH dossier and DAR for approval of an active substance respectively, new information may be received or requested in both processes, and therefore it is difficult to ensure that both processes have a common information base as a starting point. As part of the steps taken to streamline both procedures, ECHA and EFSA have agreed to exchange all documents produced in the respective processes, in order to identify any potential source of conflict as early as possible and differentiate between those that stem from differences in legal requirements or result from different scientific interpretations of data

(source: 13th Meeting of CARACAL Doc.CA/47/2013). As part of the OPC, comments were made by a National Association about the CLH process. They indicated that, in their opinion, the evaluation process for active substances in PPPs and the CLH process seems not to be totally coherent and should be re-examined, in terms of data requirements. They also suggested that the quality of CLH dossiers varies.

Consultation with a fertiliser manufacturer indicates that there is a lack of fixed rules and data requirements when it comes to demonstrating the safety and effectiveness of a fertiliser under the Fertilisers Regulation ((EC) No 2003/2003). This leads to difficulties in assessing the quality of applications submitted by operators, and it is difficult to formulate coherent conclusions regarding the validity of existing type-approvals (i.e. those included in Annex I of the regulation) (see the Task 3 Report for further details). It appears that, in practice, the information used to register the substance under the REACH Regulation may be frequently accepted as sufficient evidence of compliance with the safety requirements. As a result, consistency and efficiency appear to pose issues. The lack of fixed data requirements and rules, and the ad hoc nature of the consideration of technical files all seem to indicate that the decisions made on the basis of the procedure may involve some unjustified variation. Moreover, the relationship between the Fertilisers Regulation, the Plant Protection Product Regulation and the REACH Regulation was noted as a source of tension. The most recent example of this tension is the issue of Calcium Cyanamide, which is not subject to restrictions under the REACH Regulation and has been approved under the Fertilisers Regulation, but the application for its approval under the Plant Protection Products Regulation was withdrawn by the operator due to concerns relating to the manageability of risk management measures (pers. comm., 2016).

6.4.2 Burden of proof and stakeholder participation

As part of the legal analysis undertaken for this study, consideration has been given to allocation of the burden of proof within the legislation and whether it is consistent and appropriate. It is difficult to separate the burden of proof in relation to hazard assessment requirements from those related to risk management under the different legislation. However, in some cases, the burden of proof is clearly placed on industry, while in others it is divided between parties.

Under the Cosmetic Products Regulation applicants are responsible for assessing the hazards of their products and for ensuring that they comply with the requirements of the legislation. The applicant is also responsible for providing sufficient scientific evidence to the SCCS to enable an assessment of the safety of a product, should this be necessary due to an ingredient being newly classified for CMR properties. The assessment of the information provided by industry is undertaken by the SCCS, while the Commission, on the basis of the safety assessment carried out by the SCCS, decides which risk management measure to take (to restrict, ban or authorise a substance and lay down the corresponding conditions).

Under the Detergents Regulation, adaptation to technical progress has been triggered by new evidence coming from different sources – for instance evidence gathered by the Commission via tendered studies, or findings from studies conducted by stakeholders (Hera project launched by AISE and Cefic). Studies are generally reviewed by the scientific committee (here the SCHER).

As part of the Fertilisers Regulation, the burden of proof is on the operator to show that the substance complies with the safety and effectiveness requirements before it is approved for use (and thus included in Annex I of the regulation), however, once the substance has been approved for use the burden of proof shifts to the regulator. While this is considered appropriate, the lack of a defined risk assessment approach and associated data requirements within the Fertilisers Regulation

arguably increases the burden for operators to prove the safety of a product before approval for use (and inclusion in Annex I of the regulation) and for the regulator (albeit to a lesser extent) to prove a product is not safe for use as a fertiliser after inclusion in Annex I of the regulation. It also seems that unnecessary burdens are stemming at least from the length of the approval procedure (4-5 years or even up to 7 years in some cases). The lack of fixed data requirements or clear rules on the sufficient levels of evidence may pose issues to operators submitting technical files as part of their applications, and may prolong the discussions in the relevant working group or Committee.

From Case Study 6 regarding inconsistencies in assessment procedures for PBT and vPvB as properties of concern, there is no indication from stakeholders that the burden of proof is improperly allocated. The burden of proof is allocated according to the general principle that industry provides data and assessments and authorities check and review data and conclusions. No inconsistencies are observed from legal analysis.

In the Biocidal Products Regulation, the regular review of substance approval and product authorisation obliges applicants to update application dossiers with new scientific evidence when relevant.

In the Plant Protection Products Regulation, the regular review of substance (Part A of the Annex to Regulation (EU) No 283/2013[115]) approval and product (Part A of the Annex to Regulation (EU) No 284/2013[116]) authorisation obliges applicants to update application dossiers with new scientific evidence when relevant, with detailed requirements set out for both active substances and PPPs. There is an obligation for all authorisation holders to collect and report scientific data on the substances and products they obtained approval and authorisation for. The authorisation holder has to notify the Member State of any new information on the active substance, its metabolites, a safener, synergist or co-formulant contained in the PPP, which suggests that the PPP no longer complies with the criteria for approval of active substances or authorisation of PPP, covering in particular potential harmful effects. The obligation to notify includes relevant information on decisions or assessments by international organisations or by public bodies which authorise PPPs or active substances in third countries. In addition, the authorisation holder has to notify the Member State of any new information concerning the PPP itself, including relevant information on decisions or assessments by international organisations or by public bodies which authorise PPPs or active substances in third countries.

Stakeholders within the PPPs sector were also asked whether there should be a requirement under the CLP Regulation and the Plant Protection Products Regulation for Member State competent authorities to develop or deliver to RAC a harmonised classification proposal for an active substance. Nine of the ten respondents (80%) agreed. Comments include:

- Without a harmonised classification under the CLP Regulation, there is the potential for huge discrepancies between classification of substances and consequently for relevant products within the EU. The reason is that not all EU Member States follow the CLP Regulation. Some of them may accept the self-classification according to Article 4 of the CLP

[115] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013

[116] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013

Regulation, while others are following the opinion of EFSA for classification. In order to fulfil the harmonisation requirement under the CLP Regulation for classification, it is therefore absolutely important and necessary that Member States communicate relevant CLH dossiers to ECHA for evaluation.

- The principle of self-classification as outlined in the CLP Regulation should be applied across all sectors; therefore there should be no need for Member State competent authorities to develop any classification proposals in their evaluations of active substances under the Plant Protection Products Regulation. The only result of getting Member States involved in classification in the course of PPP evaluations is disharmonised classification of products.

PPP stakeholders were also asked whether companies should be able to submit a dossier to ECHA for the proposed harmonised classification of a PPP or biocidal product. Nine of the ten respondents (90%) to the targeted consultation that answered this question indicated that this should be the case, noting that it would be more efficient and effective if the data owner of that substance had the possibility to submit a dossier to ECHA directly before the renewal process is started by EFSA. As noted in the Task 1 report, under Articles 36(2) and 37, manufacturers of PPPs are unable to submit proposals for harmonised classification and labelling to ECHA; such proposals can only be submitted by Member State competent authorities. Under Article 37(6), it is only manufacturers, importers and downstream users who have new information which may lead to a change of existing harmonised classification that can submit a proposal for a revision of the harmonised classification. In such cases, industry is required to submit the proposal to the competent authority in one of the Member States in which the substance is placed on the market. Thereafter, the Member State shall decide whether or not to submit a CLH dossier based on the proposal received. As highlighted in Case Study 3, Member States do not always take forward a CLH dossier and therefore industry stakeholders have argued that the legislation should be changed to allow CLH dossier submission by industry.

In contrast, EFSA has argued that while industry is not able to submit a CLH dossier for a PPP active substance directly to ECHA, industry only needs to convince one Member State that there is a need to change classification in order for a CLH dossier to be taken forward. It is therefore EFSA's opinion that the current system does not need to be changed. However, it is clear that issues have occurred where Member States have not submitted a CLH dossier to ECHA when received by industry (even when the Member State has indicated that it would do so).

As part of research undertaken for Case Study 3, the UK authorities expressed the view that the current system of Member State submission of CLH dossiers provides the appropriate checks and balances and ensures the consistency and quality of submissions. Currently Member States check the quality and consistency of information included in a CLH dossier; this would need to be carried out by ECHA if industry was allowed to submit a CLH dossier directly to ECHA. UK authorities also noted that, at present, industry already works closely with Member State authorities to help prepare CLH dossiers. However, it is important to note that this is the UK position, and authorities in other Member States do not all agree, as discussed below with regard to the efficiency of procedures.

Under the Detergents Regulation the Scientific Committee on health and environmental risks (SCHER) can be requested for opinions, in particular concerning test methods, when new evidence comes up. Evidence can also be provided by stakeholders. Similarly, new evidence as well as the evaluations of new evidence made by the SCHER are discussed in the Detergents Working Group, where stakeholders are represented, which include industry (e.g. Cefic and AISE) and one NGO (WWF), as well as national administrations (Source: Register of Commission expert groups).

6.5 Timeliness, consistency and efficiency of procedures

Key findings

- There are clear procedural steps and timelines as set out in the CLP Regulation and the Plant Protection Products Regulation, for the CLH and active substance approval process respectively. However, in order to avoid divergence of opinions between these two processes, ECHA and EFSA have identified a need to align the timing of both processes.
- Stakeholders have indicated that there are issues of incoherence or inconsistency arising from different agencies (RAC, EFSA, SCCS, SCOEL, SCHER) being responsible for the classification/labelling of substances and mixtures across EU chemical legislation. It is suggested that increasing interaction between agencies is needed to help increase coherence. Although EFSA has an obligation to seek convergence under the general food law regulation, it is not obliged to wait for the outcome of the RAC opinion before deciding on the classification of an active substance for plant protection products.
- Due to the absence of a risk assessment procedure, depriving a fertiliser of eligibility for CE marking is a lengthy and time consuming process. The inclusion of a specific mechanism within the Fertilisers Regulation to enable assessment of the risks and, where appropriate, the removal of a substance from the approved list would provide a faster and more efficient procedure.
- It has been identified that PBT/vPvB status may be determined differently under the different regulatory frameworks; there are no formal mechanisms to harmonise the conclusions for any one substance across legislation although under Article 30 of the general food law regulation, EFSA must address such differences in status.

6.5.1 Speed and efficiency of procedures

As part of Case Study 3 (relating to parallel hazard assessment procedures) the assessment procedures were reviewed. It was identified that there are clear procedural steps and timelines as set out under in the CLP Regulation and the Plant Protection Products Regulation, for the CLH and active substance approval process respectively. These procedures are summarised in detail in Case Study 3. However, in order to avoid divergence of opinions between these two processes, ECHA and EFSA have identified a need to align the schedule and timing of both processes to better ensure the convergence of conclusions (thereby reducing the need for these two bodies to address differences at a later date).

In order for the two processes to run in parallel, the CLH dossier should be submitted to ECHA well before the DAR is submitted to EFSA (source: 13th Meeting of CARACAL Doc.CA/47/2013). Feedback received from ECHA during stakeholder interviews indicated that Member States are not always able to follow the timescales indicated in the Registry of Intentions as in some cases it can be years later that they submit a CLH dossier. While the Registry of Intentions aims to provide as realistic a picture as possible of what CLH dossiers will be submitted, ultimately priorities at the Member State level change or the timing may not work.

As part of targeted consultation, Member State authorities were asked whether they agree or disagree with a number of statements regarding the CLH process and coherence with other legislation (e.g. the Plant Protection Products Regulation). Comments specific to the CLH process itself are discussed under Task 1, but with respect to industry development and submission of dossiers to ensure coherence with other legislation (in particular the Plant Protection Products

Regulation), 8 out of 11 Member States agreed that companies should be encouraged to do so, thereby reducing some of the pressure on Member State authority resources. As noted earlier, PPP manufacturers believe that they should have the right to submit a CLH dossier directly to ECHA at the same time that the registration dossier is submitted to the Rapporteur Member State. In the case of authorisation renewal this would only be required in the case that changes in classification should be required (new data available, new criteria defined, etc.).

As discussed in the Task 1 report, the majority of Member State authorities agree that development of a CLH dossier and overseeing its progress through the CLH process places a high burden on the responsible Member State and that the costs of developing these dossiers restricts the number that Member State authorities can process.

When Member State authorities were asked whether they believe that the current Committee arrangements are efficient and effective, with regard to the burden that they place on Member State authorities in terms of participation in them, Member States provided a mixed response. Most responding to the question indicated that they consider the current Committee arrangements to be efficient and effective, although a few disagreed (3 out of 11). Despite this, authorities did have some suggestions, such as the need to ensure better and more coordination when the same substance(s) is affecting several related regulations, and the need for better information to allow parties to track and monitor the discussions and outcomes arising (see also Section 5 of the Task 1 report). It was also suggested that the efficiency and effectiveness of the meetings can be limited due to the late arrival of relevant documents prior to the meetings.

Authorities also commented that relatively few environmental issues are addressed at most RAC meetings. As a result, the expectation that all RAC members must attend the whole meeting is not an effective use of resources; it was suggested that, at least for CLH dossiers, it may be more efficient to hold an environment sub-group for part of the meeting to deal with all the environmental issues in a more effective manner. The ability to participate via WebEx was appreciated and allows relevant stakeholders to participate without having to attend in person.

With regards to the Fertilisers Regulation, the adaptation procedure seems to have very limited ability to respond to concerns about approved substances. The legal provisions relating to the adaptation of Annexes appear ambiguous in the sense that it is not clear whether removing entries from the list of approved fertilisers is a possibility. In practice this has never been done, although it may well be that such a mechanism is necessary.

As a recent example, the concerns raised with regard to Calcium Cyanamide in the context of the Plant Protection Products Regulation were also discussed in the working group under the Fertilisers Regulation. An opinion was requested from SCHER, in order to clarify the risks related to the substance. This opinion has now been published, which concluded that harmful effects from the use of Calcium Cyanamide as a fertiliser for humans and for the environment cannot be excluded (SCHER, 2015). So far it has not been possible to even attempt the process to remove this substance from the Annex, as no Member State has yet decided to invoke the Safeguard Clause to prohibit the marketing of this product in their national territory (Source: minutes of the Fertilisers Committee, stakeholder input). Arguably a more efficient and clear mechanism would be necessary in order to revisit the safety concerns.

There is no specific mechanism within the Fertilisers Regulation to enable a substance that is included in the approved list (Annex I) to be removed on the basis of a change in classification under the CLP Regulation. It is therefore not currently possible for the Commission to directly intervene if issues arise with regards to the use of a fertiliser that is included in the approved list. Thus, the

inclusion of a specific mechanism within the Fertilisers Regulation to enable assessment of the risks and, where appropriate, the removal of a substance from the approved list is considered to be a much faster and more efficient procedure. It is the view of the manufacturer that guidelines should be introduced outlining the data requirements for the assessment of the risks of fertilisers as this would provide a clear process and set of requirements for assessing the risks associated with fertiliser use. The above also raises potential questions regarding whether the current process sufficiently protects human health and the environment as fertilisers included in the approved list (for sale across the EU) cannot be quickly removed (see the Task 3 Report for further details).

As part of Case Study 3 (relating to parallel hazard assessments under different legislation) no information has emerged to suggest that the procedures used within the legislative framework are not fast enough in identifying new hazards, while Case Study 6 on the coherence of assessment procedures for PBT and vPvB as properties of concern, has found that the timelines and procedures are sufficiently clear within the PBT assessment processes. Although, the PBT/vPvB assessment is regarded as slow in general, as obtaining information is frequently a limiting factor, compared to e.g. the POPs convention the mechanisms to generate missing data are good.

6.5.2 Consistency of procedures

As noted above, a range of different committees and agencies have a role in hazard identification under the various pieces of legislation of relevance to this study. These include ECHA (and hence the RAC), EFSA, SCCS, SCOEL and SCHEER. The obligations on these bodies vary in terms of the existence of a legal obligation to pursue convergence in opinions where more than one scientific body may be considering the same hazard issue. Table 6-3 summarises the extent to which there is or is not such a duty. All bodies have obligations to cooperate with other scientific bodies and to seek convergence, or otherwise to establish reasons for divergence. The most significant difference relates to SCOEL which has an obligation to seek to ensure cooperation with other relevant bodies carrying out similar tasks, but is not obliged to seek convergence in so doing. In addition, besides methodological differences in the derivation of proposed occupational exposure limit values by SCOEL compared to the RAC, for example, where these are binding occupational exposure limit values there is a further complicating factor related to the need for such proposals to be subject to consultation with social partners.

Table 6-3: Evaluation questions to be addressed relating to parallel procedures

Agency or Scientific Committee	Existence of a legal obligation	Relevant legislation
European Food Safety Agency	Yes, clear obligation	General Food Law Regulation (EC 178/2002)
European Chemicals Agency	Yes, clear obligation	REACH Regulation (EC) No 1907/2006
Scientific Committee on Consumer Safety	Yes, clear obligation	Commission Decision C(2015) 5383[117] Rules of Procedure[118]
Scientific Committee on Health,	Yes, clear obligation	Commission Decision C(2015) 5383

[117] European Commission (2015): Commission Decision of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, C(2015) 5383 final. Available at: http://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf

[118] SCCS and SCHEER (2016): Rules of Procedure, European Commission, April. http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

Table 6-3: Evaluation questions to be addressed relating to parallel procedures		
Agency or Scientific Committee	**Existence of a legal obligation**	**Relevant legislation**
Environmental and Emerging Risks		
Scientific Committee on Occupational Exposure Limits	Obligations to seek to ensure cooperation	Commission Decision 95/320/EC[119]

The main issues with respect to consistency of procedures relate to those between ECHA (RAC) and EFSA. These are discussed in detail below. However, as part of the targeted consultation exercise, actors within the detergents sector (namely non-SMEs and National Associations) were asked about overlaps in legislation. Comments provided by non-SME respondents indicated that there are impacts on their activities when there was an overlap between cosmetic and biocide label requirements and when active substance supplier's classification differs from that proposed by ECHA. Another respondent indicated that due to decisions taken under other legislation that led to the proposed classification of Methylisothiazolinone (MIT) (recent RAC opinion) as a skin sensitiser cat 1A with an SCL of 15 ppm, this will require reformulation of MIT out of detergents, as the levels required as an active ingredient are above this threshold and the respondent does not want to market products that are classified as a whole as a skin sensitiser[120]. They also anticipate that the use of MIT for preservation of consumer products will not be allowed at levels above 15 ppm in the near future. The respondent also highlighted the proposed harmonised classification of salicylic acid as a CMR 2 and how this will limit the use of this substance in their hygienic cleaners, as their own internal rules restrict them from using such classified substances in the consumer products they manufacture.

Manufacturers, importers, distributors and formulators were asked a similar question and detailed comments provided by respondents include the following.

- *"Several of our substances, which we had registered under REACH as our uses do not include biocidal products, were classified under the Biocidal Product Regulation. The original proposal under the Biocidal Products Regulation did not seem to have taken into consideration the data included in the REACH dossier. Via the REACH consortium of the respective substances, we have tried to bring these classifications in line taking into account all available data. The Biocidal Products Regulation proposal seemed to follow it on an independent process, but its classification outcome affects all uses, so it should also consider data available under REACH."*

- *"Classification of coated copper flakes and nine copper compounds under the Biocidal Products Regulation and the Plant Protection Products Regulation. Classification was overly conservative, not aligned with the previous risk assessment and did not recognize the copper rich data set".*

[119] European Commission (2014): Commission Decision of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (2014/113/EU)

[120] On 22 July 2016 the European Commission published EU Regulation 2016/1198, amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. The Regulation bans the use of MIT in cosmetic leave-on products and gives industry until 12 February 2017 to make the necessary adjustments to formulations and to withdraw non-compliant products from the market.

It was noted by some industry consultees that there is a lack of transparency in the dossiers evaluation process, and that companies would wish to be able to comment on the evaluation strategy of the RMS before the full evaluation is finished. This would allow the comments of industry to be taken into account as soon as possible and the RMS to understand clearly the use of the product, thus avoiding heavy commenting at the end of the process which results in a high workload for all parties.

Ultimately, different conclusions on classification may be reached by each authority under the respective procedures. While EFSA is obliged to apply CLP criteria in the classification of a substance, EFSA may reach a different conclusion to that taken by RAC and may not always reach the same conclusion as the RMS, although as noted above the Agency is obliged to address such divergences. Such differences may arise from differences in the interpretation of data and differences in the data acting as the basis for the classification (e.g. due to differences in the timing of the activity). This has been identified as creating difficulties in the implementation of the Plant Protection Products Regulation, in particular where it concerns classification that would meet the cut-off criteria in Article 4 of the regulation. As noted earlier, differences in classification for plant protection product active substances compared to industrial chemicals causes confusion for industry as well as other stakeholders.

Although not related to the activities of EFSA or the Commission and the procedures for the classification of active substances, under the CLP Regulation, a manufacturer or importer must classify a mixture before it is placed on the market. This is also the case when a producer of a PPP is submitting an application for an authorisation to a Member State authority, under the Plant Protection Products Regulation. The producer of a PPP has to apply and conform to the classification procedures of the CLP Regulation. When an authority grants an authorisation for a product under the Plant Protection Products Regulation, this shall include classification. This means that authorities also draw conclusions on the classification of a plant protection product (not to be confused with the active substances) when granting an authorisation. Hence, this can (and does) result in two different classifications (one from the manufacturer/importer and one from the authority).

Plant protection product stakeholders were asked whether they have experienced cases in which there has been disagreement between the classification proposed by their company and the Member State authority for their products. All ten respondents indicated that they had experienced such cases. Respondents further noted that such differences in classifications are not limited to two different classifications for the same product. It is a more frequent occurrence whereby different Member States propose different classifications for plant protection products; this has resulted in more than three or four different classifications for the same product with the same data package across Europe. This has a significant impact for industry in providing different labels, as well as for the transport and storage of products. It is also noted that this can create confusion within the supply chain as downstream users do not understand why some products have different classifications in different countries. It should be noted though that Member Sates discuss classifications as part of the zonal evaluation, and this should limit the extent to which classifications vary within a zone; although the classification of a product may vary across zones, as appropriate to the hazards posed by the product. Further discussion is provided under Section 7.

Following on from the above, industry respondents also provided comments on actions that their company had taken to challenge a proposed classification. A respondent indicated that they frequently rebut proposed classifications where they believe that the pesticide competent authority has made an error. They indicated that this has had mixed results: sometimes authorities acknowledge their error and agreed with the company's classification, other times the Member

State has maintained their view. Where decisions were not challenged, companies were also asked why this was the case. Only two respondents answered the question but both indicated that this was due to a small chance of overturning the proposed classification. One of the respondents also noted that, ultimately, if you cannot persuade the competent authority of their error, the only available solution is legal action and this is too slow, expensive and time consuming.

While it is open to the Commission to proceed to a decision on the approval or non-approval of an active substance where, following this, a RAC opinion is then issued which states that the exclusion criteria are met and therefore that the substance no longer meets the criteria for approval, the Commission would be required to review the approval. Although no such cases have occurred yet, under Article 21 of the Plant Protection Products Regulation, the Commission may review the approval of an active substance at any time and where it concludes that the approval criteria are no longer satisfied, it shall adopt a Regulation to withdraw or amend the approval. It is also important to note that the reverse situation could occur whereby the Commission adopts a non-approval decision for an active substance based on EFSA's conclusion that the exclusion criteria are met, and the RAC subsequently concludes that the exclusion criteria are not met.

In cases where a RAC opinion is not available to EFSA during its peer review of the DAR, the RAC opinion should be at least available prior to a decision being taken by the Commission on the approval or non-approval of an active substance under the Plant Protection Products Regulation. As discussed in Case Study 3, it is suggested that not only should the RAC opinion on harmonised classification be available before the Commission takes a decision on the approval or non-approval of the active substance under the Plant Protection Products Regulation process, but the Commission should take the decision on harmonised classification first. As the decision on harmonised classification has consequences for the approval or non-approval of the active substance, and not vice versa, this should take priority. While the Commission has a deadline of 6 months from receipt of the EFSA conclusions to present the review report and a draft Regulation on the approval or non-approval of the active substance[121], there is no deadline as such for the adoption of a Regulation. The Commission has therefore been able to extend the approval period in cases of renewal, where the approval of the active substance is likely to expire before a decision has been taken on its renewal. As has been seen in the case of glyphosate, the approval period can also be extended for a further period to allow time for the RAC opinion to be made available.

In 2013 ECHA adopted Rules of Procedure for Cooperation of ECHA with EFSA[122], which define the framework of their cooperation with a view to sharing relevant information and ensuring coherence in the work of ECHA and EFSA, in particular on matters concerning substances for which an opinion has been sought in a food safety context. With regard to prevention of potential conflicts of scientific opinions, the following mechanisms were put in place:

- ECHA is to act proactively and on a regular basis to resolve potential sources of conflict between opinions of ECHA and EFSA (Article 2(d));
- ECHA is to identify substances that are, or are likely to be, under discussion in both ECHA and EFSA by exchanging relevant information (Article 4(1));

[121] The Plant Protection Products Regulation, Article 13.

[122] ECHA (2013): Decision of the Management Board, Rules of Procedure for Cooperation of the European Chemicals Agency with the European Food Safety Authority. Available at https://echa.europa.eu/documents/10162/13608/final_mb_30_2013_rop_efsa_echa_en.pdf

- ECHA is to facilitate the participation of experts from EFSA in working groups and seek to provide an opportunity for early exchange of views between rapporteurs of its Committees and EFSA's panels (Article 4(3) and (4)); and
- When a potential conflict of opinions between ECHA and EFSA is expected or identified, the possibility of sharing data which has been used as the basis of opinions is to be considered, and where appropriate, ECHA should facilitate an analysis of the methodologies used (Article 4(5) and (6)).

Following the adoption of the Rules of Procedure, the procedural framework and the steps taken by ECHA to align the CLH process with the peer review for active substances under the Plant Protection Products Regulation were outlined in a document following the 13th Meeting of Competent Authorities for REACH and CLP (CARACAL)[123]. In this respect, it is highly desirable that the opinion on a CLH dossier for an active substance is adopted by RAC before the Commission Comitology decision on the (non-)approval of the active substance is taken.

While ECHA, EFSA and the Commission are now required to work together to resolve the conflict, there is no set procedures or timescales within which ECHA and EFSA are to submit a joint document to the Commission, or what steps the Commission will take next. This therefore leaves uncertainty for industry as to when any decision on the approval or non-approval of the active substance will be taken. Industry representatives commented that should ECHA and EFSA reach different conclusions on classification in the future, they do not want to have to go down the Article 95 route every time.

These aspects are discussed further in Case Study 3.

[123] Document CA/47/2013, 13th Meeting of Competent Authorities for REACH and CLP (CARACAL), 26 – 28 November 2013, Concerns: Alignment of the PPP approval and CLH opinion development processes.

7 Hazard Communication

7.1 Introduction

7.1.1 Summary of communication approaches

Task 2 has included a mapping of the CLP Regulation and other EU acts which contain provisions for communicating properties of concern, including substances or mixtures classified as hazardous, or which set packaging requirements. Table 2-2 (in Section 2.3) summarises the results of the mapping exercise[124]

To facilitate comparison of the hazard communication requirements under the different pieces of legislation assessed as part of the mapping exercise, a summary table has been produced which highlights the main labelling/communication requirements (see Table 7-1). It is clear from this analysis that many pieces of legislation (in particular those relating to consumer products and professional products) outline requirements for providing instructions regarding the use of different types of products. Many pieces of legislation also require the inclusion of contact details for the responsible person(s), either on the product itself or in accompanying documentation in order to ensure traceability. The labelling of warnings and precautions are also required to inform the downstream user of any risks associated with the use of a particular product and/or conditions of use in order to prevent any health impacts from the use of the products. Lists of ingredients are also required in many pieces of legislation regulating consumer and professional products, with a small number also requiring the specific labelling of allergens (including allergenic fragrances) and nanomaterials. Although there are communication requirements included in certain pieces of environmental protection and occupational health and safety legislation, these are generally more limited compared to the legislation regulating consumer and professional products. This is to be expected given that the legislation relating to consumer and professional products is designed to ensure the health and safety of (and prevent adverse impacts to) those using the regulated products, thus there is the need to provide specific labelling and traceability requirements.

From the analysis undertaken, the communication provisions outlined in the legislation with horizontal links to the CLP Regulation is considered to be, in general, coherent. Further discussion is provided in the following sections and identifies the coherence issues that have been raised during the desk-based research and consultation process.

[124] Legislation on foodstuff, feedstuff and medicinal products (except food contact materials and contaminants in food and feed) is outside the scope of the fitness check exercise. Nevertheless, any legislation with horizontal links to the CLP Regulation is included for the purpose of this mapping exercise.

Table 7-1: Summary of the main labelling/communication requirements under different pieces of legislation									
EU act	Communication requirements								
	SDS	Warnings	Precautions	List of ingredients	Names of allergens	Nanomaterials clearly labelled	Contact details of responsible person(s)	CE mark	Use instructions
Framework legislation									
Regulation (EC) 1907/2006 - the REACH Regulation	✓	-	-	-	-	-	-	-	-
Consumer products									
Regulation (EC) No 1223/2009 on cosmetic products	-	✓	✓	✓	-	✓	✓	-	✓
Directive 2009/48/EC on the safety of toys	-	✓	✓	-	✓[1]	-	✓	✓	✓
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	-	✓	✓	✓	-	-	-	-	✓
Regulation (EC) 648/2004 on detergents	-	-	✓	✓	✓[1]	-	✓	-	✓
Council Directive 75/324/EEC on aerosol dispensers	-	✓	✓	-	-	-	✓	-	✓
Regulation (EU) No 1169/2011 on the provision of food information to consumers	-	-	-	✓	✓	✓	✓	-	✓
Regulation (EC) 1333/2008 on food additives	-	✓	-	✓	-	-	✓	-	✓
Professional Products									
Regulation (EC) No 1107/2009 on plant protection products	-[8]	-	✓	✓	-	-	✓	-	✓
Regulation (EU) No 528/2012 biocidal products	✓	✓	✓	✓	-	✓	✓	-	✓
Regulation (EC) No 2003/2003 relating to fertilisers	-	-	-	✓	-	-	✓	-	-
Directive 2014/28/EU on the making available on the market and supervision of explosives for civil uses (recast)	-	-	-	-	-	-	✓	✓	✓
Directive 2013/29/EU on the harmonisation of the laws of the Member States relating to the making on the market of pyrotechnic	✓	-	-	-	-	-	✓	✓	✓

Table 7-1: Summary of the main labelling/communication requirements under different pieces of legislation									
EU act	Communication requirements								
	SDS	Warnings	Precautions	List of ingredients	Names of allergens	Nanomaterials clearly labelled	Contact details of responsible person(s)	CE mark	Use instructions
articles (recast)									
Directive 2001/82/EC on the Community code relating to veterinary medicinal products	-	✓	-	✓	-	-	✓	-	✓
Directive 2001/83/EC on the Community code relating to medicinal products for human use	-	✓	✓	✓	-	-	✓	✓	✓
Directive 98/79/EC on in vitro diagnostic medical devices	-	✓	✓	✓	-	-	✓	✓	✓
Directive 2014/68/EU on Pressure Equipment	-	✓	-	-	-	-	✓	✓	✓
Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products	✓	-	-	-	-	-	✓	✓	✓
Environmental Protection									
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	-	-	-	-	-	-	-	-	-
Directive 2008/105/EC on environmental quality standards in the field of water policy as amended by Directive 2013/39/EU	-	-	-	-	-	-	-	-	-
Decision 2015/495/EC establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC	-	-	-	-	-	-	-	-	-
Directive 2008/98 on waste[2]	-	-	-	-	-	-	-	-	-
Directive 2000/53/EC on end-of life vehicles[3]	-	-	-	-	-	-	-	-	-
Directive 2006/66/EC on batteries & accumulators[4]	-	-	-	-	-	-	-	-	✓

Table 7-1: Summary of the main labelling/communication requirements under different pieces of legislation									
EU act	Communication requirements								
	SDS	Warnings	Precautions	List of ingredients	Names of allergens	Nanomaterials clearly labelled	Contact details of responsible person(s)	CE mark	Use instructions
Regulation (EC) No 1013/2006 shipments of waste[5]	-	-	-	-	-	-	✓	-	✓
Directive 2008/68/EC on inland transport of dangerous goods[6]	-	-	-	-	-	-	-	-	-
Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (recast)[7]	✓	-	✓	-	-	-	✓	-	-
Occupational health & safety									
Directive 98/24/EC chemical agents at work	-	-	-	-	-	-	-	-	-
Directive 2004/37/EC carcinogens or mutagens at work	-	-	-	-	-	-	-	-	-
Directive 92/58/EEC on H & S signs at work	-	✓	-	-	-	-	✓	-	-

Note: SDS = Safety Data Sheet.

[1] Refers to names of allergenic fragrances.

[2] According to Article 19, hazardous waste must be labelled in accordance with the international and Community standards in force. The Directive does not set additional labelling requirements. When transported, hazardous waste must be accompanied by an identification document as per Annex IB of Regulation 1013/2006 on shipments of waste

[3] Producers must provide dismantling information for each type of new vehicle put on the market within six months after the vehicle is put on the market. This information must identify, as far as it is needed by treatment facilities in order to comply with the provisions of this Directive, the different vehicle components and materials, and the location of all hazardous substances in the vehicles (Article 8). 'Hazardous substances' are defined by reference to the CLP Regulation (Article 2).

[4] Article 21: Labelling: symbol for separate collection, capacity, appropriate use, chemical symbol of metal contained (Hg, Cd or Pb). Also, Member States shall ensure that all batteries, accumulators and battery packs are appropriately marked with the symbol shown in Annex II (regarding 'separate collection').

[5] To 'hazardous waste' the procedure of prior written notification and consent applies.

[6] Labelling requirements from: 1) Annexes A and B to the ADR; 2) RID; 3) Annexed Regulations to the AND. Member States can adopt more stringent provisions or request derogations.

[7] Chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to, the CLP Regulation, PPP Regulation or the Biocidal Products Regulation or any other relevant Union legislation.
This requirement applies unless those provisions would conflict with any specific requirements of the importing Parties or other countries. (Art. 17(1)).

[8] Although not specified within the regulation, Safety Data Sheets (SDSs) are used to communicate hazard information to downstream users.

7.1.2 Evaluation questions

Although Task 1 includes the consideration of the effectiveness and efficiency of the communication measures and tools within the CLP Regulation, further assessment is also a key element of Task 2. In this case, we consider the effectiveness, efficiency, relevance and coherence (starting with coherence) of the measures and tools both across legislation more broadly, but also in terms of how the CLP Regulation links with the communication requirements under other legislation.

Table 7-2: Evaluation questions to be addressed relating to hazard communication and labelling	
Q #	**Evaluation Question**
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.1.1.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
1.1.2	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring the efficient functioning of the single market?
1.1.2.2	Are harmonised communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
1.1.2.3	Are the information requirements on chemicals (including on e.g. chemical content, hazard, risk, use) and the availability of this information sufficiently clear to allow their harmonised application throughout the single market?
1.1.3	Does the EU legislative framework for the risk management of chemicals meet the primary objective of enhancing competitiveness and innovation?
1.1.3.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
2.1.6	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
3.1.3	To what extent do the objectives of the legislative framework for chemicals meet the need for enabling/promoting circular economy? Are there conflicting objectives and how can they be solved? Are there synergies? Which of the risk management approaches (based on generic risk consideration or specific risk assessment) is more effective and efficient in enabling/promoting circular economy?
3.2.2	To what extent are information requirements in the current legislative framework adequate to enable informed choices, promotion of safer alternatives, safe handling and use throughout the life cycle of chemicals and products/article?
4.2.2	What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

7.2 Gaps, overlaps, inconsistencies in communication obligations

Key findings

- Cosmetic Products Regulation and Regulation on the provision of food information to consumers – current definition of nanomaterials is not in line with that outlined in the Commission Recommendation (2011/696/EU) and reflects an inconsistency, which may cause confusion.
- Cosmetic Products Regulation – the lack of requirements for environmental hazard labelling is a gap.
- Cosmetic Products Regulation and the Regulation on food additives – the assessments of

substances/mixtures focuses on safe levels of exposure based on consumer use, thus exposure scenarios for professional use are considered to be inadequate or neglected. Hence, these regulations are not considered to provide sufficient protection for professional users, which is considered to be a significant issue as this is likely to result in health impacts.

- Explosives Directive – there is a lack of explicit cross reference between this Directive and the CLP Regulation that may cause confusion. However, this has not been specifically raised as an issue by stakeholders and given that explosives are classified in line with the United Nations criteria both Directive 2014/28/EU (the Explosives Directive) and the CLP Regulation and are coherent in approach, this is not considered to cause significant impacts in reality.
- Aerosol Dispensers Directive (Directive 75/324/EEC) – repetition of CLP labelling requirements in the Aerosols Directive could lead to inconsistencies if changes are made to the requirements outlined in the CLP Regulation (although the extent of the impact would depend on any changes made and the resulting inconsistencies that may be introduced).
- Plant Protection Products – the occurrence of multiple hazard classifications for the same substance can result in inconsistencies and cause confusion within the supply chain, as different safety data sheets and labels are provided with the same product in different Member States. This has potentially significant implications for downstream user understanding of (and confidence in) the hazard communication/labelling requirements. Biocidal Products Regulation – labelling requirements under this Regulation and the CLP Regulation can overlap (e.g. in the case of treated articles and requirements to have labels in national languages).
- Safety Signs at Work Directive – inconsistencies between this Directive and the CLP Regulation with regards to the use of the 'exclamation mark' symbol under the CLP Regulation (GHS07, Warning) and the 'general danger sign' in the Safety Signs at Work Directive, which can lead to confusion.
- Toy Safety Directive – concerns have been raised with regards to products covered by the Directive being exempt from the rules outlined in the Biocidal Products Regulation, thus potentially impacting the effectiveness of the legislation.
- Toy Safety Directive – no specific labelling requirements in the Toy Safety Directive with regards to communicating the hazards and risks related to the content of chemicals in toys, unless the toy is defined as a chemical toy or such labelling is included on the packaging for fragrances in olfactory board games, cosmetic kits and gustative games, thus potentially impacting the effectiveness of the legislation in informing consumers of potentially dangerous substances which may be present, especially in hidden parts of the toy.
- Toy Safety Directive – allergens are considered by some stakeholders as too softly regulated, which is impacting the effectiveness of the legislation to protect children's health and is therefore considered to be a significant issue.
- Seveso Directive – stakeholders sometimes have difficulties in obtaining trustworthy information on the substances from the supply chain and inconsistencies between classifications can lead to situations where similar establishments that handle the same substance are not covered in the same way under Seveso. The inclusion of a specific obligation for the operator to check the classification or to employ staff that are able to do so is missing and could bring some improvement in this regard.

7.2.1 Introduction

During the process of mapping the labelling and packaging requirements of the CLP Regulation and other EU acts, potential gaps, overlaps and inconsistencies were identified. In addition, as part of the consultation process, stakeholders were asked whether they have identified or experienced any issues with regard to gaps, overlaps or inconsistencies in the communication requirements outlined

in different pieces of legislation within the chemicals legislative framework. The following provides an overview of the gaps, overlaps and inconsistencies identified in relation to labelling requirements outlined in the legislation considered under the fitness check.

Respondents to the open public consultation for the chemicals fitness check generally stressed the need for a harmonised approach across the EU for the risk characterisation and labelling of chemicals (mainly mixtures). Whilst it is recognised that interpretation of EU legislation is Member State-dependent, it is suggested that the current situation of having different hazard labels across the EU for many mixtures cannot be justified. This may also create confusion for downstream users and consumers if the same product includes different labels. Several respondents also suggest that labelling requirements under different pieces of legislation (e.g. the F-gas Regulation, Annex XVII of the REACH Regulation, the Biocidal Products Regulation and the Plant Protection Products Regulation) could be better integrated to facilitate compliance.

Further details of issues raised with regard to specific pieces of legislation are outlined below.

7.2.2 Cosmetic Products Regulation

During the exercise to map the communication requirements it was identified that, whilst labelling of certain substances that 'may cause allergenic reactions' is required under the Cosmetic Products Regulation (EC) No 1223/2009), allergens are not specifically defined. Recital 49 of the Regulation indicates that:

> *"a number of substances have been identified by the SCCS as likely to cause allergic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers' attention should be drawn to these. This information should improve the diagnosis of contact allergies among customers and should enable them to avoid the use of cosmetic products which they do not tolerate. For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as a ban or a restriction of concentration should be considered".*

Recital 49 also states that the SCCS has identified a number of substances as 'likely to cause allergic reactions' but does not set out these criteria either. This lack of definitions could be considered a gap which may impact on the communication of chemical hazards to consumers.

There are also differences between the definition of nanomaterials in the Cosmetic Products Regulation and Commission Recommendation 2011/696/EU. Article 19 of the Cosmetic Products Regulation outlines the labelling requirements with paragraph 1 indicating that "*all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets*". The first paragraph of Article 2 of the Cosmetic Products Regulation defines nanomaterials as *"… an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100nm*". However, this differs from Article 2 of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), which states that "nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%".

Article 2(3) of the Cosmetic Products Regulation indicates that the definition of nanomaterials provided in Article 2(1) must be adapted to technical and scientific progress and to definitions subsequently agreed at international level in accordance with the regulatory procedure with scrutiny. The fact that the current definition in the Cosmetic Products Regulation is not in line with the Commission Recommendation reflects an inconsistency, which may give rise to confusion for consumers[125].

Nevertheless, the reason why there is a discrepancy between the definition in the Cosmetics Regulation 1223/2009 and the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) regarding nanomaterial definition is only historical. The Cosmetics Regulation was adopted in 2009 while the more refined definition present in the Commission Recommendation 2011/696/EU has been published in 2011. However, the nanomaterial definition is currently subject to a review by the Commission. It will be discussed together with Member States and stakeholders before implementing the review of the nanomaterial definition in Article 2(1) of the Cosmetic Products Regulation as required by Article 2(3).

As noted in Section 4, there are no requirements for environmental hazard labelling in the Cosmetic Products Regulation, which is perceived by some as a gap. Cosmetics Europe (an EU-level industry association representing stakeholders in the cosmetics industry) argues that, under the Cosmetic Products Regulation, labelling is aimed at end users and is based on potential risks to human health, which may be connected with the use of cosmetic products. On-pack environmental hazard labelling for cosmetic products would, according to the association, be inconsistent with the risk-based information related to human health. The environmental safety of substances used in cosmetic products is assessed under the REACH Regulation and risk management measures must be identified and communicated through the supply chain, via the extended safety data sheets (eSDS) of substances. This is the reason that the Cosmetic Products Regulation expressly excludes environmental concerns in its preamble (recital 5) stating that "*the environmental concerns that substances used in cosmetic products may raise are considered through the application of [the REACH Regulation], which enables the assessment of environmental safety in a cross-sectoral manner*". However, it could also be argued that the REACH Regulation does not address the environmental hazards of mixtures, and cosmetics products are mixtures; as a result, there is a gap in both hazard assessment and hazard communication.

In response to consultation, a Member State authority has indicated that there can be communication issues in cases where legislation exempts certain types of chemicals from labelling according to the CLP Regulation (e.g. cosmetics and food additives). The supplier also does not have to provide a SDS for these chemicals according to the REACH Regulation. This can create challenges (under OSH legislation) for employers when they undertake a workplace assessment as a label and SDS are not required, thus they do not have all the necessary information available to them.

Another challenge identified by Member State authorities is that certain legislation is primarily directed to consumers (e.g. the rules relating to cosmetics and food additives). The assessment of substances/mixtures focuses on safe levels of exposure based on consumer use, thus exposure scenarios for professional use are considered to be inadequate or neglected. These issues can result in the false perception of employers/professional users that a substance/mixture is safe to use in the work environment (under the OSH legislation) because the substance/mixture is not considered

[125] Some stakeholders argue that lack of an explicit reference to nanomaterials in the CLP Regulation may be considered a gap, however, the CLP Regulation applies to all substances and mixtures, regardless whether they are in nanoform or not. This issue is also discussed in Section 3 of the Task 1 report.

hazardous under other legislation (e.g. waste legislation or cosmetics legislation). It is therefore the view of the Member State authority that cosmetics and food additives should be labelled according to the CLP Regulation as the Cosmetic Products Regulation and Regulation on food additives are not considered to provide sufficient protection for professional users[126]. This has potentially significant implications for people using cosmetic products in a professional context as prolonged use of certain products in a work environment could result in health impacts.

7.2.3 Provision of food information to consumers

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs whilst ensuring the smooth functioning of the internal market. As in the case of the Cosmetic Products Regulation, this Regulation requires products to include information on the presence of certain substances, listed in Annex II, that may cause allergies or intolerances on the label; again, however, allergens are not specifically defined in the Regulation.

Recital 24 of the Regulation states that:

> *"when used in the production of foods and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people, and some of those allergies or intolerances constitute a danger to the health of those concerned. It is important that information on the presence of food additives, processing aids and other substances or products with a scientifically proven allergenic or intolerance effect should be given to enable consumers, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them".*

Information on the presence of certain substances, listed in Annex II of the Regulation, that are causing allergies or intolerances must be provided on the label. In essence, this means that allergens for the purposes of the Regulation are those that are identified by the Commission and included in Annex II. However, as the criteria for allergenicity are not defined in the Regulation, stakeholders have indicated that this is a legislative gap. It is understood that the Commission is currently updating previous guidance on allergen labelling, and this may address the gap.

Article 18 of the Regulation indicates that all ingredients present in the form of engineered nanomaterials should be clearly indicated in the list of ingredients, with the names of such ingredients followed by the word 'nano'. However, there are differences in the definition of nanomaterials between the CLP Regulation and the Regulation on the provision of food information to consumers[127]. Article 2(2) of the Regulation on the provision of food information to consumers

[126] This issue is also discussed in Section 4, as Member State authorities have noted that there is gap with regards to the information on chemicals used in cosmetics products (covered by the Cosmetic Products Regulation). Currently, it is not possible for EU authorities to obtain information on the use of ingredients in cosmetics and it is also suggested that the Cosmetic Products Regulation should take into account professional use of cosmetics.

[127] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the

defines engineered nanomaterials as *"… any intentionally produced material that has one or more dimensions of the order of 100nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions or the order of 100nm or less, including structures, agglomerates or aggregates, which may have a size above the order or 100nm but retain properties that are characteristic of the nanoscale*". However, this differs from Article 2 of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), which states that "*nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%".* Although not raised as a specific concern by stakeholders, the difference in definitions between the regulations can be considered an inconsistency that may cause confusion.

7.2.4 Explosives Directive and Pyrotechnic Articles Directive

Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast) (the Explosives Directive) sets out rules for the placing on the market and supervision of explosives for civil uses in the EU.

Neither the CLP Regulation nor the Explosives Directive include explicit cross-references to each other, and yet Annex I to the CLP Regulation contains labelling and packaging requirements related to explosives placed on the market. Moreover, Directive 2014/28/EU defines explosives as the materials and articles considered to be explosives as defined by the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations, effectively providing that the test methods provided for in those recommendations are used to determine the explosive properties of materials and articles. The CLP Regulation, on the other hand, makes repeated reference to the same test methods in the context of the classification of all physical hazards, including not only explosiveness, but also e.g. flammability. These factors illustrate that there is an implicit link between the Explosives Directive and the CLP Regulation, but due to the lack of explicit cross-references this may not be clear to all stakeholders. However, this has not been specifically raised by stakeholders as an issue and given that explosives are classified in line with the United Nations criteria both the Explosives Directive and the CLP Regulation and are coherent in their approach, this is not considered to cause significant impacts in reality.

Information provided by one Member State authority also indicates that definitions included under different pieces of legislation can have different meanings. As an example, the definition of 'placing on the market' is somewhat different in the Explosives Directive (2014/28/EU) and the Pyrotechnic Articles Directive (2013/29/EU) as compared to the CLP Regulation, which may result in some confusion as regards who has the obligation to label and may result in increased burden for economic operators in identifying who has ultimate responsibility. It should be noted that the definition used in Explosives Directive and Pyrotechnic Articles Directive is aligned to the horizontal,

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European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

harmonised definition used in the New Legislative Framework and is broadly used in recent product legislation. While this inconsistency is an issue that has been raised by a single Member State authority (and hence may not be a significant issue in this particular context), it is considered important that the definitions and concepts are applied consistently across legislation within the existing chemicals legislative framework and when new legislation is introduced to ensure that all stakeholders are clear with regards to their meanings.

One Member State authority has noted that there are much more detailed requirements on the safe use of pyrotechnics in the Pyrotechnic Articles Directive, which makes the precautionary (P) statements, according to the CLP Regulation (which are less informative) superfluous. It is therefore the view of the authority that consideration should be given to waiving of the P-statements according to the CLP Regulation for pyrotechnic articles, given the more informative labelling requirements that apply under the Pyrotechnic Articles Directive. However, it should be noted that Article 23 of the CLP Regulation outlines derogations from labelling requirements for special cases and indicates that "*specific provisions on labelling laid down in section 1.3 of Annex I shall apply in respect of the following: … (e) explosives, as referred to in section 2.1 of Annex I, placed on the market with a view to obtaining an explosive or pyrotechnic effect*". Section 1.3.5 of Annex I states that "*explosives, as referred to in section 2.1, placed on the market with a view to obtaining an explosive or pyrotechnic effect shall be labelled and packaged in accordance with the requirements of explosives only*". This indicates that labelling requirements of explosives only need to be applied to pyrotechnic articles; therefore, additional labelling requirements under the CLP Regulation are not required. Hence, this is not considered to be a significant issue in reality.

7.2.5 Aerosol Dispensers Directive

As part of the consultation process, industry stakeholders and a Member State authority highlighted an overlap of requirements under the Aerosol Dispensers Directive[128] and the CLP Regulation. Currently, the labelling requirements according to the CLP Regulation are repeated in the Aerosol Dispensers Directive. This is considered unnecessary and may lead to inconsistencies if changes are made to the requirements outlined in the CLP Regulation. Therefore, it is suggested that the repetition of the CLP Requirements should be deleted in the Aerosol Dispensers Directive and replaced by a simple reference to the CLP Regulation if deemed appropriate. The potential for the development of inconsistencies between the Aerosol Dispensers Directive and the CLP Regulation suggest that this could cause a potentially significant issue in the future (although the extent of the impact would depend on any changes made and the resulting inconsistencies that may be introduced).

7.2.6 Plant Protection Products Regulation

Issues have also been raised with regard to different classifications of the same PPP resulting in the need for different hazard labels. Under the CLP Regulation, a manufacturer or importer must classify a mixture before it is placed on the market. This is also the case when the producer of a PPP is submitting an application for an authorisation to a Member State authority under the Plant Protection Products Regulation. The producer of the PPP must apply and conform to the classification procedures of the CLP Regulation.

[128] Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (75/324/EEC)

When an authority grants an authorisation under the Plant Protection Products Regulation, this shall include classification. This means that authorities also draw conclusions on the classification of a PPP when granting an authorisation. As discussed in the Task 3 report, almost all PPP producers responding to the targeted consultation (representing most of the large manufacturers) indicated that they have experienced cases where there was disagreement between the classification proposed by their company and the Member State authority responsible for granting an authorisation (although this may not be completely unexpected given the differing views/diverging perspectives of industry and Member State authorities).

A number of respondents noted that this is a relatively common occurrence and that there are often differences in the classification proposals made by different Member State authorities. This therefore results in multiple classifications for the same product (rather than a single harmonised classification); with one company indicating that around 40% of their product portfolio has more than two different classifications following evaluation by different Member States. This situation results in inconsistencies in the classification of PPPs and also causes confusion within the supply chain, as different SDS and labels are provided with the same product in different Member States.

PPP manufacturers have also indicated that there have been cases where they have had to provide explanations to customers who cannot understand why the same product has different hazard classifications. Ultimately, this may lead downstream users to consider the labelling of products to be unreliable, thus reducing their confidence in the system (and potentially affecting perceptions of the legislative framework, Member State competent authorities and the PPP industry). To avoid confusion, industry strongly promotes the view that there should be a single harmonised classification of hazards associated with PPP to prevent the inconsistencies that currently occur.

It should be noted that the authorisation process under the Plant Protection Products Regulation is facilitated through use of a zonal system, whereby the EU is divided into three zones: 1) North, 2) Central and 3) South. Member State authorities assess applications for PPP authorisation on behalf of other countries in their zone, but for some uses (greenhouse uses, post-harvest treatments, treatment of empty storage rooms or containers and seed treatments) the EU is considered a single zone and a single Member State authority can evaluate a PPP on behalf of the entire EU[129].

Therefore, in these cases evaluation of the PPP authorisation application is undertaken by a single Member State authority for the whole of the EU, thus only one classification is provided (rather than potentially multiple classification proposals when different Member State authorities are involved in the authorisation process). This indicates that differences in classification proposals will not occur in all situations.

7.2.7 Biocidal Products Regulation

From the viewpoint of the German Chemical Industry Association (VCI), there are overlaps between several parts of the CLP Regulation and the Biocidal Products Regulation that cause problems in practice (VCI, 2016)[130]. A key aim of the CLP Regulation is that it *"should ensure a high level of*

[129] European Commission (2015): Procedure to apply for authorisation of a PPP. Available at: http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure/index_en.htm

[130] VCI (2016): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation – Issues and examples from the viewpoint of Verband der Chemischen Industrie (VCI, the association of the German chemical industry) (English translation).

protection of human health and the environment". The Biocidal Products Regulation is also based around this fundamental aim.

According to the VCI, the introduction of additional labelling, exclusion criteria or extra conditions and rules leads to:

1) a very large number of products that require labelling, and
2) numerous products displaying a large number of labels.

From its perspective, the Commission indicates that any such requirements are aimed at providing increased transparency to consumers in receipt of the products and are aimed at both ensuring proper handling but also in creating an incentive to producers to shift towards other active substances which are not already subject to exclusion or substitution under the BPR.

VCI notes that an increase in labelling does not result in more careful handling of products that require special care by consumers and professional users. Instead, they argue that an increase in labelling is considered to result in a decrease in hazard awareness, with all products being deemed equally 'hazardous'. Therefore, it is the view of the VCI that the fundamental aim of the CLP Regulation (of protecting human health and the environment) can be eroded very easily by the rising number of labels/labelling requirements. Instead, the association suggests that it should be determined in each individual case which labelling items are conducive to improving the level of protection. This should include the question of whether the substances or mixtures are used industrially or by the wider public (VCI, 2016).

The VCI has also indicated that the application of additional labelling items or adaptation of existing ones, that become necessary due to changes in the classification of active substances, involves much work and cost for industry. Harmonisation of classification and labelling across the various EU Member States and the use of one label for products with identical specifications, irrespective of their intended (biocidal) use, would keep such work and cost as low as possible and enable comparability of products manufactured inside the EU and imported treated articles (VCI, 2016).

Respondents to the OPC also indicated that labelling requirements under the Biocidal Products Regulation and the CLP Regulation overlap and are sometimes contradictory. The example of treated articles was given. Respondents noted that, in the case of the labelling of treated articles (mixtures and articles), where an active substance meets certain classification criteria (e.g. respiratory sensitiser, two PBT criteria), special rules for labelling are included in the implementing regulation for the approval of the active substance. These rules do not depend on the concentration of the active substance in the treated article. For mixtures, this means a tightening of existing labelling provisions under the CLP Regulation. For example, the special rules for the approval of Iodopropynyl Butyl Carbamate (IPBC) as preservative demand information on the risk of skin sensitisation on the label of articles treated with IPBC, regardless of the concentration of IPBC in the end product. This is just one of many examples (VCI, 2016).

Other respondents to the OPC noted that Article 69(1) of the Biocidal Products Regulation refers to the provisions of the CLP Regulation, including requirements to have labels in the national languages (Article 17(2) of the CLP Regulation). However, the same issue is dealt with in Article 69(3) of the Biocidal Products Regulation giving Member States an option to adopt such provisions in their national legislation and thus creating a possible overlap.

An industry respondent to the Open Public Consultation suggested that there are inconsistencies in the labelling requirements under the Biocidal Products Regulation, the Detergents Regulation and the CLP Regulation with regards to the labelling of preservatives. This can be confusing for economic

operators that are required to meet the obligations of these regulations, however, as this issue was only raised by a single stakeholder the associated impact is considered to be relatively small. Information obtained from Case Study 9 suggests that because multiple regulations can apply to the same product, this can result in dual labelling (i.e. listing of the same ingredient twice), which adds complexity and is potentially confusing for consumers and other professional users.

7.2.8 Feed Additives

One respondent to the OPC indicated that inconsistencies exist whereby it is EFSA and the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) who deliver the re-authorisation of a feed additive and use safety-related sentences that are similar to those outlined in the CLP Regulation but which are not based on the CLP criteria. The stakeholder reported that this leads to labelling difficulties, especially for feed additives, many of which are chemicals. However, although this has been identified as an issue it has not been possible to determine its significance.

7.2.9 Safety Signs at Work

Council Directive 92/58/EEC on the minimum requirements for the provision of safety and/or health at work[131] (the Safety Signs at Work Directive) lays down the minimum requirements for the provision of safety and/or health signs at work. Some respondents to the OPC considered there to be inconsistencies between this Directive and the CLP Regulation with regard to the use of the 'exclamation mark' symbol under the CLP Regulation (GHS07, Warning) and the 'general danger sign' in the Safety Signs at Work Directive. They note that this can lead to confusion. As can be seen in Figure 7-1, both symbols employ the exclamation mark. The 'general danger' sign in the Safety Signs at Work Directive can also be confused with the 'moderate hazards' CLP pictogram, which is significant as the Safety Signs at Work Directive allows the use of either the Safety Signs at Work pictogram or the CLP pictogram where signage is needed.

Figure 7-1: Left to right - CLP pictogram GHS07 (warning toxic cat. 4, irritant cat. 2 or 3, lower systematic health hazards) and Safety Signs at Work pictogram (general danger)

In addition, under the CLP Regulation, GHS07 is accompanied by the signal word 'Warning', which is a lesser level of severity to the CLP signal word 'Danger'. It is the view of a respondent that it would be much clearer if the Safety Signs at Work pictogram was renamed 'general warning', or a different sign was designed to denote 'general danger'.

[131] The ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC.

This confusion is additionally significant because, while for stores containing only one chemical the appropriate sign either from Annex II of the Safety Signs at Work Directive (if appropriate) or the appropriate CLP pictogram should be used, for stores containing mixed chemicals the requirement is to use the Safety Signs at Work Directive's 'general danger' sign. Therefore, both stores with only chemicals classified with hazards covered by GHS07 and those with mixed chemicals, possibly including more hazardous chemicals, would have signs with an exclamation mark.

It is suggested that, given the wide range of contexts and levels of hazard covered by the use of 'exclamation mark' symbols (and in comparison with the 'moderate' level of hazard represented by the CLP GHS07 pictogram), it does not seem appropriate to designate the Safety Signs at Work sign as representing 'general danger'. Instead, signs employing an exclamation mark may be better considered to constitute an alert, informing users to 'take care' rather than specifying a level of hazard, especially as this currently differs between the Safety Signs at Work Directive and the CLP Regulation.

7.2.10 Toy Safety Directive

In the case of the Toy Safety Directive (Directive 2009/48/EC), concerns have been raised with regard to products covered by the Directive being exempt from the rules outlined in the Biocidal Products Regulation. One Member State authority has indicated that this means that toy products may contain biocides but do not need to declare these ingredients. It is the view of the authority that this needs to be changed so that there is at least a requirement to allow only approved biocides under the Biocidal Products Regulation to be used. Also, if a biocide is used, this should be labelled on the product. A Member State competent authority responding to the chemical safety assessment and labelling of toys case study (Case Study 8) also raises the same issue, noting that toys containing biocides (e.g. toy tents with an antibacterial or mosquito-repellent surface) are not being labelled with the substance(s) that has/have been applied.

In addition, legal analysis indicates that there are no specific labelling requirements in the Toy Safety Directive for communicating the hazards and risks related to the content of chemicals in toys, unless the toy is defined as a chemical toy or such labelling is included on the packaging for fragrances in olfactory board games, cosmetic kits and gustative games (in line with Paragraphs 4 and 10 of Annex V of the Toy Safety Directive). This has been highlighted by a Member State competent authority and also raised as an issue by a Public Health Authority, which has indicated that the labelling requirements are not currently precise enough with regard to the presence of potentially dangerous substances which may be present, especially in hidden parts of the toy. Another Member State competent authority has pointed out that allergens, other than fragrances, are not covered by the labelling requirements of the Directive.

Information obtained from the evaluation of the Toy Safety Directive undertaken by Technopolis *et al.* in 2015 indicates that allergens are an issue considered as too softly regulated (expressed as a concern by three Member States and a consumer representative). The issue identified in the evaluation is that the list of sensitising fragrances set out in the Toy Safety Directive is "*clearly outdated*", while all 129 contact allergens identified by the SCCS[132] should be banned from toys (Technopolis *et al.*, 2015).

[132] SCCS (2011): Opinion on fragrance allergens in cosmetic products. Available at: http://ec.europaeuropa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

As part of the consultation process undertaken for the fitness check study, stakeholders were specifically asked whether the requirements (including those related to labelling) laid down in the Toy Safety Directive with regards to allergenic fragrances are appropriate for ensuring adequate protection of children's health. One consumer association responded that the list of allergenic fragrances included in Annex II, Part III of the Toy Safety Directive is outdated and should be updated in line with the findings of the SCCS in its opinion of fragrance allergens in cosmetic products (SCCS/1459/11, 2011)[133]. This opinion concluded that many more fragrance substances (129 instead of the 26 substances identified previously and subject to labelling requirements if exceeding 0.001%/0.1% according to the Cosmetic Products Regulation) have been shown to be human sensitisers and consequently need to be subject to additional labelling provisions in the Cosmetic Products Regulation. Hence, an additional 103 substances should be subject to regulatory provisions for toys (as the list in the Toy Safety Directive is based on the Cosmetic Products Regulation) either in the form of a ban or labelling provisions.

One Member State competent authority has indicated though that, in its view, the requirements laid down in the Toy Safety Directive with regard to allergenic fragrances are not appropriate for ensuring adequate protection of children's health. Children playing with scented toys can be exposed to allergens as a result of long term skin contact. Annex II, Part III, Paragraph 11 of the Toy Safety Directive provides a list of allergenic fragrances that should not be contained in toys unless technically unavoidable under good manufacturing practice and must not exceed 100 mg/kg. Paragraph 11 also provides a list of 11 allergenic fragrances that should be affixed on a product label, on the packaging or in an accompanying leaflet if added to a toy (or associated components) in concentrations exceeding 100 mg/kg. However, these do not correspond to the limits set out in the Cosmetic Products Regulation for leave-on products (long term skin contact) in which a declaration level of 10 mg/kg (0.001%) is stipulated. It is the view of the authority that the declaration level for leave-on products given in the Cosmetic Products Regulation should be adopted in the Toy Safety Directive.

Another Member State competent authority was of the view that there should be a general ban on the use of fragrances in toy products, given that these can be allergenic. Allergies towards fragrances are one of the most common reasons for contact allergies, and in the authority's opinion fragrances are not necessary and should not be used in toy products. As an alternative to a complete ban on all fragrances used in toys, it is suggested that they should be labelled with either the specific chemical name of the fragrance or a label "*containing fragrances*", so that consumers have an opportunity to avoid the toys.

The evaluation of the Toy Safety Directive undertaken by Technopolis *et al.* in 2015 indicates that three Member States and a consumer representative consider the requirements regarding allergenic fragrances outlined in the Directive to be deficient, as in some cases only labelling is required, and sensitisers other than allergenic fragrances are not covered (Technopolis *et al.*, 2015). In addition, consumer associations and six Member States expressed concerns as regards the regulation of preservatives under the Toy Safety Directive. This is further confirmed in a study by the Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection that states that "*no specific requirements for preservatives are set in the new Toy Safety Directive – except for preservatives classified as CMRs and except for the general statement that chemical substances used in toys must*

[133] SCCS (2011): Opinion on fragrance allergens in cosmetic products. Scientific Committee on Consumer Safety (SCCS). Available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf

not present a risk of adverse effects to human health"[134] (Technopolis *et al.*, 2015). Consultation with a Member State competent authority (as part of this fitness check study) has identified that other allergens (i.e. those that are not fragrances) are not included within the Toy Safety Directive, and there are no labelling requirements for these (e.g. allergenic preservatives). It is therefore suggested that other allergens (in addition to allergenic fragrances) should be included within the Directive to ensure adequate protection of consumers' health.

However, other Member State competent authorities and representatives from industry associations consider the requirements (including those related to labelling) laid down in the Toy Safety Directive with regards to allergenic fragrances to be appropriate for ensuring adequate protection of children's health. One industry association has noted that, compared with the standards for cosmetics, the Toy Safety Directive offers clear protection of children's health at a very low exposure potential and that International Fragrance Association (IFRA) Standards and all recommendations for prohibitions are followed. In addition, the labelling requirement outlined in the Toy Safety Directive with regard to the use of allergenic fragrances above 100 mg/kg is clearly regulated and constitutes a high level of protection for children.

Given the findings of SCCS which concluded that many more fragrance substances have been shown to be human sensitisers and consequently need to be subject to additional labelling provisions in the Cosmetic Products Regulation, it seems appropriate that these are subject to regulatory provisions for toys (as the list in the Toy Safety Directive is based on the Cosmetic Products Regulation) in order to limit the associated health impacts to children.

7.2.11 Seveso Directive

Changes in the classification of substances can result in changes in the status of establishments under the Seveso III Directive. Consultation undertaken as part of Case Study 13 indicates that stakeholders sometimes have difficulties in obtaining trustworthy information on the substances from the supply chain. It was reported that inconsistencies between classifications can lead to situations where similar establishments that handle the same substance are not covered in the same way under Seveso. One establishment could be covered because the operator has received a relevant classification, while another operator did not receive such a classification for the same substance and is therefore not covered. A specific obligation for the operator to check the classification, or to employ staff that are able to do so, is missing and could bring some improvement in this regard. There are also some difficulties for market actors to determine the correct tonnages if several substances or mixtures are handled within the establishment. Member States provide support for this situation, e.g. in the form of simple excel sheets that cover the formulas from Seveso to make calculations easier.

It is also noted that even if operators do check the classifications, they struggle to find the correct information. The main source for classification information is the CLI database established by Article 42 of the CLP Regulation (see Section 6 of the Task 1 Report). Links to Seveso are only included for harmonised classifications and users do not get reliable information due to the range of notified classifications.

[134] Bmask (2013): Chemical Requirements for toys, Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection. Available at: http://www.verbraucherrat.at/content/01-news/10-2013-29-chemische-anforderungen-spielzeug/chemicalsproducts4.pdf

7.2.12 Other products

Animal skincare products are products that are applied on the skin or fur, in the ear or around the eyes of animals. Animal skincare products do not fall within the scope of the Cosmetic Products Regulation nor the Veterinary Medicinal Products Directive. The Cosmetic Products Regulation only applies to humans, while the Veterinary Medicinal Products Directive only applies to products that make medicinal claims (and may therefore apply to some, but not all, animal skincare products). As a result, animal skincare products need to comply with the CLP Regulation, similarly to other chemical products. The industry association Animal Skincare Products Europe (ASPE), representing three producers, considers this to be a challenge for its members and believes that this is a legal gap for animal skincare products, as most of the substances (around 99%) within these formulations are the same substances that are used in human cosmetic products.

Because the products are not subject to the same rules, ASPE considers there to be an inconsistent treatment of the products[135]. For example, when mixtures had to comply with the CLP mixture classification rules from 1st June 2015, this included animal skincare products. In contrast, because human cosmetic products are exempted from the CLP Regulation (in accordance with Article 1(5c) of the CLP Regulation), they did not incur CLP related costs, although they will have had to meet the costs of complying with the Cosmetic Products Regulation (and are impacted by its restrictions on the use of certain classified substances). This means that animal skincare producers have had to include hazard pictograms on their product packaging when similar products for human use continued to be placed on the market without pictograms.

Nevertheless, the coverage of animal skincare products by the CLP Regulation, rather than the Cosmetic Products Regulation, can be explained by the human exposure: the products are not meant to be used on human skin, but are handled by humans in a similar fashion to detergent products, which are also subject to the CLP Regulation.

7.3 Effectiveness of hazard communication under CLP

Key findings

- In general, some CLP pictograms are considered to be poorly understood by the general public, potentially reducing the effectiveness of the legislation.
- In general, workers have a greater understanding of hazard pictograms than consumers, mainly due to the training received from employers. Also, workers in larger organisations potentially have a better understanding of hazard labels compared to those working for SMEs as they are more likely to receive adequate training. Consumers are considered to have a relatively low level of understanding of the hazard pictograms, which in some cases is attributed to the changes in labelling under CLP, which prevents differentiation between certain hazards (i.e. products may contain the same hazard labels despite the actual hazards being markedly different), leading to inflationary labelling and consumer confusion.
- Some stakeholders indicate that information requirements do not always enable consumers/downstream users to make informed choices regarding the use of certain products (e.g. lack of ingredients lists with biocidal products and detergent products).

[135] De Lespinay Y. & Grinberg M. (2016): The need for specific EU regulations dedicated to animal skincare products, Regulatory Rapporteur, 13(4). Available at: http://www.animalskincare.eu/animal-skincare/regulatory-framework/

- Not all stakeholders agree that consumers understand the additional voluntary safe use icons that are included on certain products. However, a recent study in relation to the detergents sector suggests that consumers consider the associated safe use icons to be complementary to the existing hazard information.
- Labels can become overloaded with information, which makes it difficult for downstream users to focus on the essential hazard information, thus reducing the effectiveness of hazard communication.

7.3.1 Introduction

The Globally Harmonised System (GHS) for the classification and labelling of chemicals classifies chemicals by types of hazard and sets out harmonised hazard communication instruments, including safety data sheets (SDSs – for workers) and labels (for both workers and consumers). As discussed in Section 2 of the Task 1 report, the purpose of this system is to ensure that information on physical hazards and the (eco)toxicity of chemicals is available to enhance the protection of human health and the environment during the handling, transport, storage and use of chemicals (ECHA, 2012)[136].

The GHS is not a formal treaty, but instead is a non-legally binding international agreement. Therefore countries (or trading blocs) must create local or national legislation to implement the GHS.[137] The CLP Regulation adopted the GHS throughout the EU and introduced new rules and changes to the way in which chemical hazards were communicated through the safety labels placed on chemical household products. This included changes to the pictograms and statements used for the communication of hazard information.

7.3.2 Pictograms as a communication tool

Pictograms are one of the key tools to communicate hazard information to downstream users of chemicals. Whilst an advantage of pictograms (over written messages or warnings, for example) is that they minimise the scope for misinterpretation and can be instantaneously understood, an important disadvantage is that not all pictograms are universally understood (see Case Study 9 for further details).

Under Article 34 of the CLP Regulation, ECHA was required to carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. The results were published in January 2012 in a report on the 'Communication on the safe use of chemicals' (ECHA, 2012).[138] The study was based on the findings of two key strands of research:

[136] ECHA (2012): Communication on the safe use of chemicals – Study on the Communication of information to the General Public. Submitted by the Agency according to Article 34(1) of the CLP Regulation, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf

[137] HSE (n.d.): Background: Globally Harmonised System (GHS). Available at: http://www.hse.gov.uk/chemical-classification/legal/background-directives-ghs.htm

[138] ECHA (2012): Communication on the safe use of chemicals – Study on the Communication of information to the General Public. Submitted by the Agency according to Article 34(1) of the CLP Regulation. Available at: https://echa.europa.eu/documents/10162/13559/clp_study_en.pdf

1. A Eurobarometer survey of "*Consumer understanding of labels and the safe use of chemicals*";
2. A qualitative "*In-depth study of hazard perception of household chemical products: Consequences for the communication of information on safe use to the general public*"

Results from the Eurobarometer Survey show that the public is familiar with some of the CLP hazard pictograms, but that the level of understanding (or what they perceive as their understanding) varies considerably (as presented in Table 7-3). For example, the exclamation mark is familiar to many citizens (perhaps because it is seen in a number of different situations), but is understood by few. In contrast, the environmental hazard pictogram is familiar to few, but many citizens indicate that they understand its meaning. In certain cases, such as the 'flame' pictogram, citizens may be more familiar with certain labels because the CLP pictograms are very similar to the labels used under the previous system (ECHA, 2012).

The Eurobarometer Survey also found that even in Member States where understanding of the issues surrounding chemical products is high, the comprehension of the hazard pictograms is relatively low. Also, the diversity of risk-related behaviour across EU Member States highlights the importance of adapting hazard-related communication to national audiences. This therefore emphasises the need for communicators to be aware that a message directed at citizens of one national audience can be misunderstood by citizens of another Member State where other reflexes prevail (ECHA, 2012).

Table 7-3: Familiarity and understandability of some CLP pictograms (based on results from a Eurobarometer Survey[1])

Symbol/pictogram	% of respondents that consider pictogram to be familiar/understandable
Exclamation mark: 	Familiar to 59% but understood by 11% of respondents
Flame: 	Familiar to 88% and understood by 91% of respondents
Environmental hazard: 	Familiar to 33% and understood by 76% of respondents
Health hazard:	Familiar to 20% and understood by 44% of respondents

Table 7-3: Familiarity and understandability of some CLP pictograms (based on results from a Eurobarometer Survey[1])	
Symbol/pictogram	**% of respondents that consider pictogram to be familiar/understandable**
	
Source: (ECHA, 2012) [1]European Commission (2011): Special Eurobarometer 360 – Consumer understanding of labels and the safe use of chemicals. Available at: http://www.reach.gov.it/sites/default/files/allegati/eurobarometer%20special_360_en.pdf	

The qualitative '*in-depth study of hazard perception of household chemical products: consequences for the communication of information on safe use to the general public*' that fed into ECHA's 2012 report aimed to reveal how people evaluate chemical products in the context of use and how these judgements influence safety-relevant behaviours. Similar to the Eurobarometer Survey, this study found that hazard pictograms are perceived to indicate a hazard, but the knowledge about the meaning of the various pictograms is limited. Therefore, it is the general features of the CLP hazard symbols and not their specific meaning that plays a decisive role in perceiving hazards (ECHA, 2012).

The key findings and conclusions with regard to hazard communication from ECHA's 2012 report are outlined below:

1) CLP labels (pictograms) are poorly understood by the general public with only a small number of pictograms recognised for what they actually symbolise. Thus, awareness-raising activities are needed to enhance public understanding.

2) Within the EU, perceptions of hazards pertaining to certain products and the attention paid to sources of information on their hazards differ considerably. Awareness-raising measures therefore need to address national hazard perception patterns and should be targeted at specific audiences (e.g. families, workers, school children etc.) in a differentiated manner using a variety of didactic means (e.g. webpages, leaflets, audio-visual material, etc.).

3) Most people make their choices on the safe use and storage of household chemical products on the basis of their acquaintance with the product and on other emotional drivers which rely more on experience than on information gathered from the wording or pictograms on a package. Awareness-raising activities should therefore play on emotional drivers of risk-related behaviour and give due consideration to the fact that safety behaviours are influenced by an experience-related, rather than information-based, hazard perception.

4) Due to the novelty of CLP pictograms, it is not necessarily surprising that knowledge and understanding of them is not widespread (as of 2012). Therefore, it is considered appropriate to re-visit the level of understanding on European citizens at a later date, when consumers' experience and acquaintance with the pictograms has developed.

5) Industry should be encouraged to bring product appearance and packaging more in line with the hazard information on labels, making use of behavioural drivers to amplify the label's message: Messages expressed explicitly or inherently through the appearance of a product or through its packaging override (and may counteract) messages contained in CLP labels.

For example, the shape and colour of packaging, the presence of 'innocence' related visual elements (e.g. pictures of a child or a flower), brand recognition/appreciation, the user's perception of the usefulness of the product and understanding a product to be more 'natural' than industrial are all factors that influence hazard perception. . Therefore, efforts to harmonise packaging and content-related information, taking into account the message conveyed by the hazard, could be a potential way of raising awareness and improving behaviour on the safe use of chemicals. Authorities, manufacturers and distributors should (preferably through joint public-private action) seek to promote self-regulatory steps in this regard. Ultimately, an attractive package should not result in a consumer ignoring or taking too lightly the warnings that the CLP system has made mandatory.

6) For reasons mentioned under point 4 (above) and considering that a proposed change of the CLP pictograms would require the re-negotiation of the relevant GHS provisions established in a multilateral UN context, it is not currently considered beneficial to alter the CLP labels. Instead, it is suggested that the public should be given time to get used to the new global system and that emphasis should be placed on awareness-raising and knowledge promotion.

The results of the Eurobarometer survey that fed into ECHA's 2012 Report indicate that the levels of understanding of the risks related to chemical products differ considerably between Member States. The results also suggest that there is generally low consumer understanding of the safety measures that need to be taken when using chemical products and that most respondents feel only moderately informed or not well informed about the hazards associated with chemical products.

7.3.3 Understanding of CLP labelling information

7.3.3.1 Assessment for this study

Whilst the ECHA study provides a useful insight into consumers' understanding of CLP hazard labels, it is recognised that the surveys used to support the study were undertaken only a short time (around one year) after the CLP pictograms were introduced. As a result, they only provide a first indication of the levels of awareness and understanding of the CLP labels. Of more relevance to this evaluation is the degree to which consumer understanding has changed over the last few years in terms of its effectiveness, and hence the relevance of CLP pictograms and hazard and precautionary statements.

Case Study 9 has examined in detail the issue of consumer understanding of CLP pictograms and hazard and precautionary statements. As part of the consultation process undertaken for this study, stakeholders were asked to provide their views on whether the communication requirements outlined in the legislation considered under this Task are understandable from the perspective of downstream users. The purpose of this was to determine which aspects of the legislation (with horizontal links to the CLP Regulation) are effective at communicating the hazard information associated with the use of chemicals in different products and which aspects are less effective. Where appropriate, respondents were also asked to provide recommendations on ways to potentially improve the effectiveness and efficiency of the communication procedures to ensure that consumers and professional users understand the hazards associated with the use of different products.

The results of the consultation and subsequent analysis are provided in the sections that follow.

7.3.3.2 CLP pictograms and labels

Member State authorities were asked whether the labelling requirements outlined in the CLP Regulation and other legislation (such as the Plant Protection Products Regulation, Detergents Regulation, Biocidal Products Regulation, Aerosol Dispensers Directive, etc.) allow for appropriate communication of hazards to downstream users. Of the 14 Member State authorities that responded to this specific question, exactly half (i.e. seven) indicated that consumers do understand the CLP pictograms and information provided on labels regarding the safe use of chemicals. Four authorities disagreed, whilst three neither agreed nor disagreed. However, the majority of Member State authorities (nine out of 14, or 64% of respondents) considered some of the CLP hazard pictograms to be misrepresentative or misleading of the actual hazard. The majority of Member State authority respondents (10 out of 14, or 71%) were also of the view that consumers generally do not look beyond the label for hazard information and information on safe use. This further highlights the importance of product labels and ensuring that the hazard information on these is clear and understandable so as to prevent misinterpretation and potential health issues for consumers through misuse.

As part of the targeted consultation process, stakeholders within the detergents sector were asked about the extent to which they agreed or disagreed with a series of statements regarding the current labelling system. All seven large detergent manufacturers that provided a response indicated that they disagree that consumers understand the CLP pictograms (with four respondents (57%) indicating that they disagree and three respondents (43%) indicating that they strongly disagree). All seven of these respondents were of the view that some of the CLP hazard pictograms are misleading or misrepresentative of the actual hazard. Six of the seven (86%) also disagreed that the information currently required to be included on labels is necessary and appropriate and the majority (six of seven) agreed that a reduction in labelling requirements would ensure that the most important hazard information was communicated to users whether on the label or using other methods. Six of the seven respondents also disagreed that the labelling requirements under the CLP Regulation enable a sufficient level of distinction to be made as to the hazards of different products. Four of the seven respondents indicated that they agree that consumers would not look beyond the label for hazard information and information on safe use, thus further highlighting the need to ensure that information included on product labels is clear and understandable.

Information obtained from detergent sector national associations indicates that eight of the nine (89%) responding associations also disagreed that consumers understand the CLP pictograms (with seven respondents (78%) indicating that they disagree and one respondent strongly disagreeing). As is the view of the large companies, the majority of respondents from national associations agreed that some of the CLP hazard pictograms are misleading. The majority of national associations disagreed that the information currently required on labels is necessary and appropriate and agree that a reduction in labelling requirements would ensure that the most important hazard information is communicated to users, whether on the label or using other methods. Eight of the nine (89%) associations disagreed that the labelling requirements under the CLP Regulation enable a sufficient level of distinction to be made as to the hazards of different products. When asked whether they agree/disagree that consumers would not look beyond the label for hazard information and information on safe use, the majority of national associations did not provide a definitive response (indicating that they neither agree nor disagree).

Responses received from producers of PPPs to the targeted consultation indicate that almost half (4 out of 10) believe that consumers do not understand CLP pictograms. The remainder stated either that consumers do understand CLP pictograms, or did not provide a definitive answer to this question. Comments received from other economic operators (manufacturers, formulators, importers and distributors) also indicate that some consider CLP pictograms to be unclear and confusing from the perspective of consumers, thus hampering understanding. This is in contrast to

the views of the majority of Member State authority respondents. However, there is general agreement between Member State authorities, PPP manufacturers, detergent manufacturers and national associations and other economic operators that some of the CLP hazard pictograms are misrepresentative or misleading of the actual hazard.

Information received from consultation indicates that a Member State authority[139] undertook an assessment of consumers' understanding of CLP hazard labelling and their behaviour with regard to checking hazard information, with a focus on household products, as part of a consumer awareness raising campaign in 2015. The results indicated that 82% of consumers were aware that household products can be hazardous to human health and the environment. 63% of consumers claimed to know how to find out whether a product is hazardous and 57% often/frequently/always check the hazard labelling of household products. However, only 6% were aware of the transition to a new labelling system (CLP) and 28% knew that the new pictograms consist of a white square with red frame and black symbol.

Research undertaken by another Member State authority[140] indicates that the clarity of the new CLP pictograms was relatively low, especially for those pictograms that were completely new (e.g. GHS04, GHS07 and GHS08 – see Figure 7-3). The research revealed that the GHS08 pictogram was least understood by consumers.

Qualitative research based on a small-scale survey conducted by an industry association indicated that consumers could not distinguish relative risk indicated by different pictograms (e.g. the exclamation mark as opposed to the corrosivity pictogram). It also suggested that few consumers read the labels, in particular for products that they are familiar with (AISE, 2016)[141].

Figure 7-2: CLP pictograms – left to right: GHS04 (warning compressed gas), GHS07 (warning toxic cat. 4, irritant cat. 2 or 3, lower systematic health hazards) and GHS08 (danger or warning systematic health hazards)

Information gathered during the consultation for the present Fitness Check corroborates this finding. For instance, one Member State authority noted that some hazard pictograms may be confusing for the general public, in particular GHS08 (serious health hazard symbol) as, in the authority's view, the meaning of this symbol is not intuitive. Responses received from the SME panel also suggest that

[139] Information received from the Danish Environmental Protection Agency.

[140] Information received from the Belgian Competent Authority for CLP.

[141] AISE (2016): Safety Information on Household Products. Available at: www.aise.eu/documents/document/20161012132913-resuls_quali_research_.pdf

the GHS08 is not well understood by consumers/downstream users. Information received from the Consortium of Local Education Authorities for the Provision of Science Services (CLEAPSS) suggests that there is widespread perception that GHS08 only refers to carcinogenicity, whereas in fact it refers to all serious health hazards. Consumers' apparent lack of understanding of certain hazard pictograms is a significant issue as these are an important tool for communicating the hazards associated with the use of certain products. Misunderstanding of their meaning may lead to the inappropriate use of hazardous products, thus potentially resulting in detrimental impacts to human health and/or the environment.

Member State authorities were also asked whether labels are clear from the perspective of downstream users and workers. The majority indicated that most large employers and their employees have a good understanding of the classification and labelling data that they receive from their suppliers and use this effectively (with eight of 13 respondents indicating that they have a very clear or clear understanding of the information). Although, in general, a similar view was held with regard to small and medium sized employers' understanding of the classification and labelling data that they receive, eight Member State authorities (from a total of 14) considered small and medium sized employers to have a 'clear' or 'somewhat clear' understanding of the classification and labelling data that they receive from their suppliers respectively.

A workers organisation noted that some of the CLP hazard pictograms cover different hazards (GHS07, the exclamation mark covers both acute toxicity and hazardous to the ozone layer) and this can be difficult to understand. The respondent also suggested that for Specific Target Organ Toxicity (STOT) classification the target organ(s) should always be communicated.

During the OPC, stakeholders were asked to indicate the extent to which communication of hazards to workers and consumers is effective. The information obtained indicates that the majority of respondents consider the CLP labels to be reasonably effective in communicating hazards to workers, with these considered to be most effective by public authorities followed by other stakeholders (e.g. NGOs, consumer associations, trade associations etc.), industry and citizens. The results of the OPC analysis indicate responses from Group 1 (citizens) result in a weighted score of 3 with the most common response (32% or 7 of 22) being a score of 4 (with a score of 1 indicating that hazard communication is ineffective and a score of 5 indicating that hazard communication is very effective). This therefore, suggests that citizens responding to the OPC are of the view that CLP labels are moderately effective at communicating hazard information to workers (further details are provided in Section 3.25 of the Task 4 Report). In general, it would appear that respondents consider CLP labels to be less effective at communicating hazard information to consumers compared to workers, with the lowest average ranking given by the citizens stakeholder group (compared to industry, public authority and other stakeholders (e.g. NGO's, consumer associations, trade associations etc.) (further details are provided in Section 3.25 of the Task 4 Report).

Table 7-4 provides the views of respondents to the SME panel questionnaire with regard to hazard communication. It indicates that the majority of SME respondents consider CLP hazard pictograms to, in general, be representative of the actual hazard and that information currently required to be included on labels is necessary and appropriate. The data show that the majority of SME respondents believe that employers and workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals. The majority of SME respondents also believe that the CLP classification of a chemical product influences the choice of employers to purchase it for use by their workers. This therefore suggests that, from the viewpoint of SMEs, CLP hazard labels are effective at communicating hazard information to employers and workers.

However, the responses received from SMEs suggest a less definitive view with regard to consumer understanding of CLP pictograms and safe use information (see Section 2.4.1 of the Task 4 Report for further details). As indicated in Table 7.4, there is disagreement between respondents in relation to whether consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (with a similar number of respondents indicating that they 'agree', 'neither agree nor disagree' and 'disagree'. However, the majority of respondents indicated that consumers generally do not look beyond the label for hazard information and information on safe use and the hazard classification of a chemical product influences consumer choice, thus highlighting the importance of hazard communication on product labels and ensuring that consumers understand this information.

Table 7-4: Number of responses and level of agreement with statements related to hazard communication measures enforced by CLP (n=147 to 199 depending on statement) – Results from the SME panel questionnaire

Impact	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Don't know
CLP hazard pictograms are generally representative of the actual hazard (n=199)	1%	11%	10%	68%	11%	0%
Employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=196)	2%	15%	18%	57%	8%	0%
The CLP classification of a chemical product influences the choice of employers to buy it for use by their workers (n=186)	4%	20%	20%	39%	17%	0%
Workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=197)	1%	16%	20%	56%	8%	0%
Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=157)	11%	30%	31%	27%	1%	0%
Consumers generally do not look beyond the label for hazard information and information on safe use (n=169)	5%	18%	14%	52%	11%	0%
The information currently required to be included on labels is necessary and appropriate (n=195)	3%	6%	15%	58%	17%	0%
The hazard classification of a chemical product influences the choice of a consumer (n=176)	5%	19%	22%	44%	10%	0%

Two NGOs (one health and one environmental) also commented on this issue, with both being of the view that consumers do not understand the CLP pictograms and hazard statements. Both organisations considered some of the CLP hazard pictograms to be misrepresentative or misleading of the actual hazard, thereby reflecting the view held by the majority of Member State authority respondents.

During the targeted information collection exercise, worker organisations (e.g. trade unions) were asked to comment regarding employers'/workers' understanding of hazard labelling. One organisation indicated that employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (which supports the view held by the majority of respondents' to the SME panel questionnaire, presented above). However, the respondent strongly disagreed that workers receive adequate training to understand CLP pictograms and their implications for the safe use of chemicals. The respondent indicated that workers' understanding of the CLP pictograms and information provided on labels depends mainly on the level of training they receive from their employers, which, they suggest, is not always properly undertaken. The respondent also identified that there may be differences between workers within a large company versus those working in SMEs in terms of their understanding of labels on chemical products as workers within large companies are more likely to receive training compared to those in SMEs (and will therefore have a better understanding of labels (and SDS)). Another combined employers and workers organisation noted that whilst guidance is available from ECHA[142] regarding CLP pictograms, not all users are aware of its existence. Not all self-employed individuals, micro-enterprises and SMEs that work with chemicals belong to a trade association that engages with ECHA and disseminates information and advice; there is considered to be a need, therefore, for ECHA to engage more directly with individual stakeholders to increase the understanding of hazard symbols.

A number of respondents to the OPC were of the view that measures to communicate hazard and risk information to consumers are overly focussed on hazard information and not enough on safe use instructions. It was suggested that informing consumers about how to use and dispose of substances and mixtures, on the basis of their composition and exposure potential, would be more valuable than 'just' listing all ingredients and related classifications, which will result in an overload of information on labels. For workers, a combined hazard and risk communication approach was considered more appropriate because it is done in a more structured context, with appointed experts, training, etc. It was indicated that hazards and risks could be communicated better if, for example, the information in SDS or eSDS was formatted in a more user-friendly manner.

These findings are supported by the discussions held as part of the April workshop carried out to support this study. One of the discussion topics was hazard communication to downstream users. Information obtained from discussions at the workshop indicates that there is a different level of understanding of labels between workers and consumers. Workers generally seem to have a better understanding/awareness of hazard labels than consumers. This is because there is an obligation on the part of employers to train their employees on hazard communication and employees should be trained regularly to keep their knowledge up to date. Workshop participants suggested that this employer obligation to provide training is better at large companies than at SMEs and is not always enforced, which could be a point of improvement for worker communication.

It is important to note that a number of Member State authorities provide (or are in the process of developing) educational programmes for labelling and/or understanding of pictograms in order to transfer knowledge to downstream users and thus enhance the effectiveness of these hazard

[142] ECHA (n.d.): CLP Pictograms. Available at: https://echa.europa.eu/chemicals-in-our-life/clp-pictograms

communication provisions. Some respondents to the OPC exercise were of the view that pictograms are useful and work well in multilingual labels. However, they also noted that the new hazard pictograms are not yet well enough understood by consumers. It is therefore suggested that national authorities' awareness campaigns for consumers should be repeated/continued in order to enhance consumer understanding.

7.3.3.3 Voluntary industry icons

As part of the targeted consultation process, Member State authorities were asked whether consumers understand the additional voluntary industry icons that are included on products (e.g. cleaning products, plant protection products, biocides). The majority of respondents (9 out of 13, or 69%) did not have a definitive view; however, three indicated that consumers do not understand the meaning or role of these additional icons, with only one indicating that these are understood. One Member State authority noted that voluntary icons can be misleading and can appear at first glance to contradict the CLP pictograms. Another noted that although these can be effective at improving hazard/risk communication, large voluntary icons can divert attention away from the CLP pictograms.

Half of the PPP industry stakeholders that responded to the targeted consultation indicated that consumers do not understand the additional voluntary industry icons included on products, while the other half either provided no opinion or disagreed. One respondent agreed that consumers understand additional (detergent) safe use icons included on products better than the CLP pictograms, whilst the other respondents indicated that they neither agree nor disagree.

PPP industry stakeholders also disagreed that workers understand additional safe use icons that are included on products (e.g. cleaning products) and do not think that a reduction in labelling requirements would ensure that only the most important hazard information is communicated to users whether on the label or using other methods.

Table 7-5 provides the views of respondents to the SME panel questionnaire with regard to hazard communication (see Section 2.4.1 of the Task 4 Report for further details). This indicates that 61% of respondents either agree or strongly agree that CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals with 20% of respondents either disagreeing or strongly disagreeing and 19% of respondents neither agreeing nor disagreeing. Also, 46% of respondents to the SME panel questionnaire agree or strongly agree that workers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products) with 23% disagreeing/strongly disagreeing and 31% neither agreeing nor disagreeing, which is in contrast to the views of PPP manufacturers. In addition, 39% of respondents either disagree of strongly disagree that consumers understand the additional voluntary safe use icons that are included on certain products with 25% either agreeing or strongly agreeing and 35% neither agreeing nor disagreeing. The findings from consultation with SMEs therefore suggests that the understanding of additional voluntary safe use icons is perceived to greater among workers than consumers, which may relate to need for employers to undertake safety training.

While many respondents did not provide a definitive view (i.e. responded 'neither agree nor disagree', the Member State authorities, PPP industry respondents and SME respondents that did suggests that many are of the view that consumers do not understand the additional voluntary safe use icons that are included on certain products (e.g. detergent products), whilst there are differing views regarding whether workers understand these safe use icons.

Table 7-5: Number of responses and level of agreement with statements related to hazard communication measures enforced by CLP (n=147 to 199 depending on statement) – Results from SME panel questionnaire						
Impact	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**	**Don't know**
Workers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products) (n=171)	5%	18%	31%	39%	7%	0%
CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals (n=182)	3%	17%	19%	46%	15%	0%
Consumers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products) (n=147)	6%	33%	35%	24%	1%	0%

However, a study undertaken by AISE which looked at obtaining different stakeholders' perspectives on the effectiveness of EU labelling requirements to convey hazard and safe use information[143], indicates that AISE safe use icons were in general clearly understood by consumers, which are seen as complementary to the existing hazard information.

7.3.3.4 Amount of information

Concerns have been raised about the amount of information that is required on product labels. Certain Member State authorities believe that, in some cases, labels can become overloaded with information, which makes it difficult for downstream users to focus on the essential hazard information. Although the majority of PPP respondents (80%) considered that the information currently required to be included on labels is necessary and appropriate, most (60%) were also of the view that a reduction in labelling requirements would ensure that the most important hazard information was communicated to users whether on the label or using other methods. More than half (60%) agreed that consumers do not look beyond the label for hazard information and information on safe use.

Similarly, health and environmental NGOs were of the view that there is too much information on many consumer product labels, which may be leading to confusion. A number of national associations for the detergent sector suggested that consumers rarely read product labels with one indicating that excessive labelling (leading to 'crowded' labels) contributes to fewer consumers reading hazard labels.

AISE and a number of other respondents to the open public consultation indicated that the current CLP labels are effective tools for communicating hazards to professional users. However, they suggest that the current system is not adapted to the issues at stake when it comes to communicating hazards to consumers. Labels appear confusing, overloaded and may not provide the

[143] AISE (2016): Safety information on household products – Better Regulation and Safe Use Project (Executive Summary), Research conducted in Belgium, Poland and Spain, July 2016.

consumer with relevant and meaningful information about safe use of the product. AISE is therefore committed to participate in the development of more effective options and supports changes that will enhance consumers' perception and understanding of safety information, towards the safe use of products.

This therefore suggests that further investigation should be undertaken to identify potential ways of reducing the amount of information included on product labels to prevent over-labelling while ensuring that downstream users and consumers have sufficient information to enable safe use of products. Further details of the possible use of innovative technologies to facilitate a reduction in information contained on product labels are included in Section 7.5.2.

7.3.3.5 Inflationary labelling

Industry has raised concerns over the uncertainty that arises for private consumers due to stricter labelling of products, in particular with respect to the use of the 'corrosive symbol' instead of the familiar St Andrew's cross (see Figure 7-4 below). With the implementation of the GHS, the general concentration limits for the classification of mixtures – as regards irritant and corrosive effects on skin and eyes – were lowered considerably in the CLP Regulation (VCI, 2016)[144]. Thus, for example, for mixtures classified as Eye Dam. 1 the 'corrosive' pictogram GHS05 is assigned, while in the previous legislation (the Dangerous Preparations Directive) the St Andrew's cross would have been used (VCI, 2016). In the most extreme examples, 3% of a substance causing serious eye damage now results in the need for a 'corrosive' pictogram, whereas under the previous system even greater than 10% of a substance included in a mixture causing serious eye damage gave rise to an 'irritant' symbol. This change in the classification criteria has had a considerable impact on product labelling, especially in the cleaning products sector (EuPIA, 2015)[145].

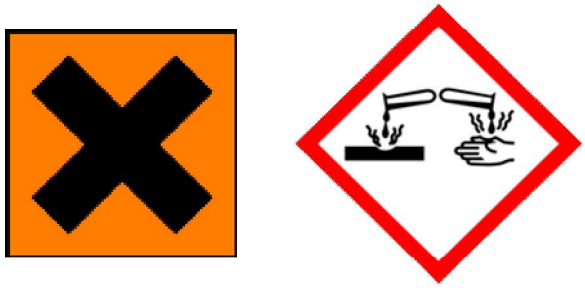

Figure 7-3: Hazard symbols (left: St Andrew's cross as used under the previous system; right: 'Corrosive' pictogram as used under the CLP Regulation)

As a consequence, mixtures that remain unchanged in their composition are now classified with a more severe hazard and labelled with the matching hazard pictograms and hazard statements. This leads to a situation where consumers assume the existence of new hazards because of more

[144] VCI (2016): Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular CLP and related legislation – Issues and examples from the viewpoint of Verband der Chemischen Industrie (VCI, the association of the German chemical industry) (English translation).

[145] EuPIA (2015): Customer Information Note – CLP Regulation: Lower Classification Limits for Eye/Skin Irritation. Available at: http://www.eupia.org/uploads/tx_edm/2015-06-23_EuPIA_Customer_Information_Note_Classification_Limits.pdf

labelling even though the risk has not changed. Moreover, inflationary labelling on products can have a 'habituation effect', i.e. labelling no longer has the intended effect of a warning for consumers (VCI, 2016).

'Inflationary labelling' has also been criticised by consumer organisations. In the periodical of July 2015, Stiftung Warentest states that hazard symbols and risk/safety statements need to be printed even on hand dishwashing products. The tighter labelling requirement for this product group has been criticised because many dishwashing agents contain skin-friendly surfactants. This tighter labelling requirement is considered to cause uncertainty amongst consumers or even decrease their awareness to such a low level that the warnings on products that really pose hazards to health or the environment are no longer taken seriously (VCI, 2016).

This issue has also been raised by Member State authorities during the targeted consultation for the present Fitness Check which expressed concern that based on conventional classification methods, the hazard symbol of many household products (such as several hand dishwashing detergents) has changed to the 'corrosive' pictogram, making these products more difficult to distinguish from corrosive products such as drain cleaners. An authority has also noted that the criteria used in the classification of substances in Annex I of the CLP Regulation are, in the case of skin corrosion and serious eye damage, considered by those affected as being too conservative. The current thresholds, when applied through the calculation method, mean that certain cleaning products are being classified for serious eye damage, resulting in the corrosive pictogram appearing on washing-up liquid. It is noted that this may have resulted in an unwanted over-labelling of products, as appropriate classification and labelling is essential for safe use by consumers. Also, as a result and to avoid labelling with the 'corrosive' symbol, the detergent industry has developed classification strategies that, in the authority's view, make questionable use of the bridging principles and which are not yet accepted across Member States and are therefore difficult to enforce (see also Section 3 of Task 1).

A national association for the detergents sector has noted that having the same severe classifications and respective pictograms (especially in the case of Eye Damage Category 1 hazards) across a range of different products (e.g. laundry detergents and oven cleaners) is considered to have resulted in consumers becoming indifferent to pictograms and hazard statements as personal in-use experience is quite different to (and less worrying than) the actual classification and labelling of the products. In their view, hazard pictograms do not reflect the real 'hazard' of a product, with the example of products classified as eye irritant or skin irritant being given, and the 'corrosive' pictogram being applied to products that are corrosive as well as those that are skin irritants. The association has noted that this results in confusion for consumers and trivialises the health hazard of products, ultimately leading to incoherence and miscomprehension of the real health hazard of a product. A detergents manufacturer, building on such arguments, has indicated that there is a need to achieve consistency between hazard pictograms in order to ensure coherence between pictograms and health hazards.

A number of detergent manufacturers have also raised concerns regarding consumer understanding of CLP pictograms, suggesting that these do not adequately distinguish the hazards associated with different products (e.g. really dangerous skin corrosives may have a similar classification to products that were formally not classified products under the Dangerous Preparations Directive). One detergent manufacturer has suggested that there is a need for more simple, clear and actionable information to be made available to consumers, instead of the rigid CLP statements and pictograms, as this would help convey the message (i.e. hazards/risks) to consumers better and, in the end, contribute to the safe use of products by consumers. A similar view was held by a manufacturer of PPPs, who indicated that, with regard to the CLP Regulation, the focus should be on simplification of

labelling to encourage users to read and understand product labels. It was also suggested that information on labels should be prioritised in order to highlight the main risks and hazards.

This is supported by findings from study undertaken by AISE which looked at obtaining different stakeholders' perspectives on the effectiveness of EU labelling requirements to convey hazard and safe use information[146]. The research concludes that, according to consumers, the new CLP classification system is not seen as a tool that allows them to differentiate the level of safety between detergents and maintenance products. Instead the CLP pictograms and text tend to present products on the same level of danger, which is seen by some to result in a potential risk of "*banalisation*" that could impact the safe use of these products for future generations (as the impression is given that products have the same level of hazard when this may not be the case in reality).

Similarly, a respondent to the OPC (see section 3.29.4 of the Task 4 Report) noted that having the 'corrosive' label on too many products means that consumers may not take appropriate account of the label, with potential adverse effects if exposed to the products at the 'bad' end of the scale. Another respondent noted that as more and more products are labelled as being 'corrosive', consumers will fail to identify those which genuinely need the most care. It is therefore suggested that there is a need for a more nuanced labelling system.

The Royal Society of Chemistry indicated that some of their members hold the view that the CLP system is too complicated and detailed, and lacks clarity. They noted that the Dangerous Substances Directive and the Dangerous Preparations Directive clearly differentiated between very toxic and toxic chemicals, with 'harmful' and 'irritant' available for less dangerous chemicals. They also noted that the CLP Regulation has the same symbol, signal word (Danger) and hazard code for substances classified as toxic category 1 (the Dangerous Substances Directive – very toxic) and toxic category 2 (the Dangerous Substances Directive – toxic), and many labels do not show the category; hence it is difficult to differentiate the toxicity of the contents of a given container.

A similar issue has been raised by Hennes *et al.* (2014) with regard to CLP labelling not differentiating between the degree or severity of the hazard. Hennes *et al.* note that the same hazard statement – 'may cause cancer' - is used for all Category 1B carcinogens regardless of their degree of hazard or potency. This is in contrast to chemicals that can cause death after a single dose, where the dose required is reflected in the hazard statement which describes them as 'fatal if swallowed' for those of high potency, 'toxic if swallowed' for those of medium potency of 'harmful if swallowed' for those with low potency. All of these categories are determined by the dose at which the chemical causes fatality in laboratory animals. They note that the current scheme, which is derived from the GHS and adopted by the EU for carcinogenicity and for reproductive toxicity, does not allow this differential communication.

It is clear from the information above that there is an issue with regard to hazard pictograms not suitably reflecting (and allowing differentiation) between the hazards associated with the use of different products. As indicated above, it is currently the case that products, such as hand dishwashing detergents and drain cleaners, use the same 'corrosive' pictogram, which makes it difficult for consumers to distinguish between the 'hazardousness' of these products and hence leads to confusion (and potential misuse of products). It is therefore suggested that further investigation is undertaken into possible ways of providing more adequate means for

[146] AISE (2016): Safety information on household products – Better Regulation and Safe Use Project (Executive Summary), Research conducted in Belgium, Poland and Spain, July 2016.

communicating information to consumers so that they can more effectively distinguish between the hazards attributed to and risks associated with the use of different products.

7.3.3.6 Precautionary statements

A manufacturer of PPPs indicated that the use of precautionary statements could be improved and harmonisation of their use could be beneficial. This is because, at present, different companies and Member States often have different precautionary statements assigned to the same classification. This suggests that not everyone is applying the same approach and, in many cases, not the approach and recommendations outlined in the ECHA guidance[147]. During the consultation process this issue has only been raised by a single manufacturer, which suggests that it is not particularly significant. However, the use of different precautionary statements for the same classification could create confusion for downstream users and potentially lead to the misuse of products. Industry and Member State authorities could be reminded/made aware of the ECHA guidance in order to ensure the consistent application of precautionary statements across the EU.

Another issue identified by a producer of PPPs relates to the selection of precautionary (P) statements under the CLP Regulation and then also under the Plant Protection Products Regulation. The respondent noted that there are no PPPs in Europe that include the same precautionary statements and safety precaution statements on their label because each Member State has different preferable statements. It is suggested that many of these statements do not make sense in the context of PPPs and create uncertainties for customers. However, these are part of the approval certificate and therefore have to be adopted. In addition, two PPP industry respondents indicated that there are overlaps in precautionary statements and safety precaution statements, which unnecessarily inflate the product label. Another respondent (consulted as part of Case Study 9) identified that, with regard to garden pesticides, the CLP Regulation is the main system for hazard communication. These products have to be labelled in accordance with CLP and pesticide labelling guidance in each Member State, which can involve the use of similar precautionary statements thus leading to some unnecessary duplication. It is not clear as to whether this overlap in labelling is having a significant impact on downstream user understanding of how products should be safely used. However, unnecessary duplication of information may prevent product users from focussing on the most important elements of product labels and therefore distract users from the key safe use messages.

7.3.4 Compliance issues

Authorities were also asked whether there have been significant compliance issues with respect to suppliers meeting CLP requirements, and in particular labelling requirements. Although some indicated that there had been no significant issues in their Member State, several provided examples of problems that had arisen. These included:

- Labelling not in the language of the country being placed on the market;
- Label did not identify substances in the mixture that contribute to the classification of mixture as set out under Art 18(3) (b) of CLP;
- Inconsistency in the label information provided on the label and SDS (section 2.2);

[147] ECHA (2011): Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008. European Chemicals Agency. Available at: http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

- Labelling and hazard pictograms did not reflect actual classification of substance/mixture - differences in classification of the same substance across Member States;
- Limited hazard information on label particularly in relation to products imported from outside the EU;
- Legibility of the labels due to font sizes; and
- Use of non-existent pictograms to cover empty diamonds.

Several authorities also identified classification issues. For example, a 2013 CLP enforcement project undertaken by Denmark in 2013 on different cleaning products with extreme pH found that out of 161 products, 73 were classified and labelled incorrectly. The products should have been labelled as corrosive but were only labelled irritant or not at all labelled.

Another Member State authority observed several enforcement cases of incorrect classification, and labelling information, of mixtures for the hazard classes 'Reproduction toxicity' and 'Eye Damage'. These seem to have arisen due to the lower concentration limits in the CLP Regulation compared to the Dangerous Preparations Directive, with companies not being sufficiently aware of this change for the classification of mixtures. Other enforcement issues that were identified include no instructions or precautions being given for cosmetics that are to be used only by professionals on the label or elsewhere.

This is considered to be a significant issue as incorrect labelling may have implications for how downstream users and consumers understand hazard labels and safety information included or accompanying products, which could have potential impacts on health if products are used incorrectly.

7.3.5 Does CLP labelling enable informed choices?

As part of the targeted consultation exercise, Member State authorities were asked whether they agree or disagree with a series of statements. One of these was whether; in general, the hazard information provided under the current legislative framework enables employers and consumers to make informed choices. The majority of Member State authorities (12 of 16, or 75%) agreed with this, while (10 of 17, or 59%) considered the hazard information provided under the current legislative framework to promote the use of safer alternatives and (in the view of 13 of 16, or 81% respondents) enable workers, professional users and consumers to use chemicals safely. 10 out of 15 Member State authority respondents (67%) indicated that the hazard information provided under the current legislative framework ensures that workers, professional users and consumers have the information needed to dispose of waste chemicals or end-of-life products safely and appropriately. Responses received from a worker organisation also indicate that, in their view, the information requirements of the CLP Regulation and the current chemicals legislative framework are adequate to enable informed choices, promotion of safer alternatives, safe handling and safe use throughout the life cycle of chemicals and products/articles.

NGOs did not necessarily agree. One noted that products, materials and articles should display the appropriate information for citizens to be able to understand their environmental and health risks, use the products, materials and articles safely, and to be able to make informed choices. It is their view that a list of all ingredients should be displayed on the label, together with indications about the presence of SVHC. It is also suggested that applications (apps) that facilitate the identification of SVHC in consumer articles, such as the Tox Fox, should be further developed for all types of consumer products. The NGO noted that there is an urgent need to improve the quality of SDS, which is the main information tool on chemical risks available to workers and to SMEs. From the

NGO's perspective, there is a general lack of information on the risks posed by chemicals to SMEs, which needs to be urgently remedied.

A number of comments received to the OPC also indicate that more information is needed on what chemicals are contained in consumer products to allow for a more informed consumer choice (for example, in Section 3.29 of the Task 4 Report). A positive example provided by one respondent is the mandatory ingredient list for cosmetics and personal care products. However, a negative example is the limited amount of consumer information that needs to be provided in the case of selling products online (e.g. for biocidal products only the pictograms are required and no information on active substances or advice for safe handling is obligatory).

One respondent to the OPC suggested that there is a need to include information on the most common allergens in the list of ingredients on product labels. They highlight the example of the allergenic substance Paraphenylenediamine, which is used in printer inks, textiles and hair dyes (amongst other uses), but is often included in ingredient lists under a number of different names (e.g. Disperse yellow 3, Disperse orange 3, 3-aminofenol, Isopropyl etc.). The respondent indicates that this creates confusion as it is not clear to the consumer when an allergenic substance (that they may wish to avoid) is present in a product. A potential solution to this problem is to ensure that all consumer products contain the most common allergens on the product labels. It is also suggested that since dermatologists use patch tests to check for allergies in patients, and the allergens and the names of the substances used in the test are generic (e.g. Nickel, resin, Paraphenylenediamine etc.), the product labels should include the generic names. This would allow consumers to make informed choices regarding the products they use and potentially reduce health issues, as they could avoid products that contain substances to which they have allergic reactions to. Another respondent also indicated that vague labelling on laundry detergent products makes it difficult for consumers to determine whether there are substances within the product that they may be allergic to. Thus, consumers are unable to make an informed decision as to whether they can use, or should avoid, certain products. Another respondent suggests that a complete declaration of all ingredients on product labels, as for cosmetic products, is desirable for detergents and all household products so that consumers can make an informed choice with regard to the products they purchase and use.

The OPC submission from the Royal Society for Chemistry indicates that, from their perspective, in general the information generated under the CLP Regulation with regard to hazard communication provides sufficient detail for consumers/downstream users to have an appreciation of the risks to health and the environment. However, experience of the Nappy Science Gang citizen project[148] with regard to the safe use of detergents for washing nappies highlights potential problems relating to access to information in order to make informed decisions/choices. Although the CLP Regulation sets out minimum package labelling requirements, these requirements do not allow the consumer or manufacturer or retailer of garments (in this case nappies) to make informed decisions when recommending or purchasing detergents. This is because the full ingredient details relating to proprietary formulations can only be made available to registered medical practitioners, in confidence; in this case, neither the CLP Regulation nor the Detergents Regulation are helpful in ensuring that manufacturers and consumers have the information they require to make informed choices regarding the use of detergent products.

In general the labelling information required under the CLP Regulation is deemed to be appropriate to allow downstream users and consumers to make informed choices regarding the products they

[148] Nappy Science Gang (n.d.): A citizen science project about cloth nappies. Available at: https://nappysciencegang.wordpress.com/

purchase and use. However, in certain cases (e.g. detergent products) a lack of detailed ingredient lists restricts the ability of consumers and downstream users to make informed decisions and thus avoid products containing certain substances. A similar issue is experienced with regards to the inconsistency regarding the labelling of allergenic substances on product labels, which causes difficulties for consumers that are actively trying to avoid products containing specific allergenic substances. The inclusion and consistent use of allergenic substance names on consumer products would enable informed choices to be made so downstream users/consumers are able to avoid substances that they are allergic too, thus reducing the associated health impacts.

Information has been provided by various stakeholders with regards to changes to the labelling system as a result of the move from the previous regulatory approach (under the Dangerous Substances Directive and the Dangerous Preparations Directive) to the CLP Regulation.

7.4 Effectiveness of communication under horizontal legislation

Key findings

- Although some stakeholders consider the hazard information currently required to be included on labels is necessary, many have also raised concerns regarding too much information on product labels leading to overcrowding, thus reducing their effectiveness in communicating information to downstream users and consumers.
- Cosmetic Products Regulation – the lack of requirements for a hazard label and safety data sheet results in employers experiencing difficulties in undertaking workplace assessments as required under OSH legislation, which is likely to result in increased burden (and costs) for employers (although the significance of these impacts is not known.
- Cosmetic Products Regulation – some stakeholders note that the Regulation does not adequately consider the risks to professional users as they do not receive sufficient information on precautions when using cosmetic products in professional applications/ environments. This is considered to be a significant issue as the lack of information prevents users of cosmetic products in professional environments from taking appropriate measures to reduce their exposure, potentially leading to health impacts.
- Cosmetic Products Regulation – the lack of requirements to communicate environmental hazards associated with cosmetic products is considered by some to be a gap, thus reducing the effectiveness of the legislation to protect the environment. However, this view is not shared by cosmetic companies.
- Aerosol Dispensers Directive (Directive 75/324/EEC) – the lack of a transition period which allows industry to adapt product labels to the changes has cost implications for industry. The introduction of a suitable transition period could help to reduce this burden as corrections to product labels (as published in the OJEU) could potentially be undertaken in line with regular market related packaging modifications.
- Toy Safety Directive – in general, the labelling requirements outlined in the Toy Safety Directive, including those that relate to other pieces of legislation, are clear and therefore understood by most stakeholders. However, in the case of warnings, it is suggested that greater clarity could be provided with regards to the additional warning requirements included in standards.
- Toy Safety Directive – in general, the current system of labelling toys is considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toy products. However, it is suggested by some stakeholders that product labels should contain information regarding the presence of potentially dangerous substances which may be present, especially in hidden parts of the

toy.

- Toy Safety Directive – a number of respondents have noted that allergens are an issue considered as too softly regulated under the Toy Safety Directive. It is also suggested that other allergens that are not specifically fragrance allergens should be regulated by the Toy Safety Directive to ensure that the health of consumers (and in particular children) is adequately protected. This is considered to be a significant issue as exposure to allergenic substances will have detrimental consequences for children's' health.
- Toy Safety Directive – in general, the Toy Safety Directive and CLP Regulation are considered to work well together and with other legislation (e.g. the Cosmetic Products Regulation) to reduce child exposure to hazardous chemical substances and mixtures in toys (thus suggesting a suitable level of coherence). However, some stakeholders have indicated that the thresholds outlined in the CLP Regulation for CMR substances were not originally intended to be used as a safe limit for consumer products and are therefore not appropriate for application to consumer products (and in particular toys as children are a vulnerable population).
- Toy Safety Directive – issues have been raised with regards to toy products not meeting the labelling requirements outlined in the Directive. Problems have been experienced with regards to the use of warnings in that they are, in some cases, applied incorrectly, written in too small a font size, which is not easily readable, and/or are not always provided in the relevant languages. Also, problems have been experienced in cases where information is missing from product labels, which is considered to be a significant issue as this can have impacts on product traceability and potentially for consumers' health if toys are not appropriately used.
- Detergents Regulation – detergent manufacturers consider the voluntary safe use icons used to communicate safe use of detergent products to be clear and understandable for consumers, however, this is in contrast to the views of national associations and SMEs.
- Detergents Regulation – multiple regulations dealing with labelling of products creates unnecessary regulatory burden. Thus, there is considered to be an opportunity for streamlining labelling requirements.

7.4.1 Overview

As indicated in Table 2-2, some chemical-related legislation has additional or different labelling requirements to those set out under the CLP Regulation.

As part of the targeted consultation process, stakeholders were asked to comment on:

- whether the communication requirements across the suite of chemicals legislation to be considered by the fitness check are deemed to be clear and understandable;
- whether the labelling requirements under the different legislation are considered to be effective at communicating hazards and risks to workers, professional users and consumers (i.e. are the labels sufficiently clear to consumers to ensure that hazards/risks are understood).

The purpose of these questions was to determine whether there are any issues regarding the clarity of communication requirements in legislation with a horizontal link to the CLP Regulation, and whether this prevents the legislation from effectively and efficiently communicating relevant information to downstream users. Equally, the questions were aimed at identifying those aspects of the communication provisions outlined in the legislative framework that are considered to work well

and that help contribute towards achieving a high level of protection of human health and the environment.

As indicated in Figure 7-5, the majority of Member State authorities considered the labelling requirements under Regulation (EC) 648/2004 on detergents, Aerosol Dispensers Directive (Directive 75/324/EEC), Regulation (EC) 1333/2008 on food additives, Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 biocidal products to be effective at communicating hazards and risks to workers, professional users and consumers.

However, Member State authorities also indicated that, in their view, the labelling requirements outlined in Regulation (EC) No 1223/2009 on cosmetic products and Directive 2009/48/EC on the safety of toys are not as effective.

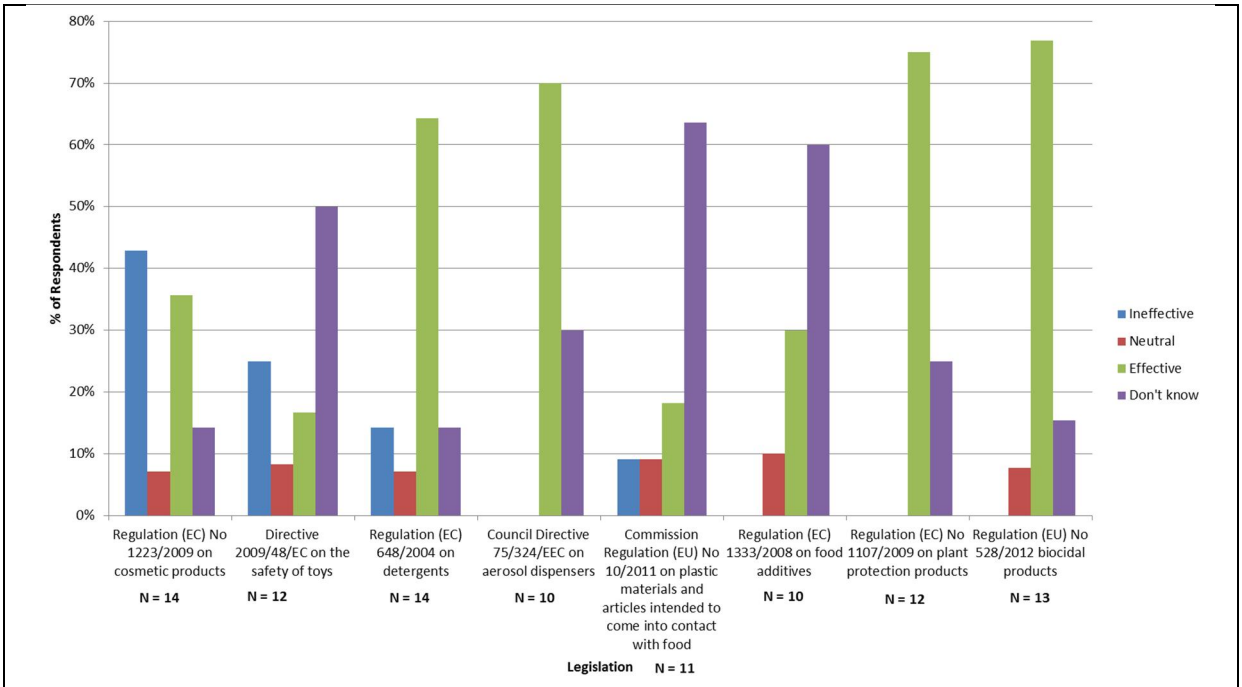

Figure 7-4: Member State authority views regarding whether the labelling requirements under the different legislation are considered to be effective at communicating hazards and risks to workers, professional users and consumers (i.e. are the labels sufficiently clear to consumers to ensure that hazards/risks are understood)

In the view of one NGO, the labelling requirements under the Toy Safety Directive and Biocidal Products Regulation are not effective at communicating hazards and risks to consumers (indicating that they therefore agree with the responses received from Member State authorities in this regard). However, the NGO also indicated that, in their view, the labelling requirements under Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and the Regulation on food additives (which refers to Regulation (EC) No 1935/2004 on articles and materials intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC) are ineffective at communicating hazards and risks to consumers. The respondent provided further comments indicating that, in their view, cosmetics, toys, detergents and food containers that include hazardous substances should clearly state them and information should be provided for hazard free substitutes.

One Member State authority noted that for the consumer product safety legislation covered by the question (see Figure 7-5), the current approach to evaluating the risk of chemical hazards is effective and proportionate, as risk evaluation and communication is a principle requirement that is underpinned by EU scientific committees (i.e. EFSA, SCCS and SCHEER) who evaluate specific chemical safety issues related to consumer products. It is, however, recognised that there are certain situations not addressed by consumer product legislation, where risk communication is required for the most vulnerable consumer groups such as children, disabled or the elderly.

One such example concerns laundry tabs, where the hazard classification and pictogram address the chemical hazard of the detergent. Most users of laundry tabs are adults, where potential dermal contact through the tab spilling its content would be the main risk. However, for children, the risk is different because the tabs are colourful; as a result, the main risks relate to them either being played with or consumed by the child, with ingestion posing a serious risk of poisoning (see also Section 6 of the Task 1 report). To minimise or remove the risk, the CLP Regulation was adapted in December 2014 (Regulation (EU) No 1297/2014) to set new requirements for laundry capsules and the packaging where the capsules are held. By requiring the packaging to limit access to the tab, the risk to the child is minimised although the hazard is still present. Moreover, the hazard pictogram was supplemented by the warnings 'Keep out of reach of children'.

This labelling change was additionally supplemented by safety campaigns conducted in 2015 by the EU and OECD, where posters were prepared to inform consumers/carers (European Commission, 2015). However, one NGO expressed the view that the changes made to the labelling of film capsules (under Regulation (EU) No 1297/2014) are not considered to be effective at communicating the hazards and risks associated with these products. The NGO noted that, in their view, it is self-evident that chemical mixtures (e.g. dish washing tablets or toilet tablets) resembling confectionary represent a risk in any household where children are living. The NGO suggested that as it is entirely possible to change the appearance of these products, this should be the preferred option, particularly as children do not read labels.

Stakeholders were also asked whether the information currently required to be included on labels is necessary and appropriate with respect to the labelling requirements outlined in the CLP Regulation and other legislation (such as the Plant Protection Products Regulation, Detergents Regulation, Biocidal Products Regulation, Aerosol Dispensers Directive, etc.). It is clear from the responses received from Member State authorities that the majority (10 of 14, or 71%) agree that the information currently required to be included on labels is necessary. Stakeholders were also asked whether, in their view, a reduction in labelling requirements to provide only the most important hazard information on the label would be appropriate, if additional information is available as part of use instructions. Of the 15 Member State authorities that responded to this question, eight did not consider a reduction in labelling requirements to be appropriate; however, six respondents were of the view that the inclusion of only the most important hazard information on the label may be more appropriate, if additional information is available in use instructions.

A number of manufacturers have indicated that the labelling information, and in particular the long phrases of hazard (H) and precautionary (P) statements, on multi-lingual labels result in a significant amount of information that becomes difficult to read and understand from the perspective of downstream users and consumers. In their view, the space required to present the hazard information under the Dangerous Substances Directive and the Dangerous Preparations Directive was much less compared to that required under the CLP Regulation and other horizontal legislation. Responses received from consultation with SME economic operators (as part of the SME panel questionnaire) also suggest a similar view in that product labels can become overcrowded as there are too many H and P statements, which are often not clearly shown on labels. Some SME

respondents indicated that labels containing too much information distract the attention of the consumer and that H and P statements should thus be made clearer, simpler and more easily readable. Stakeholders contacted as part of Case Study 9 also highlighted differing interpretations between Member States regarding the size of the pictogram on multi-lingual labels. A pictogram must be the larger of either 1/15 of the surface area of the CLP text box or 1x1cm². However, for multilingual labels, it is not clear whether the surface area refers to the full CLP information box or that of the primary language only. This is interpreted differently by different Member States under the different pieces of legislation, and clarification could perhaps be provided on this to ensure greater harmonisation in implementation.

A Member State authority indicated that, in their view, the information included on product labels should be communicated in a simpler way, to avoid too much information being included on labels and increased effectiveness of hazard/risk communication. Whilst the appropriateness of certain hazard communication tools (such as Q-R codes and bar codes) was questioned by some stakeholders, many also accepted that innovative measures to reduce information on product labels and, hence, simplify the communication of hazards associated with products is necessary to ensure that downstream users/consumers understand the hazards and risks involved from their use. Further discussion regarding appropriateness of current hazard communication tools and the potential for use of innovative methods is provided in Section 7.5. Some participants at the April workshop and a number of respondents to the OPC indicate that a significant issue in relation to regulated consumer goods is the over-abundance of labelling. In their view, the presence of too much text on product labels is confusing for consumers and, hence does not provide any added benefit. One of the OPC respondents suggested that hazard communication under the CLP Regulation has become more complete; however, this is also leading to information overload and hence reduced understanding for workers and consumers. In essence, the large amount of information is considered to deprive consumers and professional users of key/meaningful parts. This problem arises, in part, due to the simultaneous applicability of many pieces of legislation. Thus, one OPC respondent suggested that the legislative framework should strike a balance between addressing risks in a more specific manner and maintaining a reasonable degree of complexity.

Information obtained through consultation with the SME panel also indicated that there is a need to focus the messages of labels on the key hazards/risks associated with the use of products. Respondents indicated that pictograms and hazard labels should show more accurately the risks connected with the use of chemicals and should be simplified to facilitate consumer/downstream user understanding (as it is suggested that pictograms and safe use information is not read with the required attention because of the complexity and amount of information included on labels).

Other industry respondents indicated that the rigid format for consumer packaging labels often leads to repetition and lengthy text without further information, which is against good hazard communication principles. Participants at the workshop also highlighted the issue of including information on product labels in the correct language(s). It was suggested that all EU languages should be included on a fold-out label to ensure all EU consumers are able to access the necessary information; other consultees have suggested that the use of English should be mandatory, with other languages then provided as appropriate.

It is also noted by a Member State authority that when a substance/mixture becomes an article, there is no longer an obligation for a SDS for the chemicals in the article. Therefore, in their view, a harmonised format for information on hazardous substances in articles is needed. This format should follow the article through the whole lifecycle including the recycling process and into a new product lifecycle. This would then ensure that there is information on the content of the article, which enables the most appropriate treatment of the article throughout its whole lifecycle.

The following sections provide further details of issues raised with regard to the effectiveness of communication measures under key pieces of horizontal legislation.

7.4.2 Cosmetic Products Regulation

7.4.2.1 Hazard communication for professional users

In the case of the Cosmetic Products Regulation, one Member State authority noted that, for cosmetics for professional use, hazard communication under the Regulation is considered to be ineffective because it makes it difficult for employers to undertake workplace assessments as required under OSH legislation. Due to the lack of a hazard label and SDS, employers' only option is to base the workplace assessment on reviewing the substances listed on the packaging of individual cosmetics. Similar problems are also present for detergents and food additives, where consumers are the predominant communication focus and employers face challenges in undertaking workplace assessments. Although no evidence has been obtained regarding the significance of this, a lack of information increases the burden on employers, who are required to review the individual substances listing on packaging of products and determine their hazards and the procedures for ensuring safe use. Another Member State authority noted that the Cosmetic Products Regulation does not consider the risks to professional users even though this is stated in the Regulation. Therefore, professional users do not receive sufficient information on precautions when using cosmetic products in professional applications/ environments. Professional users also need more specific information in order to fulfil their obligations to substitute to less hazardous products. This is considered to be a significant issue as the lack of information prevents users of cosmetic products in professional environments from taking appropriate measures to reduce their exposure, potentially leading to health impacts.

In the United States, a different approach is taken to ensure that professional users of products that are also available to consumers have access to the relevant safety information. Discussions with the United States Occupational Health and Safety Administration (US OSHA) indicate that US OSHA's Hazard Communication Standard provides a common and coherent approach to classifying chemicals and communicating hazard information on labels and SDS. Cosmetic products are exempt from the labelling provisions of this standard; however, professional users of cosmetic products (such as workers in nail salons) are protected under the Hazard Communication Standard as they are still required to receive SDS and training from employers.

7.4.2.2 Environmental hazards

It has been noted by an industry association and several Member State authorities that environmental hazards are not communicated at all, as there is no obligation to do so within the Cosmetic Products Regulation (see also Section 3 of the Task 1 report). These authorities do not believe that cosmetics should be exempted from classification and labelling of environmental hazards according to the CLP Regulation. Cosmetics often contain environmentally hazardous chemicals, are used in high amounts, have a wide dispersive use pattern and often reach the environment, or at least wastewater treatment plants. Although the list of ingredients has to be indicated on the packaging of cosmetics, information is missing on which of these chemicals are environmentally hazardous. Classification and labelling is therefore deemed necessary in order to ensure the safe handling of cosmetics containing environmentally hazardous substances (e.g. substances hazardous to the aquatic environment). A respondent to the OPC also argued that the list of ingredients which has to be supplied with cosmetics is valuable information, but of no use for most consumers. Other mixtures, like paints and varnishes, have to bear respective precautionary

statements in order to ensure appropriate handling by consumers. The respondent noted that the same approach should be applied to cosmetics in addition to the list of ingredients.

A study undertaken by Sobek *et al.* (2013) (see also Section 4.5.2) looked at inconsistencies in EU environmental hazard classification requirements for UV filters, which have potentially environmental hazardous properties. In the EU, UV filters contained in sunscreen products are regulated by the Cosmetic Products Regulation. Environmental hazard classifications according to the CLP Regulation are required for UV filters contained in industrial chemical products, but not those contained in sunscreen products, which are exempted from the CLP Regulation. The study found that almost 50% of the investigated UV filters approved for use as cosmetic products (under the previous Cosmetics Directive) met the CLP classification as being hazardous to the aquatic environment. For other products containing UV filters (e.g. house paints), the classification of each chemical component is used to provide a classification for the whole mixture. This in turn provides information to customers on how the product should be used to minimise or avoid harm to human health and the environment. Making an informed decision on the use of sunscreen products based on potential risk to the environment requires great effort, as it implies reading the list of ingredients and making sure that there are no environmentally hazardous UV filters in the product; this is a difficult task for private consumers and other supply chain actors. Thus, the authors suggest that including cosmetic products under the scope of the CLP Regulation would contribute to better awareness of potentially negative environmental impacts caused by these products. It is also suggested that including cosmetic products under the CLP Regulation would contribute to a more harmonised and transparent regulation of potentially hazardous substances on the market (Sobek *et al.*, 2013).

An alternative to this might be for the Cosmetic Products Regulation to establish additional environmental labelling requirements for particular sets of ingredients known to be associated with environmental hazards. This type of requirement would be similar to the labelling requirements for fragrance allergens. Other types of ingredients that are likely to pose particular environmental hazards/risks could also be treated in this manner.

A contrasting view was held by cosmetic companies responding to the targeted data collection exercise and the case study work (see Case Study 9). All five respondents disagreed that cosmetics should be labelled according to the CLP Regulation for environmental hazards to ensure safe use and disposal (with two (40%) indicating that they disagree and three (60%) indicating that they strongly disagree). The respondents also considered the current system of labelling of cosmetic products to be effective at communicating the hazards and risks associated with their use. One respondent noted that the current system of labelling cosmetic products is effective in terms of communicating the risks associated with their use (and covers risks associated with normal and foreseeable use). However, it is noted that hazard communication is considered irrelevant for consumers as products have to be safe, which is ensured by the mandatory safety assessment based on known use and exposure conditions. Thus, it is their view that hazard labelling is not needed because the use of cosmetic product is clearly known and safe use information for consumers is more valuable (because it is targeted to a specific use) than hazard information.

Nevertheless, one respondent to the OPC disagreed with the view of the cosmetic companies. This stakeholder argued that exclusion of cosmetic products from the scope of the CLP Regulation leads to gaps in the information available to consumers, in terms of the presence of hazardous chemicals in cosmetic products. The respondent cites a 2012 independent study, which reviewed 41 cosmetic products according to the criteria for classification and labelling under the CLP Regulation and found

that the signal word 'warning' would have to be on the labels of 64% of products, and 'danger' would have to be included on 33% of the products (Klaschka, 2012)[149]. The respondent therefore indicates that as long as the Cosmetic Products Regulation does not guarantee effective labelling requirements to communicate risks to consumers (through the exemption of cosmetic products from the CLP Regulation), there are serious gaps in consumer awareness.

7.4.2.3 Additional tools for effective hazard communication

All five of the cosmetic companies that responded to the targeted consultation questionnaire agreed that the information that currently needs to be included on labels under the Cosmetic Products Regulation is necessary and appropriate (either agreeing or strongly agreeing with this statement). The majority of respondents (four out of five, or 80%) disagreed that a reduction in labelling requirements would ensure that the most important hazard information was communicated to users whether on the label or using other methods. One respondent indicated that they neither agreed nor disagreed. Two respondents (40%) did not agree with the statement that consumers do not look beyond the label for hazard information and information on safe use, whereas three respondents (60%) neither agreed nor disagreed.

Four of the cosmetic companies that responded to the targeted consultation also indicated that there is a need to consider the introduction of alternative vehicles and tools (i.e. digital communication) for consumer information, other than on-pack labelling to enhance the effectiveness of risk communication (further discussion is included in Section 7.5).

Cosmetics companies were also asked whether they consider there to be a need for a better labelling system for allergens and whether the International Nomenclature for Cosmetic Ingredient (INCI) names should be used in all cases, regardless of Member State views, in order to prevent double labelling. Three respondents (60%) indicated that the INCI names should be used in all cases, with one disagreeing and another not providing a definitive response. Additional explanation was provided. All respondents noted that, under the current Regulation, a better labelling system for allergens is not needed; however, it was suggested that alternative tools for risk communication (other than on-pack labels) should be considered. For example, it is argued that the use of digital media would increase communication effectiveness (as discussed in Section 7.5). All of the companies noted the importance of using INCI names for cosmetic ingredients (including allergens) across the EU, as these are internationally recognised by end users and health professionals. One respondent also notes that INCI names are used in other sectors such as detergents and toys. It is therefore considered important to maintain consistency across sectors in order to provide end users and health professionals with accurate, relevant and comparable information about ingredients.

However, one respondent also noted that double labelling (e.g. INCI list and the warnings that require the names of certain substances in cosmetics to be included on products labels - "contains X") should be avoided and, therefore, that the usefulness/relevance of the "contains X" provision should be reviewed.

[149] Klaschka, U. (2012): Dangerous cosmetics - criteria for classification, labelling and packaging (EC 1272/2008) applied to personal care products, Environmental Sciences Europe, December 2012, 24(37) DOI: 10.1186/2190-4715-24-37. Available at: http://link.springer.com/article/10.1186/2190-4715-24-37

7.4.2.4 Legislative overlaps between the Cosmetic Products Regulation and the Toy Safety Directive

During the targeted consultation process, cosmetic companies were asked whether it is clear, from their perspective, when a cosmetic product made for use by children falls under the compositional labelling requirements of the Toy Safety Directive or the Cosmetic Products Regulation. All four respondents to this question indicated that it is clear, with one noting that it is clear that both regulatory provisions apply to cosmetic products which are also toys, including those for dolls. This means that both labelling requirements would apply.

Two respondents noted though that, in their view, labelling requirements under the CLP Regulation should not apply to those products that are both toys and cosmetic products due to the difference in approaches (the Cosmetic Products Regulation is a risk-based approach whereas the CLP Regulation is a hazard-based approach). Because the Cosmetic Products Regulation takes into account the risk of the product, CLP labelling requirements are not needed. Moreover, for consistency purposes and to avoid the inclusion of too much irrelevant information and pictograms, toys which are also cosmetic products should be exempted from CLP labelling requirements. The need for such products to be labelled according to the requirements of both is a doubling of effort, and it would be clearer if such products were exempted from the labelling requirements of the CLP Regulation.

7.4.3 Aerosols

Two industry association respondents to the OPC indicated that, with regard to aerosols, CLP still includes many linguistic errors in relation to the precise wording of mandatory labelling elements. It was also noted that, when corrections are published, there is no transition period which allows industry to adapt product labels to the changes; corrections apply immediately after their publication in the Official Journal of the European Union (OJEU). The industry has therefore requested that minor variations, which do not affect the obvious meaning of hazard (H) and precautionary (P) statements, should be acceptable on labels, so that they can be addressed in an economically efficient manner given that aerosol labels are printed directly on the product container.

Although this issue was only raised by two stakeholders it is likely to be significant for aerosol manufacturers as minor changes required to hazard and precautionary statements will create a cost burden for manufacturers as there is a need to re-format the labels on product containers. The introduction of a suitable transition period could help to reduce this burden as corrections to product labels (as published in the OJEU) could potentially be undertaken in line with regular market related packaging modifications.

7.4.4 Toy Safety Directive

7.4.4.1 Clarity and understandability from the perspective of economic operators

Labelling in the context of the Toy Safety Directive also includes markings and warnings relevant to mechanical and physical hazards, in addition to specific warnings for chemical toys and fragrance allergens. It is the view of industry that the specific text and applicability of these labelling requirements is clearly set out in the standards accompanying the Directive, and that the majority of manufacturers have considerable experience in applying these. With regard to the CLP Regulation, the labelling requirements for chemical toys are also clearly set out in relevant standards. In the case of the Cosmetic Products Regulation, it is in general clear when the labelling requirements

apply to toys. The manufacturers and importers of these types of products often specialise in this area and are aware of the different requirements.

As part of the consultation process (undertaken for Case Study 8 relating to the 'awareness of toy manufacturers of chemical safety assessment and labelling requirements for toys'), stakeholders were asked whether labelling requirements outlined in the Toy Safety Directive are considered to be clear and understandable. In general, most of the stakeholders consulted[150] considered the obligations (including those related to product labels) for manufacturers (Article 4), importers (Article 6) and distributors (Article 7) to be clear.

Evidence obtained from the evaluation of the Toy Safety Directive suggests that issues have been raised with regard to a lack of clarity of the rules to affix the CE marking on toy products, especially when imported goods are concerned (Technopolis *et al.*, 2015).[151] However, the findings from the consultation undertaken as part of Case Study 8 indicate that there is general consensus that most stakeholders understand the obligations relating to warnings for safe use of toy products (Article 11 and Annex V) and obligations relating to CE marking (Article 17).

As part of Case Study 8, stakeholders were also asked whether there are any aspects of the labelling requirements outlined in the Toy Safety Directive that are particularly burdensome or could be improved. Although the majority of respondents do not consider the labelling requirements to be particularly burdensome for manufacturers, one Member State competent authority indicated that, in their view, it is not clearly stated within the Toy Safety Directive that the list of warnings in Annex V is not exhaustive and additional warnings that are given the EN71 standards must also be taken into account. In this respect, it is suggested that specific reference to the additional warnings in the EN71 standards should be included within the Directive. A Public Health Authority noted that the labelling requirements outlined in the Toy Safety Directive need to be comprehensive, clear, concise and precise. It is suggested that the label should bear all information about any toxic substances present in the toy, even if the substance is contained within the toy, as parents have the right to know such information.

In summary, there is general consensus that the labelling requirements outlined in the Toy Safety Directive, including those that relate to other pieces of legislation, are clear and therefore understood by most stakeholders. However, in the case of warnings, it is suggested that greater clarity could be provided with regard to the additional warning requirements included in standards by ensuring that specific reference is made in the Directive to the relevant standards.

7.4.4.2 Effectiveness of the current system in communicating chemical hazards and risks

As part of Case Study 8, targeted consultation with relevant stakeholders has been undertaken to obtain their views regarding whether or not the labelling system for toy products is deemed to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toys. It is the view of industry representatives that the system is effective in communicating the hazards and risks associated with chemical substances/mixtures contained in toys. One industry association has indicated that the requirements for chemical toys specifically

[150] This is the view of an industry association consumer association, a Market Surveillance Authority and four Member State Competent Authorities.

[151] Technopolis, EY and VVA Consulting (2015): Evaluation of Directive 2009/48/EC on the Safety of Toys. Available at: http://bookshop.europa.eu/en/evaluation-of-directive-2009-48-ec-on-the-safety-of-toys-pbET0216112

reference the CLP Regulation and actually go beyond what is required, as the small packaging derogation for normal consumer products does not apply. Since the Toy Safety Directive requires that toys are safe, there is no justification for further communication of hazards beyond the scenario where chemicals and mixtures that would require a classification is allowed. The proportion of toys that fall within this category is very small when compared to all toys on the market.

It is also the view of two Member State competent authorities, an industry sector association and a market surveillance authority that the current system of labelling toys is effective. Alternative views are as follows:

- One Member State competent authority was of the view that the current system is not effective, as most labelling requirements concern mechanical hazards and risks.
- Another Member State competent authority noted that there are no specific labelling requirements in the Toy Safety Directive with regard to communicating the hazards and risks related to the content of chemicals in toys, unless the toy is defined as a chemical toy or included on the packaging for fragrances in olfactory board games, cosmetic kits and gustative games (in line with Paragraphs 4 and 10 of Annex V of the Toy Safety Directive). A similar view was also held by a public health authority with regard to the presence of potentially dangerous substances in hidden parts of toys.
- Another Member State competent authority noted that allergens, other than fragrances, are not covered by the labelling requirements of the Directive. Also, toys are exempt from the biocides regulation, which means that toys containing biocides (e.g. toy tents with an antibacterial or mosquito-repellent surface) will not be labelled with the substance(s) that has/have been applied (see also Section 7.2.9).

During the consultation exercise, stakeholders were asked whether the linkages set out in Annex II, Part III point 10 (of the Toy Safety Directive) for cosmetic toys in relation to the compositional and labelling requirements for cosmetic products (where the reference is to Council Directive 76/768/EEC) are appropriate for ensuring adequate protection of children's health. It is the view of one consumer association, four Member State competent authorities, a market surveillance authority and an industry sector association that these linkages are in principle appropriate and, assuming that cosmetics for toys will be applied to the skin of children, it seems natural to apply the requirements of the Cosmetic Products Regulation.

It is further noted by a Member State competent authority that chemicals in cosmetic products are assessed in relation to their use and exposure - which is very different from the exposure from most toys. It is therefore considered reasonable for the protection of children that cosmetic toys comply with both pieces of legislation (i.e. the Toy Safety Directive and the Cosmetic Products Regulation). However, stricter limits have to be applied in some cases, for example, where Appendix C of the Toy Safety Directive establishes stricter limits compared to the Cosmetic Products Regulation or in the case of fragrances where the requirements in Annex II, Part III point 11 obviously deviate from those outlined in the Cosmetic Products Regulation. One consumer association noted that this needs clarification in Annex II, Part III point 10 of the Toy Safety Directive.

7.4.4.3 Labelling of fragrance allergens

As outlined in Section 7.2.11, some stakeholders (e.g. Member State authorities, consumer association etc.) contacted as part of Case Study 8 have indicated that the requirements for the labelling of allergenic fragrances in toys are not currently appropriate for ensuring adequate protection of children's health and this is corroborated by findings from literature review (e.g. Technopolis *et al.*, 2015).

The reader is referred to Section 7.2.11 for further detail.

7.4.4.4 Linkages with the CLP Regulation

As part of the consultation process, stakeholders were asked whether they consider the Toy Safety Directive and the CLP Regulation to work well together (and with other legislation, e.g. the Cosmetic Products Regulation) to reduce children's exposure to hazardous chemical substances and mixtures in toys. Responses were generally positive, although one Member State competent authority noted that the legislation works well at reducing exposure but does not eliminate or minimise exposure. Hence, there may still be room for improvement in this regard.

However, one consumer association noted that the thresholds outlined in the CLP Regulation for CMR substances were never intended to be used as a safe limit for consumer products. It is therefore not deemed appropriate to use these thresholds as product limits, in particular for children's products. A Member State competent authority also noted that the generic classification limits of 0.1% for human carcinogens in the CLP Regulation are too high, meaning that health risks to children cannot be excluded.

To summarise, there is a general view that the current system of labelling toys is considered to be effective at communicating the hazards and risks associated with chemical substances/mixtures contained in toy products. However, there are no specific labelling requirements in the Toy Safety Directive with regard to communicating the hazards and risks related to the content of chemicals in toys except where a toy is defined as a chemical toy or where labelling is required on packaging for fragrances in olfactory board games, cosmetic kits and gustative games. Thus, it is suggested by some stakeholders that product labels should contain information regarding the presence of potentially dangerous substances which may be present, especially in hidden parts of the toy.

The majority of stakeholders consulted (a consumer association, four Member State competent authorities, an industry sector association representative and a market surveillance authority) were of the view that the linkages set out in Annex II, Part III point 10 (of the Toy Safety Directive) for cosmetic toys in relation to the compositional and labelling requirements for cosmetic products (where the reference is to Council Directive 76/768/EEC) are appropriate for ensuring adequate protection of children's health. However, a number of respondents have noted that allergens are not sufficiently well regulated under the Toy Safety Directive. It is also suggested that other allergens that are not specifically fragrance allergens should be regulated by the Toy Safety Directive to ensure that the health of consumers (and in particular children) is adequately protected.

It is also the general view of the stakeholders consulted that the Toy Safety Directive and the CLP Regulation are considered to work well together and with other legislation (e.g. the Cosmetic Products Regulation) to reduce children's exposure to hazardous chemical substances and mixtures in toys (thus suggesting a suitable level of coherence). However, a consumer association has indicated that the thresholds outlined in the CLP Regulation for CMR substances were not originally intended to be used as a safe limit for consumer products and are therefore not appropriate for application to consumer products (and in particular toys as children are a vulnerable population).

7.4.4.5 Toy products not meeting the labelling requirements outlined in the Toy Safety Directive

Consultation with an industry association undertaken as part of Case Study 8 indicates that, in their experience, the majority of toys are correctly labelled for both physical and chemical hazards, although it is recognised that there will always be a proportion of products that may be marked incorrectly. However, this is not considered to be an issue specifically associated with imported toys. In general, the majority of toys are imported and there is no evidence of a major issue with regards incorrect labelling. A large proportion of toys are designed by EU companies (who are manufacturers under the Toy Safety Directive), but are physically made outside of the EU. In these cases, the labelling of toys will be specified by the operators who are experienced and knowledgeable in the application of the requirements of the Toy Safety Directive. The requirements of the Toy Safety Directive also place obligations on importers and distributors to check that the warnings are correct. This further minimises the risk that toys will be incorrectly labelled.

As part of the consultation exercise, stakeholders were asked whether they were aware of any issues related to the labelling of toys (e.g. incorrect labelling), and in particular in relation to chemical substances/mixtures contained in toys. Stakeholders were also asked to identify the magnitude of any labelling issues in terms of the percentage of toys affected. A minor problem was defined as affecting less than 7% of toys on the EU market; a moderate problem was defined as affecting more than 7% of toys on the EU market and a major problem was defined as affecting more than 20% of toys on the EU market.

Information received from stakeholders indicates that issues have been identified with regard to the size of the product labels (e.g. lettering too small) with the same number of respondents identifying this as a major and minor problem. This included:

- As a 'moderate problem':
  - missing information on the product label
  - incorrect information on the label
  - a lack of the manufacturer's contact details;
- As a 'moderate to minor problem':
  - product labels being included in incorrect languages,
  - the failure to label or incorrect labelling of allergenic fragrances contained in toys,
  - failure to place the CE mark on a toy product.

One Member State competent authority indicated that overall, across all toys within the EU, there is a non-compliance rate of 12% with regard to the correct labelling of toy products.

As part of Case Study 8, stakeholders were also asked to indicate the types of impacts that occur as a result of these labelling issues. One Member State competent authority noted that manufacturers may be impacted by having to deal with complaints from market surveillance authorities and, where necessary, undertake remedial action to ensure the labelling requirements of the Toy Safety Directive are complied with. Another noted that manufacturers that comply with the labelling requirements have a competitive advantage, as the lack of correct information on product labels and the need to take corrective action to meet the labelling requirements of the Directive may damage a manufacturer's reputation.

The lack of certain information on a label, or the presence of incorrect information, can also impact consumers, as there could be a safety risk if, for example, warnings are incorrect or missing; this could lead to the inappropriate use of a toy product. Also, the manufacturer/importer contact details can also cause problems as, in the case of a toy that does not conform to the requirements of the Directive or is unsafe, it is not possible to contact the responsible economic operator to inform

them of the non-compliance and to enable them to take corrective action. This is supported by the evidence obtained from the evaluation of the Toy Safety Directive undertaken by Technopolis *et al.* (2015), which indicates that twelve Member States highlighted problems with the warnings required to be placed on toy products or their associated documentation, in particular concerning the language of the labels, their clarity and legibility. The evaluation report concludes that warnings are often written in too small a font size, which is not easily readable, and are not always provided in all relevant languages. Seven Member States, three consumer associations and a large German manufacturer that contributed to the evaluation of the Toy Safety Directive request that language and font size requirements are better regulated at the EU level. A position paper regarding the application and effectiveness of the Toy Safety Directive published by ANEC also indicates that warnings on toys are often too small, hidden by other text or hidden under crumples in packaging, thus making it difficult for consumers to read and understand them. It is also noted that some authorities have experienced problems in enforcing the presentation of warnings on toys because of the lack of specified requirements in the Directive and associated standards (e.g. a minimum letter size). A definitive letter size is only defined in the explanatory guidance document to the Directive (ANEC, 2014a) (further details are provided in Case Study 8).

As noted in the evaluation carried out by Technopolis *et al.* (2015), a UK expert on toy safety and a large Italian manufacturer indicate that there is not always complete correspondence between the actual risk identified in toys and the warnings placed on them. This is particularly the case with regard to the pictogram indicating that a toy is not intended for use by children under 36 months of age. If the pictogram is missing, manufacturers incur strict sanctions, but they often place the pictogram on toys that do not raise any risks for children under 36 months in order to protect themselves from infringement sanctions (Technopolis *et al.*, 2015). In addition, consultation with a Member State competent authority as part of Case Study 8 indicates that toys sometimes bear one or more of the specific warnings set out in Part B of Annex V of the Toy Safety Directive even though these warnings conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics. This can mislead consumers and, in a worst case scenario, result in consumers buying products irrespective of the age labelling. This could result in toys that do not conform to the requirements for the age group and/or being used inappropriately, thus posing a risk to users.

A Member State responding to the evaluation of the Toy Safety Directive has proposed aligning Annex V of the Directive to the warnings listed in the EN71 standard series (which specify safety requirements for toys), as the translation of the warnings in the Directive into national languages is not always consistent with the warnings in EN71, causing problems for industry and market surveillance authorities. The lack of consistency between the warnings outlined in Annex V of the Toy Safety Directive and the EN71 standards may present a problem in terms of the free marketing and safety of toys as different interpretations of warnings could potentially hinder and slow down business and market surveillance activities. Thus, to avoid these coherence issues, the warnings listed in Annex V of the Directive and the EN71 standards could be aligned, thus ensuring consistency (Technopolis *et al.*, 2015).

The evaluation also found that four Member States have experienced problems with CE marking of toys. Specifically, one Member State noted that the marking of dual-purpose products is unclear, while another considered the marking of toys made of several parts to be unclear. However, it should be noted that the Toy Safety Directive guidance document[152] (that was first published in 2010

[152] European Commission (2016): Toy Safety Directive 2009/48/EC – Explanatory Guidance Document. Available at: http://ec.europa.eu/growth/sectors/toys/safety/guidance/

and has been frequently updated since then) outlines the requirements and procedures relating to CE marking. In addition, Toy Industries of Europe (TIE; the trade association for the European toy industry) published a brochure in 2011 focussing on the scope and rules of CE marking[153]. Both of these documents address some of the issues raised by Member States. This therefore suggests that the problem perhaps relates to the insufficient dissemination of existing documents rather than the lack of appropriate guidance. The evaluation report therefore recommended raising awareness of these guidance documents to assist stakeholders in understanding the working mechanisms of the Directive (Technopolis *et al.*, 2015).

A number of issues have been raised with regard to toy products not meeting the labelling requirements outlined in the Toy Safety Directive. In particular, problems have been experienced with regard to the use of warnings in that they are, in some cases, applied incorrectly, written in too small a font size, which is not easily readable, and/or are not always provided in the relevant languages. Also, problems have been experienced in cases where information is missing from product labels, which can have impacts on product traceability and potentially for consumers' health if toys are not appropriately used. To increase the clarity of the requirements relating to warnings and to ensure that these are clear and understandable from the perspective of the consumer, a number of stakeholders suggest that language and font size requirements should be better regulated at the EU level. The increased use of pictograms, instead of written words, along with the modification of the font and language requirements could be considered to ensure that warnings are always clear, legible and written in all relevant languages (thus increasing the effectiveness of the Directive). The use of Q-R codes could also be considered as a smart tool to provide information while detailing warnings on manufacturer websites (Technopolis *et al.*, 2015) (further details are provided in Case Study 8).

7.4.5 Detergents

To ensure the provision of appropriate information to consumers on how to use detergent products, industry association AISE has developed a set of voluntary safe use icons, which have been communicated via on-pack labelling and other communication tools since 2004. They are made freely available by AISE to any company placing soaps, detergents or maintenance products on the EU market, provided the use of these voluntary icons/messages complies with the AISE legal and technical guidelines (AISE, 2014) [154].

A survey undertaken by AISE found that information overload on product labels can be an issue and that consumers do not want the label to be cluttered. Consumers also do not want to see too much information on the label of low-risk products (AISE, 2006) [155]. In 2010-2011, AISE conducted further market research on consumers' understanding of the safe use pictograms, which confirmed that consumers had a relatively good understanding of most of the icons, but recommended improvements to some of the icons. In addition, due to the growing use of liquid laundry detergents in the form of capsules, AISE added four new pictograms in October 2012.

[153] TIE (2011): CE Marking for the Toy Industry. Available at: http://www.tietoy.org/docrestreint.api/379/9ed51b64fe32b5077a992850bf5853b349896fac/pdf/ce_marking_for_the_toy_industry-2.pdf

[154] AISE (2014): Safe Use Icons – Update 2014, International Association for Soaps, Detergents and Maintenance Products. Available at: https://www.aise.eu/library/artwork/safe-use-icons---update-2014.aspxhttps://www.aise.eu/library/artwork/safe-use-icons---update-2014.aspx

[155] AISE (2006): Evidence from consumer perception surveys: EU Classification & Labelling Regulation (GHS), International Association for Soap, Detergents and Maintenance Products, Brussels.

Additional research undertaken with regard to stakeholders' perspectives on the effectiveness of EU labelling requirements to convey hazard and safe use information on household detergent and maintenance products[156] indicates that safe use icons are generally clearly understood by consumers and are seen as 'precautions' to consider before or during product use.

The current set of voluntary safe use icons is illustrated in Figure 7-6.

Figure 7-5: AISE safe use icons

The fact that AISE has developed and introduced such icons for inclusion on labels alongside CLP pictograms and hazard statements indicates that the legislative framework does allow for a supplementary approach to hazard and risk communication. It also suggests that industry itself will respond to such a need where it is important to ensuring safe use and where the labelling requirements do not meet the needs for communicating effectively with consumers.

As part of the targeted consultation process, stakeholders from the detergents sector were asked about the extent to which they agreed or disagreed with a series of statements regarding the current labelling system for detergents. With regard to the AISE voluntary safe use icons used on detergent and cleaning products, four out of seven (57%) of the large detergent manufacturers/formulators agreed that these icons are understood by consumers. When asked whether there is confusion between CLP hazard pictograms and those of the detergents industry (e.g. for eye damage category 1), the majority of respondents indicated that they neither agree nor

[156] AISE (2016): Safety information on household products – Better Regulation and Safe Use Project (Executive Summary), Research conducted in Belgium, Poland and Spain, July 2016.

disagree (three responses) or don't know (two responses). However, two respondents suggested that there is confusion between CLP pictograms and those used by the detergents industry.

As was the view of the larger companies, the majority of national associations (seven of nine, or 78%) agreed that consumers understand the AISE voluntary safe use icons for detergent and cleaning products. It is also clear from the responses that associations consider there to be confusion between CLP hazard pictograms and those of the detergents industry (e.g. for eye damage category 1).

Information received from consultation with the SME panel for this study (presented in section 7.3.2.2) indicates that the majority of respondents believed that CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals. Most respondents were also of the view that workers' understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products). However, it is the view of the majority of SME respondents that consumers do not understand the additional voluntary safe use icons that are included on certain products (e.g. detergent products), which supports the view of the majority of national associations.

It is also suggested by some national associations and large and small companies that, although the CLP Regulation introduced a change in labels, they do not consider this to have led to an improvement in information being communicated to consumers and end-users; thus, there is not considered to have been any progress in this regard compared to the previous system (under the Dangerous Substances Directive and the Dangerous Preparations Directive).

A key point raised during the consultation process is that warning symbols inform consumers/downstream users of what not to do, but do not provide information on what users should do when using a certain product, which is not considered to be an effective method of communication. It is therefore suggested that meaningful actionable safe use advice should be provided to consumers so that it is clear how products should be used to prevent any health impacts.

In this regard, AISE voluntary safe-use icons are considered to be effective at communicating what consumers/downstream users should do when using certain products. A respondent notes that in the Netherlands there used to be a problem with hypochlorite where people mixed this with acids. A pictogram was introduced on a voluntary basis which stated 'do not mix this' and within a year the number of accidents had reduced. Later under the Dangerous Preparations Directive, a statement was included to this effect, but was not as well understood, thus the voluntary label was reintroduced in the Netherlands. This therefore demonstrates that clear symbols that inform consumers/downstream users on how to act when using a particular product can be effective communication tools.

In contrast, a respondent to the OPC indicated that laundry detergent labelling of only certain ingredients (and in percentage range quantities) makes it difficult to determine which ingredients may be triggering allergenic effects. This means that consumers that find a suitable product (i.e. that does not cause an allergy) will keep buying this product, as it is not possible to explore alternative options (as ingredient lists cannot be compared).

Information received from AISE and other industry consultees suggests that there are legislative overlaps between the Detergents Regulation and the CLP Regulation with regard to the labelling of allergens. The Detergents Regulation requires economic operators to include allergens within the list of ingredients when they are included above certain thresholds and allows the listing using INCI names on consumer products. The CLP Regulation requires the inclusion of skin sensitisers in the list

of ingredients when they occur above certain thresholds, however, the use of INCI names is challenged by some authorities. This can create problems, as most allergens are also skin sensitisers. It can also lead to double labelling of certain ingredients resulting in labels becoming overcomplicated and confusing to consumers/professional users. The case study focusing on the detergents sector (Case Study 5) also found concern within the sector that multiple regulations dealing with labelling of products creates unnecessary regulatory burden. Thus, they consider there to be a clear opportunity for streamlining labelling requirements.

A Member State authority also highlighted that, in some cases, there is no official guidance on implementation of certain Regulations, citing Regulation (EC) No 648/2004 on detergents as an example. Further desk-based research indicates that guidance relating to the implementation of the Detergents Regulation does exist, but these have been drafted by trade associations. The AISE has produced guidelines to assist industry with the implementation of the provisions on the biodegradability of surfactants and on the labelling of detergents under the Detergents Regulation (AISE, 2013)[157]. The European Committee of Organic Surfactants and Intermediates (CESIO) has produced a guidance document which gives standardised declarations on biodegradability for use on SDSs to enable surfactant manufacturers to fulfil their responsibilities under Article 9 of the Detergents Regulation (CESIO, 2007). AISE, CESIO, ECOSOL and the European Association of Chemical Distributors (FECC) have provided guidelines on the implementation of the Detergent Regulation particularly with regard to the transmission of information for surfactants biodegradability as indicated by Article 9 of the Regulation (AISE *et al.*, 2004). These guidance documents are considered to offer assistance to economic operators in understanding the requirements of the Regulation although they have not been produced by the European Commission and are therefore not 'official' guidance. One Member State authority stakeholder has raised concerns regarding the AISE document suggesting that, in their view, this is not in compliance with the Detergents Regulation. No other stakeholder has raised any issues with regards to the guidance associated with the Detergents Regulation, which suggests that this is not a significant issue.

7.5 Appropriateness of current communication tools/systems

Key findings

- In general, safety data sheets and hazard pictograms are considered to be more appropriate and effective communication tools than Q-R codes/bar codes and product websites
- There is scope for simplification of the information included on product labels and other communication methods to facilitate their understandability and usability from the perspective of downstream users and consumers.
- Consideration of the use of innovative technologies to communicate hazard/risk information is supported by a number of different stakeholders and is identified as a potential way of enhancing hazard communication.

[157] AISE (2013): Guidelines on the implementation of the Detergents Regulation, International Association for Soaps, Detergents and Maintenance Products. Available at: https://www.aise.eu/library/publications.aspx

7.5.1 Appropriateness of communication tools

As part of the consultation process for this study, stakeholders were asked to indicate whether the current tools or systems, such as labels and SDS, used to communicate hazard and risk information to workers and other downstream users are considered to be the most appropriate for doing so.

Information received from Member State authorities indicates that:

- The majority (12 of 15, or 80%) consider the instructions on safe use of products to be either effective or very effective tools to communicate hazard and risk information to downstream users.
- All Member State authority respondents (17 in total) considered CLP pictograms to be effective (10 of 15, or 67%) or very effective (seven of 15, or 47%) tools for hazard communication.
- 15 out of 17 (88%) Member State authority respondents considered CLP hazard/precautionary statements to be effective/very effective communication tools.

However, the picture is less clear for other communication tools/systems:

- In the case of voluntary industry icons, six out of the 14 authorities that responded (i.e. less than half) considered these to be an effective method for communicating hazard and risk information. Three considered them to be ineffective or neither effective nor ineffective.
- In relation to product websites, the majority of Member State authorities (10 out of 14, or 71%) were of the view that these are neither effective nor ineffective hazard/risk communication tools. In the case of bar codes/Q-R codes, the majority of Member State authorities that responded (six of 11, or 55%) considered these to be either ineffective or very ineffective tools for communicating hazard and risk information to downstream users, with five of the view that they are neither effective nor ineffective and two considering them an effective communication option. One authority noted that bar codes/Q-R codes cannot replace a product label, as in order to use these it is necessary to always have an electronic device with the required application and internet connection, which may not be available in every situation.

Responses from industry (manufacturers, formulators, importers and distributors, as well as the SME Panel) indicate that, in their view, SDS are the most effective communication tool, followed by labels; both of these are considered more effective than product websites or the use of bar codes/Q-R codes. Interestingly, in terms of the cost of communication, SDS are ranked by industry as the least costly communication tool, followed by labelling; although product websites are ranked only as being marginally more costly in terms of the costs of communicating information. Use of bar codes and Q-R codes has been identified by some as being costly and others as being relatively cost-effective. It is not clear why such differences should arise from the information provided. Contrary to the view of most companies, national authorities appear to consider the use of bar codes/Q-R codes, product websites and pictograms (and other information on labels) to be less costly communication measures than SDS.

Information received from detergent manufacturers (non-SME) indicates that the majority also consider safe use icons to be an effective communication measure, with product websites and bar codes/Q-R codes less effective at communicating hazard and risk information to downstream users. The responses received also suggest that the majority of detergent manufacturers consider the use of product websites and bar codes/Q-R codes to be more costly communication methods than SDS, safe use icons on labels and pictograms (and other information on labels).

Information received from (nine) PPP manufacturers indicates that opinions are divided with regard to the effectiveness of SDS/instructions on safe use of the product, voluntary safe use icons on labels, pictograms and other information on labels for communicating hazard and risk information to downstream users. In each case, the same proportion of respondents indicated that these communication tools were effective or not effective; as a result, it is not possible to provide a definitive view from the responses received. However, in contrast to the views of industrial chemicals manufacturers, formulators, importers and distributors and the detergents sector, the majority of companies producing PPPs consider product websites to be more effective hazard/risk communication tools compared to the other approaches. Bar codes/Q-R codes are considered to be the least effective method for communicating hazard and risk information on PPP to downstream users. The responses from this group of manufacturers also suggest that the use of product websites as a means of communicating hazard and risk information to downstream users is considered to be the least costly measure, followed by bar codes/Q-R codes and pictograms.

It is the view of a consumer association that SDS/instructions on safe use of products, voluntary safe use icons, pictograms and other information on labels are considered to be moderately effective tools for communicating hazard and risk information to consumers and downstream users. These tools are also considered to be marginally more effective at communicating hazard and risk information to consumers (and other downstream users) than product websites and bar codes/Q-R codes. A similar view is also held by a health and environmental NGO. The NGO indicates that, in their view, voluntary safe use icons on labels are the most appropriate method for communicating hazard and risk information to consumers (and other downstream users) followed by SDS/instructions on safe use of the product, pictograms and other information on labels and bar codes/Q-R codes; the least appropriate measure for communicating hazard and risk information to consumer and other downstream users is considered to be product websites.

Consultation responses from a worker organisation indicate that, in their view, SDS/instructions on safe use of the product and pictograms are the most effective tools for communicating hazard and risk information to workers and other downstream users. Safe use icons on labels, product websites and bar codes/Q-R codes are considered to be less appropriate and less effective communication tools. The respondent notes that training for workers is key to understanding hazard and risk information. It is also noted that Q-R codes on labels could potentially be used to enable easy access to SDS.

Information obtained from the OPC indicates that, in general, industry associations/businesses and public authorities consider the hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.) and workers (e.g. labels, pictograms, SDS etc.) to be more satisfactory and hence effective than citizens and other stakeholder groups (e.g. NGOs, consumers associations, trade unions etc.).

During the SME panel, most respondents indicated that the tools and mechanisms for communicating the hazards associated with substances and mixtures could be simplified and/or improved (as indicated in Table 7-6). The responses show that larger companies are more likely to reply 'yes', that tools and mechanisms used for communicating hazards of substances and mixtures could be simplified and/or improved. In total, 41% (26) of companies with 50-249 employees replied 'yes' compared with 29% (21) of companies with 10-49 employees and 26% (10) with 1-10 employees.

The main issues identified by the SME respondents relate to:

- Pictograms (in particular GHS08) not being clear or informative enough (especially for consumers); and

- Too much text included on labels, especially when this is required to appear in multiple languages, thus restricting the understandability of the information.

Table 7-6: Responses to whether tools and mechanisms for communicating the hazards of substances and mixtures could be simplified and/or improved (n=175) – Responses to SME panel questionnaire

Response	Number/%	All activities (n=175)	Manu-facturers (n=92)	Importers (n=29)	Formu-lators (n=37)	Other down stream users (n=38)	Distrib-utors (n=40)
Yes	Number	58	30	9	15	16	14
	%	33%	33%	31%	41%	42%	35%
No	Number	36	20	8	11	5	4
	%	21%	22%	28%	30%	13%	10%
Don't know	Number	81	42	12	11	17	22
	%	46%	46%	41%	30%	45%	55%

Response	Number/%	All activities (n=175)	1-9 employees (n=38)	10-49 employees (n=72)	50-249 employees (n=64)
Yes	Number	58	10	21	26
	%	33%	26%	29%	41%
No	Number	36	7	15	14
	%	21%	18%	21%	22%
Don't know	Number	81	21	36	24
	%	46%	55%	50%	38%

Consultation responses have also highlighted issues with regards to the length of SDS. Many SDS are now several pages long, which is leading to the dilution of valuable information (e.g. one respondent indicated that extended SDS can be up to 200 to 300 pages in length and mainly contain information that is useful for experts, but less so for customers/downstream users). It has been noted that previously SDS were much shorter (some around 10 pages); they are now much more complicated and too much detailed information is included that is not always understandable from the perspective of downstream users. An industry association indicated that, in their current form, many SDS are more relevant to industrial safety and health experts rather than downstream users. Members of the association have received queries/complaints from downstream users with regard to clarifying what certain parts of the SDS mean. This therefore suggests that whilst, in general, SDS appear to be viewed as an effective hazard/risk communication method, further work is required to reduce their size in order to facilitate their understandability and usability from the perspective of downstream users.

7.5.2 Potential for use of innovative hazard/risk communication approaches

During the targeted consultation, health and environmental NGOs and worker organisations were asked to indicate whether more innovative approaches should be used to provide information on chemical hazards to consumers. Of the three responses received, all agreed that more innovative hazard communication approaches should be used. The respondents also suggested that the use of new technologies could facilitate more targeted/relevant/complete information to consumers (or other downstream users), thus improving the effectiveness of hazard communication. The NGO respondents suggested that the use of IT tools (such as bar codes and consumer apps) that are connected to CLP classification would improve hazard/risk communication and therefore enhance consumer protection. One NGO respondent also suggested that IT tools allowing comparison of products on the basis of their hazardous contents would be an effective communication measure. It

would also allow consumers to make informed choices between products containing less hazardous substances/mixtures (it is noted that apps that assist consumers in finding out about SVHC in articles are considered to be an important start in this area). However, these respondents also noted that all existing sources of information should remain in place for consumers that do not have access to (or use) electronic devices (e.g. computers, smart phones etc.). One NGO indicated that, in their view, the pictogram and hazard statement process under the CLP Regulation is useful, but more targeted awareness raising activities are needed, as recommended in ECHA's study from 2012 (ECHA, 2012).

Half of the Member State authorities that responded (nine of 18) considered there to be a danger that workers and consumers will not look for safe use information if it is not readily available (i.e. if the information is not physically on the packaging). Five authorities indicated that worker and consumer safety is paramount and innovative approaches to hazard and risk communication should not be adopted until proven.

Four Member State authorities indicated that new technologies may facilitate more targeted/relevant/complete information to downstream users (workers and consumers) to improve the effectiveness of hazard communication. However, a number also noted that these cannot replace the current labelling system. Whilst it is acknowledged that new technologies could facilitate hazard/risk communication, there remains the fact that not all workers and consumers read the information physically printed on a label, thus providing this data elsewhere to be electronically accessed may not necessarily increase the effectiveness of hazard communication. Examples of where technology may potentially increase the effectiveness of hazard/risk communication provided by authorities included the use of Q-R codes, particularly for consumers, to provide the relevant information via remote technologies. For workers, it was suggested that SDS could be made available via a bar code and should be formatted in either URL or e-book format for easier access to the information. One Member State authority noted that currently the CLP Regulation requires the label to be fixed to the packaging containing the chemical throughout the supply chain and down to the point of use. It is the view of the authority that any new technologies or methods would need to complement this approach until it can be demonstrated that they offer a more effective communication option.

Information received from the SME panel indicates that the majority of respondents are of the view that providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites in order to simplify the information currently contained on product labels.

Participants at the workshop generally agreed that technology has a clear role to play in communication with the use of bar codes, Q-R codes, Tox Fox (Germany) and programs in Demark and Norway all seen as having added value. During the discussions, it was noted that the use of technology could be a way of reducing the amount of information on product labels, thus reducing information overload. Some participants preferred keeping the existing labels, however, arguing that it should be very clearly stated on the label where additional information on a product can be found (a link to a website is not enough); a Q-R code could provide a direct link to this information. In this respect, it was suggested that specific information should be readily available on the manufacturer's website while general information could be held on the websites of authorities or ECHA. However, it was recognised that not all consumers have access to electronic devices (and would not therefore be able to access the additional information), hence care would need to be taken in ensure that there were alternative methods of hazard communication and dissemination.

Responses received from cosmetics companies also indicate that there is a need to consider the introduction of alternative vehicles and tools (i.e. digital communication) for consumer information,

other than on-pack labelling to enhance the effectiveness of risk communication. One respondent noted that, from a practical point of view, the ratio between the amount of information required on-pack and the product size can be high (e.g. in case of small pack sizes). This represents a challenge for the cosmetics industry in guaranteeing that the labelling information is easily legible for end users. It may be appropriate, therefore, to investigate the possibility of using other means of communication, rather than on-pack labelling for the mid-term future. It was suggested that this could be achieved, for example, through the digitalisation of (some of) the information (e-labelling) and that the introduction of suitable alternative communication tools such as e-labelling could enhance the effective communication (better readability) of risks for cosmetic products to end users. In addition, the use of electronic forms of communication, instead of paper forms, could be beneficial as they may reduce the environmental burden and improve the competitiveness of the cosmetic industry by reducing costs (fewer changes to packaging artworks), while maintaining or improving the level of safety communication to end users, in particular for smaller packages.

One respondent to the OPC noted that, given the diversity of cosmetic products that fall within the scope of the definition provided in Article 2 of the Cosmetic Products Regulation, and the resulting complexity of the logistics involved in their manufacture and supply to markets, any requirement to add consumer information to the labelling and packaging of cosmetic products should be implemented in the spirit of Better Regulation and foresee options for compliance that are cost-efficient and contemporary, such as the possibility to make consumer information available to the consumer electronically, instead of adding it to the label. It was suggested that without the use of these alternative measures, additional consumer information will require an increase in the size of packaging, resulting in both costs to industry but also for the environment in terms of increased use of raw materials and production of waste.

National associations for the detergents sector have suggested that the CLP Regulation does not take into account modern communication technologies, which leads to unnecessarily high costs. One association has noted that, in their view, there is a need to simplify total labelling requirements for all chemical legislation and introduce the use of other means for communicating hazards and risks, for example, through websites. Further discussions as part of the case study work (Case Study 9) suggest that stakeholders involved in the detergents sector are positive about the added value of new consumer communication technologies (e.g. quick response codes, apps or other digital media) in providing additional details to complement simplified labels so as to enhance consistent and effective consumer communication. It should be noted that the Detergents Regulation mandates that there must be a website where detailed data can be found so this practice is not new for the sector. In addition, AISE members' labels refer to the 'Clean right' website[158] which provides consumer information on optimal use of detergent products in numerous EU languages.

AISE[159] also supports the development of new labels/communications tools (e.g. Q-R tags, online information) that, without compromising on safety, will streamline hazard communication, while enabling greater flexibility and innovation in Europe. Other stakeholders have also expressed the potential of using digital media to include more detailed information and, thus, allow consumers to find out more about products in addition to the information included on labels.

Finally, one Member State authority has noted that there is a general difference concerning the amount of background information available to workers compared to downstream users

[158] CLEANRIGHT (2016): Available at: www.cleanright.eu

[159] AISE (2016): Regulatory fitness check of chemicals legislation (excluding REACH) – Key priorities for the detergents and maintenance industry, Position paper.

(consumers). In the case of workers, training concerning chemicals management is necessary and is also used to inform workers of new developments in hazards and risks associated with the use of substances/mixtures. This instrument is not available for consumers, thus new technologies could potentially be used to enhance safety communication.

Whilst the appropriateness of certain hazard communication tools (such as Q-R codes and bar codes) has been questioned by some stakeholders, many also accept that innovative measures to reduce information on product labels and, hence, simplify the communication of hazards associated with products is necessary to ensure that downstream users/consumers understand the main hazards and risks involved in their use.

Whilst many respondents have indicated that that all existing sources of information should remain in place for consumers that do not have access to or use electronic devices (e.g. computers, smart phones etc.), the increasing use and availability of digital devices and media highlights their potential future importance and applicability in hazard communication.

7.6 Extent of positive/negative impacts following implementation of the CLP Regulation

Key findings

- Responses to consultation indicate that hazard communication under the CLP Regulation has had a positive impact on health and safety and the environment, due to improved access of labelling data and improved hazard communication (although some of this may be attributable to better information being available through REACH).

As part of the consultation process, stakeholders were asked to indicate the extent of the positive/negative impacts that have occurred, with respect to health and safety and the environment, following the implementation of the CLP Regulation. Tables 7-7 and 7-8 provide details of the responses received from manufacturers, importers, distributors and formulators (general chemicals).

As shown in Tables 7-7 and 7-8, the majority of respondents considered increased access to classification and labelling data for substances to have had a positive impact (low positive or large positive) on health and safety (77% of 105 respondent) and the environment (77% of 103 respondents). Most respondents (37% of 105) were also of the view that hazard communication for workers following the implementation of the CLP Regulation has resulted in a low positive impact with respect to health and safety. The situation is less clear in the case of the environment, as the same proportion of respondents (38%) have indicated that hazard communication to workers has had a low positive impact and no change with regard to environmental protection. However, combining the 'large positive' and 'low positive' responses indicates that over half (57%) of respondents consider hazard communication for workers to have had a positive impact on environmental protection.

With regard to the extent of the impacts of hazard communication for consumers, the majority of economic operators considered there to have been no significant change in terms of protection of health (33%) and the environment (41%) following implementation of the CLP Regulation. However, it is important to note that almost half of respondents considered the implementation of the CLP

Regulation and the communication of hazards for consumers to have had a positive impact (either large positive impact or low positive impact) on health and safety and environmental protection.

In terms of changes to packaging requirements resulting from the implementation of the CLP Regulation, the majority of respondents consider that these have not contributed to a significant change in health and safety (45%) and protection of the environment (46%).

Table 7-7: Economic operator views on impacts of CLP with respect to health and safety (n=105) – Responses to the targeted questionnaire

Answer Options	Large positive impact	Low positive impact	Neutral/no change	Low negative impact	Large negative impact	Don't know
Increased access to classification and labelling data for substances	39%	38%	18%	1%	0%	2%
Hazard communication for workers	26%	37%	29%	6%	0%	2%
Hazard communication for consumers	17%	28%	33%	14%	0%	7%
Changes in packaging requirements	7%	14%	45%	14%	3%	13%

Table 7-8: Economic operator views on impacts of CLP with respect to the environment (n=103) – Responses to the targeted questionnaire

Answer Options	Large positive impact	Low positive impact	Neutral/no change	Low negative impact	Large negative impact	Don't know
Increased access to classification and labelling data for substances	37%	40%	21%	0%	0%	2%
Hazard communication for workers	19%	38%	38%	2%	0%	2%
Hazard communication for consumers	18%	28%	41%	6%	0%	4%
Changes in packaging requirements	7%	15%	46%	13%	0%	16%

Tables 7-9 and 7-10 provide details of the responses received from operators in the detergents sector. As indicated in Tables 7-9 and 7-10, the majority of respondents in the detergents sector considered increased access to classification and labelling data for substances following implementation of the CLP Regulation to have had a low positive impact on health and safety and the environment. However, in contrast to the view of economic operators more generally, the majority of large detergent manufacturers considered the hazard communication for workers, hazard communication for consumers and changes in packaging requirements following implementation of the CLP Regulation to have had a negative impact on health and safety (presumably due to the view that the CLP Regulation has resulted in the over-classification of detergent mixtures and due to the large number of products that are now labelled with the exclamation mark pictogram). In the case of the environment, the majority of respondents considered the implementation of the CLP Regulation to have caused no significant change to the protection of the environment resulting from changes in hazard communication for workers and consumers and changes in packaging requirements.

Table 7-9: Non-SME detergent formulator views on impacts of CLP with respect to health and safety (n=7) – Responses to the targeted questionnaire						
Answer Options	**Large positive impact**	**Low positive impact**	**Neutral/no change**	**Low negative impact**	**Large negative impact**	**Don't know**
Increased access to classification and labelling data for substances	14%	43%	14%	29%	0%	0%
Hazard communication for workers	0%	29%	0%	29%	29%	14%
Hazard communication for consumers	0%	0%	14%	29%	57%	0%
Changes in packaging requirements	0%	14%	29%	43%	0%	0%

Table 7-10: Non-SME detergent formulator views on impacts of CLP with respect to the environment (n=7) – Responses to the targeted questionnaire						
Answer Options	**Large positive impact**	**Low positive impact**	**Neutral/no change**	**Low negative impact**	**Large negative impact**	**Don't know**
Increased access to classification and labelling data for substances	14%	57%	14%	0%	0%	14%
Hazard communication for workers	0%	29%	57%	0%	0%	14%
Hazard communication for consumers	0%	14%	57%	0%	14%	14%
Changes in packaging requirements	0%	14%	43%	0%	14%	29%

Tables 7-11 and 7-12 provide details of the responses received from producers of PPPs with regard to the positive/negative impacts of labelling/hazard communication changes that have occurred through implementation of the CLP Regulation. These responses indicate that stakeholders in the PPPs sector have a similar view to stakeholders dealing with general and industrial chemicals and the detergents sector; the majority consider increased access to classification and labelling data for substances following implementation of the CLP Regulation to have had a positive impact on health and safety and the environment. The majority PPP respondents also considered hazard communication for workers and consumers to have resulted in a positive impact on health and safety and environmental protection. However, the majority did not consider the changes in packaging requirements introduced by the CLP Regulation to have resulted in a significant change in health and safety and protection of the environment.

Table 7-13 provides details of the responses received from SMEs. In general, the majority of SME respondents considered the CLP Regulation and other EU hazard communication requirements to have increased access to classification data for substances and resulted in more consistent hazard classifications across substances. Also, the majority of SME respondents considered the CLP Regulation and other EU hazard communication requirements to have had a positive impact on the safe use of chemicals by workers and consumers, as well as increasing preparedness for industrial accidents and awareness of the potential health and environmental impacts of chemical products.

Table 7-11: Producers of plant protection products views on impacts of CLP with respect to health and safety (n=9) – Responses to the targeted questionnaire						
Answer Options	**Large positive impact**	**Low positive impact**	**Neutral/no change**	**Low negative impact**	**Large negative impact**	**Don't know**
Increased access to classification and labelling data for substances	11%	67%	22%	0%	0%	0%
Hazard communication for workers	22%	56%	22%	0%	0%	0%
Hazard communication for consumers	22%	56%	11%	0%	11%	0%
Changes in packaging requirements	0%	22%	67%	11%	0%	0%

Table 7-12: Producers of plant protection products views on impacts of CLP with respect to the environment (n=9) – Responses to the targeted questionnaire						
Answer Options	**Large positive impact**	**Low positive impact**	**Neutral/no change**	**Low negative impact**	**Large negative impact**	**Don't know**
Increased access to classification and labelling data for substances	11%	67%	22%	0%	0%	0%
Hazard communication for workers	11%	44%	44%	0%	0%	0%
Hazard communication for consumers	11%	44%	33%	11%	0%	0%
Changes in packaging requirements	0%	11%	78%	11%	0%	0%

Table 7-13: Number of responses by level of impacts of the CLP Regulation and other EU hazard communication requirements (n=200 to 203) – Responses to the SME panel questionnaire						
Impact	**Large positive impact**	**Low positive impact**	**Neutral / No change**	**Low negative impact**	**Large negative impact**	**Don't know**
Increased access to classification data for substances (n=203)	30%	33%	24%	2%	1%	9%
More consistent hazard classifications across substances (n=202)	29%	37%	21%	4%	1%	7%
Safe use of chemicals by workers (n=203)	27%	36%	30%	3%	1%	3%
Safe use of chemicals by consumers (n=203)	23%	23%	34%	3%	1%	14%
Changes in packaging requirements (n=203)	11%	24%	40%	8%	2%	15%
Preparedness for industrial accidents (n=201)	22%	31%	33%	1%	1%	13%
Increased awareness of the potential health impacts of chemical products (n=203)	32%	33%	27%	1%	1%	5%
Increased awareness of the potential environmental impacts of chemical products (n=200)	30%	37%	28%	3%	1%	3%

In general, the responses received from Member State authorities support those received from economic operators (see Table 7-14). All 16 Member State authorities considered the increased access to classification and labelling data for substances to have had a positive impact on health and safety and the environment. The majority also indicated that hazard communication for workers (69%) and consumers (62%) following implementation of the CLP Regulation has resulted in a positive impact with respect to health and safety and protection of the environment. However, unlike the responses received from economic operators, the situation is less clear with regard to authorities' views on changes in packaging requirements resulting from the implementation of the CLP Regulation, with authorities more positive about the impact these have had.

Table 7-14: Member State authority views on impacts of CLP with respect to health and safety and the environment (n=16) – Responses to the targeted questionnaire

Answer Options	Large positive impact	Low positive impact	Neutral/no change	Low negative impact	Large negative impact	Don't know
Increased access to classification and labelling data for substances	73%	27%	0%	0%	0%	0%
Hazard communication for workers	31%	38%	25%	0%	0%	6%
Hazard communication for consumers	31%	31%	25%	6%	0%	6%
Changes in packaging requirements	20%	27%	27%	7%	7%	13%

One consumer association indicated that, in their view, the CLP Regulation has increased access to classification and labelling data for substances and has had a low positive impact on health and safety. The respondent did not provide a definitive view with regard to the impacts of hazard communication for workers and consumers following implementation, however, they suggested that the changes in packaging requirements have not resulted in any significant impacts (positive or negative) on health and safety.

Responses were also received from two health and environmental NGOs, with these generally supporting the views of Member State authorities. Both NGOs believed that increased access to classification and labelling data has had a large positive impact on the protection of the environment. This was also considered to be the case with regard to hazard communication to workers. Both respondents considered hazard communication under the CLP Regulation to have had a positive impact on environmental protection. In the case of changes in packaging requirements, one respondent indicated that this has had a large positive impact on the environment, whereas the other selected 'don't know'.

Information received from a worker organisation during the targeted consultation indicates that, in their view, increased access to classification and labelling data following implementation of the CLP Regulation has had a low positive impact on worker health and safety. The organisation also noted that the CLP Regulation has not resulted in any significant changes in terms of hazard communication for workers and consumers.

Overall, the information obtained from stakeholders suggests that hazard communication under the CLP Regulation has had a positive impact on health and safety and the environment. However, the majority of respondents do not consider the changes in packaging requirements introduced by the CLP Regulation to have resulted in a significant change in health and safety and protection of the environment.

8 Packaging

8.1 Packaging requirements

8.1.1 Summary of packaging approaches

Although Task 1 includes consideration of the effectiveness and efficiency of the tools within the CLP Regulation, further assessment is also a key element of Task 2. In this case, we consider the effectiveness, efficiency and relevance of the measures and tools, both across legislation more broadly, but also in terms of how the CLP Regulation links with the packaging requirements under other legislation.

Article 35 of the CLP Regulation outlines the packaging requirements for substances and mixtures, with the requirements set out in Table 8-1 below. In addition, Article 33 of the CLP Regulation provides specific rules for labelling of outer packaging, inner packaging and single packaging.

Table 8-1: Summary of the main packaging requirements under different pieces of legislation

Article 35:

Paragraph 1 states that:

"packaging containing hazardous substances or mixtures shall satisfy the following requirements:

1. *the packaging shall be designed and constructed so that its contents cannot escape, except in cases where other more specific safety devices are prescribed;*
2. *the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents;*
3. *the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;*
4. *packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping".*

Paragraph 2 indicates that:

"*packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children or to mislead consumers, or have a similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products, which would mislead consumers*".

In addition paragraph 2 states that:

"*where packaging contains a substance or mixture which meets the requirements in section 3.1.1 of Annex II it shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II. Where packaging contains a substance or mixture which meets the requirements in section 3.2.1 of Annex II it shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II*".

Paragraph 2 also states that:

"where a liquid consumer laundry detergent, as defined in Article 2(1a) of Regulation (EC) No 648/2004 of the European Parliament and of the Council [the Detergents Regulation], is contained in a soluble packaging for single use, the additional requirements of section 3.3 of Annex II shall apply".

Paragraph 3 of Article 35 indicates that:

"the packaging of substances and mixtures shall be deemed to satisfy the requirements of paragraph 1(a), (b) and (c) if it complies with the requirements of the rules on the transport of dangerous goods by air, sea

Table 8-1: Summary of the main packaging requirements under different pieces of legislation
road, rail or inland waterways".
Article 33: Paragraph 1 states that: *"where a package consists of an outer and an inner packaging, together with any intermediate packaging, and the outer packaging meets labelling provisions in accordance with the rules on transport of dangerous goods, the inner and any intermediate packaging shall be labelled in accordance with this Regulation. The outer packaging may also be labelled in accordance with this Regulation. Where the hazard pictogram(s) required by the Regulation relate to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear on the outer packaging".* Paragraph 2 of Article 33 indicates that: *"where the outer packaging of a package is not required to meet labelling provisions in accordance with rules on the transport of dangerous goods, both the outer and any inner packaging, including any intermediate packaging, shall be labelled in accordance with this Regulation. However, if the outer packaging permits the inner or intermediate packaging labelling to be clearly seen, the outer packaging need not be labelled".* Paragraph 3 of Article 33 states that: *"single packages that meet the labelling provisions in accordance with the rules on the transport of dangerous goods shall be labelled both in accordance with this Regulation and the rules on the transport of dangerous goods. Where the hazard pictogram(s) required by this Regulation relate to the same hazard as in rules on the transport of dangerous goods, the hazard pictogram(s) required by this Regulation need not appear".*

As noted in Section 2, mapping work has been undertaken to identify other EU acts which set similar or different packaging requirements for hazardous substances or mixtures. Table 2-2 of Section 2.3 provides the results of the mapping exercise. Table 8-2 below provides an overview of the packaging requirements identified from the mapping exercise in legislation with horizontal links to the CLP Regulation.

Table 8-2: Summary of the main packaging requirements under different pieces of legislation	
EU act	**Packaging provisions**
Consumer products	
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	Article 14: appearance and content of unit packages
Council Directive 75/324/EEC on aerosol dispensers	Annex contains packaging requirements for metal and glass aerosol dispensers, and unprotected glass containers regarding capacity, coating and filing
Professional Products	
Regulation (EC) No 1107/2009 on plant protection products	Dangerous Preparations Directive requirements apply to packaging of PPP, including to packaging of PPP and adjuvants that would not fall under the scope of Dangerous Preparations Directive (Art.64(3)). Although the Dangerous Preparations Directive has now been replaced by the CLP Regulation. The authorisation can include requirements as to the packaging size and material (Art. 31(4)(j). Plant protection products and adjuvants that may be mistaken for food, drink or feed shall be packaged in such a way as to minimise the likelihood of such a mistake being made […] and shall contain components to discourage or prevent their consumption (Art.64(1) and (2)).

Table 8-2: Summary of the main packaging requirements under different pieces of legislation	
EU act	**Packaging provisions**
Regulation (EU) No 528/2012 biocidal products	Biocidal products must be classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, and with the CLP Regulation (Article 69(1)). Products which may be mistaken for food are to be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children (Article 69(1)). Where necessary because of the size or the function of the biocidal product, certain information may be indicated on the packaging or on an accompanying leaflet integral to the packaging (Article 69(3)).
Regulation (EC) No 2003/2003 relating to fertilisers	Article 10 provides where and how the above-mentioned markings must be applied to the packaging/accompanying documents.
Directive 2014/28/EU on the making available on the market and supervision of explosives for civil uses (recast)	The identification should be placed on the explosives and/or packaging. These obligations are implemented through Directive 2008/43/EC, which set up a system for the identification and traceability of explosives for civil uses.
Directive 2008/98 on waste	According to Article 19, hazardous waste must be packaged in accordance with the international and Community standards in force. The Directive does not set additional labelling requirements.
Environmental Protection	
Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (recast)	Chemicals that are intended for export shall be subject to the provisions on packaging and labelling established in, or pursuant to, the CLP Regulation, PPP Regulation or the Biocidal Products Regulation or any other relevant Union legislation. This requirement applies unless those provisions would conflict with any specific requirements of the importing Parties or other countries. (Art.17(1))

The remainder of this section provides further information obtained from desk-based research and stakeholder consultation with regard to the presence of any gaps, overlaps or inconsistencies in the packaging requirements outlined in legislation with a horizontal link to the CLP Regulation, as well as the effectiveness of the packaging requirements in the legislative framework. The associated evaluation questions are given in Table 8-3.

Table 8-3: Evaluation questions relating to packaging	
Q #	**Evaluation Question**
1.1.1	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring a high level of protection of human health and the environment?
1.1.1.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
1.1.2	Does the EU legislative framework for the risk management of chemicals meet the primary objective of ensuring the efficient functioning of the single market?
1.1.2.2	Are harmonised communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
1.1.2.3	Are the information requirements on chemicals (including on e.g. chemical content, hazard,

Table 8-3: Evaluation questions relating to packaging	
Q #	**Evaluation Question**
	risk, use) and the availability of this information sufficiently clear to allow their harmonised application throughout the single market?
1.1.3	Does the EU legislative framework for the risk management of chemicals meet the primary objective of enhancing competitiveness and innovation?
1.1.3.1	Are the communication measures to workers, consumers, and businesses (in particular SMEs) effective in reaching the above-mentioned objective?
2.1.6	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
3.1.3	To what extent do the objectives of the legislative framework for chemicals meet the need for enabling/promoting circular economy? Are there conflicting objectives and how can they be solved? Are there synergies? Which of the risk management approaches (based on generic risk consideration or specific risk assessment) is more effective and efficient in enabling/promoting circular economy?
3.2.2	To what extent are information requirements in the current legislative framework adequate to enable informed choices, promotion of safer alternatives, safe handling and use throughout the life cycle of chemicals and products/article?
4.2.2	What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

8.2 Gaps, overlaps and inconsistencies in packaging requirements

Key findings

- Transport of dangerous goods – a product packaged with a CLP 'corrosive' symbol does not need to be handled and stored in the same way as dangerous goods with a transport 'corrosive' symbol. However, the CLP 'corrosive' symbol can be confused with the transport 'corrosive' symbol resulting in unnecessary transport and storage costs.
- Transport of dangerous goods – overlaps between the CLP Regulation and international transport rules with regards to labelling of outer packaging.
- Transport of dangerous goods – implementation of the limited quantities (LQ) exemption means that there is not a need to include any additional transport or CLP hazard labels on outer packaging. However, the packages used to transport products are also often used to store them, thus, the inclusion of the LQ mark on the outer packaging means that the CLP hazard label cannot be easily seen, thus impacting hazard communication during storage and use.
- Transport of dangerous goods –the majority of respondents to the consultation process do not consider these rules to be particularly clear, suggesting that there is room for improvement in terms of ensuring that the labelling rules under the CLP Regulation and transport legislation are understood within the supply chain.
- Explosive articles – guidance on the application of CLP labels directly onto the surface of explosive articles, would help facilitate understanding of the requirements in this respect
- Packaging Directive – desk research suggests that chemical requirements relating to packaging should be strengthened to ensure that protection of human health is raised to the same level as the environment, thus ensuring adequate protection of human health from direct exposure of users to packaging.
- Packaging Directive – the Directive should include a procedure (such as delegated acts) in

order to allow the adoption or modification of limits for chemicals in packaging in a fast and flexible way (without having to change the whole pieces of legislation in the European Parliament and the Council).

- Plant Protection Products – a number of industry stakeholders are of the view that the Plant Protection Products Regulation should set out all relevant packaging requirements rather than making reference to the CLP Regulation. Although, this is not considered to be a significant issue, the removal of this linkage is considered to assist in avoiding the potential for future inconsistences or overlaps which may give rise to confusion.
- Fertilisers Regulation – this regulation makes no specific reference to the CLP Regulation and does not itself contain general packaging requirements, only specific ones. It is therefore not clear whether the packaging requirements under the CLP Regulation apply to EC fertilisers (at least those not covered by Articles 24 and 28 of the Fertilisers Regulation). However, this has not been raised as a specific concern by stakeholders during the consultation process; hence this is not considered to present a significant issue.

8.2.1 Introduction

The following discussion provides details of any gaps, overlaps or inconsistencies identified in relation to the packaging requirements outlined in legislation with a horizontal link to the CLP Regulation.

8.2.2 Transport of dangerous goods

Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods lays down common rules for the safe and secure transport of dangerous goods within and between EU countries by road, rail or inland waterway. It also covers aspects such as loading and unloading, the transfer to and from another mode of transport, as well as the stops during the course of the transport process (Eur-lex, 2015)[160].

The international transport of dangerous goods is regulated by the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) and the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). These international rules are required to be extended to national transport across the EU in order to harmonise the conditions under which dangerous goods are transported and to ensure the proper functioning of the EU's common transport market. The ADR, RID and ADN have drawn up a list of dangerous goods, indicating whether their transport is prohibited or not and defining the requirements for their transport if it is authorised. EU countries may request temporary derogations under certain conditions (Eur-lex, 2015).

As indicated above, Article 33 of the CLP Regulation outlines the rules to be followed for labelling outer packaging, inner packaging and single packaging, where packaging of substances and mixtures is required to also meet labelling provisions according to the rules on the transport of dangerous goods. The main principle of the CLP Regulation is not to override any labelling required by the transport rules, while maintaining essential hazard information on the relevant layer(s) of packaging.

[160] Eur-lex (2015): Inland transport of dangerous goods, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Atr0006

Transport 'labelling'[161] is required to appear on single or composite packages or the outer packaging of hazardous substances and mixtures if these are 'dangerous goods' according to the rules on the transport of dangerous goods. Single packages are required to include both the CLP label elements and the transport label elements, except for the CLP hazard pictograms where these are already covered by equivalent transport pictograms reflecting the same hazard. CLP labelling is required on every inner and intermediate packaging layer of a substance or mixture and may also appear on outer packaging, although this is not obligatory if those goods are carrying dangerous goods transport labelling (Vance, 2014)[162].

Figure 8-1 provides a simplified overview of when labelling according to the CLP Regulation and transport of dangerous goods rules (Directive 2008/68/EC) apply for different types of packaging.

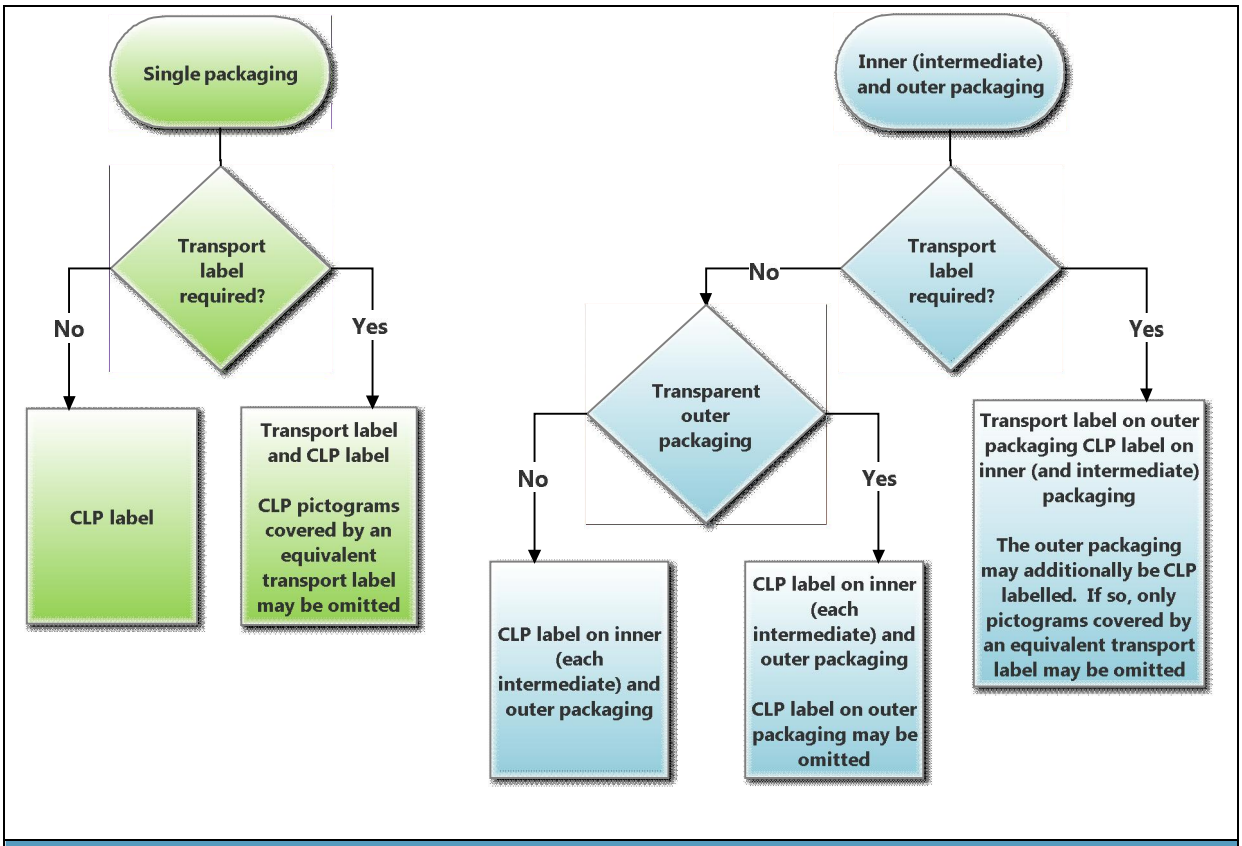

Figure 8-1: Overview of when labelling according to the CLP Regulation and transport of dangerous goods rules (Directive 2008/68/EC) apply for different types of packaging (Shi, 2011)[163]

[161] 'Labelling' includes the Excepted Quantity (EQ) package and Limited Quantity (LQ) package marks as well as the transport class danger labels.

[162] Vance C. (2014): Labelling requirements of the CLP, biocides and detergents regulations. Croner-I, available at: https://app.croner.co.uk/feature-articles/labelling-clp-biocides-and-detergents?product=34

[163] Shi Y. (2011): CLP Labelling and Transport Labelling for Substances and Mixture in Europe, Chemical Inspection and Regulation Service (CIRS, available at: http://www.cirs-reach.com/CLP/CLP_Labelling_Transport_Labelling_for_Substances_and_Mixtures_in_Europe.pdfhttp://www.cirs-reach.com/CLP/CLP_Labelling_Transport_Labelling_for_Substances_and_Mixtures_in_Europe.pdf

8.2.2.1 Specific issues

During the consultation process for Case Study 9 and from OPC responses, stakeholders have highlighted an overlap with regard to the CLP Regulation and transport of dangerous goods legislation. One particular issue identified by stakeholders (include Member State authorities and industry stakeholders) relates to Article 33 of the CLP Regulation which requires all packaging to be labelled with a CLP hazard pictogram (where necessary) even where no transport label is required. Stakeholders have noted that this can lead to problems with respect to the 'corrosive' symbol under the CLP Regulation (as indicated in Figure 8-2). This pictogram applies to both corrosivity to metals and to skin (i.e. Skin Cat. 1) under CLP and to substances which will cause severe damage when in contact with living tissue or, in the case of leakage, will materially damage or destroy other goods or the means of transport under the transport of dangerous goods legislation

The issue is that a product packaged with a CLP 'corrosive' symbol does not need to be handled and stored in the same way as dangerous goods with a transport 'corrosive' symbol.

Figure 8-2: Left to right - 'corrosive ' label under the CLP Regulation and transport of dangerous goods legislation

The inclusion of the CLP 'corrosive' pictogram on product packaging can therefore result in distributors confusing this with the 'corrosive' pictogram under the transport of dangerous goods legislation and thus storing the package according to the 'corrosive' transport pictogram. For example, under the transport legislation:

- some materials (depending on classification) may not be loaded, transported, or stored together in the same transport vehicle or storage facility during the course of transportation; and
- some materials may not be loaded, transported or stored together in the same transport vehicle or storage facility during the course of transportation, unless separated in a manner that, in the event of leakage from packages under conditions normally incident to transportation, commingling of hazardous materials would not occur.

In this case, transportation and storage of the product is more costly and insurance is required; as a result, in practice the similarity of the symbols and the lack of understanding of the difference (by distributors) can cause problems. Stakeholders indicated that confusion with the 'corrosive' pictogram under the two pieces of legislation has resulted in the consideration of the use of a different symbol under the transport legislation. This would solve the problem as, in this case, all CLP-classified products would be 'classified' for transport as well, hence a CLP label would no longer be needed on transport packaging. Although efforts were made to harmonise the way pictograms are used to symbolise hazards under the CLP Regulation and transport of dangerous goods legislation, the confusion that arises in practice was not foreseen.

Several stakeholders have also identified another overlap between the CLP Regulation and international transport rules. Paragraph 2 of Article 33 of the CLP Regulation refers to 'outer packaging' in the context of both supply and transport, where it indicates that the outer packaging must include a CLP label when it does not come under the remit of the transport of dangerous goods legislation. This has resulted in difficulties particularly for those in the distribution chain that are tasked with putting together several different chemicals for supply purposes (not classified under the transport of dangerous goods legislation) within a single outer packaging for transport reasons, where it has proved impractical to apply several CLP labels on a single outer package. This has led to unclear hazard communication on the outer packaging. It is noted that this is currently being discussed by CARACAL.

Another issue highlighted by stakeholders (see also Case Study 9) relates to the implementation of the limited quantities (LQ) exemption. Under the transport of dangerous goods legislation, an LQ exemption can be applied if products are transported in units of limited quantities (which depend on the packaging group that the product is grouped under). The LQ provisions mean that only the LQ mark (limited quantity pictogram) is required to be included on the outer package and there is not a need to include any additional transport or CLP hazard labels. However, the packages used to transport products are also often used to store them, thus, the inclusion of the LQ mark on the outer packaging means that the CLP hazard label cannot be easily seen. Stakeholders have suggested that the CLP hazard label should be easily visible to ensure user safety.

As indicated in Article 35 of the CLP Regulation, packaging materials need to *"… not be susceptible to damage by the contents…*" (paragraph 1(b)) and "*the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling*" (paragraph 1(c)). During the consultation process, it was suggested that it would be helpful if the CLP Regulation could consider packaging over the lifetime of the chemical in storage and not just during transport. This is because many users, including schools and colleges, store reagents in the packaging in which it is supplied and may need to do so for long periods (many years). This can raise problems with certain reagents. For example, concentrated nitric acid can attack plastic containers over time to the extent that they leak; hydrogen chloride permeates through the plastic bottles containing hydrochloric acid and sulphuric acid reacts with the plastic bottle material. Although users could decant reagents into fresh containers, the transfer process would raise additional risks. An employers association noted that manufacturers are reluctant to supply these chemicals in glass containers (which would be less susceptible to damage from the reagents) due to experiences of breakages in transit. The reagents are generally supplied as limited quantity (LQ) and therefore often not sent via fully-ADR-trained carriers. The plastic containers used are fully UN-compliant, but are not suitable for long term storage.

8.2.2.2 Clarity of interlinkages and rules

As part of the targeted consultation, industry stakeholders were asked whether the rules regarding labelling of outer packaging, inner packaging and over-packs were clear across the CLP Regulation and transport legislation. As indicated in Table 8-4, the responses received from manufacturers, distributors, formulators and importers indicate that most companies believe they themselves understand the rules, but that others within the supply chain may not. Note that manufacturers and distributors are the most positive about the level of understanding, with formulators and importers the most negative about the level of understanding.

Table 8-4: Views from manufacturers, distributors, formulators and importers on the extent to which rules on labelling of outer packaging, inner packaging and over-packs are clear under CLP and transport legislation (n=109) – Responses to targeted questionnaire	
Answer Options	**Yes***
To your suppliers?	51%
To your company?	84%
To your customers?	39%
To transport / shipping companies?	53%
To Member State authorities?	45%
* Note: importers were not asked about suppliers and Member State authorities	

The same question was also asked to operators in the detergents sector. The responses received from national associations and companies in the detergents sector are summarised in Table 8-5.

Table 8-5: Views from the detergents sector on the extent to which rules on labelling of outer packaging, inner packaging and over-packs are clear under CLP and transport legislation – Responses to targeted questionnaire			
Large companies			
Answer Options	**Yes**	**No**	**No. of responses**
To your company?	83%	17%	6
To transport / shipping companies?	25%	75%	4
To member state authorities?	0%	100%	3
SMEs			
Answer Options	**Yes**	**No**	**No. of responses**
To your company?	91%	9%	11
To transport / shipping companies?	43%	57%	7
To member state authorities?	86%	14%	7
National associations			
Answer Options	**Yes**	**No**	**No. of responses**
To your company?	33%	67%	9
To transport / shipping companies?	11%	89%	9
To member state authorities?	33%	67%	3

As shown in the table, while the majority of large companies and SMEs considered the rules regarding labelling of outer packaging, inner packaging and over-packs to be clear from the perspective of their company, most did not think the rules were clear to transport/shipping companies. National associations indicated that the rules were not clear from their perspective, nor from the perspective of transport/shipping companies or Member State authorities. However, in contrast, SMEs believed that the rules on labelling of outer packaging, inner packaging and over-packs are clear to Member State authorities.

Manufacturers of PPPs were also asked whether they consider the rules regarding labelling of outer packaging, inner packaging and over-packs to be clear across the CLP Regulation and transport legislation. The responses received (presented in Table 8-6) generally support the views of other economic operators in that the majority consider the rules to be clear from their company's

perspective. However, a larger proportion of PPP manufacturers believed the rules were clear for transport/shipping companies.

Table 8-6: Views from plant protection product manufacturers on the extent to which rules on labelling of outer packaging, inner packaging and over-packs are clear under CLP and transport legislation – Responses to targeted questionnaire

Answer options	Yes	No	Don't know	No. of responses
To your suppliers?	22%	67%	11%	9
To your company?	67%	33%	0%	9
To your customers?	22%	67%	11%	9
To transport / shipping companies?	44%	33%	22%	9
To member state authorities?	33%	44%	22%	9

As for the detergents sector, there were differences between the views of SMEs and larger organisations responding on behalf of the PPP sector. All non-SME respondents considered the labelling of outer packaging, inner packaging and over-pack rules across the CLP Regulation and transport legislation to be clear to their suppliers, while only 50% of SME respondents agreed with this view. Similarly, the majority of SME respondents were of the view that these rules are clear from their company's perspective and from the perspective of Member State authorities.

Overall, the majority of all respondents did not consider these rules to be particularly clear, suggesting that there is room for improvement in terms of ensuring that the labelling rules under the CLP Regulation and transport legislation are understood within the supply chain.

8.2.3 Explosive articles

During the consultation process, a Member State authority noted recent experience of difficulties for companies in achieving compliance of explosive articles (munitions) with the CLP Regulation. While there is an exemption from the CLP Regulation for certain substances and mixtures (and therefore explosive articles) in the interest of defence, difficulties have been experienced in those cases where compliance is desirable. One issue relates to the transport of ordnance munitions and explosives (OME) through the defence supply chain, which may include items that consist of inner, outer and combination packaging. As such, items may also be transported between or through various countries and jurisdictions. In such cases, the relevant labelling and packaging rules can be diffuse, complex to interpret and difficult to comply with.

In addition, it is noted that operational and safety reasons prevent the application of CLP labels directly onto the surface of explosive articles themselves, where for example munitions may not have any immediate packaging. It is suggested by the respondent that there may be scope for specific guidance on the labelling of such articles.

8.2.4 Packaging Directive

The objective of the Packaging and Packaging Waste Directive (94/62/EC) is (according to Article 1(1)) to harmonise national measures concerning the management of packaging and packaging waste in order:

- On the one hand, to prevent any impact on the environment of all Member States as well as of third countries, or to reduce such impacts thus providing a high level of environmental protection; and

- On the other hand, to ensure the functioning of the internal market and to avoid obstacles to trade and distortion and restriction of competition within the Community.

Paragraph 2 of the Directive indicates that it lays down measures aimed, as a first priority, at preventing the production of packaging waste and, as additional fundamental principles, at reusing packaging, at recycling and other forms of recovering packaging waste and, hence, at reducing final disposal of such waste.

Article 11 of the Directive sets out concentration levels for heavy metals in packaging. Article 11(1) indicates that:

> *"Member States shall ensure that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed the following:*
>
> - *600 ppm by weight two years after the date referred to in Article 22 (i);*
> - *250 ppm by weight three years after the date referred to in Article 22 (i);*
> - *100 ppm by weight five years after the date referred to in Article 22 (i)".*

In addition, there is an essential requirement in Annex II which states that "*packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimised with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled*".

It is the view of ANEC that the essential requirement set out in Annex II of the Directive is rather vague, and that it does not appear to take into account adverse health effects arising from the direct exposure of users to packaging (ANEC, 2014b).

Some additional requirements have been incorporated in the related harmonised European standards. EN 13428:2004 regarding "*Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction*" essentially requires suppliers to determine whether substances or preparations classified as dangerous to the environment (indicated by the symbol 'N') are likely to be present in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled. If this is the case, the supplier needs to be able to demonstrate that such substances have been minimised, which ANEC considers to be a highly questionable approach.

ANEC and the European Environmental Citizens' Organisations for Standardisation (ECOS) have heavily criticised this standard developed by the CEN packaging committee. As regards chemicals, it was stated that (ANEC, 2014b):

> *"The Packaging Directive calls for a general minimisation of hazardous material to the environment in packaging material. The European standard 13428, however, limits itself to a restricted number of substances or preparations, namely those classified as dangerous to the environment in accordance with legislation and which need to be labelled with the symbol 'N'. Many potentially dangerous chemicals falling in other danger classes (such as CMR) substances are not even considered. Furthermore, once a dangerous substance for the environment has been identified, according to the standard it must only be demonstrated that the minimum amount of this substance has been used to satisfy the functional requirements. Hence, it is allowed to use dangerous substances for the environment despite the general environmental concerns about the*

substance. The standard does not encourage the search of an alternative less hazardous substitute. In many cases the manufacturer will use the minimum amount for economic reasons anyway and therefore it could be argued that this standard justifies the continued use of substances dangerous for the environment".

Consequently, ANEC and ECOS called upon the Commission to solve the issues by including specific requirements within the Packaging Directive. In order to address this gap in the Packaging Directive, ANEC proposes the following (ANEC, 2014b):

- *The chemical requirements included in the Packaging Directive (94/62/EC) should be strengthened. Generally, protection of human health should be raised to the same level as the environment;*
- *The limits should be defined in legislation rather than in standards;*
- *CMR substances of categories 1A, 1B and 2 should be banned from packaging;*
- *Substances that meet the criteria of PBTs or vPvB included in Annex XIII of the REACH Regulation should be banned from packaging;*
- *Specific limits should be established based on comprehensive assessment of chemical substances used in packaging including printing inks;*
- *Nanomaterials should not be used in packaging unless endorsed by a scientific committee; and*
- *The Packaging Directive should include a procedure (such as delegated acts) which allows the adoption or modification of limits for chemicals in packaging in a fast and flexible way (without having to change the whole pieces of legislation in the European Parliament and the Council).*

See also the discussion in Section 4.6, which raises some of the same issues with regard to legislative gaps.

8.2.5 Plant Protection Products

The packaging requirements for PPPs are based on requirements outlined in both the CLP Regulation and Plant Protection Products Regulation ((EC) No 1107/2009). Article 64 of the Plant Protection Products Regulation relates to packaging and presentation with paragraph 1 stating that:

"plant protection products and adjuvants available to the general public that may be mistaken for food, drink or feed shall be packaged in such a way as to minimise the likelihood of such a mistake being made".

Paragraph 2 indicates that:

"plant protection products and adjuvants available to the general public that may be mistaken for food, drink or feed shall contain components to discourage or prevent their consumption".

Paragraph 3 states that:

"Article 9 of Directive 1999/45/EC [the Dangerous Preparations Directive - now the CLP Regulation] shall also apply to plant protection products and adjuvants not covered by that Directive".

During the consultation process, manufacturers of PPP were asked whether they consider the links between the CLP Regulation and the Plant Protection Products Regulation, with regard to packaging, to be clear, appropriate and consistent. As indicated in Table 8-7, the majority of respondents

considered that the links and requirements are clear, appropriate and consistent (although SMEs were split 50:50 on this question). However, the majority of respondents indicated that the Plant Protection Products Regulation should set out all relevant packaging requirements rather than making reference to the CLP Regulation. They therefore believe that this linkage should be removed to avoid the potential for future inconsistences or overlaps which give rise to confusion.

Table 8-7: Views of plant protection product manufacturers regarding the links between the CLP Regulation and the Plant Protection Products Regulation – targeted consultation questionnaire

Answer options	Yes	No	No. of responses
The links and requirements between the CLP Regulation and the Plant Protection Products Regulation (with regards to packaging) are clear	67%	33%	9
The links between the CLP Regulation and the Plant Protection Products Regulation (with regards to packaging) are appropriate and consistent	56%	44%	9
The Plant Protection Products Regulation should set out all relevant packaging requirements	56%	44%	9

8.2.6 Fertilisers Regulation

The Fertilisers Regulation ((EC) No 2003/2003) is similar in scope to the CLP Regulation in that it contains requirements for labelling and packaging of mixtures. Article 10 of the Fertilisers Regulation outlines the labelling requirements, with paragraph 1 stating that:

> *"the labels or markings printed on the package giving the particulars mentioned under Article 9 must be placed in a conspicuous position. Labels must be attached to the package or to whatever system is used for closing it. If this system consists of a seal, that seal must bear the name or mark of the packager". Paragraph 2 of Article 10 indicates that "the markings referred to in paragraph 1 must be and must remain indelible and clearly legible".*

Paragraph 3 states that "*in cases of fertilisers in bulk referred to in the second sentence of Article 7(2) a copy of the documents containing the identification markings must accompany the goods and be accessible for inspection purposes*". Articles 24 and 28 of the Regulation refer to packaging requirements and indicate that "*EC fertilisers covered by the provisions of this chapter [Chapter III – inorganic micro-nutrient fertilisers] shall be packaged*" and "*Ammonium nitrate fertilisers of high nitrogen content shall be made available to the final user only in packaged form" respectively*.

The legal analysis undertaken as part of this study indicates that the Fertilisers Regulation, however, makes no specific reference to the CLP Regulation and does not itself contain general packaging requirements, only specific ones. It is therefore not clear whether the packaging requirements under the CLP Regulation apply to EC fertilisers (at least those not covered by Articles 24 and 28 of the Fertilisers Regulation).

Hence, this could be considered a gap. However, this has not been raised as a specific concern by stakeholders during the consultation process; hence this is not considered to present a significant issue.

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Annex IV: Evaluation of vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification (Task 3)

Table of Contents

1 Introduction

1.1 Overview

Task 3 focuses on linkages between the CLP Regulation and downstream or vertical legislation. This is legislation that draws on CLP for classification, labelling or packaging requirements. In some cases, this is the same legislation that was identified under Task 2 as having horizontal linkages relevant to hazard identification and hazard communication. In other cases, it is only legislation that draws on CLP for risk management purposes, with a prime example being linkages to harmonised classifications for CMR properties).

The evaluation work carried out under this task has been divided into two main sub-tasks, each with prescribed requirements and outcomes:

- Sub-task 3a: Mapping of the vertical links with this including identification of references to CLP in downstream legislation and identifying whether the risk management measures in downstream legislation are triggered automatically or are subject to further assessment; and

- Sub-task 3b: Assessing the relevance, effectiveness, efficiency, coherence and EU added value of vertical links, in terms of both mechanisms and procedures, and with respect to both costs and benefits of the main provisions on risk management measures triggered by CLP.

The information needed to undertake the evaluation has been collected through a combination of desk-based research, interviews, targeted data collection and analysis of the responses to the open public consultation. The evaluation is also supported by case studies. In particular, the following case studies support this task:

- Case Study 6: differences in assessment procedures for PBT and vPvB as properties of concern;
- Case Study 10: linkages between CLP and occupational health and safety legislation;
- Case Study 11: risk management measures triggered by classification for CMR under CLP; and
- Case Study 12: use of CLP classifications as the basis for waste management.
- Case Study 13: linkages between the CLP and Seveso III Directive, including risk management under Seveso III.

In addition to these task specific case studies, there are also linkages between some of the findings with respect to the case study on classification criteria for metals (Case Study 2) and the toys case study (Case Study 8). Substance specific examples have been given in Case Study 11 and include: lead; N,N-Methylenebismorpholine (MBM); ethanol; nickel; tris(2-chlorethyl)phosphate (TCEP); formaldehyde; and gallium arsenide. Substances where classification is ongoing or classification is currently being appealed have been excluded.

The evaluation questions set out in the introduction to this report were mapped across the two sub-tasks listed above, to identify those that should be answered, at least in part, through the Task 3 evaluation. In order to report against both the sub-tasks and the evaluation questions, a set of themes has been developed to act as the basis for reporting. Each of these themes provides reporting in relation to one of the sub-tasks (in whole or in part) and against one or more specific evaluation questions.

Please note that Member State responses are still being received and will be added into the final report.

1.2 Organisation of Task 3 reporting

In order to provide a context for reporting on the evaluation against the six sub-tasks and associated evaluation questions, we start the discussion below (Section 2) with an overview of the chemicals related legislation that has been identified as having a relevant risk management linkage to CLP. This includes an overview of what the risk management linkages are (i.e. what triggers risk management), the nature of those linkages in terms of whether they are hazard based or risk assessment based, a summary of the procedures that trigger risk management, and other interactions across the legislation.

This overview is then followed by discussion of the evaluation findings, which have been organised under the following 'themes':

- Section 3: Scope and objectives of the EU chemicals legislative framework concerning hazards and risks;
- Section 4: Data and assessment approaches;
- Section 5: Processes and procedure;
- Section 6: Risk management approaches;
- Section 7: Costs and benefits;
- Section 8: Implementation and enforcement;

It should be noted that 21 pieces of downstream legislation were identified through the mapping exercise, the results of which are presented in Section 2. The evaluation is focused on a sub-set of this legislation, as being the most important regarding downstream linkages based on consultation responses, submissions to the open public consultation, SME panel and research and legal analysis carried out by the study team. Thus, at this stage and for several of the pieces of legislation, one must conclude that the linkages are appropriate and do not give rise to concerns for those regulated by it or for other stakeholders that may have an interest in its operation.

2 Relevant Downstream Legislation

2.1 Introduction

2.1.1 Mapping downstream legislation

One of the key outputs from the inception phase of the study was the development of a master list of the EU acts that utilise CLP classifications to trigger risk management measures. This was based on a mapping exercise which analysed the linkages between CLP classifications and provisions for risk management laid down in downstream legislation, i.e., whether classification automatically led to a risk management measure, or to additional steps such as risk assessment and/or further implementation measures (such as a combination of both risk assessment and socio-economic analysis).

Table 2-1 below provides an overview of the EU legislation downstream from the CLP Regulation. These acts were analysed in the inception phase to get an initial view of this vertical interaction. The analysis focused on three possibilities for how the CLP classification leads to a risk management measure (RMM):

- Possibility 1: The risk management measure is triggered automatically based on generic risk considerations; this case covers the main approach, while derogations or exemptions would fall under Possibility 1.5;

- Possibility 2: The risk management measure can only be triggered after further assessment or may be modified/exempted based on further assessment but needs no further discretion or detailing by Member States or economic operators; or

- Possibility 3: An identified risk management need (e.g. via Possibility 1) is further defined or detailed by further assessment or implementation steps by economic operators or the Member States.

Possibility 1 covers risk management based on generic risk considerations. Possibilities 2 and 3 cover risk management based on specific risk assessment. The table does not include cases of legislation linking risk management to the use of specific substances that are referred to by name, for example the RoHS Directive that restricts the use of lead, mercury, hexavalent chromium, PBDs and PBDEs in electrical and electronic equipment. Such legislation does not draw on CLP *per se.*

The table also does not include cases of 'missing links'. These 'missing links' include references to hazardous substances or mixtures without explicit reference to the CLP Regulation. An example of which is the General Product Safety Directive (2001/95/EC), which contains no reference to CLP, but which places a general obligation on producers and distributors to only place safe products on the EU market and to inform consumers of the risks associated with products[1].

[1] This is discussed further in Section 3.5.1

Table 2-1: Overview table on risk management measures				
EU Act	Possibility 1: automatic based on generic risk considerations	Possibility 1.5: Derogation/ exemption with further assessment	Possibility 2: Further assessment	Possibility 3: Further implementation steps
Consumer products				
Regulation (EC) No 1223/2009 on cosmetic products	✓	✓	✓	
Directive 2009/48/EC on the safety of toys	✓	✓		
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	✓			
Regulation (EC) No 66/2010 on the EU Ecolabel	✓			
Regulation (EC) No 450/2009 on active and intelligent materials	✓			
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	✓			
Professional products*				
Regulation (EC) No 1107/2009 on plant protection products	✓	✓	✓	✓
Regulation (EU) No 528/2012 biocidal products	✓	✓	✓	✓
Directive 2014/68/EU pressure equipment	✓			
Environmental protection				
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals	✓			
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III)	✓			✓
Directive 2010/75/EU on industrial emissions				✓
Directive 2008/98/EC on waste				✓
Directive 1999/31/EC on the landfill of waste				✓
Directive 2000/53/EC on end-of life vehicles	✓			
Regulation (EC) No 1013/2006 shipments of waste	✓			
Directive 2004/35/CE on environmental liability	✓			
Health & Safety of Workers				
Directive 92/85/EEC pregnant workers				✓
Directive 94/33/EC young people at work	✓			✓
Directive 98/24/EC chemical agents at work			✓	✓
Directive 2004/37/EC carcinogens or mutagens at work			✓	✓
*Both the Plant Protection Products and Biocidal Products Regulations also cover consumer products.				

2.1.2 RMM triggered automatically based on hazard

Possibility 1 includes provisions that trigger a RMM automatically, based on hazardous properties, and without further assessment. Any exemptions, e.g. based on socio-economic or risk considerations, would be covered under Possibility 2.

A typical example under this category is the use of a CMR classification under the CLP Regulation as a 'cut-off criterion'. For example, under the Plant Protection Products Regulation, an active substance cannot be approved for use in plant protection products if it has been classified as a mutagen category 1A or 1B according to the CLP.

Possibility 1 also includes cases where a (otherwise possible) derogation from a rule is ruled out because of a CLP classification. For example, Regulation (EC) No 450/2009 on active and intelligent materials provides that only substances may be used in respective food contact materials that are included in a Community list. Under certain circumstances a derogation from the rule is possible, however, only if the substance is not classified as CMR under the CLP.

Arguably, this category also includes provisions that, although addressed to Member States, contain a direct requirement to operators. This is the case, for instance, in the End-of-Life Vehicles Directive that provides that Member States "shall take the necessary measures to ensure that producers provide dismantling information".

2.1.3 RMM triggered after further assessment

Possibility 2 covers those cases where a RMM is triggered by the CLP classification only after a further (risk) assessment. These are assessments carried out by an EU body and not those carried out by a Member State or an operator.

Typical examples for this category are the risk assessments that are carried out under the Plant Protection Products Regulation and the Biocidal Products Regulation for the approval of (active) substances to be used in plant protection products and biocidal products, respectively. In these cases, industry provides the information required for a risk assessment and the Commission evaluates this in order to judge whether or the not the substance meets the approval criteria and its subsequent placing on the market. Another example would be the setting of binding occupational exposure limit values which is undertaken by the Commission through the Scientific Committee on Occupational Exposure Limits.

Possibility 1.5 covers derogations and exemptions from automatic risk management measures. These tend to be risk assessments, but may include an analysis of alternatives and/or socio-economic impact assessments.

For instance, according to the Biocidal Products Regulation, substances classified as CMR category 1A or 1B under CLP will be subject to a risk assessment in order to determine whether the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment, or that not approving the active substance would have a disproportional negative impact on society when compared with the risks from the use of the substance. In such cases, the substance may be approved.

2.1.4 RMM triggered after further implementation measures

Possibility 3 refers to those provisions requiring an implementation step as part of risk management. These may consist of a further assessment of the risk by an economic operator followed by a choice of different RMM, or regulatory action of Member States where Member States have discretion (e.g. granting of authorisations, setting of limit values etc.).

The most important cases are those where the RMMs depend on the judgement of an operator and, hence, may vary from case to case. For example, Occupational Safety and Health (OSH) legislation commonly contains provisions requiring the employer to assess the exposure of workers to classify substances or mixtures and to adopt appropriate RMM. These may be specified by law (e.g. use of a closed system under the Carcinogens and Mutagens Directive) or are to be decided by the employer (e.g. any 'prevention and reduction of exposure measures' where a closed system is not feasible under the Carcinogens and Mutagens Directive). This category also includes, for instance, the drawing up of a major-accident prevention policy by the operator under the Seveso III Directive.

There is a fine line between Possibilities 1 and 2 and Possibility 3 and, as a rule, an implementation step (Possibility 3) is preceded by an assessment (Possibility 2) or triggered by a hazard classification (Possibility 1). Nevertheless, for the purposes of this study, all cases where an implementation step is required have been included in Possibility 3 only. Furthermore, as mentioned above, sometimes a directive addresses the Member States. Where the RMM is specified by the directive, the case falls under Possibility 1 (see above example in End-of-Life Vehicles Directive). However, where the RMM comes under the discretion of the Member State, it is covered by Possibility 3. For example, under the Water Framework Directive, Member States need to identify the programme of measures to be taken in response to finding that there are emissions of priority hazardous substances into the environment, or where monitoring says that a water body fails to meet good status. Member States carry out a risk assessment to determine whether or not a water body is failing good status, and then a socio-economic assessment of measures to address this.

2.1.5 Key characteristics of triggers

Table 2-2 to Table 2-21 provide a summary of key aspects of the triggers contained in the set of downstream legislation considered within this task.

A legal analysis is presented in Annex 1 to this report.

Table 2-2: Regulation (EC) No 1223/2009 on cosmetic products	
Objective	Establishes rules for all cosmetic products made available on the market, in order to ensure the functioning of the internal market and the safety of cosmetic products leading to a high level of protection of human health
Type of trigger	**Automatic with further assessment (derogation)** Under Article 15 CMRs classified as category 1A, 1B and 2 under the CLP Regulation are prohibited for use in cosmetic products. There are exemptions for this under Article 15(2) whereby: CMR category 1A and 1B (note that all of the following requirements need to apply for a derogation to be granted) • they comply with the food safety requirements as defined in Regulation (EC) No 178/2002; • there are no suitable alternative substances available, as documented by an analysis of alternatives; • the application is made for a particular use for which exposure is known; and • they have been evaluated and found safe by the SCCS for use in cosmetic products. This must take into account exposure to these products, exposure from other sources and vulnerable population groups. CMR category 2 • they have been evaluated by the SCCS and found safe for us in cosmetic products.
Classification	CMR category 1A, 1B and 2
Population or environmental compartment	Human health (consumer and professional)
Advantage of the type of trigger	Prevents exposure to CMRs (unless exception is given). This is especially advantageous for these types of products as humans are exposed to multiple cosmetic/ personal care products a day and repeated dermal exposure could be an issue.
Disadvantage of the type of trigger	Could result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health.
Impacts on industry	Need for reformulation of products if exception is not granted or applied for. Dossiers for exemption can be costly.
Impacts on society	Potential to reduce exposure to CMRs and subsequent health risks.
Impacts on the environment	N/A

Table 2-3: Directive 2009/48/EC on the safety of toys	
Objective	Lays down the rules on the safety of toys and their free movement in the Community
Type of trigger	**Automatic with further assessment (derogation)** Point 3, Part 3, Annex II states that "substances that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. The derogations for this are laid out in Point 4 and 5, Part 3, Annex II. Substances or mixtures classified as CMR category 1A and 1B may be used in toys, in components of toys or microstructurally distinct parts of toys if one or more of the following are met:

Table 2-3: Directive 2009/48/EC on the safety of toys	
	• they are contained in individual concentrations equal to or smaller than the relevant concentrations established in the CLP Regulation • these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2) • a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A. This decision will be based on: ○ the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure. ○ There are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives ○ The substance or mixture is not prohibited for use in consumer articles under the REACH Regulation. Substances or mixtures classified as CMR category 2 may be used in toys, in components of toys or microstructurally distinct parts of toys if one or more of the following are met: • these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations in the CLP Regulation. • inhalation, when the toy is used as specified in the first subparagraph of Article 10(2) • a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A. This decision will be based on: ○ the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure. ○ The substance or mixture is not prohibited for use in consumer articles under the REACH Regulation.
Classification	CMR category 1A, 1B and 2
Population or environmental compartment	Children (under the age of 14)
Advantage of the type of trigger	Reduces exposure of children who are considered a vulnerable population. This may prevent health effects that would develop later on in life as a result of early exposure to CMRs.
Disadvantage of the type of trigger	The ban on use may result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health. Under the rules, there should be no access to a CMR but this is not always the case as exemptions exist. Exemptions may allow for exposure of a vulnerable population to hazardous substances.
Impacts on industry	Need for reformulation of products if exception is not granted or applied for. If products cannot be reformulated or materials substituted then products may have to be removed from the market. Dossiers for exemption can be costly.
Impacts on society	Potential to reduce exposure to CMRs and subsequent health risks.
Impacts on the environment	N/A

Table 2-4: Directive 2014/40/EU on manufacture, presentation and sale of tobacco	
Type of trigger	**Automatic** Article 7(6): Member States shall prohibit the placing on the market of tobacco products containing the following additives: (e) additives that have CMR properties in unburnt form. Article 7(9): Member States shall, on the basis of scientific evidence, prohibit the placing on the market of tobacco products containing additives in quantities that increase the toxic or additive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree. **Further implementation steps** Article 6: 2. Member States shall require manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list provided for in paragraph 1, to carry out comprehensive studies, which shall examine for each additive whether it: d) leads to the formation of substances that have CMR properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measureable degree. ***Note: This piece of legislation does not make specific reference to the CLP Regulation with respect to classification***
Classification	CMR
Population or environmental compartment of concern	Human health (consumer)
Advantage of the type of trigger given classification and population/ compartment	This does not explicitly prevent exposure to CMRs, as they are naturally occurring in the smoking process, but it does have the possibility of preventing additional exposure from additives.
Disadvantage of the type of trigger given the classification and population/ compartment	This does not prevent exposure to CMRs, only the additive effect of exposure as a result of inclusion of additives.
Impacts on industry	There may be costs associated with testing of additives and costs related to reports that need to be supplied to the Commission in relation to ingredients.
Impacts on society	Reducing the additive effect of CMRs to reduce overall exposure, which may reduce health effects of CMRs and subsequent costs.
Impacts on the environment	N/A

Table 2-5: Regulation (EC) No 66/2010 on the EU Ecolabel	
Type of trigger	**Automatic** No Ecolabel can be awarded, if substances classified as toxic, hazardous to the environment or CMR are included in the product (Art. 6(6)). Derogations are possible (Art. 6(7)) if substances cannot be substituted (including use of other materials or designs) or if the overall environmental performance of the product containing the substances is much better than others of the same category. The derogation cannot be applied to substances included in the REACH candidate list.
Classification	Toxic, hazardous to the environment, CMR[2]
Population or environmental compartment	Human health and the environment in general
Advantage of the type of trigger	All substances and mixtures are treated in a common and harmonised way based on their hazardous properties expressed via the rules of classification for H-statements. Alternatively (e.g. still present in some national Ecolabelling requirements) only specific substances e.g. phthalates are subject of the criteria while the product may contain hazardous substances in other parts. Prevention of exposure to hazardous substances in products carrying the eco-label. Ecolabel legislation supports purchasing decision making considering hazardous substance contents and is coherent with the chemicals legislation.
Disadvantage of the type of trigger	No direct disadvantages. Indirectly overall environmental impacts might not take into account/weighted; i.e. higher energy need of a product (and related CO_2 emissions) due to the use of an alternative to the substances which may not be included.
Impacts on industry	Better marketing opportunities for consumer products that do not contain hazardous substances of concern. The label can be obtained only if hazardous (classified) substances are not used or used in minimum concentrations thus manufacturers are encouraged to reformulate hazardous mixtures or redesign of articles.
Impacts on society	Consumers are informed which products are without or with minimum content of hazardous substances and push the market to greener consumption. Possibility to reduce exposure to hazardous substances by better informed decision making.
Impacts on the environment	Less exposure of the environment to hazardous substances, if consumers buy products with an ecolabel rather than products without one.

[2] This list of properties is ambiguous, as it is not fully clear, which hazard categories and types are included or not. According to a discussion document on the implementation of Art. 6(6) and 6(7) in the development of eco-label criteria, the following rules are proposed in relation to specific H-statements: Complete restrictions should be triggered by classification with the following H-statements: 340, 350, 350i, 360F, 360D, 360FD, 360Fd, 360Df. Strict requirements should apply for the following H-statements: 300, 310, 330, 304, 370, 372, 317, 334, 400, 410, 411, 420 and greater flexibility should be taken for the following H-statements: 301, 311, 331, E070, 371, 373, 412 and 413. Source: EU Commission, Joint Research Centre (2014), 'Findings of the EU Ecolabel Chemicals Horizontal Task Force Proposed approach to hazardous substance criteria development', February 2014, available at: http://ec.europa.eu/environment/ecolabel/documents/Chemicals%20HTF_Approach%20paper.pdf

Table 2-6: Regulation (EC) No 450/2009 on active and intelligent materials	
Objective	Establishes specific requirements (particularly chemical requirements) for the marketing of active and intelligent materials and articles intended to come into contact with food.
Type of trigger	**Automatic with further assessment (derogation)** Article 5 (2): By way of derogation from paragraph 1, the following substances may be used in components of active and intelligent materials and articles without being included in the community list: c) substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier provided that they do not fall within either of the following categories: i) substances classified as mutagenic, carcinogenic or toxic to reproduction in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No 1272/2008
Classification	CMR
Population or environmental compartment	Human health
Advantage of the type of trigger	Prevents oral exposure of humans to CMRs from food contact materials. Works alongside the other food contact materials legislation in order to prevent exposure to CMRs.
Disadvantage of the type of trigger	Could result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health. Under the rules, there should be no access to a CMR.
Impacts on industry	Reformulation costs as a result of not being allowed to use certain substances
Impacts on society	Potential to reduce exposure to CMRs and subsequent health care costs related to exposure.
Impacts on the environment	N/A

Table 2-7: Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	
Objective	Establishes specific requirements for the manufacture and marketing of plastic materials and articles
Type of trigger	**Automatic** Substances that are mutagenic, carcinogenic or toxic to reproduction should not be used in food contact materials or articles without previous authorisation.
Classification	CMR
Population or environmental compartment	Human health
Advantage of the type of trigger	Prevents oral exposure of humans to CMRs from food contact materials. Works alongside the other food contact materials legislation in order to prevent exposure to CMRs.
Disadvantage of the type of trigger	Could result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health. Under the rules, there should be no access to a CMR. Exposure from this source is not completely eradicated in all cases as it is possible for CMRs to be

Table 2-7: Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	
	authorised and there are cases where they have been.
Impacts on industry	Reformulation costs as a result of not being allowed to use certain substances. Costs associated with dossier submission for entry into the Union list.
Impacts on society	Potential to reduce exposure to CMRs and subsequent health care costs related to exposure.
Impacts on the environment	N/A

Table 2-8: Regulation (EC) No 1107/2009 on plant protection products	
Objective	Lays down rules for authorising the sale, use and control of plant protection products in the EU.
Type of trigger	**Automatic** Under Annex II, an active substance will not be approved if it has or is to be classified as a carcinogen, mutagen or reprotoxin of category 1A or 1B under the CLP Regulation. A substance that is considered to be persistent, bioaccumulative or toxic shall not be approved. Toxicity criteria include substances classified under the CLP Regulation as carcinogenic 1A and 1B; mutagenic 1A and 1B; reprotoxic 1A, 1B and 2; STOT RE1 and STOT RE2. An active substance that is considered to have endocrine disrupting properties shall also not be approved. **Further assessment** The active substance may be approved if the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005. (applies to C, R and EDC, no derogation for mutagenic substances) **Further implementation steps** An active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met: • it meets two of the criteria to be considered a PBT substance; or • it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B.
Classification	CMR, CMR leading to classification of toxicity under PBT
Population or environmental compartment of concern	Human health (consumer and professional users) (environmental concerns relate to PBT substances)
Advantage of the type of trigger given classification and population/ compartment	Prevents exposure to CMRs (unless exception is given) to both consumer and professional users. Consumer exposure to CMRs through use of PPPs could be problematic as they may not use the product exactly as directed which may increase exposure. For professional users preventing exposure through removal of CMR substances is advantageous as professional users may have prolonged or repeated exposure to the substance as they are using it multiple times.
Disadvantage of the type of trigger	Could result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health. Allowing for

Table 2-8: Regulation (EC) No 1107/2009 on plant protection products	
given the classification and population/ compartment	use of CMRs through exception does not provide the highest level of protection to human health.
Impacts on industry	Need for reformulation of products which contain CMR substances (especially those of category 1A) as there is little scope to get an exemption.
Impacts on society	Through preventing exposure there may be a reduction in the incidence of CMR related health issues and the subsequent health care costs.
Impacts on the environment	Greater concern given to human health criteria than to environmental. There are no environmental classifications mentioned within the legal text even though it states that an active substance shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the authority to assess such effects are available: • its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation; • its impact on non-target species, including on the on-going behaviour of those species; • its impact on biodiversity and the ecosystem.

Table 2-9: Regulation (EU) No 528/2012 biocidal products	
Objective	Harmonises the rules on the making available on the market and use of biocidal products, whilst ensuring a high level of protection for human and animal health and the environment, including the establishment of a Union level list of approved active substances and authorisation of biocidal products
Type of trigger	**Automatic** Under Article 5 active substances shall not be approved if they are a CMR category 1A or 1B, EDCs, PBTs and vPvBs. A biocidal product shall not be permitted under Article 19 (4) where it meets the criteria under the CLP Regulation for category 1A or 1B carcinogen, mutagen or reprotoxin; category 1, 2 or 3 acute oral toxicity, acute dermal toxicity, acute inhalation (gases and dust/mists) and acute inhalation (vapours) toxicity; STOT SE 1 or STOT RE1; PBT or vPvB; it is an EDC; or is a neurotoxin or immunotoxin. Under Article 10 an active substance shall be considered a candidate for substitution if any of the following conditions are met: • it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2); or • it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser. **Further assessment (derogation)** Under Article 5(2) an active substance with CMR, EDC, PBT or vPvB properties may be approved if it meets at least one of the following conditions: • the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in a closed system or under other conditions which aim at it excluding contact with humans and release into the environment;

Table 2-9: Regulation (EU) No 528/2012 biocidal products	
	• it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or • not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance. When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration. The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. The use of the biocidal product with the active substances concerned shall be restricted to Member States in which at least one of the conditions set out in this paragraph is met. **Further implementation steps** The conditions of authorisation will specify any risk mitigation measures that are to be taken for the particular biocidal product. Any control measures that are to be applied during the use phase will therefore be set out on the label of the product, e.g., whether any protective clothing or equipment needs to be worn when using the biocide, how to use the biocide without harm to humans, the environment or animals, and whether access to treated areas needs to be restricted (Article 17(5)).
Classification	CMR, acute oral toxicity, acute dermal toxicity, acute inhalation (gases and dust/mists), acute inhalation (vapours) toxicity, STOT SE 1 or STOT RE1;
Population or environmental compartment	Human health (consumer and professional)
Advantage of the type of trigger	Prevents exposure to CMRs and other hazardous substances (unless exception is given). Consumer exposure to hazardous substances through use of biocidal products could be problematic as they may not use the product exactly as directed which may increase exposure. For professional users preventing exposure through removal of hazardous substances is advantageous as professional users may have prolonged or repeated exposure to the substance as they are using it multiple times.
Disadvantage of the type of trigger	Could result in unnecessary removal of substance, which, under the conditions it is used, does not pose a risk to human health.
Impacts on industry	Need for reformulation of products which contain CMR substances if exemption is not applied for and granted.
Impacts on society	Through preventing exposure there may be a reduction in the incidence of CMR related health issues and the subsequent health care costs.
Impacts on the environment	Greater concern given to human health criteria than to environmental. The only preventative measure for an environmental classification is that of aquatic toxicity where simplified authorisation will not be granted.

Table 2-10: Directive 2014/68/EU pressure equipment	
Objective	The Pressure Equipment Directive (2014/68/EU) has two main objectives: Firstly, it seeks to enable the free trade of pressure equipment and assemblies within the European Economic Area (EEA). Secondly, it seeks to ensure a high level of safety for pressure equipment.
Type of trigger	Article 13 classifies pressure equipment according to an ascending level of hazard (pressure, size, etc.). For the purposes of such classification, 'fluids' (i.e. the contents) are divided into two groups: Group 1 (the more hazardous) and Group 2 (the less hazardous).
Classification	Directive 2014/68/EU represents a major revision to the previous Pressure Equipment Directive (97/23/EC). One of the main areas for revision was reclassifying the thresholds of hazardous properties for Group 1 fluids to be aligned with the CLP Regulation.
Population or environmental compartment of concern	The prime concern is the risk to nearby workers in the event of a major unintended release of a Group I fluid (i.e. those that are flammable. explosive, acutely toxic, etc.).
Advantage of the type of trigger given classification and population/ compartment	The division between Group I and Group 2 fluids ensures a higher level of protection for pressure equipment containing the more hazardous fluids.
Disadvantage of the type of trigger given the classification and population/ compartment	Due to the variations in the limit values for hazardous properties as defined under Dangerous Substances Directive (67/548/EEC) and under CLP, some 'borderline' fluids have been reclassified (i.e. some Group 1 fluids have now been reclassified as Group 2 fluids and vice-versa).
Impacts on industry	There will be some change to the industry costs where the nature of the fluid has been reclassified requiring, in some cases, additional conformity assessments. The associated cost has been estimated as less than €10m per annum.
Impacts on society	Essentially no change with the adoption of the new Pressure Equipment Directive to incorporate the CLP requirements.
Impacts on the environment	Essentially no change with the adoption of the new Pressure Equipment Directive to incorporate the CLP requirements.
RPA (2013): *Impact Assessment Study on the Alignment of the Pressure Equipment Directive to the CLP Regulation,* dated February 2013 available from: https://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment/directive_en	

Table 2-11: Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso Directive)	
Objective	Prevention of major accidents which might result from certain industrial activities and the limitation of their consequences for human health and the environment
Type of trigger	**Further implementation steps** Further implementation measures: If (the sum of) substance(s) with certain classifications present in the establishment, the operators are required to assess if the amounts exceed those specified in Annex I of the Directive and if they are therefore considered an upper-tier (HT) or a lower-tier (LT) site. If they fall into any of the categories, the following RMMs[3] are "automatically" triggered: • Draw up and keep up to date a Major-Accident Prevention Policy (MAPP) acc. to Art. 8 • Implement all measures need to prevent major accidents or mitigate their impacts Upper-tier establishments need to implement the following obligations in addition: • Develop a safety report and implementation of measures identified therein • Draw an emergency plan Exclusion from the scope are possible for individual substances according to Art. 4, if […] it is impossible in practice […] to cause a release of matter or energy that could create a major accident under both normal and abnormal conditions which can reasonably be foreseen.
Classification	Acute toxic cat. 1-3; STOT SE cat 1; explosive; flammable and oxidising (gases cat. 1, solids and liquids cat. 1-3); self-reactive substances; pyrophoric liquids and solids cat. 1; toxic to the aquatic environment acute cat. 1 and 2, chronic cat 1; substances emitting flammable gases cat. 1; EUH014 and EUH029
Population or environmental compartment	Workers in the establishment, neighbourhood of establishment, environment around the establishment (although, potentially, there could be long range effects)
Advantage of the type of trigger	Assessment of hazards and amounts of substances present is proxy to the extent of accidents that might occur. Major accidents, involving large amounts of chemicals should be prevented.
Disadvantage of the type of trigger	Difficult to ensure that all hazards are treated equally (in a major accident context). Some consider that chronic hazards and persistence of substances are not fully taken into account, hence impacts from accidents which cannot be mitigated / cleaned up might occur
Impacts on industry	Need to implement specific measures on-site to prevent accidents; use of substances is not limited.
Impacts on society	Prevention of exposure to hazardous substances; increased installation safety, loss prevention, and quick reaction to accidents by operators can be assumed all of which may contribute to sustainable growth
Impacts on the environment	Prevention of exposure to hazardous substances and higher likelihood of quick mitigation of impacts; however, no consideration of persistent substances

[3] Communication and information obligations to the competent authorities and the general public are not listed here. Furthermore the designation of an HT or LT site under Seveso Directive can also trigger land-use planning controls of development on and around the site.

Table 2-12: Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)[4]	
Objective	Lays down the rules for integrated prevention and control of pollution arising from industrial activities. The aim is to prevent, or where not possible, to reduce emissions to air, water and land and to prevent the generation of waste in order to achieve a high level of protection of the environment taken as a whole.
Type of trigger	**Further implementation steps** Automatic: If classified substances/mixtures are used, produced or released, operators must submit a baseline report describing the state of pollution with hazardous substances and re-assess it after ceasing operation. In case of contaminations, remediation measures are to be implemented (Art. 22). In installations falling under the Industrial Emissions Directive due to the use of organic solvents, substances or mixtures classified with the H-statements H340, H350, H350i, H360F and H360D should be replaced as far as possible and as soon as possible (Art. 58).
Classification	Substances or mixtures as defined in Article 3 of CLP Regulation (see definition in Article 3(18) of the Industrial Emissions Directive).
Population or environmental compartment	All environmental compartments, (as a side effect) partly workers (VOC substitution), neighbourhood and general population.
Advantage of the type of trigger	Emission reductions and substitution of VOCs at workplaces prevents exposure of workers. Assessment for permitting/ELV takes surroundings (e.g. more sensitive areas, other emitters) into account. Monitoring (and reporting) allows identification of pressures from large installations and potential reviews of permits, if necessary. Baseline report ensures that environmental conditions are re-installed after the installation is closed.
Disadvantage of the type of trigger	While Emission Limit Values (ELVs) are also based on risk considerations as the process acknowledges socio-economic aspects by only setting values that are technically feasible using best available techniques (BAT) that are already on the market and already achieved by the majority of installations. BAT only include ELVs for pollutants that are considered significant, i.e. a risk to the population and the environment.
Impacts on industry	ELVs need to be complied with, type of RMM is flexible. Monitoring obligations must be implemented.
Impacts on society	Prevention / reduction of exposure.
Impacts on the environment	Prevention / reduction of exposure.

[4] The Industrial Emissions Directive is not a piece of legislation formally based on CLP and the risk management explained in this table are the only ones related to CLP within this piece of legislation. In the overall context of the Industrial Emissions Directive, the risk management measures related to CLP could be considered to be relatively minor.

Table 2-13: Directive 2008/98/EC on waste	
Objective	Sets the basic concepts and definition to waste management, explaining when waste ceases to be waste and becomes a secondary raw material and how to distinguish between waste and by-products. It also lays down basic waste management principles, requiring waste to be managed without endangering human health or the environment.
Type of trigger	**Further implementation steps** RMM obligations are triggered automatically for hazardous wastes. Wastes are considered hazardous, if they have properties defined in Annex III of the Directive. Determination of whether or not a waste is hazardous involves, however, the application of classification rules according to Decision 2000/532/EC. Hazardous wastes may not be mixed (Art. 18), must be appropriately labelled and packaged and accompanied by an identification document (Art. 19), and record keeping (Art. 35). In addition, permits for waste treatment operators define, which wastes may be treated (specific hazardous wastes may be excluded) (Art. 23).
Classification	Indirect: content of classified substances may render a waste hazardous. Annex III lists hazardous properties but does not make a direct reference to the CLP Regulation. Decision 2000/532/EC refers to the Dangerous Substances Directive for the hazards very toxic, toxic, harmful, corrosive, irritant, carcinogenic, reprotoxic, mutagenic and ecotoxic. The hazard sensitisation is not defined with reference to the Dangerous Substances Directive and neither are the hazards explosive, oxidising and (highly) flammable. Here, the decision defines individual criteria.
Population or environmental compartment	Human health and the environment
Advantage of the type of trigger	Prevention of exposures from substances included in hazardous wastes.
Disadvantage of the type of trigger	Hazardous substances may be included in non-hazardous wastes, due to (challenges in the) classification of wastes; concentration limits for environmental hazards not useful in the case of PBTs because the total emission is relevant rather than a concentration.
Impacts on industry	Industries must classify their wastes according to Decision 2000/532.
Impacts on society	Less exposure from hazardous substances due to appropriate waste treatment processes and controls of operators.
Impacts on the environment	Less exposure from hazardous substances due to appropriate waste treatment processes and controls of operators.

Table 2-14: Directive 1999/31/EC on the landfill of waste	
Objective	To prevent or reduce as far as possible negative effects on the environment, particularly surface water, groundwater, soil, air and human health by introducing stringent technical requirements for waste and landfills
Type of trigger	**Further implementation steps** RMM obligations are automatically triggered for hazardous wastes, as defined in the Waste Framework Directive (2008/98/EC)[5]. Landfills may not accept and treat wastes, which under the conditions of the landfill are explosive, corrosive, oxidising, highly flammable or flammable as defined in the waste framework directive (Art. 5). Waste may be assigned to a landfill for hazardous waste after prior treatment if it exhibits total contents or leachability of potentially hazardous components that are high enough to constitute a short-term occupational or environmental risk or to prevent sufficient waste stabilisation within the projected lifetime of the landfill (Art 6 and Annex II). Landfills must have a permit, which specifies the types of (hazardous) wastes that can be accepted (Art. 9). Waste needs to be checked before acceptance at the landfill, including checking documentation, visual inspection and registration of type and quantities of hazardous wastes (Art. 11).
Classification	Indirect: content of classified substances may render a waste hazardous. Annex III lists hazardous properties but does not make a direct reference to the CLP Regulation. Decision 2000/532/EC refers to the Dangerous Substances Directive for the hazards very toxic, toxic, harmful, corrosive, irritant, carcinogenic, reprotoxic, mutagenic and ecotoxic. The hazard sensitisation is not defined with reference to the Dangerous Substances Directive and neither are the hazards explosive, oxidising and (highly) flammable. Here, the decision defines individual criteria.
Population or environmental compartment	Human health (workers and general population) and environment.
Advantage of the type of trigger	Indirect trigger via waste classification; risks from landfilling of hazardous substances should be adequately controlled preventing exposures.
Disadvantage of the type of trigger	Hazardous substances may be included in non-hazardous wastes, due to (challenges in the) classification of wastes; concentration limits for environmental hazards not useful in the case of PBTs because the total emission is relevant rather than a concentration.
Impacts on industry	Classification of their wastes; landfill operators need to ensure acceptance procedures, documentation and measurements of leachate.
Impacts on society	Risks from hazardous substances in hazardous wastes are controlled.
Impacts on the environment	Risks from hazardous substances in hazardous wastes are controlled.

[5] The Directive refers to Directive 91/689/EEC, which has been replaced by the waste framework directive.

Table 2-15: Directive 2000/53/EC on end-of life vehicles	
Objective	To make end-of-life vehicle dismantling and recycling more environmentally friendly by setting clear quantified targets for reuse, recycling and recovery of the end-of-life vehicles and their components
Type of trigger	**Further implementation steps** The End-of-Life Vehicles Directive addresses dangerous substances as defined by Directive 67/548/EEC. The use of dangerous substances (as defined in Directive should be prevented already in the design of vehicles (Art. 4). Pb, Cd, Hg and CrVI are use restricted[6] to prevent emissions to the environment, facilitate recycling and prevent generation of hazardous wastes. Derogations are defined in Annex II of the Directive (Art. 4). **Automatic** Vehicle producers should provide dismantling information, including data on the location of hazardous substances (Art. 9) The Directive is addressed to the Member States, which should encourage the implementation of measures.
Classification	Any classification as dangerous according to Directive 67/548/EEC.
Population or environmental compartment	Environment. In addition, facilitation of recycling and prevention of hazardous wastes.
Advantage of the type of trigger	Awareness increased regarding the use/selection of substances and materials for vehicles. Information on (the location of) hazardous substances in end-of-life vehicles allows dismantling, separation and adequate treatment.
Disadvantage of the type of trigger	Requirements are not specified or differentiated according to severity of effect; too much information or no information at all may result. In any case, dismantlers might not be able to identify the relevant components.
Impacts on industry	Vehicle producers should create an inventory of hazardous substances in vehicles and derive relevant dismantling information. Information collection and provision in the automotive industry works via a specific IT-system (IMDS and for dismantling IDIS).
Impacts on society	Less exposure to hazardous substances via the environment.
Impacts on the environment	Less exposure to substances from waste treatment of end-of-life vehicles.

Table 2-16: Regulation (EC) No 1013/2006 on shipments of waste	
Objective	Lays down the rules for controlling waste shipments in order to improve environmental protection, incorporating the provisions of the Basel Convention and the revision of the OECD's decision on the control of transboundary movements of wastes destined for recovery operations
Type of trigger	**Automatic** Obligations are defined for hazardous wastes. Criteria and rules for the classification of wastes as hazardous are defined in the Waste Framework Directive and the decision on the EU list of waste.

[6] The selection of these substances is not justified by their classification, at least not in the recitals and the legal text.

Table 2-16: Regulation (EC) No 1013/2006 on shipments of waste	
	No direct reference exists to any substances or mixtures classified as hazardous. Risk management measures for hazardous waste include: • Prior written notification and consent; • Making a contract between notifier and consignee; • Compilation of movement document for waste to be shipped; and • Prohibition of export of hazardous wastes for recovery to countries, to which the OECD decision does not apply.
Classification	Indirect: content of classified substances may render a waste hazardous. Annex III lists hazardous properties but does not make a direct reference to the CLP Regulation. Decision 2000/532/EC refers to the Dangerous Substances Directive for the hazards very toxic, toxic, harmful, corrosive, irritant, carcinogenic, reprotoxic, mutagenic and ecotoxic. The hazard sensitisation is not defined with reference to the Dangerous Substances Directive and neither are the hazards explosive, oxidising and (highly) flammable. Here, the decision defines individual criteria.
Population or environmental compartment	Environment, human health via environment and for workers.
Advantage of the type of trigger	Reference to hazardous waste compatible with the overall framework and operationalized for all actors in the waste sector.
Disadvantage of the type of trigger	Hazardous substances may be included in non-hazardous wastes, due to (challenges in the) classification of wastes; concentration limits for environmental hazards not useful in the case of PBTs because the total emission is relevant rather than a concentration.
Impacts on industry	Waste export options are limited to some countries, documentation requirements must be implemented and wastes classified.
Impacts on society	N/A
Impacts on the environment	Ensuring that EU standards are applied in the treatment of hazardous wastes should result in reduced environmental exposure as compared to treatment in countries, with lower standards.

Table 2-17: Directive 2004/35/CE on environmental liability	
Objective	Establishes a framework of environmental liability based on the "polluter pays principle" to prevent and remedy environmental damage
Type of trigger	**Further implementation steps** Coverage of the Liability Directive is determined via: a) Discharge of substances classified as dangerous according to Art. 2(2) of the Dangerous Substances Directive; and b) Manufacture, use, storage, processing, filling, release into the environment and onsite transport of substances and mixtures classified dangerous according to the Dangerous Substances Directive/Dangerous Preparations Directive. If activities involving hazardous substances could cause an "imminent threat or environmental damage", the operators of the activities must implement preventive measures (Art. 5) or, if damage has occurred, remediate it and inform the authorities (Art. 6).
Classification	Classification as dangerous according to the Dangerous Preparations Directive or Dangerous Substances Directive.

Table 2-17: Directive 2004/35/CE on environmental liability	
Population or environmental compartment	Environment and man via environment. (If human damage is expected/occurs, damage is to be considered as significant).
Advantage of the type of trigger	Risk prevention and remediation required for all types of hazards.
Disadvantage of the type of trigger	With view to that the primary subject of protection is the environment; the scope of hazardous properties covered appears quite broad (i.e. some human health hazards might be excluded as no relevant risks are likely).
Impacts on industry	Implementation to prevent and remediate damage from hazardous substances. If operators also have to fulfil Seveso and/or Industrial Emissions Directive respective obligations are not expected to cause additional work.
Impacts on society	Damage should be prevented and, in case damage occurs, costs are allocated to the polluters.
Impacts on the environment	Environmental damage should be prevented or remediated.

Table 2-18: Directive 92/85/EEC on pregnant workers	
Objective	To implement measures to encourage improvements in health and safety at work of pregnant workers and workers who have recently given birth or are breastfeeding
Type of trigger	**Further implementation steps** Under Article 4, for all activities liable to involve a specific risk of exposure to the agents, processes or working conditions of which a non-exhaustive list is given in Annex I, the employer shall assess the nature, degree and duration of exposure, in the undertaking and/or establishment concerned of workers within the meaning of Article 2, either directly or by way of the protective and preventive services referred to in Article 7 of Directive 89/391/EEC, in order to: • Assess any risks to the safety or health and any possible effect on the pregnancies or breast feeding of workers within the meaning of Article 2; and • Decide what measures to be taken. Under Article 5: (1) Without prejudice to Article 6 of Directive 89/391/EEC, if the results of the assessment referred to in Article 4(1) reveal a risk to the safety or health or an effect on the pregnancy or breastfeeding of a worker… the employer shall take the necessary measures to ensure that, by temporarily adjusting the working conditions and/ or the working hours of the worker concerned, the exposure of that worker to such risks is avoided. (2) If the adjustment of her working conditions and/ or working hours is not technically and/or objectively feasible, or cannot reasonably be required on duly substantiated grounds, the employer shall take the necessary measures to move the worker concerned to another job. (3) If moving her to another job is not technically and/or objectively feasible or cannot reasonably be required on duly substantiated grounds, the worker concerned shall be granted leave in accordance with national legislation and/or national practice for the whole of the period necessary to protect her safety and health.

	Under Article 6: (1) Pregnant workers … may under no circumstances be obliged to perform duties for which the assessment has revealed a risk of exposure, which would jeopardise safety or health, to the agents and working conditions listed in Annex II, Section A (CMRs).
Classification	CMR
Population or environmental compartment of concern	Human health (pregnant and breastfeeding workers).
Advantage of the type of trigger given classification and population/ compartment	This prevents exposure of the worker to CMR substances in order to protect their health but it also protects the health of the foetus and baby by preventing exposure which may cause developmental issues.
Disadvantage of the type of trigger given the classification and population/ compartment	Different CMRs are problematic at different stages of foetal development and so if a worker delays informing their employer or does not know that they are pregnant then the risk associated with exposure could be greater. The length of time taken to carry out the assessment will also have an impact on this.
Impacts on industry	Increased assessment requiring extra resources (cost). Increased costs associated with employing cover for a worker who cannot be given a different job role and requires paid leave. Lost man hours for a process which a worker normally occupies but has had to be removed from.
Impacts on society	Reduction in the number of occupational cancer cases, and prevention of harmful effects on babies which may lead to developmental problems, relieving pressure on health care services.
Impacts on the environment	N/A

Table 2-19: Directive 94/33/EC on young people at work	
Objective	Lays down the rules for young workers in order to protect their health and to protect them from exploitation
Type of trigger	**Automatic** Under Article 2, without prejudice to Article 4 (1), Member States shall to this end prohibit the employment of young people for: b) work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health. Work which is likely to entail specific risks for young people within the meaning of paragraph 1 includes: Work involving harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex. **Further implementation steps** Article 6(2), the employer shall implement the measures provided for in paragraph 1 on the basis of an assessment of the hazards to young people in connection with their work. The assessment must be made before young people begin work and when there is any major change in working conditions and must pay particular attention to the following points: b) the nature, degree and duration of exposure to physical, biological and chemical agents
Classification	CMR
Population or environmental	Human health (young workers)

compartment of concern	
Advantage of the type of trigger given classification and population/ compartment	This targets a specific risk group who may be at greater risk to exposure to CMRs. The automatic ban creates a definite and immediate prevention of exposure measure. The assessment, which must be carried out prior to a young person joining a workforce, prevents unnecessary exposure which may occur when assessments are carried out during a person's employment.
Disadvantage of the type of trigger given the classification and population/ compartment	There may be cases where a young worker is prevented from being employed due to the presence of a CMR which in reality has little to no significant effect.
Impacts on industry	Increased assessment requiring extra resources (cost). Extra costs for implementing risk management to cover young workers.
Impacts on society	Reduction in the number of occupational cancer cases, relieving pressure on health care services.
Impacts on the environment	N/A

Table 2-20: Directive 98/24/EC on chemical agents at work	
Objective	Lays down the minimum requirements for the protection of workers from risk to their health and safety which may arise from the effects of chemical agents which are present in the workplace or as a result of any work involving chemical agents
Type of trigger	**Further assessment** - Under Article 3: (1) The Commission shall evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data. (2) On the basis of the evaluation described in paragraph 1, the Commission, after first consulting the Advisory Committee on Safety, Hygiene and Health protection at Work, shall propose European objectives in the form of indicative occupational exposure limit values for the protection of workers from chemical risks, to be set at Community level. (3) For any chemical agent for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice. Binding occupational exposure limit values may be drawn up at Community level and, in addition to the factors considered when establishing indicative occupational exposure limit values, shall reflect feasibility factors while maintaining the aim of ensuring the health of workers at work. Such limit values shall be established in accordance with Article 118a of the Treaty and laid down in Annex I to this Directive. (4) For any chemical agent for which a binding occupational exposure limit value is established. Member States shall establish a corresponding national binding occupational exposure limit value based on, but not exceeding, the Community limit value. **Further implementation steps** Under Article 4: (1) In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall first determine whether any hazardous chemical agents are present at the workplace. If so, he shall then assess any risk to the safety and health of workers arising from the presence of those chemical agents, taking into consideration the following: • their hazardous properties;

Table 2-20: Directive 98/24/EC on chemical agents at work	
	• information on safety and health that shall be provided by the supplier, (e.g. the relevant safety data sheet in accordance with the provisions of Directive 67/548/EEC or Directive 88/379/EEC); • the level, type and duration of exposure; • the circumstances of work involving such agents, including their amount, - any occupational exposure limit values or biological limit values established on the territory of the Member State in question; • the effect of preventive measures taken or to be taken; and • where available, the conclusions to be drawn from any health surveillance already undertaken. Under Article 5: (1) In carrying out his obligation to ensure the health and safety of workers in any activity involving hazardous chemical agents the employer shall take the necessary preventive measures set out in Article 6(1) and (2) of Directive 89/391/EEC and include the measures set out in this Directive. (2) Risks to the health and safety of workers at work involving hazardous chemical agents shall be eliminated or reduced to a minimum by: • the design and organisation of systems of work at the workplace; • the provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work; • reducing to a minimum the number of workers exposed or likely to be exposed; • reducing to a minimum the duration and intensity of exposure; • appropriate hygiene measures; • reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned; • suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents. Under Article 6 (1) The employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum. (2) Substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health, as the case may be. Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment referred to in Article 4, the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk made pursuant to Article 4. These will include, in order of priority: • design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work; • application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organisational measures; • where exposure cannot be prevented by other means, application of individual protection measures including personal protective

Table 2-20: Directive 98/24/EC on chemical agents at work	
	equipment. Practical guidelines for protection and prevention measures to control risk shall be developed in accordance with Article 12(2).
Classification	Under Article 2 a hazardous chemical means any chemical agent which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC, whether or not that substance has been classified under that Directive, other than those that only meet the criteria for classification as dangerous for the environment. This includes substances that are: explosive, oxidising; flammable; toxic; harmful; corrosive; irritants; sensitisers; carcinogens, mutagens, toxic for reproduction
Population or environmental compartment of concern	Human health (workers' health)
Advantage of the type of trigger given classification and population/ compartment	Reduces the risk through introduction of occupational exposure limits and introduction of risk management requirements for employers. This allows for the use of hazardous chemicals in scenarios where they are truly necessary or cannot be removed.
Disadvantage of the type of trigger given the classification and population/ compartment	Relies on employers to implement the risk management measures appropriately to protect worker health which may be an issue if they do not have the resources to do so. In the case of CMRs it is difficult to establish a "safe" limit of exposure and so limit values may not be the most effective long-term risk management measure.
Impacts on industry	Costs associated with assessment and the resulting changes which may need to be made to processes to meet risk management measures. Reduction in lost work days due to illness.
Impacts on society	Reduction in the number of occupational disease cases, relieving pressure on health care services.
Impacts on the environment	N/A

Table 2-21: Directive 2004/37/EC on carcinogens or mutagens at work	
Objective	The protection of workers against risks to their health and safety, including prevention of such risks, which may arise from exposure to carcinogens or mutagens at work
Type of trigger	Further implementation measures: Under Article 3(2), in the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. Point 3 states that when assessing the risk, account shall be taken of all other routes of exposure, such as absorption into and/or through the skin. Employer obligations are laid out in Articles 4 and 5: Article 4 – Reduction and replacement (1) The employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or

Table 2-21: Directive 2004/37/EC on carcinogens or mutagens at work	
	safety, as the case may be. Article 5 – prevention and reduction of exposure (2) Where it is not technically possible to replace the carcinogen or mutagen by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system. (3) Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible. (4) Exposure shall not exceed the limit value of a carcinogen as set out in Annex III. (5) Wherever a carcinogen or mutagen is used, the employer shall apply all the following measures: • limitation of the quantities of a carcinogen or mutagen at the place of work; • keeping as low as possible the number of workers exposed or likely to be exposed; • design of work processes and engineering control measures so as to avoid or minimise release into the place of work; • evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment; • use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident; • application of suitable working procedures and methods; • collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures; • hygiene measures, in particular regular cleaning of floors, walls and other surfaces; • information for workers; • demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens; • drawing up plans to deal with emergencies likely to result in abnormally high exposure; • means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers; • means for safe collection, storage and disposal of waste by workers, including the use of sealed and labelled containers.
Classification	Carcinogen, mutagen
Population of concern	Human health (workers' health)
Advantage of the type of trigger given classification and population/ compartment	Reduces the risk of exposure through introduction of occupational exposure limits and introduction of risk management requirements for employers. This allows for the use of hazardous chemicals in scenarios where they are truly necessary or cannot be removed. This is particularly useful in the case of process-generated substances which may be classified as carcinogenic or mutagenic as they cannot be removed unless the process itself is changed.
Disadvantage of the type of trigger given the classification and	Relies on employers to implement the risk management measures appropriately to protect worker health which may be an issue if they do not have the resources to do so. In the case of CMs it is difficult to establish a "safe" limit of exposure and so limit values may not be the

Table 2-21: Directive 2004/37/EC on carcinogens or mutagens at work	
population/ compartment	most effective long-term risk management measure.
Impacts on industry	There will be costs associated with meeting the requirements of every stage of the hierarchy for risk management. Substitution can be particularly expensive and requires a lot of resources. There is also a limited time frame of 18 months which is difficult to meet for substitution as the process for finding an alternative can take years. Reduction in lost work days due to prevention of illness.
Impacts on society	Reduction in the number of occupational cancer cases, relieving pressure on health care services.
Impacts on the environment	N/A

2.2 Scientific and technical committee opinions

2.2.1 Introduction

Different scientific committees are used to formulate opinions on hazardous substance use under different pieces of legislation, as set out in Table 2-22. Each committee works to different timeframes and follows different committee procedures, which can make comparison of the processes difficult. There should be no crossover between scientific committees, meaning that for one piece of legislation only one committee would be used to formulate the opinion on the use, or in certain cases classification, on the classification of a given hazardous substance.

Table 2-22: Legislative act and corresponding responsible scientific committee / agency expert group

EU Legislation	Relevant scientific committee/ Agency expert group	Role
Regulation (EC) No 1223/2009 on cosmetic products	Scientific Committee on Consumer Safety (SCCS)	Opinion on safe use of a cosmetic ingredient
Directive 2009/48/EC on the safety of toys	Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), Toys Safety Expert Group – chemicals subgroup	Opinion on safe use of chemicals in toys
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	European Food Safety Authority (EFSA) - Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)	Opinion on safe use of a substance in food packaging
Regulation (EC) No 1107/2009 on plant protection products	EFSA Pesticide Unit	Peer review of risk assessment of active substances and assessing whether or not an active substance will meet the criteria for approval
Regulation (EU) No 528/2012 on biocidal products	Biocidal Products Committee (BPC) at ECHA	Opinions on the approval and renewal of active substances, identification of substances as candidates for substitution, applications for Union authorisation
Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures	Risk Assessment Committee (RAC)	Hazard classification of substances

For example, a suggested topic for an opinion sought under the Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Consumer Safety (SCCS) or Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) should not fall under the competence of any European agency, particularly the European Chemicals Agency (ECHA), European Medicines Agency (EMEA) or European Food Safety Authority (EFSA)[7]. There may be occasions when SCCS and

[7] European Commission (2016) Rules of Procedure: The Scientific Committees on Consumer Safety (SCCS) and Health, Environmental and Emerging Risks (SCHEER). P 45. Available at: http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)[8] join together in order to form an opinion if the scope of the opinion covers the expertise of more than one scientific committee. Stakeholder views of the scientific committee processes and procedures are discussed in Section 3.2. It should be noted that SCENIHR and SCHER have combined to form SCHEER, but these two scientific committees had not merged at the beginning of the consultation and so some stakeholder responses will refer to SCHER.

Under the SCCS and SCHEER, the deadline for formulation of an opinion is outlined in the terms of reference submitted by the European Commission or Secretariat to the Scientific Committee. For food contact materials, EFSA has 6 months to formulate its opinion based on the dossier submitted to a Member State competent authority. The timeframe for approval of active substances in plant protection products is considerably longer as there are many more steps involved than for SCHEER/SCCS opinions. The EFSA conclusion on whether an active substance will meet the approval criteria should be finalised within 180 days of receipt of the Draft Assessment Report. The Biocidal Products Committee should provide an opinion on the approval of an active substance for biocidal products 270 days after the receipt of the Member State competent authority evaluation. The RAC must deliver its opinion within 18 months of a CLH dossier passing an accordance check and being passed to ECHA. Figure 2-1 sets out the timeframes for opinion-forming by the different scientific committees.

Stakeholder involvement within the scientific committee processes varies greatly and this has been criticised by some of the stakeholders interviewed for Case Study 11. In the case of the SCCS and SCHEER, technical or public scientific hearings with stakeholders may be organised to obtain additional technical or scientific information, comments, suggestions or explanations.

During the EFSA process opinion-forming on whether an active substance will meet the approval criteria, the summary dossier from the first stage of the process and the draft assessment report are available to the public. EFSA allows a 60 day commenting period for stakeholders and in some cases there may be an additional expert consultation.

Meetings of the BPC are open to advisors, invited experts and observers. An advisor accompanies members of the Committee to provide scientific, technical or regulatory advice. Invited experts are those who are invited by ECHA, after a proposal by a Member State, to participate due to their expertise in a relevant scientific or technical field. Observers can include:

- The Executive Director and his representatives of the European Commission;
- Nominated representatives of accredited stakeholder organisations (ASO) (upon the request of ECHA Management Board), which may contribute their scientific or technical expertise;
- An applicant; and
- Representatives of third countries and international organisations (upon request of ECHA Management Board).

Applicants may participate in discussions at the meetings but they will not have access to the documents of the BPC, apart from in exceptional circumstances.

Similarly, industry may also attend the RAC meetings at which a CLH dossier is discussed, as many observers and representatives of accredited stakeholder organisations. Industry may also provide input into the RAC opinion-making process during the open public consultation on a CLH proposal.

[8] Previously SCHER & SCENIHR.

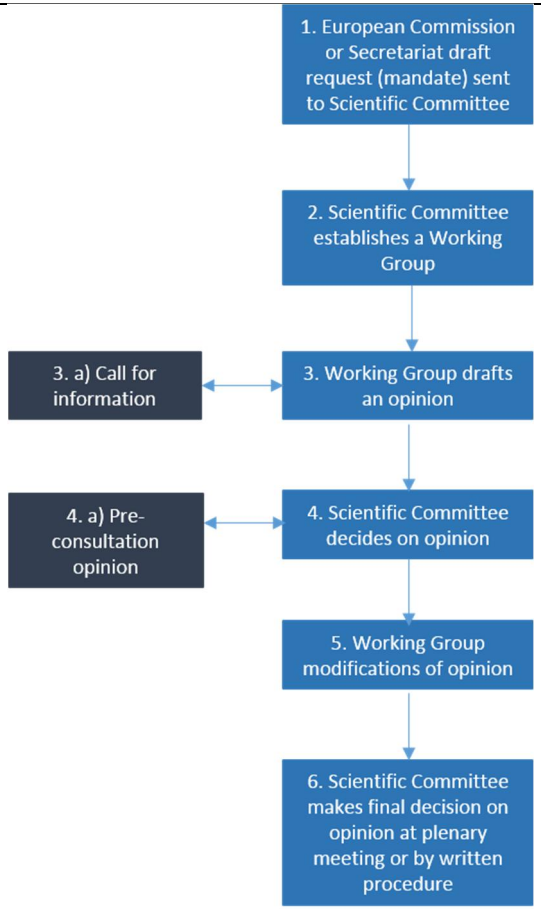
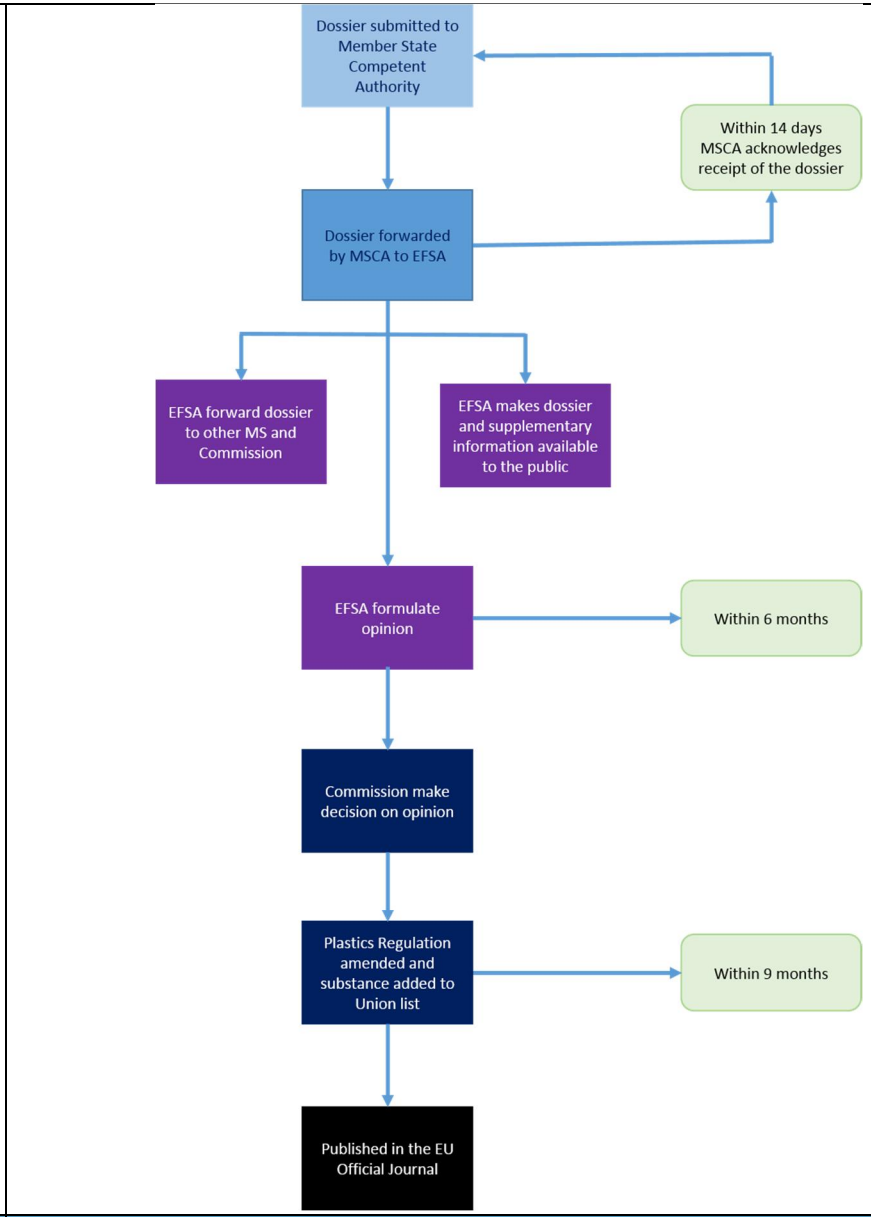


Figure 2-1: SCCS/ SCHEER, opinion on the safe use and approval of use of a CMR substance*



EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Authorisation of substances for use in plastic food contact materials

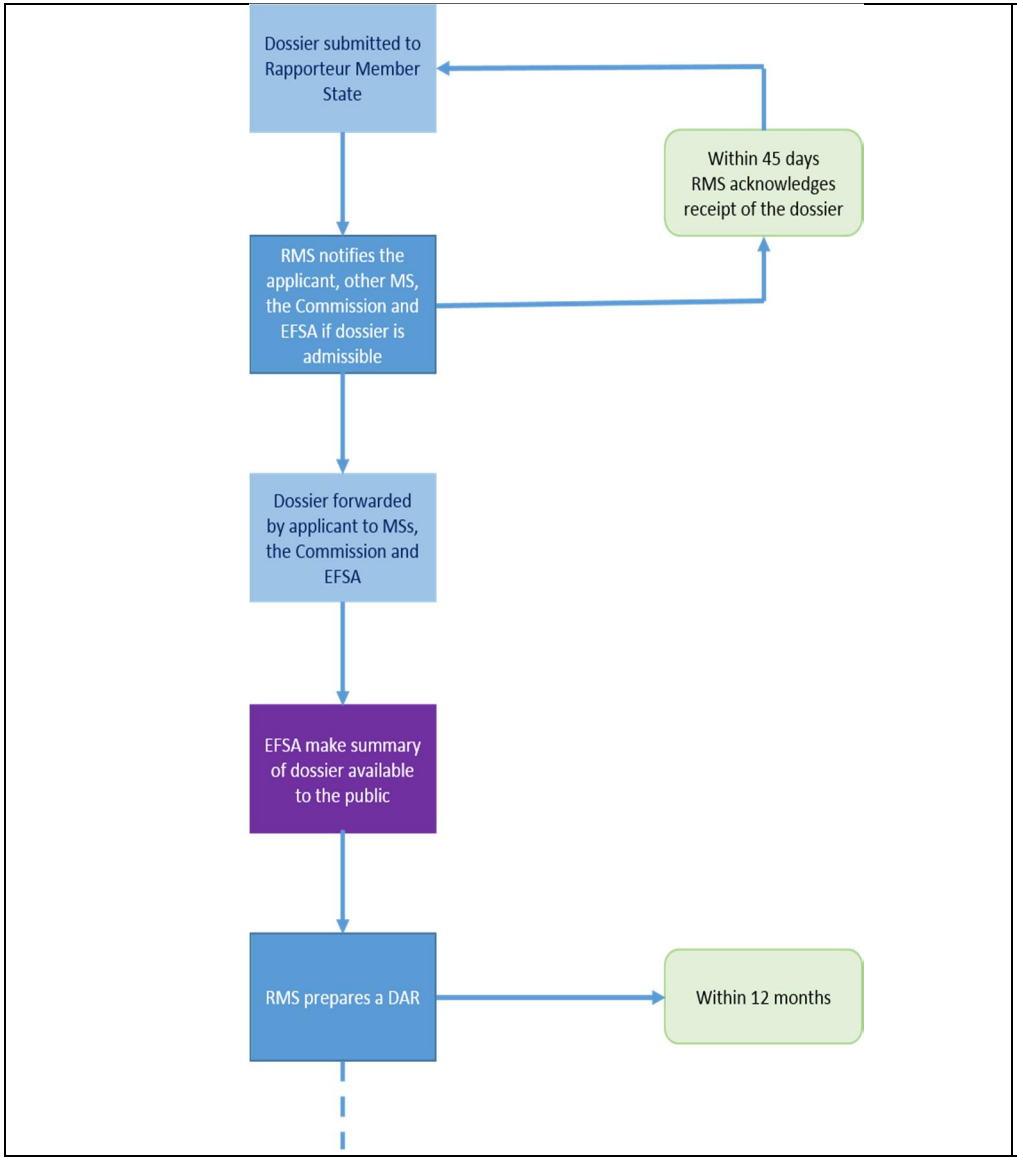
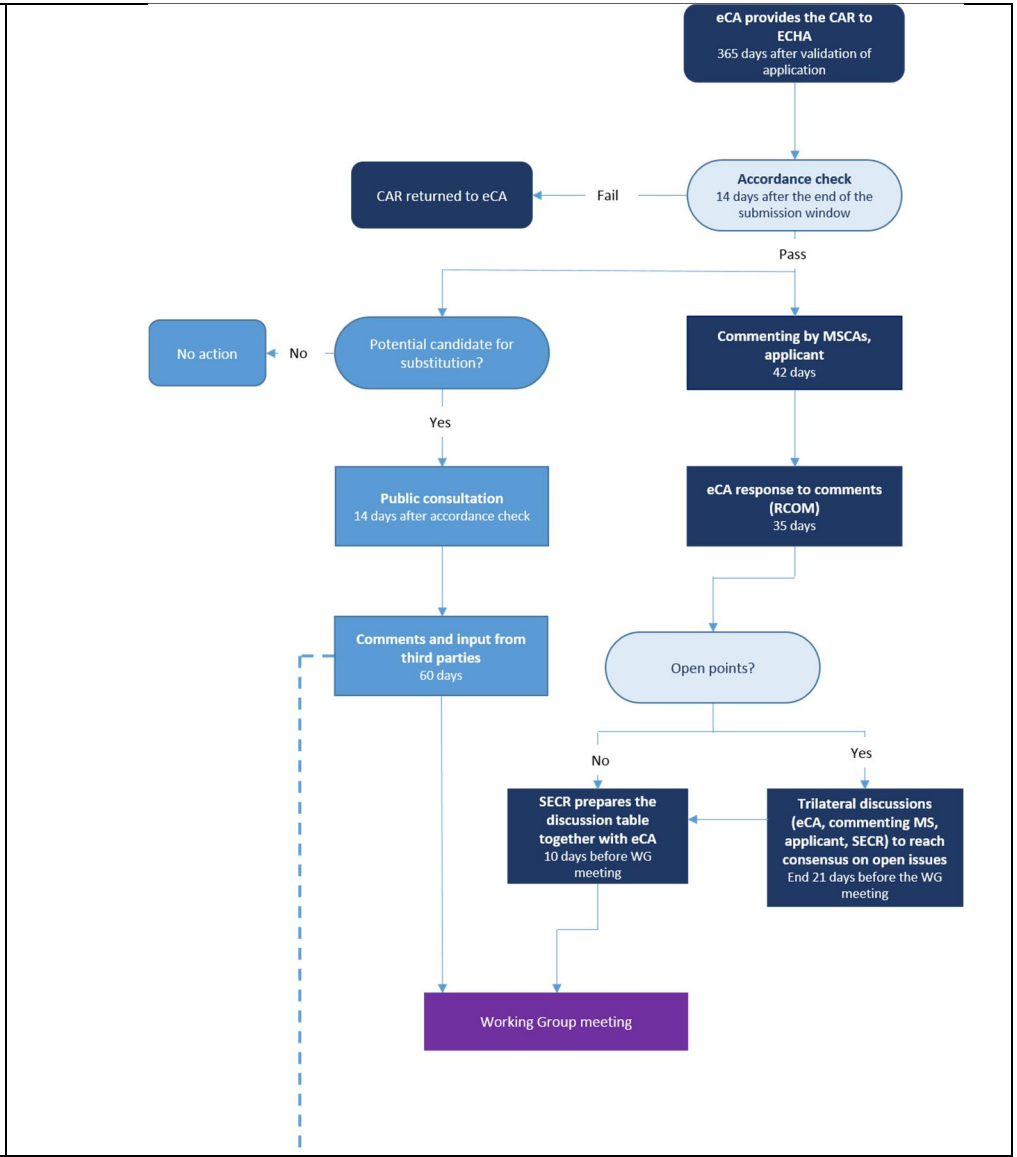


Figure 2-2: EFSA Pesticides Unit, opinion on whether a substance will meet approval criteria



BPC, active substance approval

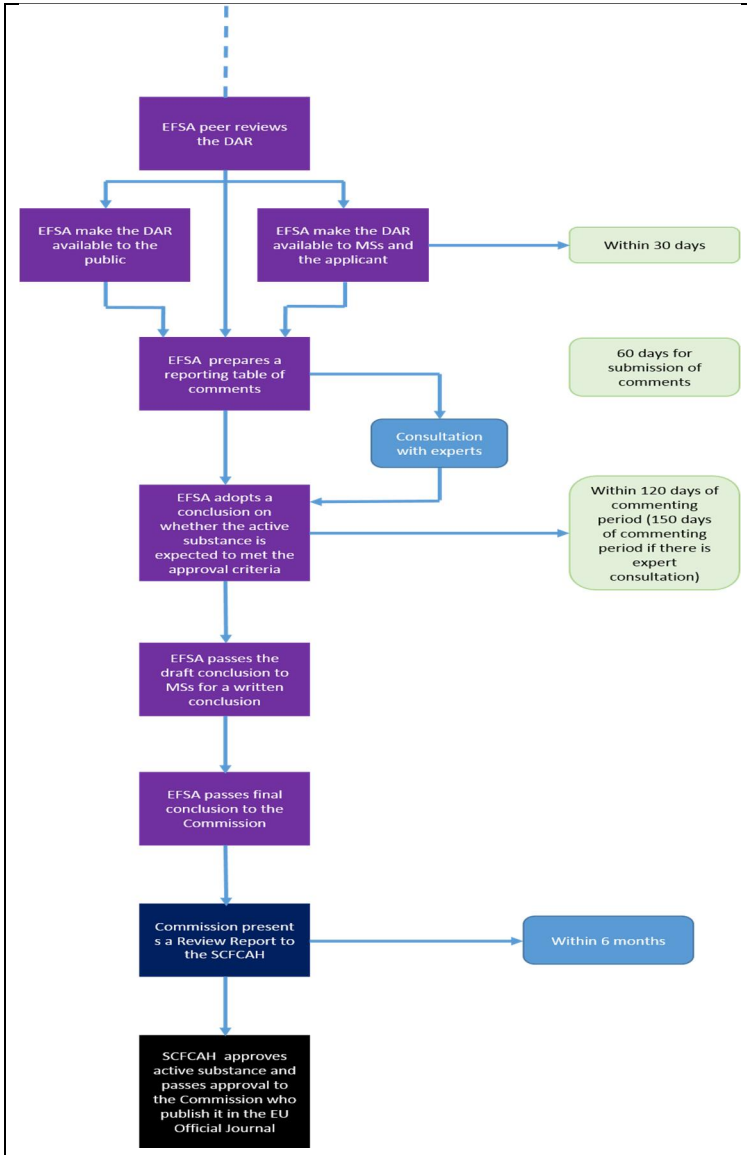
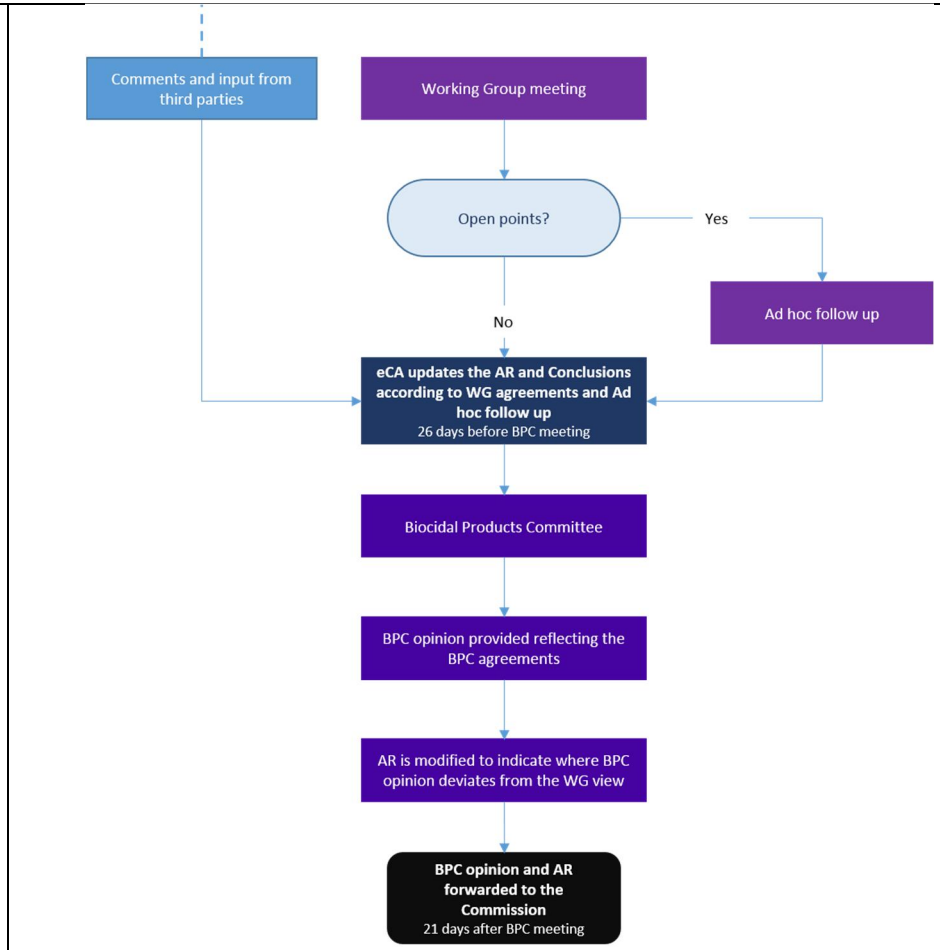


Figure 2-3: EFSA Pesticides Unit, opinion on whether a substance will meet approval criteria



BPC, active substance approval

2.2.2 Legislative inter-linkages

Each piece of legislation examined for Task 3 aims to meet the common objectives of the EU chemicals legislative framework. As shown in Tables 2-2 to 2-21, the risk management measures under the pieces of legislation considered in Task 3 are linked to different classifications of hazardous substances under CLP. Fourteen out of the 21 pieces of legislation being evaluated have risk management triggered automatically based on generic risk considerations (as a result of a CLH). These triggers include an automatic ban of a product containing that substance, a non-approval for an active substance due to it meeting the exclusion criteria or a substance being considered a candidate for substitution. The remaining six pieces of legislation have further implementation measures that must be enforced as a result of a CLH, including extra provisions for the workplace and for the safe disposal of waste.

As well as there being linkages between the 20 pieces of legislation with CLP, there are also interactions between some of this downstream legislation. For example, Table 2-23 provides an indication of the linkages which exist between the seven pieces of legislation that are examined in more detail in Case Study 11. A summary of these inter-linkages is given below. It should be noted that this table relates specifically to the pieces of legislation that are examined in detail for Case Study 11 which focuses on CMRs. There will of course be other inter-linkages, for example, between the Chemical Agents Directive and the Young Workers Directive and the use of classified substances within the workplace.

Table 2-23: Inter-linkages between downstream legislation

Legislation referred to in other legislation	Legislation referring to other legislation						
	CR	TSD	FCM	PPPR	BPR	CMD	PIC
CR		x			x		
TSD					x		
FCM		x			x		
PPPR					x		x
BPR							x
CMD					x		
PIC					x		

CR: Cosmetic Products Regulation
TSD: Toy Safety Directive
FCM: Food Contact Materials Regulation
PPPR: Plant Protection Products Regulation
BPR: Biocidal Products Regulation
CMD: Carcinogens and Mutagens Directive
PIC: Prior Informed Consent Regulation

2.2.2.1 Biocidal Products Regulation (EU) No 528/2012

The Biocidal Products Regulation is linked to a number of other pieces of legislation and this is outlined in the Biocidal Products Regulation text. There are also cases where a biocidal product is no longer treated as one under the Biocidal Products Regulation and responsibility for that substance shifts to another piece of legislation. Article 2(2) states that: "*subject to any explicit provisions to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the Plant Protection Products Regulation, the Cosmetic Products Regulation and the Toy Safety Directive. When a biocidal product falls within the*

scope of one of these instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments".

The appropriateness of these provisions shall be examined in later sections.

Article 2(3) states that: "*subject to any explicit provisions to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the Carcinogens and Mutagens at work Directive and the PIC Regulation*".

Food contact materials can also be classed as treated articles and so would be subject to the provisions of Chapter XIII of the Biocidal Products Regulation.

2.2.2.2 Toy Safety Directive 2009/48/EC

The Toy Safety Directive is linked to two of the pieces of legislation considered here, aside from the CLP Regulation. Point 10 of Part 3 of Annex II states that "*cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products*". As Directive 76/768/EEC has been repealed and replaced by the Cosmetic Products Regulation, such cosmetic toys are now subject to the requirements of that Regulation.

Point 7 of Part 3 of Annex II states that "*Points 3, 4, and 5*[9] *shall not apply to materials that comply with the specific limit values set out in Appendix C, or until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and related to specific measures to particular materials*". Regulation (EC) No. 10/2011 on plastic materials and articles intended to come into contact with food is a specific measure within the meaning of Article 5 of Regulation (EC) No. 1935/2004 and so point 7 is applicable to this too, in the case of plastics.

The appropriateness of these provisions is examined in latter sections.

2.2.2.3 Carcinogens and Mutagens at work Directive 2004/37/EC

This Directive is applicable to any workplace where carcinogens or mutagens are in use. If any formulators use CMRs in their products, then they will be subject to the conditions outlined in the Carcinogens and Mutagens Directive. This includes carcinogens and mutagens that are process generated but are not covered by the CLP.

2.2.2.4 Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals

This Regulation implements the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. Recital 8) states that "exports of hazardous chemicals that are banned or severely restricted within the Union should continue to be subject to a common export notification procedure. Accordingly, hazardous chemicals, whether in the form of substances on their own or in mixtures or in articles, which have been banned or severely restricted by the Union as plant protection products, as other forms of pesticides […] should

[9] Point 3 – restriction on the use of CMRs in toys, in components of toys or in microstructurally distinct parts of toys. Point 4 – derogation for substances classified as CMR category 1A and 1B. Point 5 – derogation for substances classified as CMR category 2.

be subject to export notification rules similar to those applicable to such chemicals when they are banned or severely restricted within either or both of the use categories laid down in the Convention". The Prior Informed Consent Regulation also requires exported pesticides to be provided with information regarding appropriate storage conditions, with suitable packaging and sizes of containers to avoid creating obsolete stocks[10]. The definition of pesticide under this Regulation is a) pesticides used as plant protection products covered by the Plant Protection Products Regulation and b) other pesticides such as biocidal products under the Biocidal Products Regulation[11].

2.3 Examples of national legislation that trigger risk management measures

2.3.1 Introduction

In agreement with the Commission, ten Member States were selected for investigation of national legislation that may trigger risk management measures (RMM), in addition to the EU legislation listed in Table 2-1.

The following ten Member States were chosen to provide a balanced geographical coverage and to include also smaller Member States: France, Germany, Greece, Italy, Latvia, the Netherlands, Poland, Spain, Sweden, and the United Kingdom. In the draft Inception Report, a list of all national legislation in the ten selected Member States that included references to the CLP (or its predecessors) was provided. It was agreed with the Commission, however, that the task should be more specific to provide added value to the study. It was therefore agreed that the desk research should focus on two categories of national legislation: 'Self-standing' national legislation and national legislation transposing EU Directives. 'Self-standing' legislation includes national legislation that links a RMM to a CLP classification without transposing an EU Directive or implementing an EU-Regulation. For example, under the German Chemicals Act, a physician whose patient's symptoms were caused by exposure to hazardous chemicals, as defined under the CLP, must inform the Institute for Risk Assessment. Such a requirement does not reflect EU legislation and is therefore 'self-standing'. An example of national legislation transposing EU Directives is occupational health and safety legislation with references to CLP classifications. The reference to the CLP Regulation may be either explicit or implicit by 'copying' the CLP hazard classifications without mentioning the Regulation itself. In the case of national legislation transposing EU Directives, it was agreed to focus on such national legislation where issues in the transposition of the vertical links have been identified due to inconsistencies, additional requirements etc., for example by applying higher or lower thresholds than foreseen under the CLP.

To identify relevant national legislation, the legislative databases of the ten selected Member States were searched for reference to the CLP or its predecessors. Following this assessment was made as to whether the national legislation transposed EU legislation, or whether it was 'self-standing'. In case of doubt regarding whether the national legislation that seemed self-standing actually transposed EU downstream legislation; this was nevertheless included in the

[10] Recital 14) of Regulation (EC) No. 649/2012 concerning the export and import of hazardous substances

[11] Article 3(5)(a) and (b) of Regulation (EC) No. 649/2012 concerning the export and import of hazardous substances.

list of self-standing legislation. In addition, e-mails including a note of explanation by DG GROW were sent to the competent authorities responsible for REACH and CLP (CARACAL) in the ten selected Member States, as well as to the Members of the EPG Working Group on REACH and CLP, where applicable. The contact details of the relevant persons were provided by the Commission.

Most of the ten Member States replied to the request. None of them identified inconsistencies between national legislation referring to CLP classification to trigger RMM and the EU legislation that it transposes[12]. Some provided lists of what they considered as 'self-standing legislation'. However, many of the provisions identified were in fact legislation transposing or implementing EU legislation. In particular legislation that merely establishes national administrative rules to implement the CLP Regulation have not been included in the below overview although it had been identified by some Member States as 'self-standing legislation'. Also legislation under which a RMM is not triggered by a CLP classification has not been taken into account, e.g. provisions applying CLP labelling requirements to non-hazardous substances.

Within the scope of the study, assessment of whether national legislation transposing EU downstream legislation presented any issues, for example additional requirements or other inconsistencies, could not be undertaken provision by provision but could only be based on the stakeholder consultation carried out as part of the study, including the above-mentioned request to CARACAL and EPG Working Groups in the ten Member States. However, the consultation activities did not bring any results in that respect. The comments made in this regard were rather general and did not indicate any inconsistencies between the national legislation and the EU downstream legislation it transposes. For example, the German Industry Association BDI calls for a decoupling of the deadlines for national transposition in case of new CLP classifications.[13]

The tables presented in Annex 1 provide an overview of national downstream legislation in the ten selected Member States.

With respect to 'self-standing' national legislation, a number of examples are presented in Box 2-1 below. The full list is presented per Member State in the above-mentioned tables in Annex 1.

Box 2-1: Examples of self-standing national legislation

Tattooing ink

Based on Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up, France and the Netherlands ban substances classified as CMR 1A, 1B and 2 (and in France also sensitiser category 1) under the CLP Regulation from the use in tattooing ink.

Cosmetics

[12] Spain identified a case of late transposition but this has not been included here since the focus is on intended or persisting differences. In Spain, the law on waste that transposes Directive 2008/98/EC on waste does not reflect the change of Annex III to the Directive through Regulation (EU) No 1357/2014 yet, concerning properties of waste which render it hazardous.

[13] BDI, DIHK, BDA and BGA position paper, July 2015, document no. 0716.

Box 2-1: Examples of self-standing national legislation

France prohibited the placing on the market and use of cosmetic products containing Chloroacetamide until measures are taken by the European Commission. The prohibition is justified on the basis of a recommendation of the European Scientific Committee on Consumer Safety and the classification of the substance as toxic for reproduction under the CLP Regulation.

Toys

In France, importation and placing on the market of foam toys known as 'puzzle matting' containing over 200 mg/kg of Formamide are suspended for a duration of one year (from October 2015). Similar orders have been issued in previous years. The suspension is justified by the classification of Formamide as a reprotoxic under the CLP Regulation.

Waste

According to the Polish Act on packaging and waste packaging, the person who places on the market hazardous substances/mixtures in packaging is obliged to organise the system of collection and ensure recovery, including recycling of waste packaging. For the definition of the criterion as hazardous the act refers to CLP. A similar provision has been identified in the German Packaging Ordinance.

Plant protection products

In France, Plant protection products cannot be used near schools and hospitals, with the exception of low-risk products, and products which have been exclusively classified as toxic for the aquatic environment or Hazardous to the ozone layer (H400, H410, H411, H412, H413, H059) under the CLP Regulation.

Public health

Under the German Chemicals Act, a physician who suspects that the disease of his patient has been caused by an exposition to hazardous substances or mixtures or articles containing or releasing such chemicals is obligated to inform the Federal Institute for Risk Assessment. Regarding the classification as 'hazardous', the Chemicals Act also refers to the CLP.

Under the UK Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013, where a conveyor of flammable gas through a fixed pipe distribution system receives notification of the death, loss of consciousness or taking to hospital of a person because of an injury arising in connection with that gas, that person must notify the competent authority of the incident. 'Flammable gas' is defined in the interpretation section as having the meaning associated with this hazard class under the CLP.

3 Scope and Objectives of the Legislative Framework Concerning Hazards and Risks

3.1 Introduction

As illustrated in Section 2, the downstream legislation with linkages to CLP classifications is broad in terms of its objectives and the scope of the activities that are regulated by it. As a result, through the linkages with CLP, a wide range of hazards and/or risks are addressed within downstream legislation, where this includes:

- Human health hazards/risks to: workers, consumers, and the general public; this includes measures more specific to vulnerable populations (e.g. children), as well as to specific groups within the general public (e.g. residents near to major hazard installations); and

- Environmental hazards/risks to: different environmental compartments, arising from different lifecycle stages, and from different sources.

Through the linkages to CLP, the scope of the hazards that may be addressed by risk management measures include physico-chemical, health related and environment related. Under some legislation, as indicated as part of the Task 2 work, additional properties are taken into account such as persistence, bioaccumulation and toxicity (PBT) and endocrine disruption (ED). The discussion here focuses on the extent to which the scope of the linkages that exist between CLP and downstream legislation are appropriate to meeting the objectives of the chemicals legislative framework. It should be noted that although there are 21 pieces of legislation considered in this task, for some, such as the Food Contact Material legislation, the Tobacco Products Directive, Prior Informed Consent Regulation and the Young People at Work Directive, there have not been any issues raised and, therefore, one would assume that this means that they meet their objectives and stakeholders are satisfied with their functioning.

Across the suite of legislation, one of the overarching objectives is ensuring a high level of protection of human health and the environment. This objective is subjective and no definition exists as to what constitutes a high level of protection. As a result, different stakeholders will have different interpretations of what this means. Our approach to evaluating whether or not this objective is being met has therefore been to consider the scope of the hazards and risks that are taken into account, and what these indicate with respect to the effectiveness, efficiency, relevance and coherence of the different triggers for risk management. Table 3-1 shows the different populations and compartments taken into account in the pieces of legislation considered in Task 3.

Case Study 11 supports this element of the evaluation by examining the risk management procedures triggered by a CMR classification under CLP, and the differences in such procedures between legislation. The pieces of legislation being examined in this case study are: the Biocidal Products Regulation (528/2012); the Cosmetic Products Regulation (1223/2009); the Carcinogens and Mutagens at work Directive (2004/37/EC); the Plant Protection Products Regulation (1107/2009); the Prior Informed Consent Regulation (649/2012); the Toy Safety Directive (2009/48/EC); and the Food Contact Materials Regulation (10/2011).

Case Study 3 is also relevant; it examines the implications of the differences in requirements for the way the criteria for persistence, bioaccumulation and toxicity (PBT) are applied, including how they link to the CLP Regulation.

Table 3-1: Populations and compartments taken into account by relevant vertical chemicals legislation						
Legislation	General	Human health				Env.
		Vulnerable populations				
		Workers	Pregnant & breastfeeding women	Young people	Children	
Consumer products						
Regulation (EC) No 1223/2009 on cosmetic products	✓					
Directive 2009/48/EC on the safety of toys					✓	
Regulation (EC) No 66/2010 on the EU Ecolabel	✓	✓*			✓*	✓
Regulation (EC) No 450/2009 on active and intelligent materials	✓					
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	✓					
Professional products						
Regulation (EC) No 1107/2009 on plant protection products	✓	✓				✓
Regulation (EU) No 528/2012 biocidal products	✓					✓
Directive 2014/68/EU pressure equipment						
Environmental protection						
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals						
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	✓	✓				✓
Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)	✓	✓				✓
Directive 2008/98/EC on waste	✓					✓
Directive 1999/31/EC on the landfill of waste	✓	✓				✓
Directive 2000/53/EC on end-of life vehicles						✓
Regulation (EC) No 1013/2006 shipments of waste	✓*	✓				✓
Directive 2004/35/CE on environmental liability	✓*					✓
Occupational safety & health (OSH)						
Directive 92/85/EEC pregnant workers			✓			
Directive 94/33/EC young people at work				✓		
Directive 98/24/EC chemical agents at work		✓				
Directive 2004/37/EC carcinogens or mutagens at work		✓				
Notes: Env. = Environment. * via the environment						

The evaluation carried out below in relation to the scope and objectives of the legislation is based on the following evaluation questions.

Table 3-2: Relevant questions on scope of risks considered and meeting the EU chemicals legislative framework's objectives	
Q #	**Evaluation question**
Effectiveness	
1.1.1.2.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the combination effects of chemicals (simultaneous exposure to chemicals)?
1.1.1.3.	To what extent does the EU legislative framework meet its objectives in relation to the protection of human health and the environment from the exposure to a substance via various sources and/or routes of exposure?
1.1.1.4.	Do the risk management measures sufficiently address all risks to human health and the environment (e.g. chemicals in articles, mixtures, endocrine disruptors, nanomaterials, new toxicity endpoints)?
1.1.1.5.	Are there any gaps in ensuring a high level of protection of human health and the environment? If yes, what are they?
1.1.1.9.	Have the incidences of consumer chemical-related accidents resulting in exposure/damage of human health or the environment been reduced?
1.1.1.10.	Have the incidences of industrial worker/professional chemicals-related accidents resulting in exposure/damage of human health or the environment been reduced?
1.1.1.11.	How has the chemicals legislative framework impacted the incidence of diseases in the general public?
1.1.1.12.	How has the chemicals legislative framework impacted the incidence of occupational disease?
1.1.1.13.	To what extent has the risk management addressing exposures of industrial/professional workers to chemicals improved as a result of the chemicals legislative framework?
1.1.1.14.	To what extent has the risk management addressing exposures of consumers to chemicals improved as a result of the chemicals legislation framework?
1.1.2.1.	To what extent does the EU legislative framework meet its objectives in relation to the functioning of the single market?
1.1.3.4.	To what extent has the chemicals legislative framework contributed to innovation in the chemicals industry?
1.1.4.2.	Is the chemicals legislative framework as effective as it can be? Are there factors that limit the effectiveness of the chemicals legislative framework and would they be avoidable?
1.1.4.3.	To what extent does the chemical legislative framework requires/encourage Member States to further reduce exposure of humans and/or the environment to hazardous chemicals and are these requirements sufficiently implemented?
1.1.4.4.	To what extent does the chemicals legislative framework promotes the access to and use of substances/products with a more favourable risk profile (e.g. by identifying such and providing for a simplified assessment/authorisation procedure)?
1.3.8.	To what extent are there synergies between the objectives of protection of human health and the environment and the functioning of the internal market? Are these synergies immediate or do they appear over time?
1.2.4.	Are there obsolete measures or gaps in the legislative framework?
1.3.1.	Which factors have the biggest positive impact on the correct functioning of the chemicals legislative framework? To what extent?
1.3.2.	Which factors have the biggest negative impact on the correct functioning of the chemicals legislative framework? To what extent?
4.1.1.	To what extent are the legal acts of the chemicals legislative framework consistent in attempting to reach the stated objectives?
4.2.6.	Does the chemical legislative framework ensure that the substances/products are assessed under the most relevant piece of legislation, especially when a specific claim is made about its function or positive effects? Does the chemicals legislative framework enable regulators to reach evidence-

Table 3-2: Relevant questions on scope of risks considered and meeting the EU chemicals legislative framework's objectives	
Q #	**Evaluation question**
	based decisions and identify false claims/misleading information?
Relevance	
3.1.1.	Do the original needs still exist or are parts of the chemicals legislative framework now redundant?
3.1.2.	Have new needs emerged in relation to the risk management of chemicals? If yes, what are they?
3.1.3.	To what extent do the objectives of the legislative framework for chemicals meet the need for enabling/promoting circular economy? Are there conflicting objectives and how can they be solved? Are there synergies? Which of the risk management approaches (based on generic risk consideration or specific risk assessment) is more effective and efficient in enabling/promoting circular economy?
3.1.4.	Does the chemicals legislative framework reflect and implement the basic principles of EU environmental policy stated in article 191 of the Lisbon Treaty (i.e. the principles of precaution, substitution, polluter pays and rectification of environmental damage at source)?
Coherence	
4.1.6.	To what extent does the legislative framework meet its objectives consistently in cases where the same chemical is used for different purposes and where the uses falls under different pieces of legislation? Are references to other legislation clear and unambiguous?
4.2.2.	Are there inconsistencies or contradictions in what is required by the chemicals legislative framework from different actors (under different pieces of legislation)?
4.2.3.	Are there duplications or overlaps that make some parts of legislation obsolete? Are there unexpected advantages or disadvantages due to the overlaps in the legislation?
4.2.4.	Is the chemicals legislative framework consistent with wider EU policies and strategies, in particular in areas of environment and sustainability, circular economy, non-toxic environment strategy, innovation, competitiveness and job creation?
EU added value	
5.1.1.	Are there national measures that could potentially reach the objectives of the chemicals legislative framework in a better way?
5.1.2.	What would be the most likely consequences of withdrawing or stopping the EU intervention in terms of protecting human health and the environment, enhancing the functioning of the internal market and enhancing competitiveness and innovation?
5.1.3.	Are there particular circumstances under which the Regulation of chemicals is more effective at national level, and what would be the consequences for the internal market of allowing more flexibility, e.g. in the context of safeguard clauses?

3.2 High level of protection of human health and the environment

Key findings:

- The majority of stakeholders (industry, NGOs, Member States) believe that the EU chemicals legislative framework meets the objective of a high level of protection to human health, yet there is a less positive view regarding protection of the environment.
- One area of particular concern is the Cosmetic Products Regulation which stakeholders have suggested does not take into account professional (worker) exposure. There is very little guidance on professional use of cosmetics and there is no clear link to OSH legislation in the Cosmetic Products Regulation.
- The exemption from the ban on CMRs in toys which relates to concentrations below the generic concentration limit for mixtures in CLP is not considered to be appropriate by stakeholders across all groups as children are a vulnerable population.
- The lack of assessment for combination effects and multiple routes of exposure is considered by stakeholders from all groups (industry, NGOs, Member States, academia) to be a gap in ensuring a high level of protection of human health and the environment, although it is acknowledged that there is not the technical ability to carry out such testing at present.
- The primary risk management measure for PBTs/vPvBs, EDCs and CMRs are bans (the Biocidal Products Regulation, Plant Protection Products Regulation etc.) and use restrictions (REACH). These effectively reduce exposure and emissions.

3.2.1 Ensuring a high level of protection

Industry stakeholders have indicated that the EU chemicals legislative framework does meet the objective of providing a high level of protection of human health and the environment, especially, if this is defined in terms of the legislation ensuring the safe use of products being placed on the market.

An example given by industry of where the chemicals legislative framework is considered to be particularly effective is in the level of protection for consumers with respect to cosmetic ingredients, where stakeholders note that there have been very few incidents of concern for consumers' health over the last 40 years. The European Trade Union Institute (ETUI) and some Member State authorities have raised an issue with the protection of the health of professional users, such as hairdressers and nail technicians, however. It would appear that some Member State authorities regulating occupational health and safety make suggestions for the protection of workers' health in this context, such as using gloves when applying hair dyes[14] and extractor hoods or downdraft tables when working with acrylic nails[15]; but there are no legal provisions for this in the legal text of the Cosmetic Products Regulation. Authorities have commented that although the Cosmetic Products Regulation should take into account professional use, in practice, risk assessment within the framework only concerns consumers. Authorities noted that under the Cosmetic Products Regulation there is "not enough information for professional users" and "they need to be able to

[14] UK HSE (2016): Hairdressing. Available at: http://www.hse.gov.uk/hairdressing/resources.htm

[15] UK HSE (2006): SR13: COSHH essentials for service and retail – Nail bars. Available at: http://www.hse.gov.uk/pubns/guidance/sr13.pdf

choose less hazardous products and know which precautions to take". Even though OSH requirements apply for professional users of cosmetics, they are not referenced in the Cosmetic Products Regulation and one Member State authority believes that this should be clarified. The Cosmetic Products Regulation is also missing any provisions for the protection of the environment, although this has been defended by one stakeholder in that environmental concerns linked to cosmetic products should be controlled under REACH.

When it comes to the protection of workers through the implementation of OSH legislation, the majority of Member State authorities that responded to the consultation believe that the risk management of chemicals and mixtures has improved in terms of reducing worker exposures. This shows progress towards reaching the objective of the EU chemicals legislative framework. Those pieces of legislation that were considered to have had a positive effect were CLP, Chemical Agents Directive, Carcinogens and Mutagens Directive, Pregnant Workers Directive, Young Workers Directive, Plant Protection Products Regulation and the Biocidal Products Regulation. Opinion was split for the Cosmetic Products Regulation, with views covering positive, neutral/no change and negative impacts. It should be noted that one Member State has expressed that there is no quantitative data to prove the reduction in worker exposure, so their answers are theoretical. One Member State praised the Pregnant Workers Directive and says that it is "still adequate" after over 20 years.

Industry stakeholders indicated that "if implemented correctly, the Chemical Agents Directive and Carcinogens and Mutagens Directive will protect workers' health". More generally, they believe that substances covered by the Carcinogens and Mutagens Directive should be assessed on a case-by-case basis, giving formaldehyde as an example of where the current legislation is adequate for protecting workers health and at present does not need revising. A second industry stakeholder expressed the opinion that "there was already high awareness when it came to workers safety but the Carcinogens and Mutagens Directive has continued to have a positive impact". Other stakeholders, including a Member State competent authority, have suggested that the Carcinogens and Mutagens Directive is not effective in its current form, as it is resulting in an over-regulation of carcinogens and mutagens in some cases; they suggest that it would be more effective for the Carcinogens and Mutagens Directive and Chemical Agents Directive to be combined and for the combined legislation to be risk-based rather than hazard based (i.e. to be more like the Chemical Agents Directive than the Carcinogens and Mutagens Directive). This type of approach would also be more efficient with respect to the use of resources and, as it would be risk based, should continue to ensure a high level of worker protection.

As carcinogens and mutagens have significant impacts on human health, and these effects may not be evident for many years after the exposure due to their long latency periods, the level of protection would have to be ensured under such an approach, for example, through the introduction of an increased number of binding OELVs and increased enforcement activities. The introduction of binding OELVs for substances in the workplace would be aimed at combatting the concern over the failure of companies to substitute carcinogens and mutagens even though this is the first step in the hierarchy of measures under the Carcinogens and Mutagens Directive.

When asked whether they agree with the view that the current approaches to chemical risk management for the following legislation ensure a high level of protection for human health, Member State authorities had a largely positive view although there are dissenting opinions, as shown in Table 3-3 (overleaf).

One of the Member State authorities who commented that they strongly disagreed with this statement in relation to the Toy Safety Directive has said that, where CMR substances are banned in accessible parts of toys above the concentration limit, in some cases concentrations below the

classification limit can still pose a risk; as a result, this requirement does not go far enough to protect human health.

Table 3-3: Member State responses on whether or not legislation delivers a high level of protection for human health (n= 14 max.)						
Legislation	**Strongly disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**Don't know**
Regulation (EC) No 1223/2009 on cosmetic products	0%	22%	11%	33%	11%	22%
Directive 2009/48/EC on the safety of toys	0%	13%	25%	25%	0%	38%
Directive 2014/40/EU on the manufacture, presentation and sale of tobacco	0%	14%	0%	29%	0%	57%
Regulation (EC) No 66/2010 on the EU Ecolabel	0%	0%	0%	50%	0%	50%
Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	0%	0%	14%	14%	0%	71%
Regulation (EC) No 1107/2009 on plant protection products	0%	0%	0%	66%	0%	33%
Regulation (EU) No 528/2012 on biocidal products	0%	0%	0%	64%	27.2%	9%
Directive 2014/68/EU on pressure equipment	0%	0%	14%	14%	0%	71%

As can be seen from Table 3-4 (next page), citizens and NGOs had a largely neutral view on whether or not the EU chemicals legislative framework has been effective in meeting its objective of providing a high level of protection to human health and the environment. Industry and public authorities appear to hold a more positive view on whether or not the objectives have been effectively met for human health. Public authorities seem to have a slightly more positive view than industry with regard to the effectiveness of meeting objective b (environment).

It should be noted that there are a high number of "don't know" responses from citizens. Those who responded with options 1, 2 or 3 were asked why they had given these answers. In the case of human health, all groups of respondents except for NGOs/others are of the opinion that the legislation is not adapted to the issues at stake (citizens = 56%, industry = 70%, public authority = 65%). Group 4 (NGOs/others = 50%) believe that the issue lies in the legislation not being effectively implemented. It is not clear what justification would be given for these opinions, especially as the legislation within the framework is sector specific and should be addressing the issues that are relevant. There may be underlying problems, such as the consideration of combination effects, vulnerable populations etc., which are being evaluated later in this report. In contrast to the mainly neutral to positive views with respect to human health, the scope of environmental protection is considered by many to be lacking, due to inadequate consideration in CLP. For example, one Member State authority put forward the opinion that (see also Task 2):

- "*the above mentioned environmental hazards (POPs, PBT, vPvB, biodegradation) are inherent compound properties that generally apply across all chemical legislation. Hence, the central inclusion of these hazards into CLP would allow for more consistency. A common harmonised classification (CLH) would significantly reduce burdens for Member State authorities and would induce legal certainty for manufacturers.*"

Table 3-4: Number and percentage of respondents identifying effectiveness of chemical legislation in achieving objectives (n=344 to 352)					
Group	Effectiveness score	Objective a: protecting human health (n=352)		Objective b: protecting the environment (n=344)	
		No.	%	No.	%
1 (citizens) (n=52 to 58)	1	7	12%	7	13%
	2	6	10%	8	15%
	3	21	36%	17	33%
	4	7	12%	3	6%
	5	4	7%	4	8%
	Don't know	13	22%	13	25%
2 (industry) (n=198)	1	5	3%	6	3%
	2	10	5%	14	7%
	3	62	31%	58	29%
	4	63	32%	65	33%
	5	51	26%	47	24%
	Don't know	7	4%	8	4%
3 (public authority) (n=43 to 44)	1	1	2%	1	2%
	2	4	9%	3	7%
	3	12	27%	12	28%
	4	16	36%	12	28%
	5	8	18%	9	21%
	Don't know	3	7%	6	14%
4 (NGO/others) (n=51 to 52)	1	2	4%	3	6%
	2	3	6%	2	4%
	3	31	60%	32	63%
	4	7	13%	7	14%
	5	7	13%	5	10%
	Don't know	2	4%	2	4%

With respect to PBT and vPvB substances, market restrictions/bans effectively restrict exposure across all routes from those products within which PBT/vPvB use is restricted/banned, the Biocidal Products Regulation and the Plant Protection Products Regulation. According to feedback from NGOs and authorities, marketing bans, which are the predominant risk management measures for PBTs/vPvBs are effective in reducing emissions and are regarded as appropriate in most cases. However, due to the persistence of such substances, the effectiveness of such risk management measures can be observed in the environment only after longer time periods. For some PBTs/vPvBs, which are regulated under the POPs Convention, a downward trend of environmental concentrations is reported by the EEA[16] in marine organisms. Industry stakeholders commented, however, that bans might be overprotective and the use of risk management measures for emission control should be considered as an option and be weighed against the benefits of being able to use a PBT/vPvB, e.g. for pest control and to avoid the risks of increased pest resistance.

EurEau have indicated that they consider micro pollutants an area of concern, in particular for the aquatic environment. These pollutants can originate from industrial processes, from

[16] Downward trends are observed for lindane, PCB, DDT and BAP; http://www.eea.europa.eu/data-and-maps/indicators/hazardous-substances-in-marine-organisms/hazardous-substances-in-marine-organisms-1

pharmaceuticals for human and animal use, personal hygiene products, industrial and household chemicals, detergents, cosmetics, textiles, pesticides, or from micro-substances in coatings and paints. EurEau believe that current technologies used in wastewater treatment plants are not entirely capable of removing micro pollutants. Although new technologies are being created, the advanced treatment processes that exist are expensive, energy intensive and often substance-specific, meaning they rarely emerge well from cost effectiveness and environmental performance analysis. They also have suggested that action is needed in specific areas, including a strategy on pharmaceutical emissions in the environment, micro plastics, pesticides, the need for specific regulation on chemicals in textiles, the phasing out of mercury in dental amalgam in the EU and better use of REACH in or to efficiently and effectively identify and combat SVHC.

ANEC (2014a) also comments on the comitology procedure within the Toy Safety Directive, which allows changes to be made to the limits for allergenic fragrances and elements (points 11 and 13 of Part III of Annex II of the Toy Safety Directive), and to "adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth" according to Article 46 of the Directive (ANEC, 2014a). ANEC argues that the scope of the comitology procedures should be expanded to allow the adoption or modification of limits for chemicals in all kinds of toys for all kinds of substances, including generic limits for groups of substances in a fast and flexible way (without having to change the whole piece of legislation in the European Parliament and the Council). Although mouthing behaviour may be more common in children under 36 months, it can be observed in children above this age threshold[17] and this could be reflected in the comitology. There is a priority which is rightly placed on toys which are intended to be placed in the mouth, but there is nothing stopping children placing other toys in their mouth and this should also be given consideration.

In response to the open public consultation, FoodDrinkEurope highlighted examples of where relevant considerations were not taken into account in the regulatory decision making on risk management. They highlight how Regulation (EC) No 396/2005 has set out the maximum residue levels (MRLs) of pesticides[18] in or on food and feed of plant and animal origin; however, problems have arisen with substances which may have more than one source. In particular, FoodDrinkEurope highlight the following sources and examples:

- Substances which are currently used or were formerly used in plant protection products but can also be found as contaminants and/or are naturally occurring (e.g. mercury, nicotine, copper and bromide);
- Substances which are used in plant protection products and in veterinary medicines (e.g. cypermethrin), including those not listed in Regulation (EU) No 37/2010;
- Substances which are used in plant protection products and/or as biocides and are found in food and feed (e.g. sanitisers/disinfectants used responsibly by the food industry under good manufacturing practices to clean food contact surfaces and equipment; DEET as a repellent);
- Substances intentionally used in, or otherwise migrating from, for example, food contact materials (e.g. biphenyl, ortho-phenylphenole and diphenylamine), including substances listed in Regulation (EU) No 10/2011; and

[17] Department of Trade and Industry (2002): Research into the mouthing behaviour of children uip to 5 years old. Available at: http://webarchive.nationalarchives.gov.uk/+/http:/www.berr.gov.uk/files/file21800.pdf

[18] MRLs are, essentially, based on a risk assessment process taking account of the likely use, exposure and toxicity of the pesticide in question http://ec.europa.eu/food/plant/pesticides/max_residue_levels/application/index_en.htm

- Substances to which the default value of 0.01 mg/kg applies but which are used as ingredients including additives according to Regulation (EC) No 1333/2008 and flavourings according to Regulation (EC) No 1334/2008 (e.g. olive oil, sodium chloride, lecithin and eugenol).

FoodDrinkEurope noted a specific example of low levels of chlorate in the water supply. Chlorate is a by-product of chlorine building agents used by the municipal water supply and industry to disinfect potable water and used by industry under good manufacturing practices to clean food contact surfaces and equipment (e.g. sodium hypochlorite), and it is also used in drinking water as an ingredient (some Member States will chlorinate drinking water to ensure it is safe), etc. These low levels of chlorate will trigger regulatory actions as it currently stands under Regulation 396/2005. In 2013, samples of vegetables and fruits placed on the German market were found to have detectable chlorate levels. Follow up by the food industry indicates that the most common source of occurrence of chlorate in foods was through the use of chlorinated water, and not through the illegal application of chlorate as a herbicide. FoodDrinkEurope suggested that this questions the validity of a default level of 0.01 mg/kg, which does not consider the "multiple use" of substances.

3.2.2 Combination effects and multiple routes of exposure

The testing of combination effects is not a requirement for any of the pieces of legislation considered in this task. This could be due to the lack of technical capacity to conduct these forms of testing. In addition, multiple routes of exposure may or may not be taken into account. At a sector specific level, multiple routes of exposure are considered within risk assessments, but these assessments may not consider exposure from other types of sources. This may be because downstream legislation is written with particular uses in mind and as such does not consider where the same chemical may be used in other products or sectors (although some of the risk assessments prepared in relation to Restrictions under REACH have considered other contributing sources of exposure, e.g. food and drinking water). This lack of assessment for combination effects and multiple routes of exposure is considered by stakeholders from all sectors (industry, NGOs, Member States, academia) to be a gap in ensuring a high level of protection to human health and the environment; for example, it is very rare that a person will only be exposed to a substance through one use, it is likely that the substance will be found in other products and this could increase their exposure.

All of the NGO respondents to a question regarding whether risk management measures in chemicals legislation adequately address all relevant risks to consumers indicated no, they do not believe that they do. One of the respondents specifically highlighted the cocktail effect and diffuse exposure as needing to be accounted for to a higher degree. Another respondent raised concerns over the absence of testing of cumulative exposures. This respondent indicated that animals and humans are now exposed to many different substances from a wide range of sources, including consumer and professional products. As a result, they are exposed to, amongst others, industrial chemicals, pesticides and biocides which may present endocrine disrupting properties. Many of these substances will have an additive action at specific endpoints, and single substance risk assessments are not adequately protective as they do not account for possible combination effects.

A workers organisation representative indicated concern over the lack of assessment of combination effects in the workplace, as cocktail effects is an area of risk to workers which is not adequately addressed. This respondent commented that in the context of the Chemical Agents Directive (where employers are required to consider any chemical agent when carrying out a workplace assessment, irrespective of whether that substance falls under the scope of CLP), toxicological data, associated testing information and exposure data based on information specific to a workplace are considered

in workplace assessments but that the hazards arising from combination effects are never considered ; this is therefore a clear gap in the protection of workers.

Two Member States also highlighted issues with regards to the assessment of combination effects. One suggested that there are only a few examples of where there is sound knowledge about combination effects; in general a precautionary approach is applied by adding the effects of substances (no synergism or antagonism is supposed). The other Member State has indicated that, in general, because chemical legislation does not take into account exposure to multiple substances, the setting of quality standards and thresholds for individual chemicals is insufficient for ensuring a non-toxic environment and the protection of human health. Hence, the chemicals legislation needs to be further developed to consider cocktail effects.

ANEC and BEUC (who have prepared a combined response to the open public consultation) indicated that there may be a link between the constant exposure from multiple sources of harmful chemicals to increasing levels of chronic and very severe diseases such as cancer, cardiovascular diseases, fertility problems, obesity and allergies. They have suggested that environmental background pollution has reached high levels and this is leading to chronic consumer exposure with unknown effects. They also indicate that biomonitoring studies show that consumers have measureable levels of chemicals in their blood and tissue, suggesting that existing measures targeting harmful chemicals are ineffective and insufficient. Multiple routes of exposure are not the only concern of ANEC and BEUC; they also raise concerns over the combination effects of chemicals.

Combination effects and multiple routes of exposure are examined further in Section 4.2.1.

3.2.3 Reduction in the incidence of chemicals-related accidents and disease through the reduction of exposures

Overall, it is difficult to determine the effectiveness of the legal framework with regard to decreases in risks for humans and the environment, in part due to the extended timeframes required for the impacts of the reduction of exposure to become evident and the short timeframe in which this current legislative framework has been in action. Furthermore, due to the existence of global emission sources and the mobility of many substances, particularly PBTs/vPvBs, it is not always possible to determine the reason for a decrease in exposures.

As noted under Task 1, the incidence of chemical-related health risks to consumers and professionals are difficult to ascertain as it is unlikely that a health impact can be attributed solely to exposure to a single chemical; the combination effect of chemicals we are exposed to on a daily basis may be a more likely cause of health related impacts, together with other factors. In some instances, where a substance is known to have an adverse effect on human health and produce a specific set of symptoms, one can assess the number of cases reported, but it should be noted that this is the exception rather than the rule and is mainly relevant to professional users (except in the case of asbestos). Carcinogens are particularly problematic as the latency period between exposure and effect can be many years. The analysis provided in Task 1 provides a high level attempt to quantify the potential benefits of CLP making available classification information, which can then act as the basis for risk management under other downstream legislation. The Task 1 analysis will not capture all of the benefits but provides a partial picture. It does not, however, enable any linkages to be made between specific downstream legislation and the manner in which it draws on CLP. Further information on the impacts of the downstream legislation considered here is given in Section 7.

The primary risk management measure for PBTs/vPvBs and CMRs are bans (Biocidal Products Regulation, Plant Protection Products Regulation etc.) and use restrictions (REACH). These

effectively reduce use and emissions and may be considered as contributing to innovation and competitiveness by triggering research and use of less hazardous alternatives as well as promoting the use of and access to safer alternatives. However, this view is not shared by industry as the loss of substances/products is regarded as lowering competitiveness. In the area of medicinal products, risk management was considered ineffective by NGOs and Member State authority stakeholders.

The general consensus from Member States is that the chemicals legislative framework has improved the protection of workers from exposure to hazardous chemicals. Table 3-5 shows that for the OSH legislation considered in this task, there has, in general, considered to have been a positive impact. Other pieces of legislation which cover professional workers but are not exclusively designed to protect them are also considered to have had a positive impact. One Member State has commented that "*there are no data to prove this but theoretically the answer is yes. It is a question of compliance rather than the fitness of legislation, so if the legislation is fulfilled then the impact would be "large positive""*.

Table 3-5: Authority views on the extent to which the risk management of chemicals and mixtures has reduced worker exposures (n=14max)

Legislation	Large positive impact	Low positive impact	Neutral/ no change	Low negative impact	Large negative impact	Don't know
CLP Regulation	40%	40%	10%	0%	0%	10%
Chemical Agents Directive	71%	29%	0%	0%	0%	0%
Carcinogens and Mutagens Directive	57%	43%	0%	0%	0%	0%
Pregnant Workers Directive	43%	57%	0%	0%	0%	0%
Young Workers Directive	50%	33%	0%	0%	0%	17%
Plant Protection products Regulation	43%	14%	0%	0%	0%	43%
Biocidal products Regulation	50%	25%	0%	0%	0%	25%

3.3 Ensuring the functioning of the single market

Key Findings:

- A lack of consistency in implementation and enforcement of the risk management measures has been identified as having the biggest negative impact on the functioning of the single market. This can only be resolved through EU-wide initiatives and clear guidance.
- Consumer and professional products legislation has a harmonised approach to the risk management of CMRs through the use of risk management based on generic risk considerations. This may have a positive impact by reducing regulatory uncertainty as to the approach to substances having these hazard classifications, but where derogations do not take into account feasibility and socio-economic considerations there may be negative impacts on EU markets, together with unintended consequences for consumers and society.
- Two further themes have emerged from the open public consultation findings that are considered to contribute to the reduction in the effectiveness of meeting the objectives of the EU chemicals legislative framework; legislation not being adapted to the issues at stake; and/or a lack of effective implementation.

It would appear that there is one factor that is having the greatest negative impact on the functioning of the chemicals legislative framework: implementation and enforcement of risk management measures (discussed further in Section 8 of this report). Differences in the enforcement of risk management measures across Member States result in barriers to trade and confusion for manufacturers and distributors. This lack of consistency may also result in product safety being compromised, allowing for substances of concern to make their way into professional and consumer products. These differences are due to the varying enforcement regimes and sanctions used by Member States, as well as the availability of resources. The efficiency of the chemicals legislative framework will also be compromised if authorities are not implementing and enforcing the legislation in a consistent manner. This is a difficult issue to combat and, as concluded in Section 8, can only be addressed by EU-wide initiatives and clear guidance. Enforcement needs to be a routine practice in order to effectively implement the framework and to identify risks or non-compliance early.

Risk management measures being set at the EU level ensures the functioning of the single market to a greater extent than would be the case if each Member State had its own national legislation. Varying rules and requirements across Member States would increase the costs to economic operators of complying with requirements, as they would need to invest greater resources into understanding national differences. This would lead to greater confusion and risk companies bringing products to the market in individual Member States that do not meet their legislative requirements. It would also advantage larger operators with greater resources and would be likely to impact on cross border trade. Cefic made the point that "*removing both trade and non-trade barriers inside the European Union helped boost growth and competitiveness in the EU chemical industry between 2003 and 2013*"[19].

[19] CEFIC (2014): The European chemical industry facts and figures 2014. Available at; http://www.cefic.org/Documents/FactsAndFigures/2014/Facts%20and%20Figures%202014%20-%20The%20Brochure.pdf

Where there is a defined approach to a certain hazard classification (be that based on generic risk considerations or specific risk assessments), theoretically there should be a contribution to the better functioning of the single market. If all CMR substances are automatically banned in consumer products (unless derogations are applied for), as occurs under the generic risk considerations approach, then manufacturers of such products should be clear that any substance with that harmonised classification should not be used in any such product across the single market. In practice, however, the approaches vary across EU legislation, in response to sector and population specific considerations. This can make it more difficult for actors to determine what requirements they must comply with, especially if they deal with a number of substances or substances that are used in a number of different processes or products, e.g. ethanol and formaldehyde (see Case Study 11).

However, the generic risk approach may also have significant impacts for the functioning of the single market, where substances are automatically banned that are critical for particular industry sectors or their continued use is in society's interest more generally. Risk management based on specific risk assessment does not provide industry with the same level of legal certainty due the outcomes being based on Committee opinions following risk assessment, however, it is preferred by industry due to the fact that it can enable the availability of alternatives and socio-economic factors to be taken into account (and a sub-set of Member State and citizen stakeholders also believe this approach is preferable – see the Task 4 report). Examples are given in Case Studies 10 and 11 of the benefits of a specific risk assessment approach, with Case Study 3 also highlighting the potential implications for the single market of bans on the use of substances due to the automatic triggers in downstream legislation. This is not to say that all industry sectors (thus markets) would appear to prefer a specific risk assessment approach. The toys sector, for example, has indicated that they are happy with the current generic risk considerations approach, given that there is the potential for derogations. From their perspective, the system is ensuring a level playing field for EU manufacturers, and also ensures that EU consumers have confidence in EU manufactured products. It is important to note though, that they also view the potential for derogations or exemptions as critical. Other sectors, such as cosmetics, would argue that the use is known and a safety assessment can be carried out such that there is no need to automatically ban a CMR.

The functioning of the single market is also considered to be disrupted by the differences between regulations and directives. It is believed that regulations are more likely than directives to enhance the functioning of the single market, as they set out the exact rules which must be enforced by a Member State, while a directive allows more flexibility in national legislation. The differences in the way a directive has been transposed can contribute to barriers to trade, as Member States may be implementing objectives in different ways. Furthermore, industry stakeholders note that it can lead to an uneven playing field, as actors in one Member State may face greater compliance requirements than the equivalent actors in another Member State. Although this difference between regulations and directives has been highlighted as a possible barrier to the functioning of the single market, stakeholders are not in agreement as to whether legislation should be regulations or directives. Some believe that regulations are best for the single market, yet others believe that in some cases, such as PPPs, they can be over-regulatory.

More generally, stakeholders are of the opinion that if the chemicals legislative framework is to improve the functioning of the single market, then appropriate and detailed guidance must be provided so as to help market actors in meeting the requirements and to ensure consistency in interpretation and implementation across Member States.

Table 3-6: Number and percentage of respondents identifying effectiveness of chemical legislation in achieving objectives (n=344 to 352) – open public consultation results					
Group	Effectiveness score	Objective c: ensuring a well-functioning internal market (n=345)		Objective d: stimulating competitiveness and innovation (n=346)	
1 (citizens) (n=52 to 58)	1	5	9%	10	19%
	2	7	13%	8	15%
	3	12	23%	10	19%
	4	8	15%	5	9%
	5	5	9%	4	8%
	Don't know	16	30%	16	30%
2 (industry) (n=198)	1	12	6%	70	35%
	2	60	30%	49	25%
	3	82	41%	52	26%
	4	14	7%	6	3%
	5	13	7%	6	3%
	Don't know	17	9%	15	8%
3 (public authority) (n=43 to 44)	1	2	5%	2	5%
	2	1	2%	8	19%
	3	10	23%	8	19%
	4	12	28%	8	19%
	5	6	14%	3	7%
	Don't know	12	28%	14	33%
4 (NGO/ others) (n=51 to 52)	1	2	4%	3	6%
	2	5	10%	5	10%
	3	13	25%	26	50%
	4	12	24%	8	15%
	5	12	24%	1	2%
	Don't know	7	14%	9	17%

As can be observed from Table 3-6, there is no general agreement amongst citizens, although the highest percentage fall into the category of "don't know". This is not surprising as both of these objectives are complex. Industry opinion appears to lie in the neutral to less effective category ranges, whilst public authorities and NGOs are between the neutral and effective category ranges.

When asked to indicate why they thought the EU chemicals legislative framework was not effective at meeting its objective of ensuring a well-functioning internal market, the majority opinion from citizens was that the legislation was "not adapted to the issues at stake" (50%); the majority opinion from industry was that the legislation was "not effectively implemented" (46%, although responses were reasonably balanced across the four response options); the majority opinion for public authorities was that "the legislation is unclear" (46%, although responses were fairly balanced across the four response options); the majority opinion from NGOs was that the legislation is "not adapted to the issues at stake" (37%, although responses were fairly balanced across the four response options). When asked to indicate why they thought the EU chemicals legislative framework was not effective at meeting its objective of stimulating competitiveness and innovation, the majority opinion for citizens was that the legislation is "not adapted to the issues at stake" (52%); the majority opinion of industry was that the legislation is "not adapted to the issues at stake" (70%); the majority opinion of public authorities is also that the legislation is "not adapted to the issues at stake" (61%); the majority opinions of NGOs is that the legislation is not effectively implemented (41%, although there were 32% of responses for "no opinion".

3.4 Enhancing competitiveness and innovation

Key findings:

- Differences in approaches to risk management on a global scale could make the EU export market less competitive as costs are transferred to the consumer.
- There is a lack of coherence in the rules applied for biocidal products in the EU and internationally, as some preservatives can be used in imported biocidal products that would not be allowed in EU manufactured biocidal products.
- An increase in substitution requirements in the chemicals legislative framework is considered to be a leading factor in encouraging innovation.
- Incentives include Ecolabel and product standards, whilst the possibility of fines for non-compliance can act as a deterrent.
- Eight out of 14 of the Member States who responded to the targeted consultation carried out for this study believe that the chemicals legislative framework has had a positive impact on the promotion of access to and use of substances/ products with a more favourable hazard or risk profile.

Enhancing competitiveness and innovation is one of the objectives of the EU chemicals legislative framework. A report by Cefic (2015) states that the chemicals industry follows the more general growth in GDP, which globally is expected to triple over the next decades from $49tn in 2010 to an estimated $140tn in 2050[20]. Although this growth is considered to be positive, the European share of global sales decreased significantly between 1993 (32%) and 2013 (17%) due to relative growth in other parts of the world, such as China and India.

Approximately one quarter of EU chemical production is exported outside of the EU, and an analysis by Oxford Economics[21] for Cefic found that the decrease in the export market share over the last 20 years has been due to declining competitiveness as opposed to slow-growing destination markets. The potential reasons given for this are: high energy prices; lagging innovation; currency appreciation; high labour costs; regulatory and tax burdens (see also Section 7, which presents the results of the Cumulative Cost Assessment for the EU chemicals industry).

Cefic believe that "highly ambitious environmental, health and climate regulation are accelerating the deterioration of European industrial competitiveness" (although the evidence for this has not been revealed in their report)[22]. Cefic believe that the high cost of regulatory compliance is a burden to industrial competitiveness and this cost is made worse by frequent changes to the regulatory framework. They comment that this increases costs, and introduces uncertainties that lead to

[20] Cefic (2015): Competitiveness of the European Chemicals Industry: How to regain ground in the global market. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Competitiveness-of-the-European-chemical-industry-2014.pdf

[21] Oxford Economics (2014) Evolution of competitiveness in the European chemical industry: historical trends and future prospects. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Oxford-Study-2014.pdf

[22] Cefic (2015): Competitiveness of the European Chemicals Industry: How to regain ground in the global market. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Competitiveness-of-the-European-chemical-industry-2014.pdf

"investor risk"[23]. In particular, the research suggests that there has been a decline in the EU market share of consumer chemicals, due to worsening competitiveness[24] (see also Case Study 1, and the Task 1 report.)

The EU prohibits the use of CMRs in consumer products such as toys, biocides and cosmetics. This is not a provision that is applied globally, with different countries having different requirements. It appears that America and Canada use a specific risk assessment approach to hazardous substances in cosmetics and toys, creating a prohibited list of substances as opposed to restricting the use of a classification. This difference could have a negative impact on competitiveness for the EU. Where a substance is classified as a CMR and subsequently banned, manufacturers will incur reformulation and substitution costs, which may be transferred to consumers, thus reducing the competitiveness of the pricing of their products on the export market. There should be no competitive disadvantage in the import market as those countries that wish to sell their products on the EU market will need to abide by the same rules as EU manufacturers.

It has been brought to our attention, however, that this is not always the case for biocidal products. Substances that are listed in category 1 of Annex I of the Biocidal Products Regulation which are authorised as food additives can be used as active substances in biocidal products, where there concentration does not exceed the generic concentration limit for mixtures under CLP. If they are above this, then they do not qualify for the simplified procedure. In contrast, articles that were treated/preserved with such active substances can be imported onto the EU market without authorisation or restriction[25].

The requirement to replace hazardous substances in processes and products is a leading factor in the need for innovation. As discussed below in Section 6.2.1, substitution is considered to be key to the protection of human health. It prevents manufacturers from having to entirely remove a product from the market if reformulation with a suitable and less harmful alternative is achievable, whilst preventing exposure to harmful substances. Nine out of the 20 pieces of legislation considered in Task 3 have requirements which drive the substitution of substances which have certain harmonised classifications, most notably: carcinogenic; mutagenic; reprotoxic; persistence, bioaccumulation and toxicity; and acute toxicity.

Such triggers force or incentivise industry to establish alternatives. In some cases, alternatives will already exist and grouping approaches can be used to establish which substance is the most feasible alternative; although it must be noted that this does not always lead to a substitution that leads to an overall reduction in risks. In cases where a grouping approach cannot be employed, and alternatives are not as readily found, industry may be forced to either innovate their working practices in order to remove the hazardous substance, increase research and development operations in order to find a suitable alternative or withdraw from the market. As such, the substitution requirements of many of the pieces of legislation under the chemicals legislative

[23] Cefic (2015): Competitiveness of the European Chemicals Industry: How to regain ground in the global market. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Competitiveness-of-the-European-chemical-industry-2014.pdf

[24] Oxford Economics (2014): Evolution of competitiveness in the European chemical industry: historical trends and future prospects. Available at: http://www.cefic.org/Documents/RESOURCES/Reports-and-Brochure/Oxford-Study-2014.pdf

[25] VCI (2016): Study on the regulatory fitness of the ;legislative framework governing the risk management of chemicals (excluding REACH), in particular CLP and related legislation: Issues and examples from the viewpoint of Verbund der Chemischen Industrie (VCI, the association of the German chemical industry)

framework can be a trigger for innovation. Although not considered in the scope of this study, REACH has been found to be a catalyst for R&D, with Registration being highlighted in particular[26]. It should be noted though that substitution does not always have a positive impact on innovation. In some cases, resources are diverted from R&D in order to meet the substitution requirement, possibly stifling innovation for several years[27].

It is not only the legislative requirements for substitution that may trigger innovation. As consumers become more aware of the health risks associated with certain hazard classifications (most notably carcinogens) or substances, industry is having to reformulate their products in order to meet expectations of consumer safety. Member States have also suggested that awards of ecolabels and product standards are incentives for industry to meet the legislative requirements and to innovate within their processes. Fines are also considered to be an incentive to replace hazardous chemicals.

Eight out of 14 of the Member States who responded to the targeted consultation carried out for this study believe that the chemicals legislative framework has had a positive impact on the promotion of access to and use of substances/products with a more favourable hazard or risk profile. Although there is the belief that the legislative framework has had a positive impact, it has also been suggested that the legislative framework is more geared towards providing information than promoting alternatives with a more favourable hazard or risk profile. This opinion is not shared by all authorities, as most view the ban on the use of certain hazard classes and the requirement for substitution as promoting the use of alternatives which have a more favourable hazard or risk profile.

One example of a process that is considered to promote the use of less hazardous substances is simplified authorisation under the Biocidal Products Regulation. Article 25 of the Biocidal Products Regulation sets out the eligibility criteria for the simplified authorisation procedure. In order to do obtain this simplified authorisation, the biocidal product must meet all of the following conditions:

a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;
b) the biocidal product does not contain any substances of concern;
c) the biocidal product does not contain any nanomaterials;
d) the handling of the biocidal product and its intended use do not require personal protective equipment.

The definition of "substance of concern" is "any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect"[28]. This simplified authorisation is not available for plant protection products, which has been criticised by stakeholders as they believe that this alternative for less hazardous substances would promote and encourage the use of substances with a less hazardous profile.

[26] CSES consortium (2015) Monitoring the impacts of REACH on innovation, competitiveness and SMEs. Available at: http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations

[27] CSES consortium (2015) Monitoring the impacts of REACH on innovation, competitiveness and SMEs. Available at: http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations

[28] Article 3(1)(f) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

In addition, in order to promote less hazardous substances, it has been suggested that more information and guidance is required for industry and more money needs to be available for research and development. As commented by industry, "it is very difficult to replace hazardous substances if the capital is not there to perform the needed research and development".

3.5 Obsolete measures and gaps in meeting the objectives of the EU chemicals legislative framework

Key findings:

- No obsolete measures were identified within the chemicals legislative framework.
- The lack of information provided for cosmetic products is considered to be inappropriate and it should be brought in line with CLP, as professional users are not be adequately protected.
- A key gap exists in relation to consumer products that are not covered by the sector specific legislation reviewed under this task. The General Product Safety Directive is not considered to be adequate for addressing all issues relating to consumer product safety.
- Neurotoxicity, immunotoxicity and endocrine disruption have all been suggested by stakeholders as endpoints of concern that should be given consideration for classification under CLP in order to further meet the objective of a high level of protection to human health.

3.5.1 Overview

It would appear that there are no obsolete measures contained within the legislative framework as the objectives remain relevant.

As the legislative framework covers so many sectors and uses of chemical products, it is unlikely that a stage will be reached at which risk management is not required. The use of hazardous chemicals may reduce over time as a result of risk management measures and the move towards a non-toxic environment, but there will always be the need for certain hazardous chemicals, whether that be as part of processing activities or to deliver particular functions in products. The need for pesticides in order to maintain crop yields and ensure food security for the European population is discussed in further sections and is a good example of where certain hazardous chemicals will continue to be required into the future.

3.5.2 Gaps in legislation that affect risk management

Member States have identified gaps in the legislative framework between CLP and other chemicals legislation. Of relevance to the downstream legislation, a gap related to the Cosmetic Products Regulation has been identified (see also Task 2), which impacts on the ability of operators to fulfil their risk management obligations.

Labelling of cosmetics is based on the listing of ingredients and there is no requirement to provide hazard statements, precautionary statements or hazard pictograms in accordance with CLP, or a SDS. The lack of classification information and a SDS provided is considered to be of great concern for professional users of cosmetics, particularly hairdressers and nail technicians. Hairdressers are exposed to a number of harmful chemicals, such as sodium hydroxide (Skin Corr. 1A),

phenylenediamine (Acute Tox. 3(H301, H311, H331), Skin Sens. 1, Eye Irrit. 2, Aquatic Acute 1, Aquatic Chronic 1), ammonia (Flam. Gas 2, Skin Corr. 1B, Acute Tox. 3, Aquatic Acute 1), yet only some come with precautionary warnings on their labelling. An example of which would be phenylenediamine which advises professional users to wear gloves. There is little to no guidance given on what chemicals should not be used together or warnings as to the consequence of accidental mixing or contamination. Although hairdressers and nail technicians may be taught the basic understanding of interactions of certain substances, they are not chemists and cannot be expected to understand the interactions of all the chemicals in their workplace and their associated hazards.

Under the OSH Framework Directive 89/391/EEC, Article 6(3)(a) states that: "*Without prejudice to the other provisions of this Directive, the employer shall, taking into account the nature of the activities of the enterprise and/or establishment:*

(a) Evaluate the risks to safety and health of workers, inter alia in the choice of work equipment, the chemical substances or preparations used, and the fitting-out of work places."

This requirement would be very difficult to fulfil if employers are not provided with information on the chemicals that they are using in the workplace. If a SDS was required for chemical products under the Cosmetic Products Regulation, then employers would be provided with greater information on which to base their risk assessment and there should be a greater level of protection of the workers. This gap could also be bridged by bringing the Cosmetic Products Regulation under the labelling and packing requirements of the CLP Regulation. It is acknowledged that this is not an option that is favoured by the cosmetic industry as they believe that the use of a cosmetic product safety assessment means that cosmetic products are safe enough not to require hazard communication on the labelling.

Gaps in worker protection have been identified by workers organisation stakeholders and Member State authorities. As noted above, authorities believe that the Cosmetic Products Regulation should better take into account the health of workers exposed to cosmetic products, particularly as their level of exposure can be greater than that of consumers, with an example being hairdressers who work with hair care products and dyes on a daily basis. Over one million people work in the hairdressing industry and a report published by the European Agency for Health and Safety at Work summarises national statistics which highlight a number of issues[29]. For example, a UK study reported that 70% of hairdressers have suffered from work-related skin disorders at some point during their careers, while a French study has found that while hairdressers represent about 1% of the entire workforce, 20% of women that are affected by work-related asthma are hairdressers. Although professional users are supposed to be considered in the cosmetic product safety assessment, in practice the focus is on consumers, with Member State authorities left to ensure that professional users are protected under OSH legislation.

3.5.3 Gaps in regulation concerning different routes of exposure

3.5.3.1 Gaps related to human health

As indicated in Section 2, many of the pieces of downstream legislation contain derogations or exemptions, which allow substances subject to automatic hazard-based triggers to be placed on the market. One NGO stakeholder has expressed the very strong opinion that: "derogations undermine

[29] EU-OSHA (2014): Occupational health and safety in the hairdressing sector

the high level of protection objective. There are no good arguments for derogations and all should be removed as they violate the rules of the precautionary principle."

Other stakeholders (NGOs and Commission Services) have raised concerns regarding a gap in the protection of consumers in the current legislative framework. They believe that at present there is no comprehensive approach to hazardous substances in consumer products. Certain consumer products are covered by sector specific legislation, such as cosmetics, toys, or medical devices. Those that are not covered by sector specific legislation are regulated under the General Product Safety Directive [30]. Although the General Product Safety Directive places obligations on manufacturers and suppliers to ensure that consumer products are safe, these are not considered to be clear enough to be effective. In this respect, there appears to be a significant gap in the legislative framework with regard to consumer protection.

One example that has been given with regards to hazardous substances in consumer products is that of tattoo inks. These products are neither covered by the Cosmetic Products Regulation or REACH and so fall under the scope of the General Product Safety Directive. Stakeholders are unclear as to why certain substances which may appear in tattoo inks (POAs, aromatic amines, etc.) would be banned under the Cosmetic Products Regulation but are not banned under the General Product Safety Directive. This is considered to be a gap in the protection of human health. One question which has been asked is that if there are approximately 2000 substances banned for use in cosmetics, would it not be reasonable to ban such substances in tattoo inks as well? This is considered especially relevant, as the substances are contained in the dermis (making it permanent), rather than simply applied to the epidermis.

Of course, there are counter examples where restrictions are placed on the presence of hazardous substances in consumer products (such as nickel in jewellery) under REACH Annex XVII[31].

Member State authorities have also noted that appropriate chemical provisions are (almost) non-existent for many products consumers come into contact with, such as materials in contact with drinking water, products releasing emissions to indoor air, clothing and consumer textiles, child use and care articles, other articles for children (excluding toys), tattoo inks, personal protective equipment, furniture, sports and playground surfaces and equipment, car interiors etc. Some of these products will be covered by the General Product Safety Directive but this is still not considered to be adequate to ensure a high level of protection to consumers. Note that ANEC and BEUC identify these gaps as an issue and set out proposals for these products in their position paper[32].

This absence of legislation in several areas has been the subject of strong critique by interested parties, including industry (e.g. in areas of food contact materials, materials in contact with drinking water). This has led to suggestions that a horizontal approach to address chemicals in products should be developed. This would require close consideration of potential overlaps with REACH, however. In contributing to the targeted consultation carried out for this study, ANEC and BEUC jointly identified other areas where, in their view, the protection of consumers is considered to be inadequate:

[30] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

[31] ECHA (2016): Substances restricted under REACH. Available at: https://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach

[32] ANEC (2014): Position paper – Hazardous chemicals in products: the need for enhanced EU Regulations. Available at: http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

- the Medical Devices Directive does not stipulate a single threshold for any chemical substance;
- the Packaging Directive only contains limits for some metals and ignores other substances;
- the RoHS Directive does not include limits for many substances identified in various studies[33]; concerns with regard to the management of nanomaterials and of hormone-disrupting chemicals, as well as sensitisers and other chemicals of similar concern.

The lack of opportunities to regulate medicinal products for human use that are identified as PBT/vPvB is considered a gap which decreases the level of protection and potentially prevents achieving the goals of the Water Framework Directive by NGOs and authorities. NGO and authority representatives also stated that PBTs/vPvBs should be banned from use in veterinary medicinal products (with the option to derogate based on socio-economic considerations).

Case study box 3-1: General Product Safety Directive (2001/95/EC)

The General Product Safety Directive applies in the absence of specific European regulations on the safety of certain product categories and complements the provisions of sector legislation, which do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks[34]. The Directive does not contain any information or criteria with respect to hazard identification, physical and chemical properties, exposure controls, personal protection, toxicological information, ecological information or transport information.

The General Product Safety Directive acknowledges that it is difficult to adopt Community legislation for every product which exists or which may be developed. As such, the General Product Safety Directive establishes general safety requirements for any products placed on the market or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions, even if not intended for them. Although not written for professional products, the General Product Safety Directive is applicable to products designed for professional use that have subsequently migrated to the consumer market.

Enforcement is the responsibility of Member States but where a product is restricted, withdrawn or recalled from the market, the Commission should be informed.

In Article 1(2) the definitions are set out, this includes how 'product' shall mean any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned. The product definition does not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

The General Product Safety Directive is an umbrella Directive without any specific details on chemicals; the requirements are that a consumer product must be "safe". The generic definition for this is:

'safe product' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into

[33] The RoHS is constantly updated.

[34] http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/general_product_safety_directive/index_en.htm

Case study box 3-1: General Product Safety Directive (2001/95/EC)

account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.[35]

The Community Rapid Information System (RAPEX) is outlined in the General Product Safety Directive. It is a requirement of the General Product Safety Directive that the Commission is notified when a Member State adopts or decides to adopt, recommends or agrees with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk. For 2015, the Commission found that "chemical" risks accounted for around 25% of all notifications in the system. The types of products notified included textiles, toys, cosmetics, tattoo inks, liquids for e-cigarettes containing nicotine and detergents.

Under Article 13 of the General Product Safety Directive, if the European Commission becomes aware that certain products present a serious risk to the health and safety of consumers, it may, subject to certain conditions, adopt a decision requiring Member States to take measures intended in particular to restrict or make subject to specific conditions the availability on the market of such products. Dimethylfumarate (DMF), a mould preventing biocide, was found to be the cause of damage to the health of consumers in France, Poland, Finland, Sweden and the UK when it was identified in furniture and footwear. This lead to Commission Decision 2009/251/EC, prohibiting products containing DMF being placed or made available on the market, withdrawal of products containing DMF which have already been placed on the market and the recall of products from consumers, making sure consumers have been adequately informed of the risk posed by such products.

Some consumer products which have sector specific legislation have certain aspects controlled but the General Product Safety Directive. An example of which would be toys, where Article 5(1), subparagraphs 3 and 4 of the General Product Safety Directive have a specific provision on identification of the product itself, for example by a product reference. In the Toy Safety Directive Article 8(1)(b) requires a manufacturer to have detailed information available concerning the design, manufacture and conformity of a toy. This does not however specifically require identification of the product. The General Product Safety Directive will also for example require follow up of consumer safety after products are marketed, information from producers to the competent authorities about dangerous products, co-operation with public authorities, distributors' obligations, adopting rules on penalties, attribution of powers to competent authorities, approach to market surveillance and rapid intervention procedures.

3.5.3.2 Gaps related to environmental protection

Exceedance of environmental quality standards under the Water Framework Directive does not automatically trigger a review of approval decisions and/or Industrial Emission Directive permits for

[35] Article 1(2)(b) of Directive 20001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

the respective substances, although Member States may undertake such reviews as part of national measures.

The legal analysis of downstream legislation on installations, mixtures and articles shows that no particular measures restricting the use of PBT/vPvB substances are included. Due to a lack of PBT/vPvB identification in registration dossiers, this gap is currently not likely to be filled under REACH. The provisions of REACH Article 33 only require communication of but no use and emission reduction is triggered.

3.5.4 Gaps in timing of legal obligations

If a PBT/vPvB is identified (under other legislation), or new information becomes available that could prove a substance is a PBT/vPvB, the cut-off criteria in the Biocidal Products Regulation and the Plant Protection Products Regulation will be triggered. It has been claimed that substances fulfilling the PBT/vPvB criteria which have been approved under the older Biocidal Products Directive and the Plant Protection Products Directive are still in use until their approval is reviewed. This is considered a gap in the level of protection by some NGOs and authorities.

3.5.5 Gaps in properties considered

Gaps have also been identified with regard to other toxicity endpoints. Neurotoxicity, immunotoxicity and endocrine disruption have all been suggested by stakeholders as endpoints of concern that should be given consideration for classification under CLP in order to further meet the objective of a high level of protection to human health. These are discussed more fully in the Tasks 1 and 2 reports, and are not repeated here.

The Cosmetic Products Regulation has been identified as having a gap with respect to the lack of consideration of environmental hazards, which is not discussed in Task 1 as it fits better under this discussion on the operation of downstream legislation. When consulted, an industry representative noted that environmental protection was covered by REACH, and there was no need for it to be covered in the Cosmetic Products Regulation as this piece of legislation is concerned with the protection of human health. Other stakeholders are of the opinion that environmental protection should also be covered by the Cosmetic Products Regulation. For example, in recent years, concern for microbeads in cosmetic products has been brought to the foreground. These are not of concern for human health but have been proven to have an impact on aquatic life; they will also not fall under the scope of REACH with respect to their size but only chemical constituents. Some stakeholders believe that if there was comitology for issues which allowed them to be considered under the Cosmetic Products Regulation, then the risk management for cosmetic products would be much more efficient. At present, it is unclear which piece of legislation is to lead the approach for microbeads.

In 2014, ANEC produced a position paper on the application and effectiveness of the Toy Safety Directive (2009/48/EC). ANEC (2014a) suggests that the Directive has significant shortcomings, such as the lack of adequate provisions to exclude exposure to CMR substances generally and particularly in toys intended for use by children under 36 months of in mouth-actuated toys. ANEC argues that these shortcomings can only be solved by a fundamental revision of the chemical requirements of the Directive (ANEC, 2014a). In June 2014, ANEC published the Position paper 'Hazardous chemicals in products - the need for enhanced EU Regulations' (ANEC, 2014b). With regard to toys, ANEC makes a series of suggestions (ANEC, 2012; ANEC, 2014a; ANEC, 2014b) aimed at addressing what it views as the shortcomings with respect to the protection of human health. These include, for example:

- Strengthening concentration limits for CMR substances to protect children's health, with an even stricter approach adopted for toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth;
- Establishing an approval system (positive list system) for materials in toys intended for use by children under 36 months, or in other toys intended to be placed in the mouth based on current legislation in the field of food contact materials;
- Strengthening of requirements for allergenic fragrances, taking into account amongst other things the opinion by the Scientific Committee on Consumer Safety (SCCS) (see also Task 2);
- Sensitisers other than allergenic fragrances should be addressed within the legislation; and
- Chemicals falling in other classes of dangerous substances such as "very toxic", "toxic", "corrosive", "irritant" or non-classified (or not yet classified) substances which pose health risks should be covered by the Toy Safety Directive.

In addition, ANEC puts forward a series of other actions that it believes should be adopted to improve the effectiveness of the legislation in addressing substance specific concerns, e.g.: in relation to lead and other elements, nitrosamines and nitrosatable substances, PAHs, and other substances; the use of nanomaterials in toys; the use of PBT and vPvB chemicals in toys; and the use of endocrine disrupting chemicals in toys.

The 2015 evaluation of the Directive (Technopolis et al., 2015) revealed that some (5) of the consumer associations and Member States expressed a similar view, indicating that several hazards are not properly covered (or not covered at all) by the Directive. In particular, concerns were raised over the current provisions with regard to CMR substances. Under the current Directive, the presence of CMRs in toys is limited to a maximum concentration corresponding to the values established for the classification as CMR in mixtures[36]. Derogation from the limit is accepted only when a CMR substance is present in inaccessible parts of toys[37] or a decision permitting its use has been taken[38]. However, one European consumer association argued that nothing ensures that these substances cannot leak out and that CMRs should be reduced to a minimum in toys, as it is impossible to set a specific safety level[39]. Allergens were also raised as an issue, but are further discussed in Task 2.

[36] According to the CLP Regulation (Annex I), the generic concentration limits of ingredients of a mixture classified as CMRs that trigger classification of the mixture are:

- 0.1% for carcinogens category 1A and 1B, germ cell mutagens category 1A and 1B;
- 1% for carcinogens category 2 and germ cell mutagens category 2;
- 0.3% for reproductive toxicants category 1A and 1B;
- 3% for reproductive toxicants category 2.

These concentrations apply to solids and liquids (w/w units) as well as gases (v/v units). However, generic concentration limits only apply if no specific concentration limits are set in Annex VI to the CLP Regulation. If a specific limit is set therein, then it also applies for the purposes of the Toy Safety Directive.

[37] Directive 2009/48/EC on the safety of toys, Annex II, Part III, point 4(b).

[38] Directive 2009/48/EC on the safety of toys, Annex II, Part III, point 4(c).

[39] ANEC (2014): Position paper – Hazardous chemicals in products: the need for enhanced EU Regulations. Available at: http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

Recommendations on what modifications could be made to the Toy Safety Directive to make it more effective with respect to chemical hazards include the introduction of a positive list[40], as this has been identified in other legislative areas, such as under the Food Contact Regulation, as leading to better control and increasing the clarity of the legislation[41]. However, a UK expert on toy safety argued that such a system would be a very restrictive way of legislating and it will necessarily remain incomplete. The expert underlined the impossibility of listing everything allowed and to update the list frequently enough to take into account all possible scientific developments that would require it to be either enlarged or narrowed (Technopolis et al., 2015).

3.6 Continuing relevance of the EU chemicals legislative framework objectives

Key findings:

- The three objectives of the EU chemicals legislative framework continue to be relevant and will remain so into the future as chemicals will remain important to the EU economy. As such, the original needs of the EU chemicals legislative framework continue to exist.
- Additional needs have been identified. Stakeholders believe that the approaches to the risk management of nanomaterials are not yet sufficient in the chemicals legislative framework. There is no harmonised approach to nanomaterials, which may be due to no single approach being suitable for effectively and efficiently regulating their use.
- Legislation, such as the Biocidal Products Regulation and Plant Protection Products Regulation, employ the precautionary principle and can be considered in line with Article 191 of the Lisbon Treaty; other examples exist.

3.6.1 Relevance of the main objectives

The main objectives of the EU chemicals legislative framework are to ensure a high level of protection of human health and the environment; to ensure the efficient functioning of the internal market; and to enhance competitiveness and innovation. These objectives continue to be relevant and will remain so into the future as chemicals will always be a part of society. It is not possible, at least in the foreseeable future, to eliminate the production and use of all hazardous chemicals completely from society. Some hazardous substances are also naturally occurring, making it impossible to completely eliminate all potential exposures to hazardous chemicals. As such, the original needs of the EU chemicals legislative framework remain.

Additional needs have been identified. Stakeholders believe that the approaches to the risk management of nanomaterials are not yet sufficient in the chemicals legislative framework. There is no harmonised approach to nanomaterials, with only some pieces of legislation enacting risk management requirements, such as the Cosmetic Products Regulation which requires nanomaterials to be notified to the Commission and labelled on products. Under the Cosmetic Products

[40] According to two consumer associations and to one representative of a Czech Notified Body and test laboratory, the development of a positive list of allowed chemicals in toys would be much more effective and clear than the actual negative list, which contains the chemicals that are forbidden in toys.

[41] ANEC (2014): Position paper – Hazardous chemicals in products: the need for enhanced EU Regulations. Available at: http://www.anec.eu/attachments/ANEC-PT-2014-CEG-002.pdf

Regulation, where the Commission has concerns with regards to the safety of a nanomaterial, it requests an opinion from the SCCS. Under Article 19(1)(f) of the Biocidal Products Regulation, nanomaterials which are contained in biocidal products are required to have a separate assessment in order to evaluate their risk to human and animal health and the environment; in other words, nanomaterials are subject to a specific risk management approach as they require risk assessments when they appear in processes or products. Nanomaterials may also be subject to generic risk management measures, although this is would not be due to their being a nanomaterial, but instead relate to their classifications as a CMR.

PBT/vPvB substances are still in use and it is likely that more will be identified over time, as more information becomes available. The legal framework is therefore still relevant with regard to its original purpose in this respect. Several proposals have been made to extend the PBT criteria in order to better cover all substances, i.e. to include criteria reflecting other bioaccumulation behaviour than via lipid partitioning. Furthermore, additional substance groups have been highlighted as deserving attention, such as persistent, toxic and mobile substances (see also Case Study 6).

3.6.2 Circular economy considerations

Assessing the interaction between the EU chemicals legislative framework and the circular economy is a large task and requires more specific consideration than can be given as part of this study. A circular economy is one that is restorative and regenerative by design, whilst aiming to keep products, components and materials at their highest utility and value at all times[42]. The material flows within this are designed to re-enter and circulate within the system, preventing waste being formed.

The EU chemicals legislative framework has to work in harmony if it is to enable and/or promote a circular economy. It is difficult to assess which risk management approach – based on generic risk considerations or on specific risk assessment – is the most efficient and effective for this, as they work together within the chemicals legislative framework. There is concern from industry that the generic risk considerations will lead to the inability to undertake recycling of key resources, such as metals and metal alloys, with this working against the circular economy. In this respect, a specific risk assessment approach followed by further technical or socio-economic assessment would appear to be more appropriate, as it can identify those cases where the benefits of recycling outweigh the risks of substances remaining within the supply chain.

3.6.3 Relevance with respect to the precautionary principle

Article 191 of the Lisbon Treaty lays out the objectives and basis for environmental policy in the European Union. The objective is to ensure a high level of protection through:

- *"Preserving, protecting and improving the quality of the environment;*
- *Protecting human health;*
- *Prudent and rational utilisation of natural resources;*
- *Promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change*".

[42] Ellen MacArthur Foundation (2015): Available at: https://www.ellenmacarthurfoundation.org/circular-economy/overview/concept

The basis of this is the precautionary principle and the principles that preventative action should be taken, that environmental damage should be rectified at source and that the polluter should pay. In the case of PBT substances, the majority of legislation uses generic risk considerations in risk management. The automatic ban on their use in biocidal products and plant protection products can be judged as utilising the precautionary principle as substances that are of concern to the environment are not permitted for use. It should be noted though that the environment is not considered in all pieces of chemicals legislation, as is the case with cosmetics and toys. As discussed earlier, there is an argument for not considering the environment in cosmetics legislation, but there is also a strong argument for including it.

The Waste Framework Directive is based strongly on Article 191 of the Lisbon Treaty, and is also clearly relevant to achieving circular economy goals. It "*defines key concepts such as waste, recovery and disposal and puts in place the essential requirements for the management of waste, notably an obligation for an establishment or undertaking carrying out waste management operations to have a permit or to be registered and an obligation for the Member States to draw up waste management plans. It also establishes major principles such as an obligation to handle waste in a way that does not have a negative impact on the environment or human health, an encouragement to apply the waste hierarchy and, in accordance with the polluter-pays principle, a requirement that the costs of disposing of waste must be borne by the holder of waste, by previous holders or by the producers of the product from which the waste came*[43]".

The classification of waste is linked to the classification of substances and mixtures under CLP:

> *"The classification of waste as hazardous waste **should be based, inter alia, on the Community legislation on chemicals**, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose. Hazardous waste should be regulated under strict specifications in order to prevent or limit, as far as possible, the potential negative effects on the environment and on human health due to inappropriate management. Furthermore, it is necessary to maintain the system by which waste and hazardous waste have been classified in accordance with the list of the types of waste as last established by Commission Decision 2000/532/EC, in order to encourage a harmonised classification of waste and ensure the harmonised determination of hazardous waste within the Community*[44]."

The Waste Framework Directive not only encourages the polluter pays principle but it has also introduced extended producer responsibility. Article 14(1) outlines that "in accordance with the polluter pays principle, the costs of waste management shall be borne by the original waste producer or by the current or previous waste holders". Although, Article 14(2) allows for Member States to decide how this shall be implemented: "*Member States may decide that the costs of waste management are to be borne partly or wholly by the producer of the product from which the waste came and that the distributors of such products may share these costs*".

Article 8 of the Waste Framework Directive outlines the requirements of extended producer responsibility. The aim of this is to strengthen the re-use and the prevention, recycling and other recovery of waste by Member States taking "*legislative or non-legislative measures to ensure that any natural or legal person who professionally develops, manufactures, processes, treats, sells or*

[43] Recital 1 of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

[44] Recital 14 of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

imports products (producer of the product) has extended producer responsibility". This can mean the acceptance of returned products and the waste that remains after they have been returned or the subsequent management of the waste and the financial responsibility for such activities. Article 8(2) states that "*Member States may take the appropriate measures to encourage the design of products in order to reduce their environmental impacts and the generation of waste in the course of production and subsequent use of products, and in order to ensure that the recovery and disposal of products that have become waste take place in accordance with Articles 4 and 13*".

As the Waste Framework Directive is working in harmony with the rest of chemicals legislation, it can be concluded that the legislative framework is making efforts to meet the requirements of the Lisbon Treaty. It should be noted that as with all risk management measures, the implementation and enforcement of these provisions by Member States will have a great impact on the extent to which the legislative framework meets the requirements of the Lisbon Treaty.

As long as the single market is in existence there is a need for the chemicals legislative framework to facilitate this. As discussed earlier, by having a chemicals legislative framework that is dictated at Union level, the single market has the ability to operate in a more efficient and effective manner. Competitiveness and innovation aid in the meeting of the other two objectives and will continue to be relevant in a society where chemicals are used. Competitiveness is an important aspect of the functioning of any market and continues to be relevant. Innovation is key to being able to meet the objective of a high level of protection of human health and the environment, as safer working environments and professional and consumer products cannot be achieved without innovation of working practices and research and development into suitable alternatives.

3.7 Coherence within the EU chemicals legislative framework

Key findings:

- Concern has been raised with the coherence between EFSA and the RAC with regards to hazard classification of Plant Protection Product active substances (discussed further in Task 2, Sections 4.5.6 and 6).
- Coherent approaches to risk management have been taken for CMRs, PBTs and EDCs, in cosmetics, toys, biocides, pesticides and food contact materials, whereby their use is automatically prohibited.
- There is a lack of coherence, however, with respect to the criteria for derogations or exemptions across the legislation, in particular with respect to biocidal product and plant protection product active substances.

Each of the pieces of legislation covered by Task 3 takes steps to meet this objective, either through generic risk measures banning the use of hazardous substances, or the specific case-by-case risk assessment of substances in order to assess whether they are safe to use.

Although the criteria for exemptions or derogations within the different legislation may differ, many require the opinion of a scientific committee on the safe use of a substance (see also Case Study 11). The opinions of the technical and scientific committees on a substance may be different but this reflects the differences in the use of concern, and the different expertise and approaches of the committees. It should be noted though that stakeholders believe that harmonisation of data requirements for risk assessment would ensure better coherence of the work of different

committees/agencies and could be beneficial to meeting the objectives of the EU chemicals legislative framework.

It is very difficult to assess whether the framework meets its objectives with regards to a substance which has multiple uses or uses under multiple pieces of regulation, as the risk management measures that may be required are not identical across all pieces of legislation. Although there is a generic approach to risk management for CMRs in professional and consumer products covered by sector specific legislation, no such approach exists for consumer products more generally. In addition, the derogations available under the legislation are not the same and so substances can be placed on the market in one sector when they would not be granted a derogation for use in another (again see Case Study 11 for further discussion of the possibilities for derogation). This may not reflect a lack of coherence between legislation, as the use and exposure to a substance may vary across sector; as such, it is appropriate that these differences exist.

It is generally well established across the chemicals legislative framework that industry are responsible for providing the correct and adequate data when they are seeking a derogation or the approval of a substance for use, while Member States may be responsible for getting these dossiers through the system. OSH and the Seveso III legislation are different from professional and consumer product legislation, as it is responsibility of the employer/operator to ensure that risk management is undertaken and assessments are carried out in the workplace, not by an external committee or agency. Member States are responsible for enforcement of all legal acts under the EU chemicals legislative framework, although there may be Community wide enforcement as well.

Some legislation makes reference to other pieces of legislation (excluding CLP). Where this occurs (e.g. the Toy Safety Directive referring to cosmetic toys being subject to the conditions of the Cosmetic Products Regulation), stakeholders believe that this is clear and there is no confusion as to which piece of legislation is applicable. Member States have raised concern with respect to the link between the Toy Safety Directive and the Biocidal Products Regulation. Where biocidal products are included in products under the Toy Safety Directive, they are exempt from the conditions of the Biocidal Products Regulation and as such their presence is not declared. Some Member States believe that this needs to be changed so that at least only approved biocidal products can be contained in toys and where they are used they should be labelled.

Concern has been raised with the coherence between EFSA and the RAC with regards to hazard classification. This has been discussed in Task 2 (sections 4.5.6 and 6, and Case Study 3) and is an issue that has been raised by numerous stakeholders. Stakeholders are of the opinion that the only Agency that should be responsible for developing opinions on the harmonised classification of substances is ECHA. If EFSA require a classification then approval by the Commission should be put on hold until after an opinion has been provided by ECHA's RAC on a CLH dossier; alternatively, the EFSA approval process should run in parallel with the RAC CLH process. It has been brought to our attention that this is being rectified through a common format whereby one document is sent to EFSA and the RAC so that the RAC can do the CLH and EFSA can do the assessment.

In general the legislative framework can be regarded as consistent regarding PBT/vPvB management, as all legal acts have commonalities in structure regarding the burden of proof, division of tasks between industry and authorities, market restrictions as primary RMM and a multi staged process of hazard identification including the involvement of different experts and the Member States. Overall, PBT/vPvB management appears to be consistent with wider EU policies and strategies.

Inconsistencies in risk management triggers are generally justified by the expected benefits of a product for human health (pharmaceuticals for human use, pest control) or animal health

(pharmaceuticals for veterinary use). However, some NGO and authority stakeholders believe that veterinary medicinal products should be regulated in the same way as biocidal products (automatic ban with derogation options). Also stricter risk management should be enabled for pharmaceuticals for human use according to some NGOs and authorities.

In relation to toys, biocides used in toys were exempted from the authorisation requirement for biocides when the Regulation "concerning the making available on the market and use of biocidal products" (no 528/2012) was approved. This means that biocides used in toys do not need to be authorised, which is considered to be a serious omission. ANEC suggests that either an approval system for biocides should be introduced in the Toy Safety Directive, or the exemption for toys in the Biocidal Products Regulation should be removed. There is no evidence of contradictions between the 2009 Directive and the other relevant EU legislation for toys, as concerns both limit values for chemicals and other provisions. However, confusion is likely to arise when toys are "indirectly" regulated via legislation other than the Toy Safety Directive. This is true for instance as regards CMR substances. The Toy Safety Directive sets a limit for CMR substances in toys corresponding to the relevant concentration limit established in the CLP Regulation. However, specific – usually lower – limits for certain CMR substances, which are specifically applicable to toys, are also set in the REACH Regulation. In these cases, economic operators may find it difficult to identify the proper requirements to comply with, particularly when reference is made to several pieces of legislation (Technopolis et al., 2015).

As pointed out in a previous study[45], legislative confusion increases administrative costs for economic operators – and particularly manufacturers – who have to double-check what requirements they are subject to (further details are provided in Case Study 8).

However, as also stated by different stakeholders (three consumer associations, an Italian industry association, a large Italian manufacturer and a Czech Notified Body), bearing in mind the vulnerability of the target group - i.e. children - the current framework should be maintained even if it sometimes turns out to be cumbersome and time-consuming. After all, stakeholders do not experience any major contradiction or overlapping between the Directive and other pieces of EU legislation. Also some economic operators (an Italian industry association, a large Italian manufacturer, a Belgian and a Danish manufacturer) stressed that all current pieces of legislation are necessary as they regulate different products or products serving different purposes (Technopolis et al., 2015). As no major contradiction or overlapping was detected, only a few points have been raised with regard to the link between the Toy Safety Directive and the other EU relevant legislation for toys (Technopolis et al., 2015).

Further assessment is required in order to assess whether the chemicals legislative framework is consistent with wider EU policies and strategies, in particular in areas of environment and sustainability, circular economy, non-toxic environment strategy, innovation, competitiveness and job creation.

[45] Milieu (2012). Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps. Final Report.

3.8 EU added value of the current EU chemicals legislative framework

Key findings:

- There is a general consensus that the EU chemicals legislative framework provides EU added value through enhancing the functioning of the internal market.

Stakeholders are of the opinion that in order to reach the objectives of the EU chemicals legislative framework, having a harmonised community-wide approach is appropriate. National measures work for certain aspects, such as OSH, because an enforcement agency in a Member State will be more conscious of their market and the current climate. In order to allow for the functioning of the internal market whilst maintaining a high level of protection for human health and the environment, risk management measures need to be set at a Community level so that there are no barriers to trade which may occur if there are national differences. If the EU intervention was substituted for a national approach then manufacturers, producers, distributors and importers may face barriers to trade as where different countries have different approaches to risk management, e.g. the approval of hazard classes in consumer products, certain products may not be able to make it to the market when under the EU regime they would be approved for use.

In addition, the creation of EU-wide expert groups, such as the chemical expert group on toy safety, are viewed positively across the different stakeholders, as these enable both harmonisation of approaches but also a sharing of expertise and resources.

An EU association highlighted an example of national level compared to EU level implementation: at present the debate on waste is left to national authorities and an EU association sees discrepancies that do not lead to better RMMs; they indicate that there is no transparency across sectors. The EU association also indicated that they believe in harmonised communication on hazards and risks, particularly as companies trade globally.

4 Data and Assessment Approaches

4.1 Introduction

Effectiveness of the legislation will also depend on the quality of the data used and the extent to which the legislation takes into account scientific and technical developments (relevance related considerations). It also depends on other factors such as the potential for considering a group of chemicals together for risk management purposes, as this helps ensure that users of chemicals do not substitute one for another with the same group and with properties of equivalent concern.

These aspects are considered below with respect to the evaluation questions listed in Table 4-1.

Table 4-1: Relevant evaluation questions on data quality and accounting for scientific developments

Q #	Evaluation questions
1.1.1.7.	Are data requirements (on hazards, uses, and exposures) in the chemical legislative framework adequate to identify and assess all risks to human health and the environment for all substances and uses?
1.1.1.8.	Is the scientific data on which the regulatory decisions are based of good quality, complete and reliable? Are quality requirements (e.g. GLP) appropriate?
4.2.9	Are there any inconsistencies as regards quality requirements for data?
3.1.6	Does the chemicals legislative framework ensure that the scientific and technical development is taken into account on a regular basis (e.g. through periodic review of the legislation)?
3.3.1.	To what extent do the risk assessment procedures and risk management decisions take into account the latest scientific findings?
3.1.7	Is there a mechanism to ensure that the hazard identification and risk assessment are based on the latest state-of-the-art method and sufficient to identify all risks for health and environment?
2.2.4.8.	Are procedures for hazard/risk identification and assessment implemented in the least burdensome manner?
2.2.4.2.	Is the level of evidence required to identify hazard and risks appropriate?
2.2.4.9.	To what extent are substances assessed on an individual basis and to what extent are similar substances assessed together? What differences are there in the efficiency of these approaches?
2.2.4.10.	To what extent is it efficient to assess substances which are structurally related, used for the same purpose or otherwise similar assessed individually or together?
2.2.4.11.	To what extent do the current provisions provide for assessments of chemical groups and if so are they applied? What are the pros and cons of these approaches e.g. effectiveness, efficiency, relevance.

4.2 Quality of data, scientific and technical development

Key findings:

- Multiple routes of exposure are considered in exposure assessments but those assessed vary between legislation and this has been raised as an inconsistency in data requirements across the legislative framework.
- Combination effects are not considered to be taken into account in risk assessment and this is considered by stakeholders to affect the accuracy of risk assessment. It has been acknowledged that the lack of combination effect assessment is due to a lack of technical ability.
- A lack of data sharing across the chemicals legislative framework has been raised as an issue and stakeholders believe that it should be encouraged in order to prevent unnecessary replication of testing.
- Where detailed and extensive risk assessment requirements exist to gain active substance approvals, it is not clear that a generic risk considerations approach is more effective and it is unlikely to be more efficient.

4.2.1 Use of data in exposure and risk assessments

One of the recurring themes for CLP and downstream legislation relates to use of risk assessment, data interpretation and data adequacy. With respect to downstream legislation, a key concern surrounds the exposure assessments being carried out and the differences between pieces of legislation. It is accepted by stakeholders that exposure assessments are central to identifying the impacts of a hazardous substance and should be used to prove their safe use (or lack of it). Of the Member States who responded to our consultation, 60% believed that exposure was given adequate consideration when trying to decide on the correct risk management measures to be employed. 40% of Member State respondents believed that too little weight was given. When conducting a risk assessment, stakeholders are of the opinion that multiple routes of exposure must be taken into account (see also discussion under Section 3.2 above), as this would allow for all avenues of risk to be explored.

Industry stakeholders in particular noted that not all substances present a risk from all exposure pathways. As a result, risk management should focus only on those uses which relate to identified exposure pathways; this suggests that testing across all routes of exposure should act as the basis for identifying those uses that are safe. This is particularly important in the case of substances which are widely used, with the example given of ethanol. In this case, the route of exposure of concern is oral, with this linked to cancer effects[46]. By confirming that there is only one exposure route of concern, risk management measures can be employed to protect consumers and workers from the risk of oral exposures, whilst not preventing uses of the substance which have been found to be safe through an exposure assessment. This type of approach contrasts to an automatic trigger under the generic risk considerations approach applying to all uses, regardless of whether or not the risk arises from relevant exposure pathways. Indeed, where detailed and extensive risk assessments are undertaken one can question the need for generic risk considerations, as sufficient information for

[46] Bagnardi, V., Blangiardo, M., La Vecchia, C., and Carrao, G. Alcohol consumption and the risk of cancer: A meta-analysis. National Institute on Alcohol Abuse and Alcoholism. Available: http://pubs.niaaa.nih.gov/publications/arh25-4/263-270.htm

risk management decision making purposes should be provided by the risk assessment (resulting in an equivalent level of effectiveness but greater efficiency).

There are also conflicting opinions between industry and NGO stakeholders with regard to routes of exposure covered under the Plant Protection Products Regulation. One NGO expressed the view that the risk assessment only considers the oral route of exposure, whilst industry representatives have argued that multiple routes of exposure are covered. Further investigation indicates that the routes of exposure considered depend on the population of concern and the use scenario, and more than one exposure pathway will be considered. For mixing and loading by operators, dermal and inhalation pathways are considered[47]. Exposure estimates for individual tasks are the sum of dermal and inhalation exposures. For workers, exposure is estimated for activities that involve contact with treated crops. The main routes of exposure of concern for these activities are dermal and inhalation[48]. Although there may be secondary exposure via the oral route through hand to mouth transfer, this route is considered to be negligible in comparison with dermal and inhalation exposure. Inhalation exposure estimates for workers who are using PPPs outside are only necessary in exceptional circumstances. For overall exposure, the sum of all sources and routes should be calculated. Resident and bystander exposure is slightly more complex. Four pathways of exposure are to be considered: spray drift (at the time of application); vapour (may occur after the PPP has been applied; surface deposits; entry into treated crops. Dermal, inhalation and secondary oral (from hand to mouth and object to mouth (for children)) exposures are to be calculated[49].

Although the majority of stakeholders agree that multiple routes of exposure are taken into account, they believe that the assessments only consider the particular defined use and not possible/probable uses. One Member State has explained that: "different uses of the same compound under different legislations and the concurrent use of thousands of compounds in commerce will result in spatial and temporal exposures not yet covered by any of the current risk assessment procedures".

An academic stakeholder voiced a similar view, noting: "although we are aware of this issue [multiple routes of exposure], there are limitations to our scientific abilities…. in an ideal world, exposure from all routes and uses would be calculated but this is not yet practical".

As noted in Section 3, concern has been raised with respect to the consideration of combination effects of chemicals. Stakeholders suggest that the risk assessments being carried out are not always based closely enough on scientific evidence and so are not taking into account combination effects. An example of where combination effects of chemicals were highlighted as needing to be considered is given by solvents, as they have the ability to form complexes which can breach the skin barrier. There is no requirement under the pieces of legislation considered here to examine such combination effects. Stakeholders argue that testing methods are inadequate and at present such effects can only be assessed thorough 'addition calculations'. One academic pointed out, however, that the failure to examine combination effects does not prove a gap in the legislation; it is simply a reflection of the state of science and the ability to carry out relevant testing. There is hope that with advances in science, combination effects may begin to be added to risk assessments.

[47] EFSA (2014) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. Available: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3874/epdf

[48] EFSA (2014) Guidance on the assessment of exposure of operators, etc.

[49] EFSA (2014) Guidance on the assessment of exposure of operators, etc

Suggestions have been made by some stakeholders aimed at improving current risk assessments. For example, in the case of CMRs, an industry association has suggested that potency could be employed as an additional indicator of hazard as part of the classification process, as a substance may not be hazardous at certain potencies, whereas it may be extremely hazardous at others (see also the Task 1 report). This and the above proposals regarding better accounting for the actual exposure routes of concern fit with the request of industry to make the process for risk management decision-making more scientific and realistic, so that the safe use of a product is assessed properly and products do not have to be removed from the market when they pose no risk. This being said, it can be difficult with CMR substances to determine whether or not it is possible to deem that there is no risk at all.

When asked whether the characteristics of a substance are given enough consideration in hazard and risk assessment for risk management purposes, stakeholders unanimously believed that they were and considered this to be a positive. The use of the substance is also considered to be adequately considered in risk assessment, including misuse. Intentional misuse is not included which is considered to be appropriate, as this may cause RMMs to be overly cautious.

However, assessment of exposures of vulnerable populations has been raised as an issue by some stakeholders. Of the Member State who responded to the consultation, 44% believed that too little weight was given to the protection of vulnerable groups, whilst 56% believed that appropriate weight was given. One authority noted that vulnerable populations are not taken into account in the Carcinogens and Mutagens Directive although some are covered by other pieces of legislation such as the Pregnant Workers Directive (92/85/EEC) and the Young People at Work Directive (94/33/EC). With respect to other stakeholders, there is no consensus between industry and NGOs. Although there is agreement that vulnerable populations are considered in risk assessment, there are differing views on whether this is sufficient. An example of where consideration of vulnerability is lacking is that of night workers. It has been proven that night shifts make people more vulnerable to chemicals but this is not taken into account in risk assessments.

4.2.2 Data availability and quality of data

Data availability has not been highlighted as an issue by stakeholders. One issue that has been raised however is the lack of data sharing across legislation. This is believed to be an important missing link in the chemicals legislative framework as it would prevent unnecessary testing. There are requirements under some legislation, such as the Biocidal Products Regulation and Plant Protection Products Regulation, for parties to share information on vertebrate studies in order to prevent the need for new animal testing and this may help to substantiate a derogation argument. There may also be the possibility for sharing of data for the Biocidal Products Regulation and Plant Protection Products Regulation as they are considered to be registered under Article 15 of REACH. If this obligation was included in all legislation and extended not just to animal testing, as is done in REACH, then there would be greater and faster access to information for industry, authorities and committees. From industry's perspective, however, this would compromise competition and they believe that confidential business information should not be openly shared as testing is an expensive process. However, it may also be to the advantage of industry to find better mechanisms for information sharing so as to facilitate processes for all concerned, and to avoid decisions taken under one piece of legislation due to a lack of data from those operators affected by it having unintended consequences for other operators. A suggestion put forward by one Member State in order to ensure data availability is "competent authorities have access to respective data from other legislation, even if these are generally confidential". This would in theory allow for Member States to be able to check dossiers across all relevant evidence without industry having to share data with each other, which they are not always happy to do.

The lack of easy access to data may be problematic when stakeholders are seeking a derogation. The timeframes for derogation can be relatively short in comparison with the time it takes for new and sufficient data to be gathered to prove safe use.

Risk management decisions under the Biocidal Products Regulation and Plant Protection Products Regulation are based in part on the PBT status of a substance (c.f. Case Study 6 regarding data quality for PBT assessment). If derogations are applied for biocidal active substances, risk assessments, socio-economic data and/or information on alternatives to pest control as well as potential risks for resistance of organisms are to be compiled for justification. No related guidance exists. This has led NGO representatives to comment that there is insufficient information and rules on the necessary data, its evaluation and criteria for decision making.

It has been suggested by some industry stakeholders that the lack of easy access to available data could be combatted by industry carrying out an RMOA. They believe that this would make data on which risk management is based more readily available on request and this would in turn make procedures run more efficiently.

However, in discussions with NGOs, such a proposal was criticised as being inappropriate. Allowing industry to do this could introduce bias into the system which may not currently be there. Instead, independent studies should be conducted and reviewed by independent scientists to act as the basis for risk management decision making.

The use of Good Laboratory Practice (GLP) is discussed in detail in the Task 1 report, but a comment is also relevant here. GLP is an important and useful way of standardising quality requirements for test facilities, and ensuring repeatability and consistency in data generation. However, many stakeholders (citizens, industry, Member States, NGOs, academics) believe it is not necessarily the only form of data that should be used for assessments, particularly as important evidence may be missed. Comments from the open public consultation have highlighted that:

- GLP does not guarantee reliability or intelligent study design;
- Systematic peer-review should be applied impartially to GLP and non-GLP studies to allow for accurate and robust conclusions; and
- Independent academic and government research may not be GLP and this may mean that there is an over-reliance on industry-funded studies[50].

A consumer association has suggested that if a way of assessing the reliability and reproducibility of existing non-GLP data could be introduced, then both forms of data could be used, reducing problems regarding the lack of data to feed into assessment and allowing non-GLP studies to contribute to the weight of evidence approach. This could be a systematic peer-review, as suggested in the open public consultation. Academic research could also be incorporated through the weight of evidence approach.

[50] It is worth noting that one of the national GLP monitoring authorities responded to this comment as follows: "*There may be some misunderstanding around what GLP is used for. GLP is not concerned with research and development work, it is just concerned with the conduct of regulatory safety studies. Most academic labs do not perform regulatory studies but there is still a common misconception among academics that if their laboratory is not GLP compliant it somehow undermines the validity of their work.*"

and, furthermore: "*…a number of academic labs are members of the GLP compliance programme. Most of these work as small contract research organisations offering specialist services. In the main they are run as independent businesses and separated from R&D operations within the University.*"

4.3 Substance-specific versus grouped approaches

4.3.1 Introduction

When considering the appropriate risk management for chemicals, a substance can be assessed in an isolated context (substance-specific) or as part of a group. Grouping of chemicals for risk management purposes can be a solution to the problem of regrettable substitution, as chemicals with similar properties can be (in principle) used as an alternative to the substance of concern.

The OECD defines a chemical category as "a group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity".[51] The similarities may be based on the following:

- a common functional group (e.g. aldehyde, epoxide, ester, specific metal ion);
- common constituents or chemical classes, similar carbon range numbers;
- an incremental and constant change across the category (e.g. a chain-length category);
- the likelihood of common precursors and/or breakdown products, via physical or biological processes, which result in structurally similar chemicals (e.g. the metabolic pathway approach of examining related chemicals such as acid/ester/salt).

It should be noted that a chemical class is "*a set of compounds sharing a common structural feature to which is attached a variable part (or parts) defining a specific compound of the class. The common feature is often a functional group to which one or a small number of variable parts are attached (e.g. aldehydes, ketones)*".[52]

There are two approaches to chemical grouping: the category approach and the analogue approach. The category approach to the grouping of chemicals reduces the need for *in vivo* testing, as not every chemical in the group will need to be tested. Data for the chemicals and endpoints that have been tested for can be used to estimate the corresponding properties for the untested chemicals and endpoints. The analogue approach can be used when the target and source chemicals share a common mode of action. All groups of chemicals are not based on the same properties, and each group can be defined by different criteria, depending on the regulatory purpose and/or risk management measures.

4.3.2 Grouping within the legislative framework

The actual and potential use of grouping methods for risk management purposes under the different pieces of legislation varies. For example, risk management for PBT and vPvB properties under the Plant Protection Products Regulation is based on substance by substance considerations. Similarly, the Directive on Medicinal Products for Veterinary Use applies to individual substances. In all three of these cases this is because substances are individually approved or authorised for use. In

[51] http://www.oecd.org/chemicalsafety/risk-assessment/ groupingofchemicalschemicalcategoriesandread-across.htm

[52] Glossary of Class Names of Organic Compounds and Reactive Intermediates Based on Structure - Commission on Nomenclature of Organic Chemistry (Peter A. S. Smith, Convenor of the Working Group); Commission on Physical Organic Chemistry (Paul Müller, Convenor of the Working Group). Available at: http://www.chem.qmul.ac.uk/iupac/class/intro.html

contrast, the Water Framework Directive includes some substance groups (e.g. dioxins, PAHs), as does the REACH candidate list and the POPs Regulation.

In contrast to the Plant Protection Products Regulation in particular, under the Biocidal Products Regulation (Annex IV, point 1.5), "substances whose physico-chemical, toxicological and ecotoxicological properties are similar or follow a regular pattern as a result of structural similarity may be considered as a group or category of substances". The group concept requires physico-chemical properties, human and animal health effects, environmental effects and fate to be predicted using the read-across approach. Similarities can be based on:

- A common functional group indicating the presence of dangerous properties;
- Common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; or
- A constant pattern in the changing of the potency of the properties across the category.

The Biocidal Products Regulation also allows for biocidal products to be authorised as a biocidal product family. The products must have similar uses, the same active substances, similar composition with specified variation and similar levels of risk and efficacy. Under Article 19 (6), "the assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family". A biocidal product family shall only be authorised if:

a) "The application explicitly identifies the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the assessment is based, as well as the permitted variations in composition and uses referred to in point (s) of Article 3(1) together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and

b) It can be established based on the assessment referred to in the first subparagraph of this paragraph that all the biocidal products within the family comply with the conditions set out in paragraph 1".

Carcinogens, mutagens and reprotoxins tend to be grouped together for risk management purposes under the pieces of legislation being considered in this task. This is due to some substances exhibiting all three types of hazard and their high level of toxicity. It should be noted that reprotoxins are not a part of the Carcinogens and Mutagens Directive and this is considered a gap by stakeholders. They are covered by the Chemical Agents Directive but as they are grouped so often with carcinogens and mutagens, and present what could be determined as similar level of risk due to toxicity, some stakeholders believe that the Carcinogens and Mutagens Directive should be amended to include reprotoxins. In the case of consumer and professional product legislation, such as the Biocidal Products Regulation, the Plant Protection Products Regulation and the Cosmetic Products Regulation, a CMR classification results in an automatic ban as there are exclusion criteria for the use of such substances in these products.

5 Processes and Procedures

5.1 Introduction

The efficiency, relevance and coherence of the legislative framework rely to a great extent on the processes and procedures involved in its operation. From an evaluation perspective, four different aspects are of interest, relating to:

- Allocation of the burden of proof;
- The speed and timeliness of the processes and procedures;
- Transparency of the processes and procedures; and
- Coherence of the procedures across the legislation.

The relevant evaluation questions are set out in Table 5-1.

Table 5-1: Evaluation questions relevant to processes and procedures

Q#	Evaluation questions
2.2.4	Are the provisions and procedures for hazard and risk identification and assessment efficient?
2.2.4.1.	Are the procedures fast enough to identify new hazards/risks?
2.2.4.3.	Is the burden of proof properly allocated?
2.2.4.4.	To what extent are the stakeholders able to contribute to the procedure for hazard/risk identification?
2.2.4.6.	Is there a clear interpretation of what amount and quality of data is sufficient as basis for a risk management decision?
2.2.4.8.	Are procedures for hazard/risk identification and assessment implemented in the least burdensome manner?
2.2.5.1.	Are the procedures fast enough to adopt the necessary risk management measures?
2.2.5.2.	To what extent are the stakeholders able to contribute to the procedure for the adoption of risk management measures?
2.2.5.3.	Are the procedures and timelines sufficiently clear and reliable?
2.2.5.4	Are the procedures able to achieve timely, consistent and efficient conclusions
3.3.2.	To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?
4.1.2.	To what extent are the legal acts of the chemicals legislative framework coherent in terms of: Risk assessment and risk communication - Risk management measures and provisions
4.2.5.	Does the chemicals legislative framework establish thresholds and limit values in a coherent way?
4.2.7.	Are there any inconsistencies (e.g. resulting from multiple committees) as regards hazards and risk assessments performed under the chemical legislative framework?
4.2.10.	Are there any inconsistencies in allocation of burden of proof?
2.2.1.	What aspects of the functioning of the framework are the most efficient?
1.2.1.	Are there unnecessary regulatory burdens?

5.2 Burden of proof

Key findings:

- It is the responsibility of Member States, EU institutions or a Committee to monitor and evaluate the information received and, if necessary, request additional information and come to a conclusion on the status of the substance. Usually, one Member State is responsible for information review and development of draft assessment reports, whereas other Member States contribute on the basis of the initial assessment.
- Legislation which has an automatic ban on hazardous substances such as CMRs lays the burden of proof on European authorities, such as in REACH restrictions.

The burden of proof can be affected by the data requirements for hazard identification and risk assessment and the costs and resources associated with the production of a risk assessment dossier for evaluation and subsequent committee procedures.

5.2.1 Burden of proof in relation to PBT/vPvB criteria

The overall burden of proof that a substance fulfils the PBT/vPvB criteria is consistently allocated under all relevant legislation, requiring industry/applicants for authorisation/approval to provide information on a substance, including a PBT assessment. The authorities (Member States, EU institutions as such or in a Committee or both) manage that information and, if necessary, request additional information and come to a conclusion on the status of the substance. Usually, one Member State is responsible for information review and development of draft assessment reports, whereas other Member States contribute on the basis of the initial assessment.

A different process is foreseen under the Water Framework Directive, which regulates from the environmental perspective and, hence, places the burden of PBT identification on the authorities (with stakeholder involvement in an expert group). This allocation of responsibility is regarded as justified because the legislation is environmental media-driven. This allocation of burden of proof was generally viewed as being consistent and useful.

The overall burden of proof could be decreased if parallel PBT assessments were prevented, e.g. by coordinating and improving the timing of approval procedures and SVHC identification under REACH. Furthermore, data requirements for PBT assessment and cut-off criteria should be harmonised to prevent the situation that different data needs to be generated under different legislation (e.g. degradation tests at different temperatures to identify if a substances fulfils the persistence criterion). Authority representatives showed a degree of preference for centralising the PBT assessment, e.g. at ECHA's Committee for Risk Assessment (RAC) to ensure the procedure is not carried out several times.

5.2.2 Burden of proof in relation to CMR properties

As in the case of PBTs, the burden of proof for CMR substances tends to initially lie with industry. For active substance approval for plant protection products, the entity seeking approval must submit test results and studies to a Rapporteur Member State (RMS). The RMS is then required to prepare a Draft Assessment Report within 12 months. The review of this dossier is carried out by EFSA.

For biocidal products, the submission of a dossier to ECHA lies with the applicant. They must also inform the Member State that they would like to evaluate their dossier. Written evidence of the Member State being willing to evaluate the dossier must also be provided. It is the applicant's responsibility to monitor the status of their application and react to requests from the authorities in R4BP 3[53]. An application may be rejected if the applicant fails to meet a deadline, e.g. for fees, or at a later stage, requests for additional information[54]. An evaluation may also be completed without taking into consideration additional information if it is submitted after the deadline[55].

For cosmetic products, it is the responsibility of the responsible person to ensure that the product has undergone a safety assessment and produced a cosmetic product safety report in accordance with Annex I before a product can be placed on the market[56]. For plastic materials intended to come into contact with food, in order to use a substance it must first be entered into the Union list. The procedure for authorisation requires an application to be sent to a national competent authority who in turn forwards the application to EFSA. The burden of proof in this case falls on the applicant.

In the case of OSH legislation, the burden of proof for meeting requirements falls onto the employer. National authorities are required to monitor the implementation of these requirements but they are not responsible for undertaking the risk assessments needed to establish appropriate risk management measures.

Legislation which has an automatic ban on hazardous substances such as CMRs lays the burden of proof on European authorities, such as in REACH restrictions. The burden of proof will shift to industry when a company seeks a derogation for the use of a CMR.

5.3 Speed of processes and procedures

Key findings:

- Stakeholders (industry, NGOs and Member State) interviewed believe that the combination of the processes for agreeing harmonised classifications followed by the triggering of risk management procedures occurs within an adequate timeframe after early signals of potential risk.
- Timeframes for Committee opinions vary between agencies and can be anywhere between 6 months and 280 days.
- The lack of a rigid timeframe for risk management decision making can reduce legal certainty and predictability of outcomes, putting a burden on industry.
- Timeframes for bringing derogation dossiers to Committees may need further consideration as it has been noted that there is insufficient time in certain sectors, e.g. biocidal products and cosmetics.
- Guidance needs to be clear and justified with regard to timeframes for decision making and implementation of risk management in order to prevent confusion.

[53] ECHA. Practical Guide on Biocidal Products Regulation: Approval of active substance. Available at: http://echa.europa.eu/documents/10162/21742587/pg_on_bpr_1_approval_active_substances_en.pdf

[54] ECHA. Practical Guide on Biocidal Products Regulation – *as previous footnote*

[55] ECHA. Practical Guide on Biocidal Products Regulation – *as previous footnote*

[56] Article 10 (1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

5.3.1 Timeframes

For the purposes of answering the evaluation questions with respect to the speed of processes, we consider efficiency in terms of both the speed of the processes (Committee and Authority opinion forming processes and risk management decision making processes), as well as the costs involved in implementing or participating in the process.

Of course, whether or not a process is "fast enough" is a subjective question, and varies depending on stakeholder interests. For industry stakeholders, fast enough will relate to the length of time it takes to gain a decision on whether or not they can place a product on the market. From a Member State authority perspective, it will relate to the level of time and effort that is required on their part for processes to be complete, although there will also be concerns to ensure that the decision is reliable from a risk management perspective. For NGOs, the question will focus more on whether sufficient time was allowed for consideration of all evidence, as well as on ensuring that action is taken as early as possible to control risks to human health and the environment. In all cases, there is a desire to reduce uncertainty.

As a starting point, it should be noted that committees that formulate opinions on whether or not a hazardous substance is suitable for use work to different timeframes and follow different committee procedures. Table 5-2 outlines the timeframes for formulating opinions on the use of a substance in consumer and professional products.

Table 5-2: Timeframes for scientific committee procedures

Legislation	Committee/agency	Timeframe
Cosmetic products	SCCS	Outlined in the terms of reference submitted by the Commission or Secretariat to the Scientific Committee
Toys	SCHEER	Outlined in the terms of reference submitted by the Commission or Secretariat to the Scientific Committee
Biocidal active substances	BPC at ECHA	270 days
Plant protection products	EFSA	180 days
Plastic food contact materials union list	EFSA	6 months
Classification	RAC	18 months
Notes: Any suggested topic for an opinion sought under SCHER, SCCS or SCENIHR should not fall under the competence of any European agency, particularly ECHA, EMEA or EFSA[57]		

Overall, stakeholders interviewed to date believe that the combination of the processes for agreeing harmonised classifications followed by the triggering of risk management procedures occurs within an adequate timeframe after early signals of potential risk.

The lack of a rigid timeframe for SCCS and SCHEER opinions could lead to legal uncertainty for stakeholders and prevent the timely adoption of risk management. It should be noted that for many of these pieces of legislation the committee opinion is not the only process involved in the authorisation of the use of a substance, as the dossier must be first passed to a Member State for

[57] European Commission (2016) Rules of Procedure: The Scientific Committees on Consumer Safety (SCCS) and Health, Environmental and Emerging Risks (SCHEER). Available at: http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

evaluation, then to the opinion forming committee, then to the Commission for the final decision. For plant protection products, the whole process of approval can take between 2.5 and 3.5 years. For biocidal active substances, the whole process can take a minimum of 2.5 years. Processes can be extended if there is a need for additional information and this can increase legal uncertainty and increase costs to companies whilst they wait to put products on the market.

One Member State has commented that "the current arrangements for the RAC meetings are overall both efficient and effective. This is especially true for the CLH-part of the committee work (being the process within the committee work where RAC has the longest experience) and the restriction part". They also commented that "since there are four meetings per year and all RAC members are also rapporteurs for a number of opinions, and ideally also should participate by commenting between meetings on other opinions, it is obvious that this work requires considerable resources from Member States and perhaps even more important dedicated RAC members." Another Member State has commented that committee meetings are long and need a lot of preparation due to the workload, but overall that the arrangements are efficient and effective.

An industry stakeholder has said that timelines are tighter in the Biocidal Products Regulation than they were in the former Biocidal Products Directive and that the importance placed on adherence to timelines is reducing the quality of information coming out of scientific committees. The tight timelines for submission of new data under the Biocidal Products Regulation means that outstanding issues cannot be addressed. An industry stakeholder believes that if the questions were raised at the right time, then the applicant could address these and would not risk a non-approval decision. Another industry stakeholder has suggested that to better improve the process, the peer review component should come earlier or the time between the start of the peer review and the scientific committee discussion should be sufficiently long to allow adequate time for questions to be asked and answered. Overall, the decision making on risk management measures under the Biocidal Products Regulation and REACH are subject to strict timelines. This may lead to situations that the data requested from applicants/industry cannot be taken into account for (initial) decision making (substance approval, SVHC identification, restrictions, substance evaluation).

With regard to the Committee processes for derogations and exemptions from the automatic ban on CMR use, there are differing opinions between stakeholders. Some are of the opinion that the timeframe in which industry must prepare and submit their dossiers is adequate, whilst others believe that the timeframes are not suitable and industry are not given enough time to prepare dossiers. This is of particular concern for the cosmetics industry as it takes around 2 years to produce the risk assessment which must be put into the dossiers, yet they only have 15 months between a CMR being added to Annex VI of CLP and it being added to Annex II of the CPR, when it is prohibited for use.

This particular timeframe has met with a great deal of criticism from stakeholders. All of the respondents to the cosmetics sector questionnaire indicated that they did not think that the 15 month period for inclusion in Annex II was sufficient time to gather and submit evidence to the SCCS in order to obtain an opinion on the safe use of a CMR substance in a cosmetic product. One stakeholder commented that the 15 month timeframe does not "reflect the complexity of the procedure required under the Cosmetics Regulation, namely the establishment of a safety dossier, submission of the dossier to the SCCS, evaluation, the possible requirement for extra data, SCCS opinion and amendment of the legislation". Another stakeholder explained the current difficulties facing the cosmetics industry with regards to this deadline:

- *"The cosmetic industry cannot finalise a safety dossier for submission to the SCCS before the public consultation on the harmonised classification (CLH) dossier takes place since this is the time when the cosmetic industry can have full access to the data submitted by the Member State(s) to justify the proposal of harmonised classification. These safety data are not available at the time the substance is posted in the registry of intention of the ECHA website. Also, the cosmetic industry cannot consolidate a dossier to the SCCS before the scientific opinion of the Risk Assessment Committee (RAC) is issued, considering that the RAC may not necessarily endorse the proposed harmonised classification and may consider a milder or more severe classification, more appropriate for the substance after having examined the available information. Therefore, the cosmetic industry can only submit the dossier to the SCCS once the conclusion of the RAC are available*".

One Member State has noted that "…the link between the cosmetics (Art 15) and the CLP Regulation is not clear regarding the transitional time. Especially for products already on the market". This shows that this question of timing is not only an issue for industry. This issue has been clarified at the meeting of the Working Group and Standing Committee on Cosmetics in late September 2016. The Commission has declared that a CMR substance is not prohibited for use in cosmetic products until it has entered into Annex II of the Cosmetic Products Regulation, its classification and entry into Annex VI of CLP does not mean that the CMR substance has been automatically prohibited for use.

It has been brought to our attention that one of the reasons timeframes may be extended is that it can be difficult for committees to reach a consensus. There can be a large group of experts (toxicologists, epidemiologists etc.) in the committee and they may not have the same opinion on the evidence being presented, making it more difficult to reach a decision on safe use. It has also been suggested that the extension of timeframes can be due, in part, to the lack of resources (experts) available to committees in order to process the number of applications and requests for opinions.

5.3.2 Timeliness of action

Implementation of OELs has also been criticised by one stakeholder who has said the comitology needs to be faster as having a long adoption process creates uncertainty and inefficient risk management of hazardous substances. This type of finding also applies to other legislation. For example, there has also been criticism of the speed of risk management in general, with one stakeholder noting that it has taken 15 to 16 years for acrylamide to be subject to risk management measures (RMMs) (from initial listing for risk management to measures coming into force).

With respect to the timeliness of action in terms of the transition times given to adopt risk management, these are at the discretion of the Commission and are generally stated in the legislation, although the Commission can be bad at communicating changes. Overall, stakeholder opinion is split with regards to transition times for duty holders. Of those interviewed that answered the question, 60% of interviewees (across targeted stakeholder groups) believed that the transition times for duty holders were adequate and no one had requested more time. 40% did not believe that the transition times for duty holders were adequate. One industry stakeholder said that people are not sure of dates and timeframes and importers get a shock when a substance becomes banned in cosmetics as they have to look in more places than just the Cosmetic Products Regulation and some do not know where to look or understand the process.

A number of industry stakeholders claimed that some Member States do not allow any transition time following a CLH being added to Annex VI of CLP, and this makes it difficult for industry to make the necessary changes triggered by risk management requirements under downstream legislation.

This stakeholder did not confirm which Member State they were referring to, and it is clear that there are differences in practice across Member States. For example, one industry stakeholder noted that transition times are adequate and that in general they have found that they can gain an extension of months (but not years) where there is good justification.

5.3.3 Potential for more timely action

Several authorities commented that they do not see opportunities to speed up the processes, if the level of participation and scientific assessment is to be maintained. However, opportunities for optimising the processes were identified. For example, some authorities believe there is the potential to reduce the level of parallel hazard assessment that is undertaken, e.g. for classification and PBT identification.

It has been suggested that if the process for active substance approval was faster than the adoption of RMMs could be faster. This viewpoint is not one held by all stakeholders, however, as it is clear from the consultation that both industry and NGO stakeholders have an issue with the lack of time available for stakeholder contribution to the biocidal product active substance approval process. Still focusing on PPPs and BPs, NGOs argued that reviews of substance approvals should not follow the regular time plan but should be carried out earlier in those cases where a substance is known to have PBT/vPvB properties. This would enable more timely action to be taken with respect to these substances. However, given the length of time these processes take, such an approach may run the risk of over-burdening the current processes at a point when Member States already face difficulties in finding the resources to support dossiers.

The 2015 evaluation of the Toy Safety Directive reports another suggestion for making the processes more efficient. In this case, the suggestion is that chemical limit values are set through harmonised standards rather than in an annex to the Directive, so as to be able to update them more quickly and in a more transparent way; this would also enable the legislation to track scientific progress more quickly (Technopolis et al., 2015). However, Technopolis et al. concluded that there are no major issues with respect to these processes in terms of the operation of the Directive.

5.4 Transparency

Key findings:

- Transparency of Committee and Agency opinion forming has been raised as a concern by industry and NGO stakeholders.
- It is acknowledged that there is a need for different Committees to deal with different sectors as one Committee would not have the resources, knowledge or expertise to be able to form opinions on the safe use of chemicals across all possible uses.
- Committee composition has been noted as a contributing factor for the hindrance of transparency as different experts will have different opinions and interpretations of data.
- Stakeholder participation in Committee opinion forming varies depending on the legislation. The SCCS has been criticised for not having enough stakeholder participation, whilst RAC and SCOEL have been praised.
- ECHA has also been praised by industry and NGO stakeholders in providing greater transparency into the processes for which it is responsible.

5.4.1 Clarity, reliability and consistency

5.4.1.1 General remarks

The transparency of Scientific and Technical Committees and Agencies is a subject that cannot be agreed upon by stakeholders. Responses from representatives of workers organisations indicate that ECHA has a better reputation than EFSA for transparency and its ability to implement chemicals legislation in accordance with its objectives and intentions. ECHA has also been praised by industry and NGO stakeholders in providing greater transparency into the processes for which it is responsible. In contrast, while some consider the SCCS and SCHER procedures to be transparent, others claim that there are issues with the transparency of SCCS.

Stakeholders have suggested that inconsistencies do exist between Committees with regard to data requirements and processes; however, this does not mean that there should be one Committee for all of the different downstream legislation, as it would not be possible for such a Committee to have all of the knowledge and expertise needed to formulate the appropriate opinions. Instead, stakeholders would support greater cooperation between Committees, in order to help streamline the overall approach to the protection of human health and the environment. Inconsistencies may also exist due to a different understanding of chemical interactions and modes of action.

One Member State has commented that:

- "*agencies and committees with less strict guidance/criteria will become more dependent on which individuals participate, their (e.g. regulatory) experiences, and their ideas on what level of transparency is needed to explain their expert judgements. There will always be differences between groups of people, and therefore it is important to have very transparent justifications of decisions (and not only reference to expert judgement) to understand and perhaps also accept the differences*".

Another Member State has agreed with this and believes that it is very important that all Agencies and committees explain the reasons for their decisions very transparently. All groups of stakeholders are aware that different scopes of legislation and opinions may lead to different results but the methods should always be clear.

A further Member State stated that:

- *"While we appreciate the need for the various committees, as they all deal with different issue, it can be difficult for a smaller Member State to input into each committee effectively and efficiently. Moreover, in a Member State, the nominees to these committees come from a range of authorities and regulators at the national level so this further complicates the inputs. This can mean the outcomes are compromised due to the large number of committees and workloads therein*."

5.4.1.2 Biocidal Products Regulation and Plant Protection Products Regulation

As a general default, EU legislation assumes that no safe exposure levels can be defined for PBTs/vPvBs. As the PBT/vPvB status of substances under this legislation automatically triggers a non-approval as the "only RMM" under the Biocidal Products Regulation and Plant Protection Products Regulation, the end outcome in such cases is clear and transparent. However, both industry and authorities have noted that there can be issues with respect to data interpretation and there may not be enough communication to ensure transparency in this respect. For example,

Member State authorities have noted that more communication between the Member State rapporteur and the applicant for substance approval could resolve problems related to the understanding of study designs or data interpretation and hence prevent unnecessary delays or misunderstandings and increase transparency on the dossier assessment on the side of industry. NGOs noted that there is a lack of transparency in the decision making on derogations from non-approval decisions and/or exemptions from product authorisations under the Biocidal Products Regulation. NGOs stated that the criteria for the interpretation of socio-economic factors are unknown and the argumentation for exemptions and derogations could not be followed as it is not published; this would also decrease the predictability of how PBT/vPvB are regulated in general.

There has also been criticism by industry of the clarity and predictability of the active substance approval process under the Plant Protection Products Regulation due to the parallel hazard assessment processes between ECHA and EFSA in establishing a harmonised classification. In order to obtain approval for an active substance and in order for EFSA to formulate an opinion on whether the active substance will meet the approval criteria, the substance must have a classification. EFSA is required to review scientific literature and come to a conclusion whether the active substance "is not or has not to be classified"[58] as CMR according to the CLP Regulation. There is the possibility that ECHA and EFSA may reach different conclusions on the classification of a substance (see Case Study 3). In the case of CMRs, this would have a large impact on whether or not a substance or product will be approved as these classifications are exclusion criteria under the Plant Protection Products Regulation. Information received from the Commission indicates that, in such an event, it is unlikely that the issue of the difference in classification will be taken up until the next review cycle for the renewal of the authorisation of the substance and subsequent products that it is an active substance for. In light of new information, the approval status of an active substance or the authorisation status of a product can be reviewed before the review cycle but it is not clear if this will be done in the event of a CLH being given under the CLP. An attempt is being made by the Commission to prevent this by encouraging Member States to submit their CLH dossier before they go to EFSA with an active substance approval dossier. There is already a harmonised format which means that one document is sent to both RAC and EFSA, to allow for RAC to develop the CLH while EFSA does the risk assessment review.

Active substance approvals under the Biocidal Products Regulation and Plant Protection Products Regulation are reviewed after the time period defined in the approval decision. Information that could influence the approval decision should be communicated to the authorities but does not automatically trigger review of approval decisions. Also under the product authorisation scheme, new information on hazards or risks from product use would only be taken into account if the authorities decide to review a product authorisation, e.g. due to imminent risks.

There is also concern over clarity and reliability when it comes to PPP authorisation. Since this occurs at the national level, there may be inconsistencies in the RMM introduced via product authorisations for similar products authorised by different Member States, where the same active ingredient is used in different products. Such differences in national level decision making raise both clarity and transparency issues, and gives rise to confusion within the PPP supply chain.

5.4.1.3 Water Framework Directive

Under the Water Framework Directive, the Commission is to identify the needs for RMM via a review of the environmental status of EU water bodies and chemical pressures being placed on

[58] Regulation (EC) No 1107/2009, Annex II, 3.6.2, 3.6.3, 3.6.4

these. While the process by the Commission is clear and the results are published, the outcome of the assessment is not predictable, as several types of measures under other legislation could be relevant and achieving risk management depends on action at the national level, which may itself draw on derogations (e.g. Articles 4.4 and 4.5 of the Water Framework Directive). At the Member State level, risk management measures should be implemented for substances exceeding environmental quality standards through the adoption of appropriate programmes of measures at the river basin level; these can require actions of varying types and can be implemented through different national approaches (soft regulation, national standards, etc.). Formal consultation on programmes of measures is required, ensuring transparency within the process for agreeing RMMs.

5.4.1.4 Toy Safety Directive

The 2015 evaluation of the Toy Safety Directive notes that economic operators widely acknowledge the value of the adaptation mechanisms, which make the Directive flexible enough to adapt to new safety hazards. According to a large Danish manufacturer, mandates play a great role in keeping the Regulation around toys up to date and responsive to technological, scientific and social developments. In particular, a large UK manufacturer and a French industry association praise the comitology procedure, which allows aligning chemical limit values to scientific developments. Nevertheless, some concerns were raised since political interests – rather than scientific evidence – seem sometimes to trigger and drive amendment procedures and results (e.g. Technopolis et al., 2015).

Consumer associations on the other hand stress that the Toy Safety Directive is not flexible enough to address possible changes and new risks. They question the too limited scope of the Committee procedure as it only applies to Annex I[59]; points 11 and 13 of Part III of Annex II[60]; Annex V[61]; Appendix A on the permitted use of CMR substances and Appendix C on the specific limit values for chemicals intended for use by children under 36 months or in toys intended to be placed in the mouth. Essentially, these stakeholders wish to broaden the scope of the comitology procedure so as to include all kinds of toys and kinds of dangerous substances thereby increasing the effectiveness of the legislation. Moreover, they argue that standards are an inadequate way of ensuring adaptation to the latest scientific and technological developments, since adapting or creating new standards is a long process, and it could be too slow to promptly address new risks (Technopolis et al., 2015). However, the evaluation of the Toy Safety Directive concluded that there was no evidence of major safety risks that could not be addressed by the current adaptation mechanisms.

5.4.1.5 Cosmetic Products Regulation

A case illustrating a lack of clarity under the Cosmetic Products Regulation has been identified from consultation. An opinion was sought on the safe use of Poly(hexamethylene) biguanide hydrochloride (PHMB), a category 2 carcinogen, in cosmetics. The SCCS opinion claims that it is not safe for use in cosmetic products above 0.3% and the Commission has followed this advice and placed it on the banned list of substances in Annex II of the Cosmetic Products Regulation. In spite of this, PHMB is still being used. This is not an issue with the legal text but an issue with the wording of an opinion that has created legal uncertainty and subsequently a lack of enforcement has allowed for an unsafe product to be placed on the market.

[59] Annex I provides a list of products that are not considered as toys within the meaning of the Directive.

[60] Part III of Annex II concerns chemical properties of materials used for toys.

[61] Annex V regards warnings.

5.4.2 Clear interpretation of data required for risk management

The 2015 evaluation of the Toy Safety Directive notes that several Member States have highlighted a need for clarification on different issues (finding 29). In relation to chemical requirements, one Member State noted that "they are worded in a very convoluted way and are barely comprehensible", whilst another Member State claims that chemical requirements need a more precise and transparent structure and simpler wording. Furthermore, one Member State observes how economic operators often find it difficult to understand which Regulation (e.g. the Toy Safety Directive rather than REACH) should apply for limits on chemicals (Technopolis et al., 2015).

When considering the level of evidence needed for Committees to make a decision on the exemption or derogation from the ban on CMR use, stakeholders expressed a level of concern regarding the lack of consistency in the data required for dossiers. Based on this view that there is a lack of consistency in data requirements, some stakeholders consider there to be no predictability in the Committee process and no consistency in the resulting opinions. When considering Committee procedures across the pieces of legislation included in Case Study 13, it is difficult to come to a firm conclusion, however; for example, in the case of cosmetic products ingredients, there have only been 3 or 4 appeals against a CMR ban so far.

NGOs have expressed the view that the risk assessment process in relation to the Plant Protection Products Regulation and Biocidal Products Regulation is not transparent and the type and quality of data used, in particular for derogations based on socio-economic grounds (Biocidal Products Regulation), is regarded as unclear.

5.4.3 Stakeholder participation

Stakeholder involvement in Committee procedures is dependent upon the legislation concerned. There is a different level of input between the Biocidal Products Committee (BPC) and the SCCS, for example. There is also reportedly a lack of industry consultation on opinions under the SCCS which is viewed as problematic by stakeholders. The ECHA Committees (including BPC and RAC) are recognised as the most transparent committees, with this potentially being due to the fact that they are newer.

Table 5-3: Stakeholder participation in key scientific committee or agency activities

Scientific Committee and Agencies	Stakeholder participation
SCCS	Technical or public scientific hearings with stakeholders to obtain additional technical or scientific information, comments, suggestions, explanations or contributions on the scientific basis of the opinion.
SCHEER	Technical or public scientific hearings with stakeholders to obtain additional technical or scientific information, comments, suggestions, explanations or contributions on the scientific basis of the opinion.
EFSA	60 days of period for submission of comments by the public
SCOEL	The Commission may invite EEA/EFTA countries to submit proposals for scientists to attend meetings as observers. The Commission may invite scientific experts from outside the committee who have specific competence on the agenda to participate in the work on an ad hoc basis.
BPC	Meetings of the Committee are open to advisors, invited experts and observers. An advisor accompanies members of the Committee to provide scientific, technical or regulatory advice. Invited experts are those who are invited by ECHA, after a proposal by a Member States, to participate due to their expertise in a relevant scientific or technical field.

Table 5-3: Stakeholder participation in key scientific committee or agency activities	
Scientific Committee and Agencies	**Stakeholder participation**
BPC (cont.)	Observers can include: o The Executive Director and his representatives of the European Commission. o Nominated representatives of accredited stakeholder organisations (ASO). (upon the request of ECHA Management Board) They may contribute their scientific or technical expertise. o An applicant Representatives of third countries and international organisations (upon request of ECHA Management Board)

As noted above, transparency has been raised as an issue for the majority of scientific committee procedures, although there are differing views when it comes to each committee. The working groups under EFSA that formulate the opinions for approval of active substances have been criticised by stakeholders for their lack of stakeholder input. The main mechanisms for such input are there but they are not considered to be sufficient. It has been suggested by one stakeholder that although the procedures for scientific opinions are appropriate, because the process is not always transparent, it is not entirely clear to either industry or civil society how a decision is made.

It has been claimed by stakeholders that SCCS allows little to no stakeholder participation in practice. The committee procedure in this case allows the committee to call upon stakeholders to provide further scientific information as and when required, and the potential for public consultation is available.

The BPC has also been criticised for its lack of transparency, compared to the system that applied under the BPD; it is claimed that there is now less opportunity for discussion with Member States than there was previously, with this impacting on the clarity of decisions. For example, several stakeholders noted that once active substance dossier enters the scientific committee, reliance has to be placed on the Rapporteur Member State to fully understand the dossier and defend the information presented. If the RMS cannot answer a specific point, then the applicant risks severe restriction or non-approval as there are strict rules on participants in the BPC meetings. It has been suggested by industry representatives that the process could be improved by having the peer review earlier or lengthening the time between the start of the peer review and the scientific committee discussion; either of these would allow more time for industry stakeholder participation with respect to answering questions that are outstanding or feeding in missing information. It may also provide the opportunity for more meaningful participation by NGOs (e.g. they could respond to the findings of the peer review).

Member State authorities have highlighted the lack of representation of Member States in the working groups on chemicals and particularly in SCOEL. However, SCOEL more generally has been put forward as providing a good level of stakeholder participation in their processes even though this is not outlined in their rules of procedure as it is for other committees. Member States note that the RAC is both efficient and effective, especially for the CLH process, even though the overall workload has increased over the years and each meeting can stretch over two weeks (see also the Task 1 report where this process is reviewed in more detail). More generally, authorities have noted that participation of stakeholders (excluding Member States) is dependent on the committee concerned.

5.4.4 Committee membership

In 2014, PAN Europe released a report investigating conflicts of interest within expert panels of scientific committees which carry out cumulative risk assessments (CRA)[62]. The analysis focused on:

- Articles in scientific journals, checking names of authors, co-authors and content to see if industry points of view were favoured and if the authors had any link to International Life Sciences Institute (ILSI) or industry;
- Publications of each member in the last 5 years to see if they are actively publishing scientists, which may increase their likelihood of being aware of developments in science;
- EFSA's declarations of interest (DoI) and online research connections with industry activities or other industry ties (conflicts of interest);
- Access to documents (ATD) requests; and
- People promoting certain industry tools, asking for research funding to develop further tools and being active in research programs such as the Acropolis program.

Of the 27 people analysed at EFSA who have worked on CRA, 19% had a formal connection with ILSI, 37% published scientific literature with co-authors who were connected with ILSI, 52% had a connection with industry, 22% were active researchers, and 26% were considered to have a dual role by contributing to EFSA while promoting industries' views on CRA through EFSA research and/or the Acropolis program. The issue that PAN Europe is trying to highlight is that EFSA opinions are supposed to be independent, as covered by the conflict of interest declarations that must be submitted. However, in discussions on this issue, PAN Europe indicated that given these concerns, DG SANTE has been vital in ensuring that EFSA addresses and prevents conflicts of interest arising.

5.5 Coherence of processes and procedures

Key findings:

- The OELV process under SCOEL is reasonably consistent for IOELVs and BOELVs, except that IOELVs include a socio-economic assessment.
- It has been suggested that there is some confusion related to implementing IOELVs and BOELVs for operators and as such, the wrong limit value is being used. This is not an issue with Member State implementation, but with the company itself.
- Differences in threshold values have been raised as an issue, particularly between OSH and waste; REACH and the Biocidal Products Regulation /Plant Protection Products Regulation.
- The use of generic concentration limit values for mixtures as of CLP are not considered to be suitable for derogation criteria for CMRs under the Toy Safety Directive as children are a vulnerable population and more susceptible to the effects of hazardous substances.
- The same framework is used for risk assessment across legislation but the methods for assessment differ in practice due to differences in sectors and use.
- Issues of consistency in opinions on hazard classification between EFSA and RAC for plant protection product active substances have been raised by stakeholders. It has been expressed that EFSA should not be classifying substances and should wait for the CLH decision from RAC before they make their decision on the approval of an active substance.

[62] PAN Europe (2014): A poisonous injection: how industry tries to water down the risk assessment of pesticide mixtures in everyday food. Available at: http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-a-poisonous-injection.pdf

Questions have arisen over the coherence of the processes and procedures between committees and Agencies, although it must be acknowledged that they have different mandates and therefore could not operate through identical processes. This has been discussed in the preceding subsections; the focus here is on the coherence in thresholds, limit values and risk assessments between committees.

5.5.1 Thresholds and limit values

5.5.1.1 OSH legislation

Stakeholders have highlighted confusion with respect to the use of indicative occupational exposure limit values (IOELVs) and binding occupational exposure limit values (BOELVs) under the Chemical Agents Directive and Carcinogens and Mutagens Directive. Occupational exposure limit values (OELVs) are defined in the Chemical Agents Directive as "the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period".

Under Article 3 of the Chemical Agents Directive, on the basis of an assessment of the relationship between the health effects of hazardous chemicals and the level of occupational exposure, the Commission is to propose European objectives in the form of indicative occupational exposure limit values (IOELVs) for the protection of workers from chemical risks, with these then set at the Community level. Under Article 3(3) where an IOELV is set at Community level, "Member States shall establish a national occupational exposure limit value, which takes into account the Community IOELV, determining its nature in accordance with national legislation and practice". This means that there is flexibility for Member States to decide on the limit value to be applied nationally, as long as they have given consideration to the Community IOELV. This national OELV can be higher than the IOELV if the Member State can justify it and decides that, in light of the use scenarios undertaken in their country, the IOELV is too conservative.

In contrast, BOELVs provide Member States with less leeway. These are set under the Carcinogens and Mutagens Directive and Member States must adopt these for national implementation or set national limits below the Community BOELV. In other words, a Member State cannot decide to raise the national OELV for that substance above the BOELV, even if the use scenarios are as such that the workers are considered to be at lower risk.

The process by which the SCOEL derive an OELV appears coherent for both IOELVs and BOELVs, as detailed in Figures 5-1 and 5-2. It should be noted that when the process moves into the formal legislative procedure, differences occur between the IOELV and BOELV processes. BOELVs take into account socio-economic and technical feasibility, whilst IOELVs only consider scientific aspects.

This could be considered a gap, although this difference could also be justified by acknowledging the fact that a binding OELV is stricter and so must assess the ability of the workplace to be able to enact these restrictions. In addition, given the flexibility allowed to national authorities when setting the corresponding national OELVs, there is the potential for socio-economic factors to be considered at this point in time.

Stakeholders have identified some issues with national implementation of binding OELVs. Several, including representatives of workers organisations, have noted that employers confuse the IOELVs of the Chemical Agents Directive and the BOELVs of the Carcinogens and Mutagens Directive. If the Commission is not providing sufficient guidance on the implementation and adoption of OELVs, and is not monitoring this activity in Member States then there is the possibility that workers health and

safety could be compromised where a BOELV has been exceeded (whether intentionally or accidentally). In the case of non-threshold carcinogens, a binding OELV could be considered a reasonable measure for protecting the health of workers as the limit should not be exceeded under any circumstance.

Member States have also raised concerns regarding the differences in derivations of OELVs between the RAC and the SCOEL, as discussed previously. The issue arises from differences in the methodologies that are adopted by the two committees, as well as their remits with respect to the interpretation of data. In this respect, consultees note that the RAC must follow the risk assessment guidance developed for use under REACH (even though this was set to ensure consistency in industry submitted chemical safety assessments), while SCOEL consists of a panel of experts which is able to interpret the scientific data and take into account broader factors when setting BOELVs.

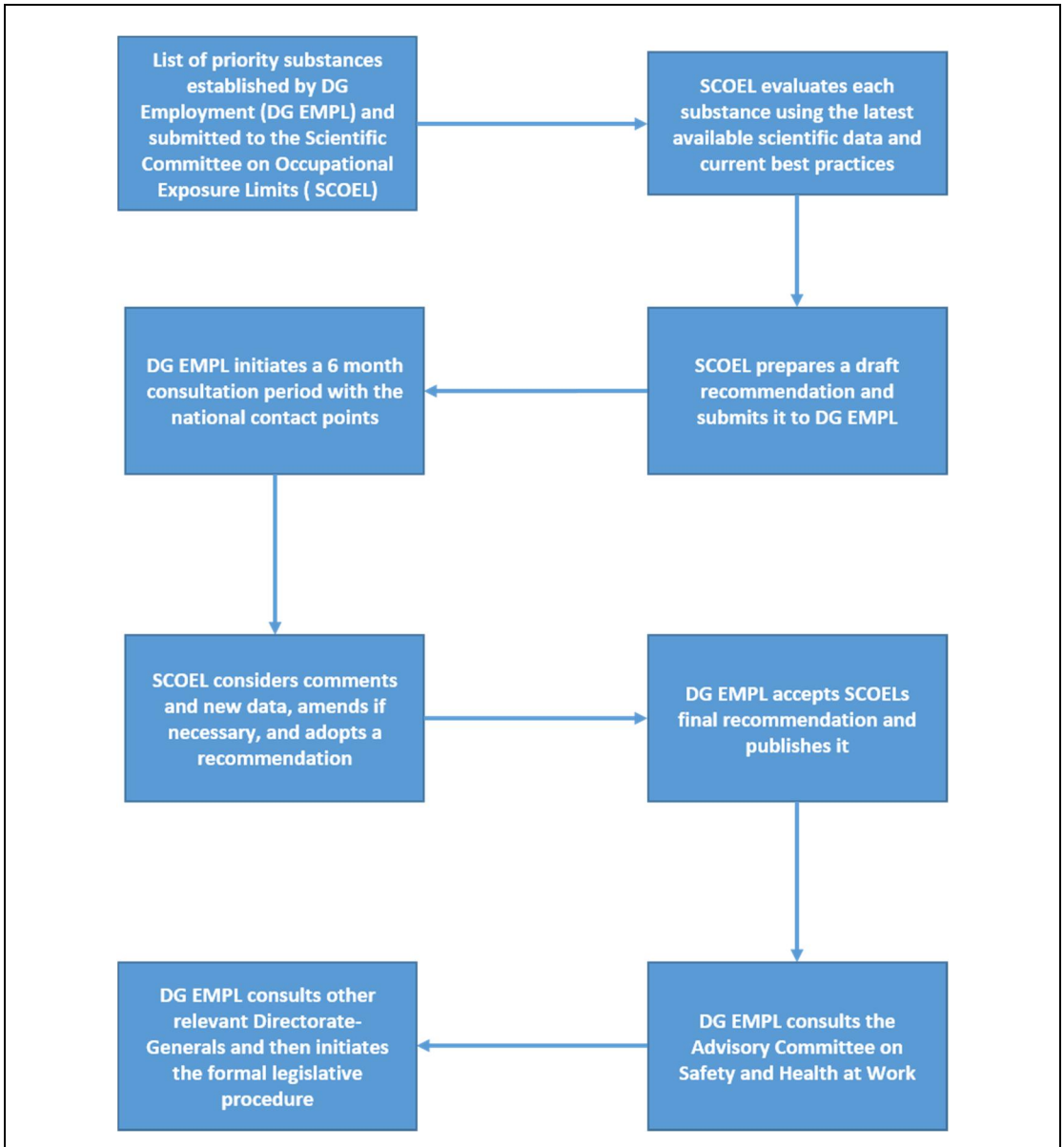


Figure 5-1: SCOEL's involvement in setting Occupational Exposure Limit Values
Source: http://*ec.europa.eu/social/BlobServlet?docId=3879&langId=en*

Figure 5-2: The formal legislative procedure for developing EU OELVs
Source: http://*ec.europa.eu/social/BlobServlet?docId=3879&langId=en*

5.5.1.2 Thresholds for waste versus OSH

One Member State has identified a lack of coherence in the regulation of wastes contaminated with asbestos. They believe that there is a gap in this as there are one set of thresholds given for OSH legislation in order to protect human health and higher thresholds given for waste legislation. This

difference in thresholds needs to be explained and if possible one set of thresholds should be developed for both the exposure of workers to asbestos and the disposal of waste asbestos.

5.5.1.3 Thresholds for PBT / vPvB

No concentration thresholds exist for PBT/vPvB in biocidal products and plant protection products as in both cases active substances, safeners and synergists used in these products that fulfil (the relevant) PBT/vPvB criteria shall not be approved. However, in the case of biocidal products, derogations from non-approval of active substances are possible. These are (in line with Article 5.2 of the Biocidal Products Regulation):

- The exposure during normal and foreseeable use is shown to be negligible;
- The use is essential for pest control (i.e. there are no or too few alternatives to prevent resistance); and
- Non-approval would result in disproportionate societal disadvantages.

REACH establishes that PBTs/vPvBs in mixtures should be identified in the SDS if included in concentrations above 0.1%. Communication requirements according to REACH Article 33 also are triggered above a concentration limit of 0.1% in articles. Thus, REACH sets higher thresholds for action than the Biocidal Products Regulation or the Plant Protection Products Regulation. Some have questioned these concentration thresholds in terms of their environmental relevance, because the total load rather than the concentration in a product is the driver for the extent of potential environmental damage.

Under the Water Framework Directive, Environmental Quality Standards (EQS) are defined for substances in Annex X; these are derived from effects data, based on expert judgement and submitted to a political agreement process for each substance individually. This approach for defining EQS for PBTs/vPvBs could be questioned, as the overall paradigm based on the precautionary principle for PBTs/vPvBs is that no safe exposure levels can be defined. However, due to background concentrations of substances and the need for an RMM trigger, the approach may be considered valid. However, NGOs have questioned this approach, with respect to the extent that it ensures the objectives of the chemicals legislative framework are being met.

5.5.1.4 Thresholds for CMRs

As noted earlier, concern has been raised by the range of stakeholders with regards to one of the conditions for derogation of the use of CMRs in toys:

> "*Substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:*
>
> - *these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances*;"[63]

[63] Point 4, Part 3, Annex II of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys

This also applies to substances and mixtures of the categories laid down in Section 4 of Appendix B of the Toy Safety Directive. The limit values given for CMRs under CLP are given in Table 5-4. These are generic concentration limits for a mixture classification, which were not derived with the aim of protecting children (they are based on adults). As children are more susceptible to the effects of CMRs due to their body weight and behaviour, the limits are considered by many stakeholders as reflecting an unacceptable level of risk. Many are of the opinion that whilst these generic concentration limits may be applicable to some CMRs, they will be too high for others which will pose a risk at concentrations below that concentration. One Member State is also of the opinion that there should be no limit value to exempt a CMR from the ban in toys as children are exposed from so many other sources that toys should not contribute to this. The general consensus is that the Toy Safety Directive needs precautionary limit values due to the legislation being concerned with a vulnerable population.

Table 5-4: Generic concentration limits for classification of mixtures				
Ingredient classified as	Concentration limits triggering classification of a mixture as:			
		Category 1A	Category 1B	Category 2
Category 1A	Carcinogen Mutagen Reprotoxin	≥0.1% ≥0.1% ≥0.3%		
Category 1B	Carcinogen Mutagen Reprotoxin		≥0.1% ≥0.1% ≥0.3%	
Category 2	Carcinogen Mutagen Reprotoxin			≥1% ≥1% ≥3%
Note: There is an additional category based on the effects on or via lactation from reprotoxins which lies at ≥0.3%				

The comitology in which a specific limit value can be introduced into Appendix C of the Toy Safety Directive is considered to be a useful action, although this has been criticised for the fact that it only extends to children under the age of 36 months and for toys intended to be placed in the mouth. Several stakeholders are of the opinion that this provision should be extended to apply to all children, regardless of age, given that it is hard to place an age limit on the mouthing behaviour of children (which can continue well into the teens). Member States have also expressed an interest in the level of lead in toys being reduced as they believe that the current allowable limit remains too high.

5.5.2 Consistency in risk assessments

5.5.2.1 Risk assessment methods

Risk assessments carried out under the EU chemicals legislative framework generally follow the steps set out below, although there may be differences in the application between different scientific and technical committees and agencies depending on the sector of use of the substance.

1. Hazard identification – identify the effects of concern and determine or review classification.
2. Hazard characterisation – estimation of the relationship between the dose (level of exposure) and the incidence and severity of the effect. This can be referred to as the dose-response.
3. Exposure assessment – estimation of the concentrations/doses to which a population or environmental compartment is or may be exposed.

4. Risk characterisation – estimation of the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance. This may include risk estimation (the quantification of the likelihood). Where relevant, combined exposure to multiple chemicals and dietary risk assessment should be considered.

In particular, the populations and effects examined will differ depending on the sector and which is responsible for conducting the risk assessment. It is the view of Member State authorities that the common parts of a risk assessment should be harmonised across all pieces of legislation, while retaining specificities in cases where the use will make a clear difference to the risk.

For example, those which are carried out under the Biocidal Products Regulation must examine the potential toxic effects via exposure by inhalation, oral and dermal routes. This includes CMR related effects, acute toxicity, irritation, corrosivity, sensitisation and repeated dose toxicity, for professional users (and industrial workers, non-professional users (including the general public), and humans exposed via secondary pathways.

Cosmetic products require a Cosmetic Product Safety Report in order to demonstrate that the product complies with Article 3 of the Cosmetic Products Regulation. The risk assessment involved for each ingredient contained in the product follows the risk management process described above. During risk characterisation, a Margin of Safety (MoS) is used to evaluate the risk of threshold compounds, with an ingredient considered to be safe if the MoS≥100[64]. This is applicable to cosmetics intended for use by children. The weight of evidence (WoE) approach can be used in this process[65].

For plant protection products, risk assessments must be carried out for all scenarios of exposure of operators, workers, residents and bystanders that can be expected to occur as a consequence of the proposed uses of the product. Adverse effects of pesticides are currently assessed and regulated on a single substance basis, even though it is quite possible that humans will be simultaneously exposed to more than one pesticide, particularly through their diet. EFSA guidance says that most exposure scenarios can be expected to fall into the category for which a standardised first tier exposure assessment can be applied. Scenarios which are not covered by these standardised methods will need to be subject to an *ad hoc* (higher tier) approach. Where a higher tier exposure assessment is used, this must be justified.

The decision on which type of risk assessment is required will depend upon who is expected to incur exposure as a consequence of the intended use of a PPP and whether the PPP has potential for systemic toxicity from exposure during a single day[66]. No risk assessment is required for bystanders if the PPP does not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Table 5-5 provides an outline of which form of risk assessment is required. Standardised first tier methods of exposure assessment are to be used where available in order to assess potential daily exposures.

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[64] CIRS (2015): Guidelines on Safety Risk Assessment of Cosmetic Products (Draft) Issued in China for Public Comments. Available at: http://www.cirs-reach.com/news-and-articles/guidelines-on-safety-risk-assessment-of-cosmetic-products-(draft)-issued-in-china-for-public-comments.html

[65] Article 10(1)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

[66] EFSA (2014): Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

Exposures may be combined where an operator will be performing more than one operation during use, with risk assessment defined for the most commonly occurring exposure scenarios:

- The type of individual exposed – operator, worker, resident, bystander;
- The type of PPP – e.g. whether it is formulated as a solid or a liquid;
- The operations that will be carried out with the PPP and the equipment that will be used – e.g. mixing and loading; and
- The intended uses.

Ad hoc or higher tier methods can be used where standardised first tier methods of exposure assessment are not available or where *ad hoc* methods are more appropriate. This is normally based on higher tier field studies with a necessary number of subjects. Where a first tier assessment has been deemed inadequate, a higher tier assessment can be used if there is convincing evidence that it will be more appropriate. A tiered approach to risk assessment can also be used for combined exposure to multiple chemicals.

Table 5-5: Risk assessments that may be required for PPPs

Exposed group	PPPs with no potential acute systemic toxicity	PPPs with potential for acute systemic toxicity
Operators	L	A, L
Workers	L	A[(a)], L
Residents	L	L (A covered by bystander)
Bystanders	L (covered by residents)	A

[(a)]An acute assessment is in principle needed but in the current Guidance insufficient data are available to perform it

A – acute risk assessment, L – longer term risk assessment

Source: EFSA (2014): Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

5.5.2.2 Consistency across scientific committees

Although the overall framework for risk assessment is similar across the legislation, as different pieces of legislation deal with different sectors and users, the methods of assessment may vary in practice, with this raised as an issue by industry and authorities.

In interviews, relevant industry associations raised what are considered to be inconsistencies in the assessments employed for approval of CMRs, especially between EFSA and the RAC. Another example is given with respect to the SCCS which has the knowledge and experience to carry out assessments of cosmetic ingredients, while the RAC does not and should therefore not be undertaking such assessments under REACH or in relation to biocidal properties.

Member State authorities also commented that, in the case of biocidal products, the risk assessment regarding human health would partly take into account cutaneous applications, which is the core of the exposure assessment of cosmetic products. Member States have commented that due to the differing scope under which risk assessments are undertaken, the variations in the procedures that are adopted give rise to different scientific evaluations for the same substances. As one noted:

> *"…there are examples of differing hazard/risk assessments between different agencies/committees. The different agencies have specific areas of expertise (e.g. EFSA – food safety, ECHA – chemical safety). It seems that a lot of work has been done to improve the exchange of knowledge and to encourage parallel processes, e.g. when it comes to the*

assessment of active substances under the Plant Protection Product and the Biocidal Product Regulations and the subsequent harmonised classifications. Such alignment of the various processes provides a better basis for providing coherent risk assessment. Ensuring better coherence of the work of the different agencies would in most cases be beneficial".

One industry stakeholder has raised the issue that risk assessments are often very precautionary and seem to become more precautionary when guidance is amended. They believe that this has been happening more frequently since the introduction of the Biocidal Products Regulation. This stakeholder suggested that the more frequent amendment of guidance and risk assessment methods may be due to the fact that the responsibility for managing biocides now lies with ECHA.

The use of expert judgement in the risk assessment process has also been criticised by stakeholders as they believe this can be based on assumption and personal belief rather than evidence. There has been a request from one stakeholder that perhaps the risk assessment methods for cosmetic products and toys could be aligned, particularly as some cosmetic products are designed for use by children.

As raised earlier, Member State authorities also believe that there is a gap in the assessment of cosmetic products. They believe that professional users are not given enough weight in risk assessments. This is particularly problematic as professional users of cosmetics are exposed to a far greater degree than those using consumer products.

5.5.2.3 Risk assessment for mixtures

In 2016 the JRC published a scientific paper[67], which reviewed regulatory requirements and recent case studies to illustrate how the risk assessment of chemical mixtures is conducted, considering both human health and the environment. It concluded that that regulatory requirements for the risk assessment of mixtures across various regulatory frameworks is scarce. The authors indicated that the assumptions made in the risk assessment, predictive model specifications and the choice of toxic reference values can greatly influence the assessment outcome, and should therefore be specifically justified. Also, novel tools could support mixture risk assessment mainly by providing a better understanding of the underlying mechanisms of combined effects. In this respect, it is understood that the JRC are currently developing case studies and practical guidance to support the assessment of combination effects across different regulatory sectors.

[67] Kienzler, A., Bopp, S., van der Linden, S., Berggren, E., Worth, A., (2016), Regulatory assessment of chemical mixtures: Requirements, current approaches and future perspectives. Regulatory Toxicology and Pharmacology.

6 Risk Management Approaches

6.1 Introduction

As outlined in the fitness check roadmap, there are two basic principles to risk management:

- Risk management based on generic risk considerations whereby substances are automatically banned or automatically subject to specific measures such as substitution or use in a closed system. This covers Possibility 1 in our mapping; or

- Risk management based on a specific risk assessment approach whereby a risk assessment is carried out on the substance before its conditions for use can be decided upon. This covers Possibility 2, assessment carried out by EU agencies, and Possibility 3, assessment carried out by Member States or an operator.

The ban on CMRs under the Biocidal Products Regulation, Plant Protection Products Regulation, Cosmetic Products Regulation and the Toy Safety Directive are examples of a generic approach to risk management; it is the classification under CLP that causes risk management measures to be triggered, with these attached to any substance that bears a CMR classification. An example of the specific risk assessment approach is that in the Chemical Agents Directive where, under Article 3, the Commission is required to evaluate the relationship between the health effects of hazardous chemicals and the level of occupational exposure by means of an independent scientific assessment and to propose European IOELVs for the protection of workers.

Depending on the piece of legislation, there may be a combination of approaches. Although there is an automatic ban on the use of CMRs in biocidal products and plant protection products, this ban is not applicable to all substances that have been given a CLH under CLP, only those with a CLH for C, M or R. For all substances that fall under these two pieces of legislation, a risk assessment is required in order to gain approval for sale and use, which would bring these pieces of legislation under the specific risk assessment approach, as well as the generic approach to risk management for CMR properties. With respect to PBT properties, the generic approach applies.

For those pieces of legislation which have based risk management on generic risk considerations through the automatic ban of a substance due to its CLH, there may be a possibility for derogation or exemption once a further assessment has been carried out. This means that the risk management approach in certain cases is based on a combination approach. An example of this would be for CMR substances in cosmetic products, where, although these substances are automatically banned, they may be approved for use if they meet the derogation criteria.

Table 2-1 in Section 2 outlined the risk management approaches taken by the pieces of legislation of concern in this task. These approaches are analysed in more detail here.

As a starting point, there is general consensus that hazard classification under the CLP Regulation is a good basis for risk management decision making, whether through a generic approach or a specific risk based approach. All stakeholders (industry, NGOs, Member States, Commission services) believe that a CLP hazard classification is the most appropriate starting point for establishing the overarching criteria to be referred to and on which a risk management decisions should be based.

6.2 Effectiveness of risk management measures

Key findings:

- Stakeholders believe that different pieces of legislation should use different risk management approaches as they depend on different uses and subsequent exposure scenarios.
- Stakeholders, in particular Member States, believe that if there was a harmonised approach to risk management across the chemicals legislative framework then all populations would be covered as their exposure to harmful chemicals would be restricted on all levels.
- For substances that are considered to be SVHCs, such as CMRs; PBTs; vPvB or EDCs, it is considered by NGO stakeholders to be appropriate to employ risk management based on generic risk consideration as this is considered to be the most timely approach for removal of hazardous substances from the market. Member States have mixed views on this but it is acknowledged that it is a more timely approach. There is a concern regarding the loss of substances for which exposure is negligible and therefore poses little risk.
- Although industry believes that the automatic approach is timely, the majority are not of the opinion that risk management based on generic risk consideration is appropriate as they have raised concern with the unnecessary removal of substances and removal of essential substances.
- Substitution is considered to be key to achieving a high level of protection of human health and the environment and stakeholders believe that it should be incorporated across the entire legislative framework.
- Risk management based on generic risk considerations appears to result in swift risk management through the automatic restriction of the use of substances with certain hazard classifications, particularly CMRs and the subsequent PBT, vPvB and EDC classifications, but it may also result in significant impacts on industry, consumers and society. It may also impact on the competitiveness of the EU by removing substances which do not pose significant risks in use, and hinder innovation.
- Risk management based on specific risk assessment can be dependent on a lengthy assessment process and expert judgement in the peer review, but is more precise, taking into account the exposure scenario and risk of the specific substance.

Many of the preceding sub-sections have made points regarding the effectiveness of risk management measures, as this is linked to views on whether or not automatic triggers are appropriate, whether the appropriate factors are taken into account in risk management decision-making. These arguments are not repeated here. More general considerations are addressed instead, with the relevant evaluation questions set out in Table 6-1 below.

Table 6-1: Effectiveness of risk management measures

Q #	Evaluation questions
1.3.6.	To what extent do the two different risk management approaches applied in the chemicals legislation provide for high level of protection of human health and the environment?
1.3.7.	Where trade-offs are made between the different objectives of the chemicals legislative framework in the implementation of the legislation, do these trade-offs influence the effectiveness of the legislation? Are these trade-offs based on sufficient/appropriate analysis? Do such trade-offs generally go in any particular direction (e.g. towards protection of health and environment or towards the functioning of the internal market)?
2.1.5.	What are the total socio-economic costs/benefits for society resulting from approaches mainly

Table 6-1: Effectiveness of risk management measures	
Q #	**Evaluation questions**
	based on generic risk considerations and from specific risk assessments?
2.2.6	Are the risk management measures adopted efficient?
2.2.6.1.	Are the adopted risk management measures precise and clear enough?
2.2.6.2.	Are they easy or burdensome to put in place?
2.2.6.3.	Are the transition times for duty holders upon the adoption of the new risk management measures adequate?
3.1.5.	In particular, to what extent does the chemicals legislative framework lead to substitution of hazardous chemicals with safer alternatives or technologies where justified by human health, environmental and socio-economic considerations (e.g. by providing mechanisms and procedures for this purpose)?
2.2.6.5.	Are the risk management measures triggered at adequate time after identification of early signals of potential risks?
1.3.5.	To what extent do the two different risk management approaches applied in the chemicals legislation provide for predictability of the decisions?
1.3.3.	Which factors were taken into account in identifying the appropriate risk management approach, whether based on generic risk considerations or specific risk assessment (e.g. characteristics of the substance, exposure, vulnerable groups, legal certainty and predictability, transparency, flexibility, enforceability, costs/benefits for public authorities, costs/benefits for industry, costs/benefits to society)? Were these factors appropriately considered? Are any factors missing?
3.2.3.	To what extent are socio-economic consequences with relevance for citizens and stakeholders taken into account in the implementation of the legislative framework?
3.3.1.	To what extent do the risk assessment procedures and risk management decisions take into account the latest scientific findings?

6.2.1 Contributing to a high level of protection

As mentioned at the beginning of this section, the hazard classification under CLP is considered to be an appropriate starting point for risk management decisions. One Member State noted that "*we approve of the importance of having a uniform approach to the hazard assessment of substances and mixtures using the criteria of the CLP Regulation as a starting point. The hazard assessment forms the basis for the subsequent risk assessment under different use conditions (in specific products, articles etc.) and e.g. for setting emission and quality standards for air, water, packaging etc. We consider that both the generic and specific approach is required and that the hazard assessment is key to both approaches*".

Table 6-2 sets out the views of Member States responding to targeted consultation on the extent to which the risk management approaches adopted under the different legislation is meeting the objective of a high level of protection for human health and the environment. As can be seen from the table, views are generally positive.

Member States also acknowledged that it is not possible for single pieces of legislation to address all populations (within human health, animal health and the environment) as they tend to be concerned with one group, such as cosmetics being linked to the protection of consumer health. They believe that if there was a harmonised approach to risk management across the chemicals legislative framework then all populations would be covered as their exposure to harmful chemicals would be restricted on all levels, e.g. the Cosmetic Products Regulation dealing with consumer health, OSH dealing with workers health in the cosmetics industry.

Similarly, an environmental NGO indicated that "*hazard and risk needs to coexist in EU regulation in order to have efficient and protective chemicals legislation, where a substance should primarily be regulated based on hazard, while an authorised use of the same substance should be based on risk*".

Table 6-2: Member States authority views on the extent to which the current approaches to risk management ensure a high level of protection for human health and the environment? (n=14max)

Name of Column 1	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Don't know
Regulation (EC) No 1223/2009 on cosmetic products	0%	22%	11%	33%	11%	22%
Directive 2009/48/EC on the safety of toys	0%	13%	25%	25%	0%	37%
Regulation (EC) No 66/2010 on the EU Ecolabel	0%	0%	0%	50%	0%	50%
Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	0%	0%	14%	14%	0%	72%
Regulation (EC) No 1107/2009 on plant protection products	0%	0%	0%	66%	11%	22%
Regulation (EU) No 528/2012 on biocidal products	0%	0%	0%	64%	27%	9%
Directive 2014/68/EU on pressure equipment	0%	0%	14%	14%	0%	72%
Seveso III Directive (2012/18/EC)	0%	0%	14%	86%	0%	0%
Directive 2008/98/EC on Waste	0%	17%	17%	50%	0%	17%
Directive 2010/75/EU on industrial emissions	0%	0%	40%	20%	0%	40%
Directive 1999/31/EC on the landfill of waste	0%	17%	17%	33%	0%	33%
Directive 2000/53/EC on end-of-life vehicles	0%	14%	14%	29%	43%	0%
Regulation (EC) No 1013/2006 on shipments of waste	0%	0%	50%	25%	0%	25%
Directive 2004/35/EC on environmental liability	0%	0%	20%	0%	0%	80%

They also suggest that companies benefit from hazard-based regulation as it helps them in prioritising what chemicals to focus on and to work towards substitution, making it a driver of innovation and inherently safer products. Other NGOs are of the opinion that derogations may undermine the high level of protection and they should be removed as they violate the rules of the precautionary principle. Where derogations do exist, it is suggested that it may be appropriate to introduce review periods to assess whether or not the derogation should continue, as advances in science may mean that an alternative has become available.

As part of the targeted consultation, workers representatives were asked whether the provisions outlined in the Plant Protection Products Regulation for restricting the use of active substances in PPPs that are classified as CMR category 1A or 1B are adequate to protect workers. Respondents suggest that the ban on CMRs as active substances in pesticides is good in principle; however, there are numerous derogations and potential misuse by some Member States. It is argued that derogations need to be exceptional. Similar remarks were made with respect to the provisions in the Biocidal Products Regulation for restricting the use of biocidal products that are classified as CMR category 1A and 1B. In this case, the exclusion criteria for active substances are good but there

are the exceptions, for example, some CMRs 1A/1B are used as active substances in wood preservatives or for control of rodents. It is important to put these comments in context, as most of the derogations being referred to will have been decided under the preceding directives for plant protection products and biocidal products.

With regards to derogations from automatic bans under the generic approach, industry opinions are split as to whether they are appropriate for maintaining a high level of protection to human health and the environment. It has been suggested by an industry association stakeholder that the Plant Protection Products Regulation should contain a derogation based on potency. Currently CMR classification does not consider potency, especially in relation to carcinogens. The use of potency would assist in the ability to determine the degree to which a substance may cause cancer, thus providing significant additional information on which risk assessment and management could be made.

It is of note that where trade-offs are made between the different objectives of the chemicals legislative framework, these can result in less environmental protection in favour of an increase in protection of human or animal health (derogations for biocides, authorisation of medicinal products). One authority commented that "considering the environment, many aspects of analysing such trade-offs appear to be in need of more transparency, consistency and more balanced considerations. More focus on the benefits of regulations for the environment is needed. In order to better describe such benefits, methods need to be developed".

6.2.2 Substitution with less hazardous alternatives

Substitution is considered to be a key risk management measure in protecting human health and the environment, although the requirements for substitution vary across the chemicals legislative framework. The majority of the pieces of legislation (Biocidal Products Regulation, Cosmetic Products Regulation, Food Contact Materials Regulation – plastics, Plant Protection Products Regulation, Toy Safety Directive, Ecolabel Regulation, Industrial Emissions Directive, Carcinogens and Mutagens Directive, Chemical Agents Directive) considered here involve substitution of hazardous chemicals in order to protect human health and the environment. However, the strength of the impetus for substitution varies.

Under the Carcinogens and Mutagens Directive, carcinogenic or mutagenic substances should be replaced so far as is technically possible. If this is not technically possible, the carcinogen or mutagen has to be manufactured and/or used while working in a closed environment. The use of a substance is permitted as long as workers' exposure does not exceed the relevant BOELV. Under the Chemical Agents Directive, risks must be reduced to the minimum level achievable. Meanwhile, under REACH, substitution must be considered by those applying for the authorisation of the use of a substance of very high concern (SVHC) a SVHC does not refer only to health risks, but also risks to the environment. Therefore, the scope of substitution on this basis is broader than that required under the OSH directives. Some consultees indicated that this adds further complexity for employers.

Other consultees note that substitution should be included as a risk management measure across all pieces of legislation, and that this is an issue that the Commission should consider further. It has also been suggested that substitution should be encouraged more, perhaps by financially supporting research into alternatives, as this is a timely and expensive process.

6.2.3 Clarity of risk management and ease of circumvention

The generic approach to risk management appears to result in clear and precise risk management through the automatic restriction on the use of substances with certain hazard classifications, particularly CMRs and the subsequent PBT, vPvB and EDC classifications. The legal texts clearly set out which hazard classifications are restricted and subject to an automatic ban. With regards to PBTs and vPvBs, market restrictions are precise and clear, relatively easy to implement (although the search for alternatives can be more difficult and costly due to the resources required) and enforceable. Conditions of use included in product authorisations are less easy to implement.

The specific approach to risk management can result in less clarity as risk management decisions are dependent on a lengthy assessment process and expert judgement in the peer review following a risk assessment. This is not considered a negative by industry, which prefers the risk based approach to risk management, as they believe it allows the true risk to populations of concern to be taken into account, as opposed to the hazard based approach which removes substances without assessing their exposure and subsequent risk.[68]

The Cosmetic Products Regulation is one of the few pieces of legislation that has been brought to our attention as having issues with respect to the clarity for risk management. This is related to the timeframes for the automatic ban on CMRs in cosmetic products, which has been discussed in previous sections and has now been clarified by the Commission.

6.2.4 Predictability of risk management decisions

There is no general consensus on the predictability or consistency of risk management decisions. Stakeholders have highlighted positives and negatives in the predictability of the outcome of decisions under certain pieces of legislation.

A generic approach to risk management can be considered to be more predictable than a specific risk approach as the risk management decision is clear and is not dependent on further assessment. RMM decisions under the Biocidal Products Regulation and Plant Protection Products Regulation are predictable because they are based on an identified status for intrinsic properties, e.g. PBT/vPvB. Under the OSH legislation considered in this task, it is clear what risk management measures must be undertaken in order to protect workers' health. Predictability is not an issue as certain classifications will require certain actions, such as a C or M classification requiring an employer to implement risk management according to the hierarchy of risk management measures.

Predictability of risk management decisions can be more difficult when it requires the input of a committee. The transparency of committees can be key to predictability but, as noted earlier, stakeholders have raised concerns over the predictability of decisions arising from committee opinions, especially across committees. They are of the opinion that a decision on safe use will be

[68] As part of the open public consultation, CLEAPSS indicated that they believe that the framework is generally balanced, however they suggest that it needs to allow for small-scale uses involving low risks of exposure of chemicals that pose relatively low risk. They suggest that the current emphasis tends to cause unnecessary alarm in situations where the real risk is relatively low and that this may lead to disproportionate attention being given to such risks, masking and diluting the need to consider and control more-significant risks. CLEAPSS is the Consortium of Local Education Authorities for the Provision of Science Services (CLEAPSS) is an advisory service that works with all local authorities in the British Isles (excluding Scotland) providing support in science and technology.

dependent on the committee composition. Different experts will bring with them different expertise and opinions on how to interpret data and, as a result, the decision on safe use will vary. If two committees have different members but are formulating an opinion on the same substance, then there is the possibility that they will not formulate the same opinion (with examples given in Case Study 3). In addition, derogations and results from cost-benefit analysis (medicinal products for veterinary use) are less science-based and (may) involve societal considerations, including the weighting of protection goals and making trade-offs. This is regarded as less transparent (metrics and process) and therefore, less predictable, by industry and NGO stakeholders.

PPPs and biocidal products require approval before an active substance can be used and authorisation before a product can be placed on the market. As discussed, the automatic ban in both the Plant Protection Products Regulation and the Biocidal Products Regulation based on the CMR exclusion criteria can be overturned through derogation. Under the Plant Protection Products Regulation, a carcinogen or reprotoxin can be approved if:

> *"the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005 (on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC)"*[69].

Stakeholders have an issue with the term "negligible" as this has not been defined and they do not know what the justification for a decision based on negligibility would be. This is both an issue with the clarity of the legal text and the transparency of decision making within the committee process for approval of active substances in pesticides, both of which are considered to lead to a lack of predictability in risk management decisions.

Another inconsistency of concern in this case is the potential for differences in EFSA and RAC opinions on classification. It would appear that there may be the possibility that EFSA would not classify a substance as a mutagen 1A or 1B but classify it as a carcinogen instead, meaning that a substance which may be considered by the RAC to be mutagenic would be allowed a derogation under the Plant Protection Products Regulation for carcinogenicity. This potential inconsistency in classification has been raised before, under the discussion on processes and procedures (see also Case Study 3), but it is of concern here in relation to the rules for derogation under the Plant Protection Products Regulation and what these imply for consistency in risk management.

The term "negligible" also appears in the Biocidal Products Regulation for the exemptions of CMRs, EDCs and PBTs. As in the case of the Plant Protection Products Regulation, this term is not defined and so stakeholders are unclear what this actually means. There is the addition of "in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment", although it is unclear whether this is considered to be the definition of "negligible".

The impact of interactions between numerous pieces of legislation may also have an effect on the predictability of risk management decisions. Risk management decisions under the Water

[69] Paragraph 3.6.3 and 3.6.4 of Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Framework Directive are not easily predictable, because of the various (legal) instruments that could be employed, including River Basin Management Plans.

As noted above, the specific risk assessment approach can be lengthy and it is difficult to predict what the outcome will be as it is based on the interpretation of a range of results rather than an already established criterion (the intrinsic properties of a substance that has led to a classification).

6.2.5 Factors taken into account in risk management decision making

Key findings:

- Risk management based on generic risk considerations is triggered only by the intrinsic properties of a substance. Risk management based on specific risk assessment will depend on a number of factors. Of the seven pieces of legislation considered in Case Study 11, socio-economic factors are only considered in the Biocidal Products Regulation.
- There is no general consensus on whether the costs to industry and society are given enough weight, with differing views from industry, Member States and NGOs. Member States and NGOs appear to agree that costs to society are not given enough weight in risk management decision making.
- Vulnerable populations are not explicitly mentioned in risk management based on generic risk considerations but the approach aims to protect all populations through the outright and automatic ban on a hazardous substance.
- The specific approach and the further assessment for derogation may or may not differentiate between the general public and vulnerable populations. This is dependent on the sector. The Toy Safety Directive and the Cosmetic Products Regulation pay particular attention to vulnerable populations and they are explicitly mentioned in the legal texts.

6.2.5.1 Socio-economic factors

The factors taken into account in risk management decision making are dependent on the approach to risk management. As the generic risk management approach is based on a hazard classification, there is therefore no consideration of the socio-economic impacts of the RMM. Socio-economic factors are considered in derogation for the Biocidal Products Regulation, but they are not present in derogations or exemptions in the Cosmetic Products Regulation, Toy Safety Directive, Plant Protection Products Regulation, Food Contact Materials Regulation.

As discussed in Task 1, some commentators believe that socio-economic factors should be taken into account in the CLH process under CLP, although others (the majority) are of the opinion that this should be covered in the downstream legislation and the CLH process should remain hazard based. Suggestions that have been put forward by stakeholders in order to enable socio-economic issues to be raised before risk management decisions are considered under downstream legislation are: greater use of RMOA, including a mechanism for SEAC opinion-forming, provide a concrete step for submission of data to the Commission, or include a new risk assessment/ socio-economic step prior to the triggering of downstream legislation. In order to retain the scientific basis of the CLH process, one option could be to revise as appropriate the linkages between the CLP (and a CLH decision) and downstream legislation, by introducing further risk assessment steps or enabling socio-economic factors to be better taken into account (regardless of whether any of the above are also implemented).

The specific approach to risk management is based on scientific evidence via a risk assessment of the substance of concern. As discussed in Section 5.5.2, the risk assessment examines the intrinsic properties (hazard) of the substance combined with the exposure of populations to that substance. In some instances, socio-economic impacts may be taken into consideration but this is not standard practice across all of the chemicals legislation.

There are some derogations from the automatic bans that consider socio-economic impacts. Under the Biocidal Products Regulation, Article 5(2) requires evidence to meet one of the derogation criteria in order for the derogation from the automatic ban to be granted. Two of these criteria are based on the socio-economic impacts. A derogation may be granted if:

- It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

- Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

The first point is not considered to be a direct assessment of the socio-economic impact of the ban on CMRs, but it does examine the impact of the ban through considering the prevention or control of a serious danger. An example of this would be that of the impact on farmers as a result of not preventing or controlling a serious danger to animal health. As animals are a product for farmers to trade, e.g. as meat or dairy, the consequences of not protecting them and subsequently compromising the health of livestock are clearly socio-economic as well as animal welfare based.

The second point is a direct link to the socio-economic impact of removing a substance from the market based on its hazard classification. The Biocidal Products Regulation is the only piece of legislation analysed for this task that includes a derogation based on socio-economic considerations, and this is considered to be a gap by many of the stakeholders: industry, civil society and Member States. The Plant Protection Products Regulation does not have a similar derogation and justification for this cannot be found. If a pesticide is removed from the market due to its hazard classification with no consideration of the socio-economic impacts of that ban then there may be unforeseen consequences. Pesticide resistance is a significant problem and there may be cases arising where only one pesticide product is suitable for a particular use. If this is the case, then there can be considerable impacts on crop yields, for those crops which cannot be adequately protected by the pesticides that are available; as such, there can be direct impacts on market actors and food security. This lack of a socio-economic derogation for pesticides appears at odds with the ability to gain such a derogation under the Biocidal Products Regulation.

Industry stakeholders are of the opinion that the impacts on manufacturers, downstream supply chains and consumers are not adequately taken into account in most of the risk management decision making processes considered here. One industry association stakeholder opined that "*the way regulations operate now is over protective and as such, valuable substances, the essential tools for farmers, are being lost and thus putting EU farming at a disadvantage in the global market*". Another stakeholder has commented that "*if society wants affordable food commodities all year round then the continued use of PPP is essential and necessary. To realise a sustainable agricultural market in Europe, farmers must be allowed the tools to deliver crops competitively in a global market*". Although there is a need to use PPPs in certain situations where they are essential in order to protect crop yields and maintain food security, there needs to be a balance and where a hazardous substance can be replaced by an alternative substance with a lower or no hazard then this should be the case.

An example of the consequences of an automatic ban is given by the example of ethanol, which is used in a variety of sectors, particularly as an industrial solvent and in many mixtures intended for consumer use, e.g. skin and surface detergents in hospitals and private households, detergents and cleaning products and in cosmetic formulations. Box 6-1 provides a summary of issues identified by industry in relation to ethanol. As discussed under the Task 1 report, if it is possible to differentiate routes of exposure in hazard classes and then in the downstream legislation then, where there is only one route of exposure which is of concern this could be taken into account better. This may help to combat unwarranted impacts from the removal of a substance such as ethanol because of a generic hazard classification.

Box 6-1: Issues raised by risk management based on generic risk considerations– ethanol example

There are studies that provide evidence of the carcinogenic and reprotoxic effects of ethanol via the oral route of exposure. These studies are largely based on the consumption of ethanol as a beverage. Oral exposure is expected primarily in the consumption of foodstuffs and so it can be ruled out for all other consumer practices and products, professional use and occupational health and safety. Inhalation and dermal exposure are the pathways of concern for all other uses except from use in a foodstuff. Even though there is not expected to be any oral exposure to ethanol under the scope of EU chemicals legislation, it may be classified as a carcinogen pursuant to Annex I, point 3.6.2.1 of CLP whereby a classification can be made based on only one route of exposure "if it can be conclusively proved that no other route of exposure exhibits the hazard". As such, ethanol would be classified as carcinogenic based on oral exposure even though it is not relevant.

From our targeted consultation it is clear that some stakeholders from across industry sectors believe that the cost, resources and use conditions which would arise as a legal consequence of a C, or R classification for ethanol would be disproportionate to the risk posed by the use of ethanol outside of foodstuffs and medicinal products. This classification is also not considered to raise the protection of human health. It has been found that in 2013 60 million hectolitres were produced in the EU and 7 million hectolitres were imported. Only around 10% of this was used in foodstuffs meaning that the impact of a classification would be great on other sectors.

If ethanol was to be given a CLH for carcinogenicity 1A or reprotoxicity 1A it would be banned under numerous pieces of legislation, including cosmetics, and would meet the exclusion criteria of the Biocidal Products Regulation. It would also be subject to the conditions of OSH legislation, including the Carcinogens and Mutagens Directive. The result of these classifications would be the need to substitute ethanol in products and processes. This is not always possible as ethanol has different functions in different fields. Ethanol is obtained from renewable resources (from fermentation or agricultural raw materials) and it should be noted that where substitutions are available, it would be replaced by a petrochemical solvent which will have its own human health and environmental impacts. Where substitution is not possible, companies would need to employ other forms of risk management from the risk management hierarchy of the Carcinogens and Mutagens Directive, all of which incur costs. Dermal and inhalative exposures of workers to ethanol is below critical ethanol concentrations and so are not considered to be a risk to workers, even so, the OSH legislation would have to be adopted in light of a C or R classification.

If ethanol was to be classified as a carcinogen category 1A or reprotoxin category 1A then it would banned under Article 15 of the Cosmetic Products Regulation. It is possible to get a derogation but this requires considerable workload and cost and the outcome can be uncertain. Ethanol is an important constituent of cosmetic products, particularly skin creams, facial tonics, deodorants, perfumes, sunscreen, oral care products, nail varnishes, mascara and lipstick. The concentrations vary but can be as high as 90% in perfumes, hairsprays and deodorant sprays. In the case of substitutes, there are no substitutes for ethanol in the perfume industry.

Continued overleaf

Box 6-1: Issues raised by risk management based on generic risk considerations– ethanol example

As ethanol is used in so many sectors, the true impacts of a hazard classification for carcinogenicity or reprotoxicity are outside of the scope of this case study. Other sectors that would be impacted include: detergents (professional and consumer); motor fuels; in vitro diagnostic/ medical devices; process solvents and analytics; printing inks and varnishes.

Based on: VCI (2015) Impacts of classification under the CLP Regulation on other pieces of legislation – example ethanol, position paper submitted as part of consultation.

Industry also note that too little weight is given to information on the use of PBTs/vPvBs, the implemented risk mitigation measures and hence 'real world' exposure levels. As a result, there are overprotective risk management decisions which can lead to unnecessary substitution.

From a different perspective, NGOs are of the opinion that costs to society are not taken into consideration in the identification of appropriate risk management, particularly in the case of derogations. They consider the derogations under chemicals legislation to be too lenient and too focused on the benefits to industry, as opposed to the benefits to society (human health, environment, the avoidance of future clean-up costs, etc.). They argue that, if the aim of the European chemicals legislative framework is to protect human health and the environment, then the derogations that are in place to allow the use of hazardous substances, particularly CMRs, should be removed, and a more precautionary approach should be adopted.

Of the seven Member States that responded to this question as part of the targeted consultation, only one believed that too much weight was given to the costs and benefits to industry in risk management decisions. With regards to costs and benefits for society, five out of nine Member States believed that too little weight is given, with the remainder indicating that the appropriate weight is given.

One of the reasons that too little weight is given to the costs and benefits for society could be the difficulty that analysts face in quantifying such impacts for comparison against the costs to manufacturers, downstream users and consumers. Literature review and stakeholder comments confirmed the lack of information on the benefits of risk management decisions linked to CLP classifications, and particularly in the case of PBT/vPvBs. Some cost figures for the clean-up of environmental damage from PBTs/vPvBs, in particular PCBs and older POPs, exist but these do not necessarily reflect the scale of benefits. It is therefore difficult to provide a balanced socio-economic assessment to guide risk management decisions.

6.2.5.2 Vulnerable populations

The consideration of vulnerable populations in risk management decisions has been discussed previously in this report. The generic approach to risk management aims at protecting all populations through the automatic ban of certain hazardous substances. The specific approach and the further assessment for derogation may or may not differentiate between the general public and vulnerable populations. This is dependent on the sector, as indicated in Table 6-3. Toys and cosmetics pay particular attention to vulnerable populations, in particular children.

Table 6-3: Vulnerable populations considered in risk management decisions	
Legislation	**Vulnerable populations taken into consideration**
Regulation (EC) No 1223/2009 on cosmetic products	Children under three years of age, the elderly, pregnant and breastfeeding women and people with a compromised immune system
Directive 2009/48/EC on the safety of toys	Children
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	None listed
Regulation (EC) No 1107/2009 on plant protection products	Pregnant and nursing women, the unborn, infants and children, the elderly, workers and residents
Regulation (EU) No 528/2012 biocidal products	Pregnant and nursing women, the unborn, infants and children, the elderly, workers and residents
Directive 2004/37/EC carcinogens or mutagens at work	No - other OSH legislation protects pregnant workers and young workers
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals (recast)	None listed

In some cases risk management measures are made for the protection of specific populations within a piece of legislation that is designed to protect human health in general. An example of which would be the addition of bitrex to household laundry products and child resistant closures. These aim to protect children from consumer products which are not designed for their use (unlike the Toy Safety Directive) and would present a great danger to their health due to their chemical composition.

However, NGOs commented that vulnerable populations are not given enough weight in risk management decisions. For example, it is particularly rare to see a lengthy discussion on the protection of pregnant women in the case of consumer products (pregnant and breastfeeding women are covered in the workplace by the Pregnant Workers Directive). Similarly, there is a lack of consideration for workers who undertake night shifts, which have been shown to make people more susceptible to the harmful effects of chemicals; this is not, however, taken into consideration in OSH legislation[70].

6.2.5.3 Other factors

An EU association has indicated that hazard correctly addresses the intrinsic properties of a chemical. However, to do proper risk management, hazard should not be considered on its own without consideration of exposure/uses. In addition, for metals some of the criteria used to define hazards (and possible resulting classifications) sometimes miss to take specific aspects of metals and metal compounds and their mixtures (modes of action, bioavailability or fate) into account. They suggest that this could be improved by developing and recognising metal-specific hazard assessment approaches and rules for inorganic substances, and by ensuring that hazard assessment experts in the EU do apply such metal-specific approaches whenever applicable.

[70] It should be noted that the effects of night shifts are not just on the susceptibility of the body to chemical interactions, but also a number of other health effects that are not linked exclusively to work with chemicals.

6.3 Efficiency of risk management measures

Key findings:

- Where the specific risk assessment approach is used, and detailed risk assessments are required, it can take years for these to be completed. As such, the substance will be on the market for longer than it would be if it had been subjected to an automatic ban under risk management based on generic risk considerations.
- Risk management based on generic risk considerations may lead to regrettable substitutions and unintended consequences for industry and society. It may also lead to inefficiencies by banning substances that pose a low level of risk under actual exposure scenarios. A specific risk assessment approach is more targeted and should be more efficient as risk management will be carried out on a case by case basis.
- Derogations may increase the efficiency of the generic risk considerations approach, but only if they also take into account technical feasibility and socio-economic factors.

Table 6-4: Efficiency of risk management procedures	
Q #	**Evaluation questions**
2.2.7.	Are the legislative provisions for risk management measures efficient?
2.2.6	Are the risk management measures adopted efficient?
2.2.8.	Could the same results/effects be achieved in a more cost-effective way?
2.2.9.	Have new tools emerged enabling a more efficient risk management of chemicals? If yes, what are they?
2.2.10.	How easy is it to launch, initiate and complete the necessary procedures to identify and assess hazards and risks of chemicals?

6.3.1 Balance between costs and benefits

A detailed analysis of the costs and benefits of risk management in the chemicals legislative framework can be found in Section 7. Risk prevention is commonly regarded as most effective and efficient if it is implemented from the top-down, e.g. via substitution[71]. Whether or not more cost-effective ways exist to achieve the same goal is difficult to judge because this is likely to differ across different cases and the application/use of a PBT/vPvB, CMR or other hazardous substance. From their perspective, industry stakeholders argue that substitution can be an expensive and resource intensive exercise, especially if new chemistries or technologies are required. Where an alternative already exists, substitution can be a more financially efficient approach to risk management for producers of chemicals, but it may lead to significant additional costs for downstream users, especially when they have to adapt production methods, technologies or cease normal production activities.

In the survey on substitution and assessment of alternatives recently carried out by RPA in the context of the study to support the Non-Toxic Environment Strategy of the European Commission, around 40% of industry stakeholders consulted estimated that over 50% of the substitutions implemented have been with substances that are part of the same functional or structurally similar group. This raises the issue of regrettable substitutions. In order to avoid regrettable substitution,

[71] Oosterhuis and Brouwer (2015): 'Benchmark development for the proportionality assessment of PBT and vPvB substances', Report R-15/11, The Netherlands.

authorities have resorted to grouping approaches to restrict the use of groups of structurally related chemicals. For example, Article 2 of the 1991 Geneva Protocol concerning the control of emissions of Volatile Organic Compounds (VOCs) or their trans-boundary fluxes requires that "*in implementing the present Protocol, and in particular any product substitution measures, Parties shall take appropriate steps to ensure that toxic and carcinogenic VOCs, and those that harm the stratospheric ozone layer, are not substituted for other VOCs*".

Research[72] has found that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure. However, robust comparative risk analyses need a high level of information and can be resource and time intensive. It is also argued[73] that substitutes may not serve the same economic utility as the original chemical, thereby generating other types of risks to human health and the environment. For example, the substitution of lead containing solders in electronic and electrical equipment with lead-free solders had the consequence of creating failures to the board of the components and of operating at higher temperatures, with higher energy consumption. Moreover, lead free solders may need an increased amount of rosin added to the flux, with rosin fumes have been identified as cause of occupational asthma[74].

Automatic bans on hazardous substances also have been criticised as a more expensive form of risk management as they require immediate reformulation of products, although this should not necessarily come as a surprise to industry as there is a degree of forewarning through the tracking systems provided by ECHA, for example. In addition, though an automatic ban would require reformulation, derogations do exist (Cosmetic Products Regulation, Toy Safety Directive, Ecolabel Regulation, Plant Protection Products Regulation, Biocidal Products Regulation) and the risk based approach could also result in reformulation if the substance is found to exhibit an unacceptable risk. Risk assessments will also have associated costs as they can require extensive monitoring, modelling and testing, with the latter being particularly expensive.

Table 6-5 below provides a summary of the legal requirements triggered under legislation as a result of the risk management response to a classification. For CMR substances, there is a ban on their use in consumer products, resulting in costs for reformulation and substitution. This cost to industry should be weighed against the benefit to society of the removal of hazardous substances such as CMRs from products used in daily life. Where derogations exist and are granted, there is the possibility to prevent the removal of a substance and thus eradicate the reformulation and substitution costs. In this respect, derogations based on technical feasibility and socio-economic considerations may be important to ensuring the efficiency of risk management, as well as the extent to which it impacts on competiveness and innovation. Substance specific examples of the impact of risk management on costs and benefits have been provided in Case Study 11.

[72] Abelkop and Graham (2014): Principles and tools of chemical regulation: a comment on 'the substitution principle in chemical regulation: a contructive critique'. Journal of Risk Research, 17(5): 581-586. Available at: http://www.tandfonline.com/doi/full/10.1080/13669877.2013.841742

[73] Lofstedt, R (2014): The substitution principle in chemical regulation: a constructive critique, Journal of Risk Research, 17(5): 543-564. Available at: http://www.tandfonline.com/doi/abs/10.1080/13669877.2013.841733

[74] European Commission (2012): Minimising chemical risk to workers' health and safety through substitution, Part I: Practical Guidance and Part II: Study report on identifying a viable risk management measure', July. Available at: http://ec.europa.eu/social/BlobServlet?docId=9606&langId=en

The TCEP case highlights the potential value of the automatic triggers within the Toy Safety Directive in ensuring the protection of children as a vulnerable population from CMR substances. It appears that industry could move to alternatives, or at least could ensure that concentrations of TCEP in foams were kept below the regulatory threshold set in the Toy Safety Directive. As no applications for authorisation were submitted under REACH, it would appear that industry in the EU has moved away from its use. It is found that the market for toys for mouthing by young children which may contain TCEP is approximately €7.5 million. Removal of the substance may have a negative impact on industry, but as noted earlier, they appear to have found alternatives.

Table 6-5: Summary of legal requirements triggered under different legislation	
Legislation	**Risk management requirements triggered by CMR classification**
CLP Regulation	Changes in labelling, Safety Data Sheets and potentially packaging.
Cosmetic Products Regulation	Withdrawal of substance use from products if no exemption is granted following a risk-based evaluation and for Cat 1A and 1B if there are no suitable alternatives. Specific labelling and any other procedures as determined by SCCS if exempted.
Toy Safety Directive	Withdrawal from the market if no derogation can be granted in line with Part 3 of Annex II.
Regulation on Plastic Materials in Contact with Food	Withdrawal of product from the market if substance is not added to the Union list following a risk assessment; reformulation to meet migration limits may be required.
Regulation on Plant Protection Products	For Cat 1A and 1B, withdrawal of active substance from the market unless exposure is negligible and where residues on food and feed do not exceed default values for maximum residue levels of pesticides; in the case of mutagens, there is no potential exemption.
Biocidal Products Regulation	For Cat 1A and 1B, withdrawal of active substance from market unless exemptions apply based on negligible risk, essentiality, or disproportionate negative impacts on society and the availability of substitutes.
Carcinogens and Mutagens Directive	Hierarchy of measures to be applied, starting with substitution and where this is not technically feasible involving prevention of exposure.
Prior Informed Consent Regulation	Export of a CMR Cat 1A or 1B is not allowed.

In the case of ethanol (see also Box 6-1), the loss of the substance as a result of a CMR classification could have a considerable impact on both industry and the EU economy. Ethanol is a vital ingredient in the cosmetic industry, particularly in the perfumery sector. There is no alternative for ethanol in the perfume industry and this poses a risk to these products. This industry employs 660,000 people directly and provides 940,000 direct, indirect and induced jobs. The direct economic benefits of the perfumery sector is €30 billion. It is not just the cosmetic industry that will be affected as ethanol is also used as a solvent and a biocide. In Germany alone, the market for ready-for-use disinfectants is €50 million; ethanol in glass cleaners is €20 million; and virucidal hand sanitisers is €80 million. In such a case, derogations would be very important, especially as the evidence for carcinogenic effect is via the oral route, which is not a relevant route of exposure for cosmetics or biocides.

The case of gallium arsenide (GaAs) clearly indicates the benefits of the hierarchical approach to risk management under the Carcinogens and Mutagens Directive. As the only alternative to the use of GaAs in the semiconductor industry is not economically or technically feasible, the substitution requirement under the Carcinogens and Mutagens Directive cannot be met. As such industry must meet the lower requirements of the hierarchy, such as use in a closed system. The flexibility of the

Carcinogens and Mutagens Directive reflects the reality of industry and contributes to the efficient protection of human health in the workplace.

6.3.2 Speed of risk management

In terms of the speed of risk management, NGOs and Member States believe that the automatic triggers help to prevent exposure to harmful substances in a fast and efficient way and this is considered to be a benefit. They highlight that the costs of inaction can be high and this needs to be taken into account. There is merit in these arguments, as risk assessment can be a lengthy process and during this period a hazardous substance will remain on the market. However, where automatic triggers exist, the legislation sets legal timeframes for the provision of data to support a risk-based derogation, for example, with this reducing the extent to which any harmful exposures would continue.

A non-industry stakeholder however has suggested that risk management would be more efficient if it was changed from automatic to risk based, as the most cost-effective form of risk management is dependent on a number of factors, including use characteristics and populations of concern.

More generally, industry associations do not consider risk management across EU chemicals legislation to be efficient. They believe harmonisation could be achieved through the use of exposure assessments rather than basing risk management on hazard classification. One authority suggested the introduction of a requirement for industry to carry out Risk Management Option Analyses (RMOAs) for hazardous substances as this would provide the information required to make an informed decision on the risk management measure that should be adopted, and improve the overall efficiency of the system. As previously discussed, NGOs are not happy with this suggestion, as they believe it would introduce more industry bias into the system.

Member State authorities highlighted the difference between OSH legislation and REACH and CLP, indicating that the process of decision making under OSH is different and can take longer than those under other pieces of legislation, it then also requires national transposition. They believe that better use of the data generated under REACH and CLP for OSH purposes, and streamlining between the two systems, could be beneficial to ensuring measures for workers' protection are introduced as quickly as possible. It is of note that the rate of progress made under the OSH legislation, and in particular under the Carcinogens and Mutagens Directive, is highlighted in the OSH fitness check as an issue[75].

Respondents (82%) to the targeted consultation for the plant protection products industry believed that there were aspects of the process for approving/renewing and the use of active substances that could be improved or streamlined. In order for the approval of an active substance to be efficient, stakeholders believe that the classification of an active substance by RAC should take place before the renewal process starts at EFSA. They believe that the assessment of hazardous properties of a substance should occur before establishing the risk assessment and safe use. Where this is not possible, they believe that the processes should run in parallel so that EFSA do not need to be

[75] IOM, Milieu, COWI (2015): Evaluation of the Practical Implementation of the EU Occupational safety and Health (OSH) Directives in EU Member States. Available at: https://www.ibec.ie/IBEC/DFB.nsf/vPages/Occupational_Health_and_Safety~European_News~'evaluation-of-the-practical-implementation-of-the-eu-occupational-safety-and-health-(osh)-directives-in-eu-member-states'--june-2015,-dg-employment,-social-affairs-and-inclusion-19-08-2015/$file/OSH_Dir_Final_Main_Report_1+0.pdf

classifying substances. Stakeholders are also of the opinion that if the data and classification criteria have not changed then classification should not be reopened. Where a substance is being reviewed, the RMS should only review new information in order to make the risk management decision more efficient.

There has been no indication as whether or not new tools have emerged to make risk management measures more efficient. A navigator has been suggested that would enable actors to search by type of substance and be provided with information on the applicable regulations for that substance, its applicable risk management and its classification status. This would increase transparency and would contribute to international capacity building. The stakeholder that suggested this believes that being able to easily find what legislation and risk management applies to a chemical would ensure greater compliance.

Industry stakeholders have suggested that where a CLH triggers a risk assessment before the use of a substance, the risk management measures should be enacted early enough in order to prevent future risks. NGOs argue that the automatic links help ensure that risk management measures are triggered after the early identification of potential risks, with some arguing that RMMs are not adopted fast enough and all areas of chemicals legislation are too slow in providing protection following an early signal of potential risk. It has also been suggested by Member States that although industry may consider automatic RMMs as a cost burden, they are the only way to speed up the implementation of RMM and the protection of human health or the environment.

Industry stakeholders have argued though that risk management measures are often implemented based on theoretical risks rather than signals of potential risks, with this being due to the "precautionary nature of the system". In this respect, risk management is considered to be carried out prematurely, without adequate consideration of what the real risks are and what the trade-offs involved in taking action are.

Other key findings with regard to whether or not measures are triggered early enough are as follows:

- Non-approval of active substances is triggered automatically in the Plant Protection Products Regulation and Biocidal Products Regulation after PBT/vPvB identification or CMR classification. Similarly, other "relevant" substances in the final biocidal or pesticide products should automatically trigger a market restriction. Under the Biocidal Products Regulation, derogations require an assessment of risk (negligible exposure; non-control of pests, resistance management and lack of alternatives) and the costs of non-approval (e.g. societal costs, loss of crop);

- However, for already approved biocides and pesticides that fulfil the PBT criteria and CMR classification, automatic RMM triggers might not become effective until the review of the substance approval is due;

- Under the Water Framework Directive no concrete measures are directly triggered at Community or national level due to a CLH or a PBT conclusion under other legislation. It is of note that one national authority has commented that the exceedance of a Water Framework Directive EQS should automatically trigger reviews of the respective approval decisions under the Biocidal Products Regulation or Plant Protection Products Regulation, as the failure for this to happen impacts on the extent to which the Water Framework Directive's objectives can be met.

Finally, Box 6-2 provides a summary of efficiency considerations with regard to the current possibilities for risk management under the Fertilisers Regulation.

Box 6-2: Fertilisers Regulation – risk management approach

The Fertilisers Regulation ((EC) No 2003/2003) was introduced to ensure the free circulation on the internal market of "EC Fertilisers", i.e. those fertilisers that meet the requirements of the legislation in terms of nutrient content, safety and absence of adverse effects on the environment. It replaced the 18 different European Directives governing mineral fertilisers that had been introduced since 1976 (CSES, 2010[76]; ALA, 2016[77]). The Regulation defines the composition and definition of all fertilisers that have been approved as EC fertilisers. All EC fertilisers can be traded freely within the EU. It is important to note that the current Fertilisers Regulation only applies to mineral fertilisers made up of one or more plant nutrients (or fertilising elements), but also liming materials (to control soil pH) and agronomic additives (e.g. chelating, complexing agents and inhibitors). The Regulation sets out detailed technical provisions regarding the scope, declaration, identification and packaging of four types of fertiliser: inorganic primary nutrient fertilisers (e.g. nitrogen, phosphorus, potassium), secondary inorganic fertilisers (e.g. calcium, magnesium, sodium and sulphur), inorganic micro-nutrient fertilisers (e.g. boron, cobalt, copper, iron, manganese etc.), ammonium nitrate fertilisers of high nitrogen content (Eur-Lex, 2014)[78]. The Regulation in its current form applies only to inorganic mineral fertilisers and does not affect other categories of fertilisers, i.e. "national fertilisers", placed on the market of Member States in accordance with national legislation. These include organic and organo-mineral fertilisers, but also non-fertiliser products such as growing media, organic soil improvers and plant biostimulants. "National fertilisers" are covered by Regulation (EC) No 764/2008 on mutual recognition which ensures the intra-Community free movement of goods in the non-harmonised area (CSES, 2010).

Annex I of the Fertilisers Regulation provides a list of types of EC fertilisers, with all types of fertilisers appearing in this annex and complying with the provisions of the Regulation able to bear the words "EC fertiliser". In order for a fertiliser to be listed the manufacturer is required to apply to the competent authority of a Member State and constitute a technical file on the characteristics of the fertiliser. The applications are then sent to the European Commission which, based on an opinion of a Regulatory Committee, either accepts or rejects the application (Eur-Lex, 2014).

Issues have been raised, regarding the adequacy of the current approach outlined in the Fertilisers Regulation for assessing the risks of fertiliser use, particularly in the case of fertiliser types that are already included in Annex I of the Regulation.

As indicated in Article 14 of the Fertilisers Regulation "*a type of fertiliser may only be included in Annex I if… c) under normal conditions of use it does not adversely affect human, animal, or plant health, or the environment*". Article 31(1) of the Regulation indicates that "*the Commission shall adapt Annex I to include new types of fertilisers*" and Article 31(2) states that "*a manufacturer or its representative which wishes to propose a new type of fertiliser for inclusion in Annex I and is required to compile a technical file for that purpose shall do so by taking into account the technical documents referred to in Section A of Annex V*". Article 15 of the Regulation provides details of the safeguard clause, which allows Member States to temporarily prohibit the placing on the market of a fertiliser if there are justifiable grounds for believing that it constitutes a risk to safety or health of humans, animals or plants or the environment. In such cases, the product is

[76] CSES (2010): Framework Service Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations – Interim, final and ex-post evaluations of policies, programmes and other activities – Evaluation of Regulation (EC) 2003/2003 relating to Fertilisers. Centre for Strategy & Evaluation Services. Report accessed from the European Commission website. Available at: http://ec.europa.eu/smart-regulation/evaluation/search /download.do?documentId=4416

[77] ALA (2016): Fertilisers legislation EU. Webpage from the Agricultural Lime Association (ALA) website. Available at: http://www.aglime.org.uk/issues/fertiliser_legislation_eu.php

[78] Eur-Lex (2014): Fertilisers. Text accessed from the Eur-Lex website. Available at: http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32003R2003&qid=1455725230106

temporarily withdrawn from the market by the Member State and the Commission has 90 days to decide whether this measure was justified.

It is clear that fertiliser types that present a risk to health or the environment should not be approved for use and therefore not included in Annex I of the Regulation. Member States are able to temporarily restrict the use of fertilisers where justification can be provided as to the health or environmental risks associated with their use via the safeguard clause). However, the Fertilisers Regulation does not provide clear guidelines as to the specific approach (and associated data requirements, procedures and actors to be involved) for undertaking an assessment of the risks associated with the use of a fertiliser (and removal of a fertiliser type from the approved list where relevant). This can raise questions regarding the utilisation and suitability of alternative risk assessment approaches as highlighted in the case of calcium cyanamide.

Calcium cyanamide is currently included in Annex I of the Fertilisers Regulation as an EC fertiliser type and can therefore be circulated freely within the EU. However, concerns have been raised with regards to the human health impacts of the use of calcium cyanamide fertilisers. In November 2012 the Fertilisers Working Group established under the Fertilisers Regulation examined requests from some Member States to clarify the potential impacts of calcium cyanamide on human health and the environment (SCHER, 2013)[79]. To address these concerns, the Commission consulted SCHER for its opinion on the potential risks to human health and the environment from the use of calcium cyanamide as fertiliser (SCHER, 2013). It was noted by SCHER that no specific risk assessment methodology has been developed for fertilisers in the EU that could be applied to the questions posed to SCHER. Therefore, SCHER chose to apply, as far as possible, the methodology developed for the registration of plant protection products (PPPs) (SCHER, 2015)[80]. It was concluded by SCHER that harmful effects from the use of calcium cyanamide as a fertiliser for humans and for the environment cannot be excluded (SCHER, 2015). SCHER's opinion therefore brings into question the suitability of calcium cyanamide for use as fertiliser.

It is the view of a manufacturer of calcium cyanamide that the approach used by SCHER to assess the risks of calcium cyanamide was not appropriate. This is because SCHER applied the risk assessment approach developed for the registration of PPPs, which is considered by the manufacturer to be too strict and not adapted to the exposure scenario of a fertiliser and therefore overestimates the risks associated with its use. The manufacturer indicated that there are no guidelines within the Fertilisers Regulation for undertaking a risk assessment, with the Regulation only specifying that fertilisers should not pose any unacceptable risk to humans or the environment. They therefore consider the introduction of guidelines outlining the data requirements regarding the assessment of risks of fertilisers to be necessary (as this would provide a clear process and set of requirements for assessing the risks of fertiliser use).

Discussions with the Commission indicate that the lack of a defined risk assessment approach and associated data requirements within the Fertilisers Regulation means that it is currently difficult to formulate coherent conclusions about the validity of the existing type-approvals. Hence, the inclusion of a specified procedure for assessing the risks of fertiliser use along with the necessary data requirements within the Fertilisers Regulation would be of help in this case.

In summary, the adaptation procedure outlined in the Fertilisers Regulation seems to have limited ability to respond to concerns regarding approved EC fertiliser type specifications. The legal provisions relating to the adaptation of Annexes appear ambiguous in the sense that it is not clear whether removing entries from the list of approved fertilisers is a possibility. In practice this has never been done, although it may well be that

[79] SCHER (2013): Request for an opinion about the potential risks to human health and the environment from the use of calcium cyanamide as fertiliser, Scientific Committee on Health and Environmental Risks (SCHER). Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_104.pdf

[80] SCHER (2015): Opinion on potential risks to human health and the environment from the use of calcium cyanamide as fertiliser, Scientific Committee on Health and Environmental Risks (SCHER). Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_169.pdf

such a mechanism is necessary. In the case of calcium cyanamide it has not been attempted to initiate the process to remove this substance from Annex I, as no Member State has yet decided to invoke the safeguard clause to prohibit the marketing of this product in their national territory. The inclusion of a specific mechanism and the introduction of data requirements within the Fertilisers Regulation would assist in providing a clear process and set of requirements for assessing the risks associated with fertiliser use and, where appropriate, the subsequent removal from the approved list.

6.4 Generic vs. specific - Can differences in risk management measures be justified?

Key findings:

- The need for risk management based on generic risk considerations in the case of approval of plant protection products and biocidal products active ingredients is not clear, given that an extensive risk assessment is carried out during their approval process. The classification of a substance, as well as its modes of action, will be taken into account as part of these risk assessments as will the residual risk associated with the use of a substance. The use of generic risk considerations (automatic trigger) could be considered unnecessary in ensuring the effectiveness of the legislation and may impact on efficiency.
- The chemicals legislation is not consistent with regard to the potential for derogation, and the reasons for this are not always clear, for example, differences in the plant protection products and biocidal products legislation, and with regard to mutagens versus carcinogens for plant protection products.
- A better balance may be achieved by introducing greater potential for consideration of technical feasibility and socio-economic factors as part of derogations, as it is not clear on what basis differences in legislation for substances having the same properties are based.

Table 6-6: Generic versus specific risk assessment / risk management	
2.2.6.6.	Are the risk management measures triggered automatically or does their triggering depend on the discretionary intervention of one/several actor(s) involved?
1.3.4.	Has the right balance been struck in the chemical legislative framework between risk management measures based on generic risk considerations and risk management measures based on specific risk assessments?
4.1.5.	Can differences in hazard identification, risk assessment and risk management measures and provisions between different pieces of legislation be justified?
4.2.1.	Is the chemicals legislative framework consistent in using approaches based on generic risk considerations or approaches based on specific risk assessment where these are required? If not, what are the inconsistencies?

6.4.1 Differences in risk management implied by the different approaches

The triggering of risk management varies across each piece of legislation and depending on the classification of concern. Of the twenty pieces of legislation covered under this Task, 13 have a generic approach to risk management linked to a CLH under CLP:

- the Cosmetic Products Regulation;

- the Toy Safety Directive;
- the Ecolabel Regulation;
- the Regulation on active and intelligent materials;
- the Regulation on plastics intended to come into contact with food;
- the Plant Protection Products Regulation;
- the Biocidal products Regulation;
- the Pressure Equipment Directive;
- the Prior Informed Consent Regulation;
- the End-of-life Vehicles Directive;
- the Waste Shipment Regulation;
- the Environmental Liability Directive; and
- the Young People at Work Directive.

The automatic risk management measures for these pieces of legislation are generally linked with classifications for carcinogenicity, mutagenicity or toxic for reproduction (although others may also be a trigger) and the subsequent classification of toxicity (under PBT and vPvB) and endocrine disruption for which criteria can be based on a C, M or R classification. The remaining legislation is based on a specific risk assessment approach, with or without further implementation steps.

Tables 6-7 to 6-9 illustrate the types of impacts that arise under each of three possible approaches to risk management for three pieces of legislation to illustrate how impacts may vary under the different approaches. In part, these highlight the fact that different pieces of legislation have different scopes and will need to respond to certain issues differently in order to function in the most effective and efficient way.

Table 6-7: Examples of legislation and logic for adoption of Possibility 1	
Possibility 1 and 1.5	**Risk measure triggered automatically**[1]
Example of legislation	Cosmetic Products Regulation
Specific case	The banning of CMR cat 1 and 2 substances in cosmetic products
Disadvantages of applying the approach described by possibility 2 or 3	• Further assessment would examine exposure routes and levels of absorption, but may entail extensive risk assessment and testing. • Case by case evaluation would increase the costs to (e.g.) the Commission and the Scientific Committees should industry apply for derogations on a more frequent basis than currently. • Industry could face reputational loss where it is recognised that classified substances are being used whilst being under evaluation. • Consumers could face greater risks given the added time that a substance will remain in products. • Approach 3 could result in differing ingredients in products, hindering cross-border trade.
Advantages of applying the approach described by possibility 2 or 3	• Substances assessed on a case by case basis, reducing the unnecessary removal of substances which are proven to not pose a risk. • Where substances are not removed, there would be no need to reformulate or substitute and bear that cost, which may be passed on to consumers. • By not removing products when they are deemed safe under approach 2, there remains a variety of choice of cosmetic products for consumers. • As testing is carried out already for the cosmetic product safety assessment, there would not need to be further testing to prove the need for safe use.
Note 1: The ban on CMRs in cosmetic products comes into force when the substance is entered into Annex II of the Cosmetic Products Regulation, it is not automatically restricted when it enters into Annex VI of CLP.	

Table 6-8: Examples of legislation and logic for adoption of Possibility 2	
Possibility 2	**Risk measure triggered only after further assessment[2]**
Example of legislation	Directive on chemical agents at work
Specific case	Setting of binding occupational exposure limit values
Disadvantages of applying the approach described by possibility 1 or 3	• Approach 1 does not allow for continued use of a substance where it is essential or exposure can be controlled. This may cause processes and industries to be lost, especially where no alternative is available. • Process-generated substances which cannot be prevented would be banned and this would require a change in process. • Approach 3 may not provide the level of protection warranted, by allowing for employers to set their own higher levels.
Advantages of applying the approach described by possibility 1 or 3	• In this case there would be no advantage to approach 1 for industry but there would be the elimination of exposure for workers. • Approach 3 may allow employers to set higher limits than those given in a BOELV where they have assessed that their working practice still offers a high level of protection.
Note 2: Approach 2 is used for the setting of BOELVs (binding occupational exposure limit values) but approach 3 is used for IOELVs (indicative occupational exposure limit values)	

Table 6-9: Examples of legislation and logic for adoption of Possibility 3	
Possibility 3	**Risk measure is defined following further assessment by Member States or economic operators**
Example of legislation	Seveso III Directive
Specific case	Evaluation of risks and development of risk management regime for individual sites
Disadvantages of applying the approach described by possibility 1 or 2	Neither approach is capable of accounting for the specific characteristics of sites with respect to the materials present, the quantities of those materials, potential routes of exposure, variability in the processes and equipment used, or the proximity of operations to (e.g.) human settlements. A failure to account for the specific characteristics of sites could lead to a significant over- or under-estimation of risks, generating excess burden of cost to industry or impact to the public, respectively. HSE (2015) provides analysis of the economic impacts of major accidents at regulated facilities. The work highlights a significant variation in the costs associated with different types of risk and different activities in different locations, strengthening the arguments in favour of a case by case assessment as the most efficient route for minimising risks.
Advantages of applying the approach described by possibility 1 or 2	Approach 2 may reduce the workload for Member States with regard to performing assessments as it would be the responsibility of the another body

6.4.2 Consistency and balance

Table 6-10 below provides an overview of the type of risk management approach used for substances/mixtures with different properties under different pieces of legislation.

Table 6-10: Type of risk management approach under different legislation		
Legislation	**Properties**	**Type of risk management**
Regulation (EC) No 1223/2009 on cosmetic products	CMR PBT/ vPvB EDC	Generic risk considerations* No provision No provision

Table 6-10: Type of risk management approach under different legislation		
Legislation	**Properties**	**Type of risk management**
Directive 2009/48/EC on the safety of toys	CMR PBT/ vPvB EDC	Generic risk considerations* No provision No provision
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	CMR PBT/ vPvB EDC	Generic risk considerations No provision No provision
Regulation (EC) No 66/2010 on the EU Ecolabel	CMR PBT/ vPvB EDC	Generic risk considerations No provision*** No provision***
Regulation (EC) No 450/2009 on active and intelligent materials	CMR PBT/ vPvB EDC	Generic risk considerations No provision No provision
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	CMR PBT/ vPvB EDC	Generic risk considerations No provision No provision
Professional products*		
Regulation (EC) No 1107/2009 on plant protection products	CMR PBT/ vPvB EDC	Generic risk considerations*, ** Generic risk considerations Generic risk considerations*
Regulation (EU) No 528/2012 biocidal products	CMR PBT/ vPvB EDC	Generic risk considerations* Generic risk considerations* Generic risk considerations*
Directive 2014/68/EU pressure equipment	CMR PBT/ vPvB EDC	No provision No provision No Provision
Environmental protection		
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals	CMR PBT/ vPvB EDC	Generic risk considerations Generic risk considerations No provision
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III)	CMR PBT/ vPvB EDC	Specific risk assessment Specific risk assessment Specific risk assessment
Directive 2010/75/EU on industrial emissions	CMR PBT/ vPvB EDC	Specific risk assessment Specific risk assessment No provision
Directive 2008/98/EC on waste	CMR PBT/ vPvB EDC	Specific risk assessment Specific risk assessment No provision
Directive 1999/31/EC on the landfill of waste	CMR PBT/ vPvB EDC	No provision No provision No Provision
Directive 2000/53/EC on end-of life vehicles	CMR PBT/ vPvB EDC	No provision No provision No Provision
Regulation (EC) No 1013/2006 shipments of waste	CMR PBT/ vPvB EDC	Specific risk assessment Specific risk assessment No provision
Directive 2004/35/CE on environmental liability	CMR PBT/ vPvB EDC	Generic risk considerations Generic risk considerations**** No provision

Table 6-10: Type of risk management approach under different legislation		
Legislation	**Properties**	**Type of risk management**
Health & Safety of Workers		
Directive 92/85/EEC pregnant workers	CMR PBT/ vPvB EDC	Specific risk assessment No provision No provision
Directive 94/33/EC young people at work	CMR PBT/ vPvB EDC	Specific risk assessment No provision No provision
Directive 98/24/EC chemical agents at work	CMR PBT/ vPvB EDC	Specific risk assessment No provision No provision
Directive 2004/37/EC carcinogens or mutagens at work	CMR PBT/ vPvB EDC	Specific risk assessment No provision No provision
* Derogation based on specific risk assessment. ** No derogation for mutagens. *** Substances may be subject to authorisation under REACH for these properties and subsequently have risk management based on generic risk consideration. **** Only meets toxicity criteria, no mention of persistence or bioaccumulation.		

When considering hazard identification, risk assessment and risk management measures across legislation, the general consensus of the stakeholders (industry, NGO, academia and Member States) interviewed is that it is appropriate for different pieces of legislation to have different approaches as they are concerned with different sectors and end-users. There has been criticism, however, of both approaches to risk management and opinion is divided as to which approach offers the highest level of protection, as discussed in the preceding sections. In order not to repeat previous arguments, the discussion here is focused on specific legislation.

It should be noted that very few NGOs participated in the targeted consultation on this aspect. Those NGOs that did respond argue that the best approach to the protection of human health and the environment is the automatic ban on hazardous substances like CMRs, for which a safe level of exposure cannot be established (risk management based on generic risk considerations). Member State authorities provided mixed views on this issue in response to the targeted consultation, with some in favour of retaining generic triggers and others supporting a more specific risk based approach across all downstream legislation.

Impacts of classification decisions on the substance base available to industry are also raised as an issue by a range of associations in response to the open public consultation. One industry association representative commented that "the existing automatism of referring to classification gives no consideration to the fact that the classification criteria of CLP are based on the intrinsic properties of substances, with no differentiation by exposure situation and real risk of the respective substance use". They also suggest that it is for this reason that legal consequences need to be examined as to their proportionality and relevance to risk. Examples provided by this stakeholder are[81]:

[81] Issues under national legislation are also identified with respect to formaldehyde and impacts under the TA Luft (German air quality requirements).

- Seveso – substances are covered that cannot pose a major-accident hazard, which is the original intention of this legislation; and
- Waste classification – new hazardous properties criteria for waste should not lead to changes for purely formal reasons, i.e. where the properties of waste have not changed, in the existing classification of hazardous waste.

The paint sector has raised concerns about the loss of active substances (formaldehyde releasers and isothiazolinones) as part of the Biocidal Products Regulation review. The substances are used as in-can preservatives in water-based paints that might otherwise have problems with micro-organisms. The removal of these substances is based on their meeting the exclusion criteria of the Biocidal Products Regulation, as a result of CLH for formaldehyde for carcinogenicity. The industry suggests that there are no substitutes that can easily fulfil all the technical and safety requirements, and that a more holistic, risk based approach is needed to ensure that in-can preservatives will remain available in the future to formulators.

The Biocidal Products Regulation and Plant Protection Products Regulation are not consistent with regard to the potential for derogation with regard to mutagens versus carcinogens for plant protection products, and the reasons for this is not clear from the legal text or guidance, making it difficult to tell whether an appropriate balance has been struck. It is assumed that this is because mutagens are non-threshold substances and thus that a safe use level cannot be derived (similar to the arguments regarding their being no derogations for PBTs). This may be an effective way of providing protection to human health, but appears inconsistent in that some carcinogens are also non-threshold substances (although one could assume that non-threshold carcinogens would find it more difficult to obtain a derogation)[82].

The generic hazard-based approach for CMRs in cosmetic products is also not considered to be appropriate by the industry, as they believe that because cosmetics have a defined use and the exposure is known, a case-by-case basis for risk management is more suitable. As the Cosmetic Products Regulation requires a safety assessment for all cosmetic products, the risk of a CMR substance would be determined anyway, as part of the process for placing the product on the market. Industry therefore argues that the responsibility for risk management should be shifted directly to the Cosmetic Products Regulation, rather than being triggered by a CLH classification under CLP, with the CLP hazard classifications acting as the basis for a risk assessment. The risk assessment should then form the basis for the risk management measure.

Turning to PBTs and vPvBs, most consulted stakeholders agreed that the status of a substances being a PBTs/vPvBs should apply across all pieces of legislation. However, one industry association stated that the use conditions and fate under environmental conditions should be taken into account in the PBT assessment, as this might lead to different conclusions on the PBT classification of a substance; in particular this may be the case for metals (see also Case Study 2 on metals classification).

With regard to the risk management of PBT/vPvBs, stakeholders confirmed the view that differences in risk management could be justified by the use pattern and the benefits of a product. However,

[82] Hodgson and Levi (1987) note that "a large body of work on chemical carcinogenesis has now demonstrated that the carcinogenic potency of a compound is correlated with its mutagenic ability, suggesting that DNA is the ultimate target of carcinogenic initiation. In recent years, many chemicals known to be carcinogenic have been found to be mutagenic as well; likewise, many known mutagens have been found to be carcinogenic". E. Hodgson & P. E. Levi (1987) A textbook of modern toxicology. Elsevier Science Publishing Co. Inc.

the lack of an automatic trigger for bans of PBT/vPvB in medicinal products for veterinary use and the lack of opportunities to restrict the use of medicinal products for human use or manage risks via other measures was noted as not justified by some representatives of NGOs and authorities.

The General Product Safety Directive has been heavily criticised for its lack of precise protection of consumers yet one stakeholder is of the opinion that the General Product Safety Directive has the ability to enforce quick measures without too much discussion. This could be considered a positive for the General Product Safety Directive as it can be very difficult to remove some substances from the market for certain uses.

This evaluation concludes that hazard classification under CLP is considered to be an appropriate starting point for risk management decisions. The use of generic risk considerations results in swift risk management through the automatic restriction on the use of substances with certain hazard classifications, particularly CMRs and the subsequent PBT, vPvB and endocrine disrupting chemicals classifications. It is laid out in the legal texts which hazard classifications are restricted and subject to an automatic ban. In the case of the consumer sector there are vulnerable populations (such as children, pregnant and breastfeeding women etc.) who are more susceptible to the effects of exposures to substances such as CMRs. Where risk management based on generic risk considerations is employed in the case of CMR substances in consumer products, the aim is to be precautionary and prevent future health effects due to exposure. As consumers are exposed to a number of products in their daily life, generic risk considerations help minimise exposure to CMRs through multiple pathways.

The specific approach to risk management is often dependent on lengthier assessment processes and expert judgement in the peer review following a risk assessment. Industry do not consider this to be a negative, who prefer the specific risk based approach to risk management, as they believe it allows the true risk to populations of concern to be taken into account, as opposed to the generic risk based approach which does not consider substance specific aspects. The specific risk assessment approach is therefore considered to be more effective as exposure assessments act as the basis for identifying the appropriate risk management approach, as the presence of a hazardous property does not necessarily mean that there is a risk that needs to be controlled. In other words, an automatic ban may not be effective in terms of delivering human health or environmental benefits, but it may have significant impacts on the effectiveness of the legislative framework with respect to the single market and achieving the objectives towards enhancing competitiveness and innovation. These are in addition to concerns over the efficiency of such an approach, given the potential for significant socio-economic costs and unintended consequences.

There is also an argument, that the existence of automatic triggers (generic risk considerations) is not necessary where sectoral legislation also requires extensive and detailed risk assessments (e.g. such as those under the Biocidal Products and Plant Protection Products legislation for active substance approval), which must cover risks across different environmental compartments and populations. These specific risk assessments should in themselves provide an indication of the level of residual risk associated with the continued use of a substance. Furthermore, these specific risk assessments should reflect differences in the properties of substances falling under the generic risk consideration (i.e. differences in the potency of carcinogens, differences in the level of persistence or toxicity of a PBT, hazards relate to only one route of exposure). As a result, the data should exist to enable decisions to be based on a specific risk assessment carried out for a given substance and the specific characteristics of its use in a particular context. Relying on a specific risk assessment in such cases rather than the generic triggers may also help de-politicise, for example, decisions on where to set cut-off criteria for properties of concern and ensure that these remain science based

(e.g. for endocrine disruptors), as the choice of cut-off criteria alone would not automatically ban the future use of substances.

With respect to the OSH Directives, it seems that the right balance has largely been struck, allowing for the circumstances of each workplace to be taken into account while providing for minimum protection requirements and guidance to employers for making the risk assessment. It is also of note that although OSH risk assessments rely on CLP classifications, employers also (at least in theory) have to take into account other information when preparing their workplace assessments, e.g. unclassified hazardous substances such as those that are process generated (wood dust, fumes, etc.).

Finally, stakeholders highlighted the need to harmonise legislation outlining risk management both within the EU legislative framework and with other world regions. They claim that "industry has recognised that the Chinese RoHS and the EU RoHS have some different requirements, and new RoHS-type legislation is being developed in South America". It has been confirmed by the Commission that there are over 50 pieces of legislation in different countries which have a similar scope to the RoHS. As such, harmonising the risk management framework would make it easier and clearer for industry. It is not entirely clear whether non-industry stakeholders will agree with this position.

7 Costs and Benefits

7.1 Overview

This section draws together evidence found on the costs to industry and the cost savings to society as a result of risk management. It draws on evidence from the published literature as well as more qualitative data from the consultation responses, especially the open public consultation. The aim is to give a summary of information on the costs and benefits of the main legislative provisions on risk management measures triggered by CLP classification in order to assist in answering the evaluation questions listed in Table 7-1 below. Where possible, additional calculations and extrapolations have been made based on the available data. Finally, an assessment is made of the overall efficiency of the legislation in achieving the health and environmental objectives in relation to the business costs of the legislative requirements.

It should be recognised though that data on the costs and benefits of legislation linked to CLP is very sparse. Impact assessments providing ex-ante estimates were identified for a number of Regulations and Directives, but not for all. Detailed ex-post assessments are lacking and in general it is not possible to determine whether the anticipated benefits of the legislation have been realised, particularly with respect to the linkages between classifications and the avoidance of human health and environmental impacts.

Table 7-1: Efficiency related to costs	
Q#	**Question**
2.1.1.	What are the costs associated with the chemicals legislative framework for:
2.1.1.1.	• Regulators at EU and national level
2.1.1.2.	• Industry, including SMEs
2.1.1.3.	• Workers, consumers
2.1.1.4.	• Society / economy in general
2.1.3.	What are the benefits associated with the chemicals legislative framework for:
2.1.3.1.	• Regulators at EU and national level
2.1.3.2.	• Industry, including SMEs
2.1.3.3.	• Workers, consumers
2.1.3.4.	• Environment
2.1.4.	To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?
2.2.3.	Are there unnecessary costs or burdens imposed on actors (e.g. industry, regulators) as a result of the chemicals legislative framework? If so, which areas have potential for improvement?
2.2.11.	At Member State level, are there significant differences between Member States as regards the benefits, costs and administrative burdens?
1.2.2.	Have any automatic mechanisms triggered significant costs or benefits?
1.2.3.	Has the specific risk assessment approach triggered significant costs or benefits?

7.2 The legislation covered

Table 7-2 sets out the legislation covered in this Task with a summary of the legislation that has health and/or environmental objectives and the types of impacts likely to arise (costs (-), benefits (+), both costs and benefits (+/-), or neither (0)) on industry (including down-stream users), society, the environment and regulatory authorities. This qualitative assessment is based on the description of the key aspects of the triggers, as described in the tables provided in Section 2.1.5 of this report.

Table 7-2: Overview table on risk management measures						
EU Act	Objective		Impacts on (based on Section 2.1.5)			
	Health	Env.	Industry	Society	Env.	Authorities
Consumer products						
Regulation (EC) No 1223/2009 on cosmetic products	Y	N	-	+	0	-
Directive 2009/48/EC on the safety of toys	Y	N	-	+	0	-
Regulation (EC) No 66/2010 on the EU Ecolabel	Y	Y	+/-	+	+	-
Regulation (EC) No 450/2009 on active and intelligent materials	Y	N	-	+	0	-
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	Y	N	-	+	0	-
Professional products*						
Regulation (EC) No 1107/2009 on plant protection products	Y	Y	-	+	+	-
Regulation (EU) No 528/2012 biocidal products	Y	Y	-	+	+	-
Directive 2014/68/EU pressure equipment	Y	Y	+/-	+	0	-
Environmental protection						
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals	Y	Y	+/-	+	+	-
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	Y	Y	+/-	+	+	-
Directive 2010/75/EU on industrial emissions	Y	Y	-	+	+	-
Directive 2008/98/EC on waste	Y	Y	-	+	+	-
Directive 1999/31/EC on the landfill of waste	Y	Y	-	+	+	-
Directive 2000/53/EC on end-of life vehicles	N	Y	-	+	+	-
Regulation (EC) No 1013/2006 shipments of waste	Y	Y	-	0	+	-
Directive 2004/35/CE on environmental liability	N	Y	-/0	+	+	-
Health & Safety of Workers						
Directive 92/85/EEC pregnant workers	Y	N	+/-	+	0	-
Directive 94/33/EC young people at work	Y	N	+/-	+	0	-
Directive 98/24/EC chemical agents at work	Y	N	+/-	+	0	-
Directive 2004/37/EC carcinogens or mutagens at work	Y	N	+/-	+	0	-
*Both the Plant Protection Products and Biocidal Product Regulations also cover consumer products.						

The remainder of this section then identifies what the impacts might be, describes the impacts (supporting the description with comments from the open public consultation) and quantifies them where possible (referring to impact assessments of legislation and published reports on the costs and benefits of chemicals legislation).

7.3 Types of costs and benefits

The types of costs and benefits to be considered in this analysis are taken from the definition as set out in Box 2 of Tool #51 (Typology of costs and benefits) of the Better Regulation Toolbox (reproduced as Figure 7-1, next page). Subsequent sections of this report are focused on identifying, describing and, where possible, quantifying each type of cost and the organisations or groups of individuals that are likely to incur them. The key types of costs are:

- Direct costs:
  - Direct compliance costs[83]: covering regulatory charges (fees, levies, taxes, etc.), compliance costs (investments and expenses faced by business in order to comply with the legislation) and administrative burdens which are generally linked to the transfer of information between relevant parties, be they businesses, regulators or civil society organisations; and
  - Hassle costs: these are often associated with businesses, but they apply equally well to consumers. They include costs associated with waiting time and delays, redundant legal provisions, corruption etc. No evidence has been found to indicate that hassle costs are prominent for the legislation under assessment here and on this basis this class of cost is not considered further.

- Enforcement costs:
  - One-off adaptation costs of changes required of regulatory authorities (similar costs to industry were covered above as 'administrative burdens');
  - Information costs;
  - Monitoring compliance and levels of health and environmental protection;
  - Enforcement of the law; and
  - Adjudication.

- Indirect costs are incurred in related markets or experienced by consumers, government agencies or other stakeholders that are not directly targeted by the initiative/regulation. These costs are usually transmitted through changes in the prices and/or availability and/or quality of the goods or services produced in the regulated sector. Changes in these prices then ripple through the rest of the economy changing prices in other sectors and ultimately affecting the welfare of consumers. They cover:
  - Indirect compliance costs, in other words, costs related to the fact that other stakeholders have to comply with legislation; and
  - Other indirect costs: covering reduced efficiency, competition, innovation, substitution effects, transaction costs, reduced market access, uncertainty.

[83] These terms differ in name only from those used in the Commission's Cumulative Cost Assessment (Technopolis, 2016) in which regulatory charges are referred to as monetary obligations; compliance cost investments as CAPEX (capital expenditure); compliance cost expenses as OPEX (operational expenditure; and administrative burden is used in both sources.

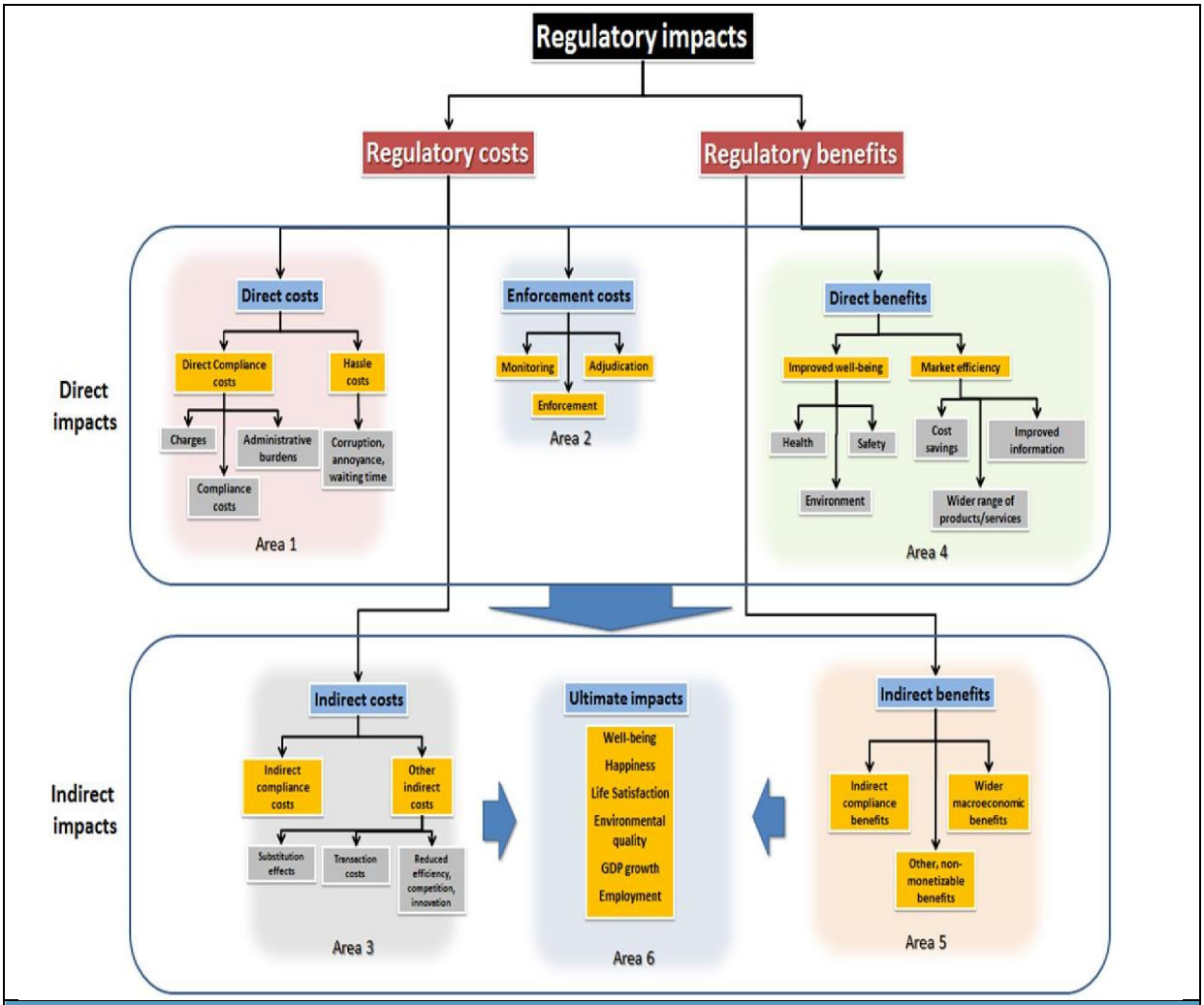

Figure 7-1: Typology of costs and benefits (from Tool #51 of the Better Regulation Toolbox)

Whilst the key types of benefit are listed in the better Regulation Toolbox as follows:

- Direct benefits:
  - Improved well-being: covering the benefits of improved health, safety and environment; and
  - Market efficiency: covering cost savings, improved information and wider range of products/services.

- Indirect benefits:
  - Indirect compliance benefits (spill-over effects related to third-party compliance with legal rules);
  - Wider macroeconomic benefits including GDP improvements, productivity enhancements, greater employment rates, improved job quality etc.; and
  - Other, non-monetisable benefits such as protection of fundamental rights, social cohesion, reduced gender discrimination, international and national stability.

The costs and benefits combined can then be assessed (to the extent that data permit) against a series of 'ultimate impacts' listed in the better Regulation Toolbox as:

- Well being

- Happiness
- Life satisfaction
- Environmental quality
- GDP growth
- Employment

There is clear potential for overlap between these categories. For example, increased employment would be expected to add to GDP growth, life satisfaction, happiness and well-being. Instead of a line by line accounting of these benefits it seems more reasonable to take this list as an indicative guide of the issues that may be considered from evaluation of any data gathered.

7.4 Qualitative information from the open public consultation

The open public consultation responses regarding the costs and benefits arising under the legislative framework are provided in full in Annex 1. There is a general lack of quantitative evidence provided from the consultation. The following sections summarise particular issues that were raised beyond issues that simply reflect the objectives of the legislation, and noting that these are the views as expressed by respondents rather than conclusions reached through this research.

7.4.1 Qualitative assessment of direct costs

The following issues were raised in the open public consultation responses (see also Table A3-1 in Annex 3):

- Administrative burdens were thought higher than necessary in a number of cases because of:
  - Differing views between Member States, and EFSA systems are less transparent than those used for REACH (Food Contact Materials).
  - The dual roles of ECHA and EFSA creates inefficiency (Plant Protection Products) with similar concerns raised about the need to report the same data to several authorities also creating inefficiency.
  - The heterogeneous composition of waste makes it difficult to check composition (Waste).
  - The application of CLP to waste creates an unpredicted burden for waste management (Waste).
  - Changes in guidance and in interpretation by authorities occur too frequently (generic to chemicals legislation, also specifically mentioned for biocidal products).

- Compliance costs:
  - Allowing insufficient time for adaptation (general to chemicals legislation) leading to loss of contracts. Specific mention was made of exemption 8h of the End of Life Vehicles Directive for which the phase-out date preceded the publication date of legislation.
  - Insufficient time allowed for submitting a dossier to SCCS in appeal against a CMR2 substance being automatically banned (Cosmetic Products).
  - Differences in transitional periods between Member States, with insufficient time given to adaptation to new regulations (Biocidal Products).
  - Duplication of testing requirements (Plant Protection Products, Biocidal Products).
  - Testing requirements are too onerous for the household appliance industry (Food Contact Materials, Biocidal Products).

- National fees are variable and too expensive (Biocidal Products).
- The standard 6-12 month grace period when an active substance is withdrawn from the market may be insufficient to allow the product to be used without incurring disposal costs for the supply chain (Plant Protection Products).

These comments raise concern about several possible inefficiencies within the existing system, inconsistency between authorities, and inadequate time being allowed for change.

7.4.2 Qualitative assessment of enforcement costs

The following issues were raised in the open public consultation. As elsewhere, there is a general lack of quantitative evidence provided from the consultation.

- Enforcement:
  - Exhaustive market surveillance to stop the majority of dangerous toys entering the EU market would be very costly for authorities, especially in relation to online toy sales which require authorities to check internet channels (Toys).
  - The so-called "unless-clause" in the uniform principles has led to considerable increase in the expenditure of competent authorities in risk assessment (Plant Protection Products).

- Adjudication:
  - Even when the legislation foresees a system of mutual recognition between Member States, Member States are re-evaluating the first evaluation performed by the lead Member State. These costs are charged back to industry through a system of fees (Biocidal Products).

7.4.3 Qualitative assessment of indirect costs

The following issues were raised in the open public consultation with responses provided in full in Table A3-3 in Annex 1. Again, there is a general lack of quantitative evidence provided from the consultation.

- Reduced efficiency:
  - Expenditures on 'defensive research', diverting resource from investment in R&D where legislation is hazard based and not linked to risk per se (a general comment on hazard based legislation, and specifically for Cosmetic Products).

- Competitiveness:
  - Reduced innovation capacity through the banning of substances (Plant Protection Products, Biocidal Products).
  - Products with improved human health or environment profiles will likely be competitive only in Europe if cost or performance is adversely affected (Biocidal Products).
  - Seveso provisions have significant effects on competitiveness.
  - Overlap between CLP, REACH make the Chemical Agents at Work Directive anti-competitive.
  - Variable interpretations of requirements at the national level (Waste).
  - There is a need for more extensive use of socio-economic analysis to assess the merits of regulatory measures (Biocidal Products).

- Transaction costs:
  - Hazard classification makes a significant impact on transport (Waste).

- Reduced market access:
  - Relocation of chemical suppliers outside the EU for servicing less restricted markets (generic to chemicals legislation).

- Uncertainty:
  - Timescales in legislation are often too short to find alternatives (generic to chemicals legislation).
  - Timelines for approval of substances are not predictable (Biocidal Products).
  - Lack of planning certainty leading to substitution of substitutes (generic to chemicals legislation).
  - Different requirements between Member States (Toys).
  - Inconsistency in wording, raising potential for variable interpretations of requirements (Plant Protection Products, Waste).
  - Lack of guidance (Biocidal Products).
  - Lack of clarity on the meaning of the requirement to reduce occupational exposure 'as low as technically possible' (Chemical Agents at Work).

It is notable that many concerns related to uncertainty, which may in some cases be relatively easy to resolve. Several concerns were also raised in relation to competitiveness. These will be harder to deal with in the short term, if protection levels are to be maintained.

7.4.4 Qualitative assessment of direct benefits

The following issues were raised in the open public consultation with responses provided in full in Table A3-4 in Annex 1.

- Improved well-being:
  - Risk management measures triggered by CLP classifications reduce exposure to hazardous substances. The reduction of exposure is observed in all stages of the chemical-life cycle, from manufacture of the substances to the waste stage, passing from the applications in industrial processes and in the manufacture of products. This has direct benefits on workers, consumers, vulnerable groups and the environment, with a reduction of diseases attributable to chemicals' exposure.

With regard to market efficiency, no comments on the benefits of the legislation were provided during the open public consultation.

7.4.5 Indirect benefits

No qualitative information relating to indirect benefits was obtained through stakeholder consultation.

7.4.6 Efficiency and effectiveness

The open public consultation responses on efficiency and effectiveness are provided in full in Table A1-5 in Annex 1. The following summarises particular issues that were raised beyond issues that simply reflect the objectives of the legislation:

- Conflicts in testing requirements between legislation (e.g. CPR and REACH).
- Overlaps between regulations (e.g. food contact materials and biocides, CPR and Toys, Battery Directive and the End-of-Life Vehicles Directive, Chemical Agents Directive and CLP).
- Consequences of fulfilling PBT/vPvB criteria are different between REACH and Plant Protection Products Regulation.

7.5 Quantitative assessment of costs and benefits

7.5.1 Introduction

The European Commission, in the framework of the Regulatory Fitness Programme (REFIT) for the chemicals policy area, has commissioned several studies looking at different aspects of the legislation, some of them focusing on the costs and benefits. These are:

- Cumulative Cost Assessment for the EU chemical industry (Technopolis et al, 2016);
- Monitoring the impacts of REACH on competitiveness, innovation and SMEs (CSES et al., 2015);
- Study on the calculation of the benefits of the chemicals legislation on human health and the environment – development of a system of indicators (RPA et al, 2016); and
- Cumulative Benefits Assessment of the chemicals legislation (ongoing, publication expected for early 2017).

Technopolis (2016) analysed the cumulative costs of the most relevant legislation (not only the legislation on chemicals) with a bearing on the EU chemical industry for the period 2004-2014. The authors followed the "Standard Cost Model" methodology and provided a quantitative assessment of all costs, differentiated in monetary obligations, capital expenditures (CAPEX), operating expenses (OPEX) and administrative burden). Data were collected from a panel of 31 "typical companies" and validated on a sample of 90 companies. The cumulative costs for each subsector were then calculated grossing up the costs for individual companies on the basis of the ratio cost/turnover for individual companies and the turnover for each subsector available from Eurostat. Due to the limitations of the methodology followed, the figures provided by the study are only an estimate of the order of magnitude of the costs borne by the EU chemical companies.

The study found that, during the period 2004-2014, the cumulative costs for the EU chemical industry due to legislation approached €9.5 billion (around 2% of the total turnover or 12% of the value added), with the legislation on emissions and industrial processes representing approximately 33% of the total, the chemical legislation around 29% and workers' health and safety legislation around 24%. The administrative burden represents around 10% of the total figure, monetary obligations around 20% and CAPEX and OPEX around 70%.

CLP classifications trigger measures that have been accounted for in the different legislative packages, such as workers' safety, emissions and industrial processes, product-specific legislation and even transport and customs and trade legislation. Although the study provides estimates (in terms of percentages of the total cost) of the costs attributable to the different legislative packages (Figure 7-2), it is not possible to estimate how much of these costs is due to risk management measures that were implemented due to either generic risk considerations or more specific risk assessments. Nor does the study isolate the costs attributable to decisions made based on generic risk considerations (rather than costs under previous legislation for Plant Protection Products and Biocidal Products Regulation).

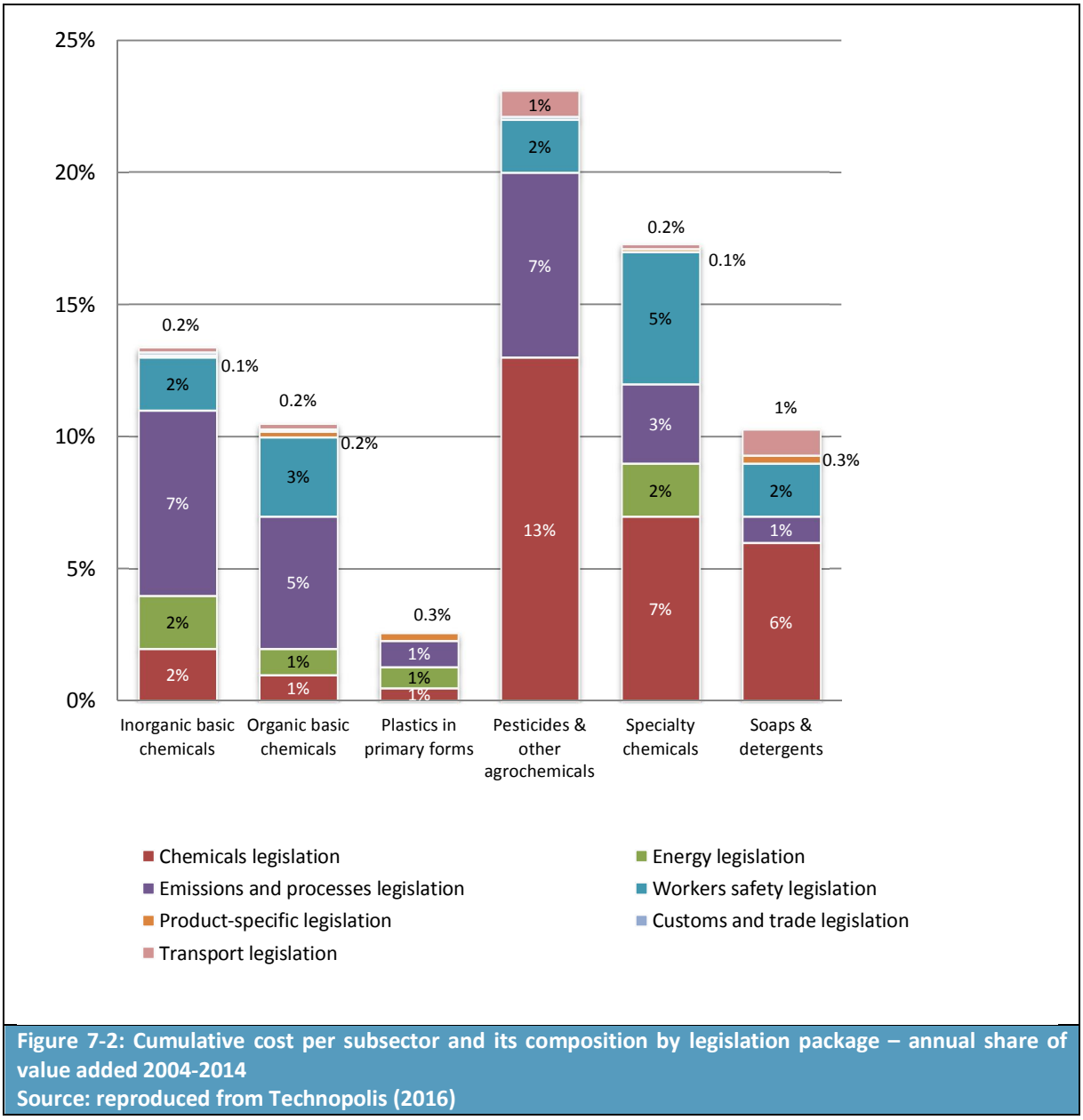

Figure 7-2: Cumulative cost per subsector and its composition by legislation package – annual share of value added 2004-2014
Source: reproduced from Technopolis (2016)

The study on the impacts of REACH on innovation, competitiveness and SMEs found that around 50% of the respondents to the surveys conducted for the purpose of assessing the impacts of REACH reported that there has been an improvement in risk management procedures and the management of environmental emissions and waste because of REACH. The percentage varies depending on the size of the company and on the position in the supply chain. The authors noted that various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and calculated the Return on Prevention (ROP) to be 2.2[84] or the Benefit-Cost Ratio to be between 1.04 and 2.70[85]. Although the study focused on REACH, new risk management measures are

[84] Kohstall et al (2013): Calculating the international return on prevention for companies, Costs and benefits of investments on occupational safety and health. DGUV.

[85] EC (2011): Socio-economic costs of accidents at work and work-related ill health, DG for Employment, Social Affairs and Inclusion.

triggered by changes in CLP classifications of substances on the basis of new (eco)toxicological information generated by the REACH Regulation.

RPA et al (2016) propose four output indicators[86] of the benefits of the chemicals legislation, two of which refer to the synergy between REACH and CLP:

- Substances with harmonised classification and labelling implemented after the entry into force of the REACH and CLP Regulations per hazard class; and

- Change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations.

The increase in the number of substances with harmonised classification and labelling (CLH) denotes an improvement in knowledge of properties and safe uses of chemicals. The first output indicator counts and lists the substances with harmonised classification and labelling per hazard class.[87] The REACH registration requirement leads to new and better physicochemical and (eco)toxicological information for the classification of substances. The second output indicator measures the change in self-classifications (per hazard class) since the entry into force of the REACH and CLP Regulations. The results are presented in Table 7-3. It is not possible to establish why such significant changes in self-classifications have occurred for some of the endpoints, where changes were not introduced by CLP. It may be due to new information or to manufacturers reviewing the properties of substances.

Table 7-3: Data summary for the output indicators 1 and 2 (RPA et al (2016))

Hazard class – PBT/vPvB – Endocrine activity	No. of substances with CLH (June 2008 – April 2016)	Change in self-classifications (January 2005 – February 2016)
Acute toxicity	80	+32%
Skin corrosion / skin irritation	30	+51%
Skin Sensitisation	37	+132%
Serious eye damage / eye irritation	30	+164%
Respiratory Sensitisation	1	+538%
Mutagenicity	13	+3,329%
Carcinogenicity	41	+264%
Reproductive toxicity	47	+229%
Specific Target Organ Toxicity	72	+4,127%
Aspiration hazard	9	+251%
Hazardous to the aquatic environment	90	+99%
Hazardous for the ozone layer	0	+80%
PBT/vPvB profile	-	-
Endocrine activity	-	-

[86] Output indicators relate to the deliverables that the legislation is expected to produce and aim to measure the specific actions of the legislative mechanisms (operational objectives) (Better Regulation guidelines).

[87] Since harmonised classification and labelling is a mechanism that has not been newly introduced by the CLP Regulation, the indicator quantifies the harmonised classifications and labelling that have been implemented after the entry into force of the REACH and CLP Regulations.

The authors also developed result and impact indicators[88] and presented available data on the evolution of chemicals' exposure (in terms of changes of concentration of chemicals in different samples) and of diseases attributable to chemicals' exposure (in terms of changes of incidence, prevalence and mortality).

The available information shows a general decrease in chemical exposures and in diseases attributable to chemicals' exposure, although the data have strong limitations in terms of geographical scope, monitoring periods, changes in monitoring practices and diverging statistical measures across the EU. Changes are the likely result of multiple factors, such as an increased awareness on health and safety in workplaces, the pro-active adoption of better risk management measures, the reduction of the workforce in sectors where workers are particularly exposed to hazardous substances and technological progress in the production processes. Moreover, for long latency diseases (e.g. chronic obstructive pulmonary diseases, cancers), the authors concluded that attribution is more complex and requires a number of assumptions which seriously limit the value of any indicator trying to measure the marginal contribution of chemicals legislation in lowering the burden of disease. For these reasons, only two impact indicators on changes in incidence and prevalence of occupational skin diseases and occupational asthma attributable to the exposure to chemical substances were monetised, resulting in total estimates of benefit of, respectively, around €1.6-1.9 billion and €250 million for the period 2004-2013.

With regard to environmental benefits, due to a lack of monitoring data, changes in monitoring practices, and the absences of economic valuations, the authors believed that the environmental result indicators provide the most appropriate set for illustrating the benefits – in a non-monetised manner – of chemicals legislation. It should be noted that the study focused on developing a system of indicators rather than on the monetisation of the benefits of the chemical legislation. Monetary estimates are expected to be provided by the ongoing cumulative benefits assessment (to be published in early 2017).

7.5.2 Findings of Task 1 on costs and benefits

It is important to note that the estimates presented in the report on impact indicators will overlap with those presented in the Task 1 report for this Fitness check (see Annex II). The Task 1 report provides updated estimates and presents these on an annual basis for comparison to costs. The key findings from Task 1 are as follows:

- Total annual costs are estimated at over €1.0 billion for SMEs and around €260 million for larger companies, based on data submitted to the targeted consultation (cost data are presented, broken down by activity (see the Task 1 report for further discussion on uncertainties). The greater cost burden on SMEs arises because they exist in substantially greater numbers than the large companies.

- The estimate of around €1.3 billion as the annual costs of CLP implementation compare to a maximum figure of €1.47 billion as calculated by the Cumulative Cost Assessment. Although the Cumulative Cost Assessment figures cover obligations under other legislation, it also

[88] Result indicators measure the immediate effects of the legislation on the direct recipients (specific objectives) and have therefore been defined in terms of changes in exposure to chemical substances. Impact indicators measure the ultimate consequences of the legislation beyond its direct interaction with recipients. This has been interpreted as moving from changes in exposures to changes in effects, either in terms of chemicals related diseases or chemicals related impacts on environmental ecosystems and biota.

considers a smaller number of industry sectors and hence companies. The figure of €1.3 billion does not include poison centre reporting costs, which are estimated at around €1.7 billion for harmonised reporting obligations.

- A necessarily partial analysis of benefits indicates that the average annual value of reductions in poisoning incidents, occupational skin and respiratory diseases and occupational cancers since 2000 is between €391 and €512 million per year and since 2008 between €217 and €338 million per year. Part of the quantified benefit is linked to a reduction in productivity losses, and hence provides a direct benefit to the affected industries.

7.6 Legislation-specific estimates

Key findings:

- Compliance with the different legislative requirements following the classification of a substance entails significant costs for industry. Different legislative approaches (automatic triggering of risk management measures following CMR listing, through to triggering only after further assessment at EU, Member State, or economic operator level) are used to address the specific characteristics of the risks associated with different legislative scopes.
- It is not possible to fully appreciate the benefits of the legislation, as its implementation ensures the avoidance of some of the impacts on human health and the environment attributable to the exposure to hazardous chemicals, but the magnitude of these impacts cannot be quantified.
- There is evidence for significant benefits of chemicals regulation as a result of CLP classification, for example linked to the Seveso Directive. For other legislation, the picture is more mixed; for example, measures under the Toy Safety Directive for a specific substance (lead) demonstrate a high cost-benefit ratio but the impact assessment for the Directive as a whole is more equivocal.
- As a result, evidence for unnecessary burdens imposed on stakeholders is mixed: analysis of possible options on Plant Protection Products, for example, suggests possible large impacts on agricultural production if legislation were to follow a particular course.

7.6.1 Plant Protection Products and Biocidal Products Regulations

Plant Protection Products (PPPs)[89] and Biocidal Products[90] both contain substances that are deliberately released into the environment during use and lead to exposure of humans and the environment. They are intentionally bioactive, a property that is, naturally, necessary for control of

[89] Several parts of the impact assessment regarding EDCs at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0211&from=en

[90] European Commission (2009): Commission Staff Working Document – Accompanying document to the proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products: Impact assessment. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0773&from=EN
Several parts of the impact assessment regarding EDCs at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0211&from=en

pests and plant diseases. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used. The legislation, therefore, sets out harmonised rules to protect human health, animal health and the environment; it is also intended to strengthen the functioning of the internal market; the Plant Protection Products Regulation also includes an objective to improve agricultural production.

7.6.1.1 PPP Impact Assessment (2006)

The 2006 Impact Assessment[91] concerned measures to improve the efficiency of implementation of legislation on plant protection products, moving from the initial Directive to a Regulation. The main objectives of the proposal were as follows:

- Simplification, better definition and streamlining of procedures;
- Increasing the level of harmonisation throughout the EU; and
- Coherence of the text with the general EU policy in the same subject area.

Recognition is given to the diversity of stakeholders that would be affected, the general public, farmers, the pesticide industry, consumers and Member States, and a series of policy options were defined:

- Policy action 1: Authorisation of PPP containing a new active substance/national provisional authorisation;
- Policy action 2: Mutual recognition of PPP containing an active substance already approved;
- Policy action 3: Comparative assessment of PPP;
- Policy action 4: Data sharing for the renewal of approval of an active substance; and
- Policy action 5: Informing neighbours on PPP use.

The impact assessment then considers a number of options for each policy action against the following impact categories:

- Economic impacts: Administrative burden, Indirect costs for PPP users, Investment of producers in R&D, PPP industry competitiveness;
- Social impacts: Employment, information, animal welfare; and
- Environmental impacts: Environment, human health, unauthorised cross border sourcing of PPP.

Effects were not quantified, but were scored on a scale from ++ (very significant positive impact) to – (very significant negative impact). In some cases the direction of impact was unclear and a +/- score was given, this applying particularly to Policy action 4. Of course, a drawback in any such system is the subjectivity of the scoring and in the aggregation of scores across categories. More detailed information is available in a study for the Commission by the Food Chain Evaluation Consortium (FCEC), provided in the Annexes to the Impact Assessment[92]. However, again, the level of

[91] European Commission (2006): Commission Staff Working Document – Report on the impact assessment for a regulation replacing Directive 91/414/EEC on plant protection products. Available at: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2006/sec_2006_0931_en.pdf.

[92] European Commission (2016): EU legislation on MRLs. Available at: http://ec.europa.eu/food/plant/pesticides/legislation/docs/report_impact_assessment_2006_annexes_en.pdf

information provided falls short of a quantitative assessment of the benefits of action to health and the environment.

7.6.1.2 Biocidal Products Regulation

Like plant protection products, biocidal products are biologically active by design. The Impact Assessment addressed the following issues, with a number of options explored for each:

- Extension of scope to cover processing aids and food contact materials, and treated articles;
- Product authorisation;
- Data sharing focused on animal testing;
- Changes to data requirements; and
- Fees charged by Member States for carrying out the procedures of the Biocides Directive.

The Impact Assessment goes into some detail on the costs of the options. However, for benefits it is stated that '*the impact assessment shows that the extension of the scope to treated materials will result in significant environmental and human benefits even though these are difficult to quantify. The other policy options will help maintain the current high level of environmental and human health protection. Regarding the social impacts, no significant impacts on employment are expected. However, the individual policy options, in particular the changes in product authorisation, obligatory data sharing, improved waiving provisions and the revised concept for low risk biocidal products may have positive impacts on employment.*'

The cost and cost saving estimates are largely administrative costs, though in part this reflects the nature of the provisions assessed in the Impact Assessment, as can be seen from the table below.

Table 7-4: Costs and cost savings from the Impact Assessment of the Biocidal Products Regulation (2015 prices)

Preferred option	Total costs / cost savings
Scope: extend scope to treated articles	Costs between €210 and 780 million spread over 10 years
Product authorisation: Facilitation, improvement and strengthening of mutual recognition	Cost savings up to €770 million spread over 10 years
Product authorisation: Community authorisation for certain categories of products	Cost savings up to €2.1 billion spread over 10 years
Data sharing: Mandatory sharing of vertebrate animal test data at product authorisation and active substance approval stage	Cost savings between €1.5 and 3 billion spread over 10 years
Data requirements: Rewording provisions concerning data waiving and the use of existing information	Cost savings between €470 and 850 million spread over 10 years
Data requirements: Reformulating the system for low risk biocidal products	Cost savings between €180 million and 370 million spread over 10 years
Fees: Partially harmonized fee structure	N/A
Fees: Specific provisions for SMEs	Cost savings between €83,000 and 700,000 spread over 10 years
Total costs	**Between €210 and €780 million spread over 10 years**
Total cost savings	**Between €3 billion and €6.3 billion spread over 10 years**

The analysis on extending the scope to include treated articles came to the following conclusions on benefits:

- Benefits would arise from the creation of a level playing field with third-country manufacturers of treated articles, particularly in the markets for treated wood where imports amount to 10-20% of the market and for wool carpet where imports amount to 25-45% of the market;

- The human health impacts are likely to be significant given the size of the market with treated articles in the EU, though as elsewhere there was no quantification of effect given a lack of response data. It was, however, observed that exposure to biocidal substances can lead to severe allergic reactions in sensitive groups and for workers; and

- Environmental impacts may also be significant. They include leaching of hazardous substances to soil and groundwater, impacts on aquatic organisms and the local ecosystems.

7.6.1.3 Impact on European crop yield of a pesticide ban to reduce EDC contamination

The Commission's impact assessment on defining criteria for EDCs[93] highlights the difficulties in quantifying impacts, noting that there was a lack of reliable and sound data to assess impacts. It also stated that: *"… The preliminary assessment of the evidence concluded that it would not be possible to quantify impacts, as data would neither be of sufficient quality nor reflect reality due to the high level of uncertainties and assumptions made. In addition, some approaches to estimate impacts would - as a consequence of the variable data availability in the different areas – create a strong imbalance between the assessments of the areas."*

A multi-criteria analysis was applied in lieu of economic analysis, so there are no estimates of costs or benefits that can be referenced here. It is of note though that Option 2 in the Impact Assessment (which is the option that the Commission is currently proposing) would result in an estimated 26 active ingredients in plant protection products and 5 active ingredients in biocidal products being identified as endocrine disruptors (out of a screening of 347 plant protection and 98 biocidal products active ingredients).

A recent study by Steward Redqueen for ECPA (the European Crop Protection Association, representing the crop protection industry) found that, as a result of the EU moving towards hazard-based legislations, several substances for plant protection used in the EU are at risk due to the automatic bans on approval linked to classification as a PBT/vPvB, mutagenic or an endocrine disruptor. The study identifies 75 active substances out of the 400 currently available that may be impacted by classification and other regulatory decisions (e.g. under the Water Framework Directive), as well as the final choice of endocrine disruptor criteria. The latter is the most important with the majority of the substances identified as potentially meeting cut-off criteria for endocrine disruption. The study notes that if substances are withdrawn they will not be easily replaced for two reasons: firstly, the development of new active ingredients up to market introduction takes about 11 years and costs over €280 million, and the pipeline of products waiting for approval for the European market is also declining due to rising research and development (R&D) time and costs (i.e. 70 substances in pipeline in 2000, down to 28 in 2012).

[93] European Commission (2016): Impact Assessment – Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation, Main report, Staff Working Document, SWD(2016) 211 final, Part 1.16, 15 June. Available at: http://ec.europa.eu/health/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

The economic losses linked to the potential loss of the 75 substances considered by Steward Redqueen were estimated for 7 staple crops at the EU level and 24 specialty crops across 9 EU Member States, representing 49% (in value) of EU crop output (indicated as being €204 billion). The study found that for the 7 staple crops alone, losses to farmers could equate to around €17 billion in crop value due to lower yields and increased production costs; this is associated with 1.2 million direct jobs, 30% of which could be lost due to lost margins (profits) for these crops. If the analysis for sugar beet is correct, it would be likely that farmers would seek alternative crops unless they considered sugar beet critical to their rotation. Further implications in terms of self-sufficiency and land use were also identified.

Table 7-5: Yield loss for EU-28 from main crops owing to ban of 75 substances used in crop protection products

Crop	Increased variable costs, €million	Lost revenues, €million	Total cost, €million	Loss of gross margin
Wheat	694	3,424	4,118	39%
Vine	850	3,256	4,106	37%
Potatoes	316	1,853	2,169	37%
Oilseed rape	604	1,428	2,032	46%
Sugar beet	488	1,265	1,753	>100%
Barley	185	1,429	1,614	51%
Maize	168	1,111	1,279	35%
Total	**3,305**	**13,766**	**17,071**	

The figure of €17 billion represents 8% of the value of EU-28 crop production in 2015. However, it is important to note that the Steward Redqueen work is subject to a number of important assumptions, as listed on page 13 of their report:

1. All 75 substances are removed from the market at once.
2. No other substances are introduced in the next five years. The authors state that "given lengthy R&D and approval processes this might not be an unrealistic scenario", though the study appears not to consider substance development that is already in the pipeline.
3. The counterfactual scenario adopts the best currently available alternative solution in the farmers' toolbox and Good Agricultural Practices (including chemical, biological, mechanical and cultural practices).
4. The various crops are studied in isolation; crop rotation (or any significant change in the rotations) or other changes in the production area have not been taken into consideration. However, farmers would undoubtedly respond in the event that production was significantly affected, perhaps by growing different varieties of crop or different crops altogether.
5. Analysis is based on 5-year average productivity and costs (2009-2013). Steward Redqueen state that "further, we look at the average effects for all farmers per crop in each country to obtain a conservative insight at the national and EU level. However, we recognised volatility in yields and prices are important aspects in agriculture. Therefore, the results might be rather conservative".
6. Yield and variable costs per hectare are subject to change ceteris paribus, that means the utilised area and ex-farm prices are assumed to be fixed.

Whilst the authors are keen to stress factors that bias their analysis towards conservatism, assumptions 1 and 4 are not conservative, and the same seems likely to apply to assumption 2. It is not clear why assumption 5 might be 'rather conservative'. Assumption 6, with ex-farm prices fixed,

is clearly a major simplification, as reduction in yield would tend to push up prices received by farmers, though of course this has a consequent dis-benefit for consumers.

The Steward Redqueen report provides analysis for the UK on a slightly different basis to its analysis of other European countries. Instead of considering all substances at high and medium risk of being lost to the market, the UK analysis follows the analysis by Anderson (2014) in only considering those at high risk (although it does include a few additional substances that are specific to the UK market). Whilst results for the UK are broadly consistent with the EU average for wheat and oilseed rape, they are considerably lower for barley (10% UK loss vs. 17% EU average loss), potato (12% vs. 20%) and sugar beet (12% vs. 37%). These results demonstrate the sensitivity to assumptions on what will and will not be included in the legislation.

In contrast, the Commission's Impact Assessment considers that it is not yet possible to determine what the impacts would be. Furthermore, the above estimates are for 75 key active ingredients rather than the 26 identified by the Commission. However, the above figures indicate the potential impacts of the end selection of the criteria to the agricultural sectors. These costs do of course need to be set against the potential benefits to human health and the environment, which may be significant. For example, in Olsson et al. (2014), the total tangible and intangible costs to society in relation to male reproductive health are estimated to range from €59 million to €592 million per annum across the EU-28, depending on the etiological fraction of diseases assumed to be directly caused by endocrine disruptors. Obviously, these costs will be linked to a much broader set of chemicals than just those used in plant protection products.

7.6.1.5 Costs of introducing new active ingredients

A recent study undertaken by Phillips McDougall for CropLife America and the European Crop Protection Association found that the average cost of discovering, developing and registering a pesticide active ingredient rose by €33 million or 11.7% to €320 million between 2005-08 and 2010-14. The study noted a major increase in the number of new active ingredients that are synthesised and subjected to biological research in order to lead to the registration of each new crop protection product. The number of active ingredients being researched in the period 2010-14 was more than three times the number researched in 1995. However, the average number of products which make it through to the developmental stage has declined from an average of four in 1995 to only 1.5 on average in 2010-14.

The survey also examined expenditure by leading crop protection companies on R&D, the proportion spent on its various aspects and changes between 2014 and 2019. The total cost of agrochemical R&D expenditure in 2014 for the 11 companies surveyed, including the top six, was €2,920 million, a value equivalent to 5.4% of their agrochemical sales. The expectation of R&D expenditure in 2019 was an increase of 22.6% to €3,600 million, at an average annual rate of increase of 4.1%.

Respondents were also asked to provide a regional breakdown of development and stewardship costs (all the R&D criteria except research of new active ingredients). Europe accounted for the largest share of the development budget in 2014 at 41.1%.

7.6.1.6 Exposure to pesticides and biocides and impact on cancer

A variety of cancers have been associated with exposure to pesticides, including cancer of the lung, pancreas, colon, rectum, bladder, prostate and brain, non-Hodgkin lymphoma, leukaemia and melanoma (Weichenthal et al, 2010). Increased incidence of cancers has been noted in both workers and children (see Chen et al, 2015). Although ex-post analysis of benefits through a reduced number of cancers is lacking, there is some evidence from Sweden (PAN-UK, 2006) and Germany

(RPA, 2016) that there has been a reduction in the number of cases of occupational disease, including cancers, linked to the use of pesticides and other chemical agents. Precise quantification of these benefits of the legislation, however, is not possible, because of other factors, such as increased awareness of health and safety practices and changing practices in the workplace. Data on the benefits of legislation on biocides is similarly limited.

7.6.2 Regulation (EC) 1223/2009 addressing risks from cosmetic products

The 2008 Impact Assessment on cosmetic products[94] starts from the position that the number of adverse reactions to cosmetic products is very low. Considering that each year approximately 10 billion units of cosmetics are sold, it is anticipated that the incidence of undesirable effects will be around 10,000 to 20,000 per year across the EU. Most of these effects are not serious, in other words, they would not cause "*permanent or significant disability/incapacity, hospitalisation, congenital anomalies, immediate vital risk or death*".

Figures from the French competent authority reported 40 serious undesirable effects in 2005 and a similar number in 2006. Most "non-serious" adverse reactions take the form of minor allergic reactions and irritations. It is also noted that since the Cosmetics Directive (and subsequently the Regulation) came into force there had been no major safety crisis. However, whilst the Directive appears to have worked well on this basis, the assessment notes that complacency is not an option, given the large volume of goods sold, the constant change in formulations and the use of new ingredients, including nanomaterials.

This level of innovation creates difficulties for impact assessment and it is stated that:

> "*It is not possible to quantify – let alone to quantify in monetary terms – the impact of future innovation in the cosmetics sector on product safety and consumer health*."

The Impact Assessment considered the following objectives, for each of which a series of policy options were identified:

- Objective 1: Clear and coherent single legal text including facilitated managing of the cosmetics legislation;
- Objective 2: Removing divergences between national law;
- Objective 3: Ensuring a high level of safety in cosmetic products in the light of innovation in the industry; and
- Objective 4: Introducing a possibility to regulate CMR cat 1 and 2 substances on the basis of their actual risk.

Objective 1 is not linked to issues related to the CLP Regulation. Objective 2 could be, depending on the nature of the divergences in question, though no quantification of benefits is provided in the Impact Assessment. The benefits highlighted concern chiefly reduced costs of administration and improvement of the single market. Discussion of Objective 3 deals with a number of possible measures that could be taken, but the impact discussion is focused on costs rather than benefits (noting the statement cited above, that effects on product safety and health could not be quantified).

[94] Regulation (EC) 1223/2009 addressing risks from cosmetic products. Impact assessment for the Directive (used here for illustration of the effects of the Regulation): http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_0117_en.pdf

An example given for Objective 4 concerns the widespread use of ethanol in perfumes (see also Case Study 11). Classification of ethanol as a CMR cat 1 or 2 substance would automatically ban its use in perfumes for application to the skin under the Cosmetic Products Regulation, but uses for direct consumption in food and drink would persist – creating an obvious inconsistency in risk management. However, a concern discussed in the Impact Assessment was that there could be some public perception that a move from a hazard based approach to a risk based approach would reduce consumer safety. Two policy options beyond business as usual were considered for this objective, factoring risk into the classification stage (policy option 2), and allowing in exceptional cases the use of a CMR cat 1 and 2 substance provided that the use of the substance is safe (policy option 3). Of these, policy option 3 was recommended in the Impact Assessment. Given the requirement for demonstration of safe use, this option should have no impact on health or the environment.

This Impact Assessment thus provides no information on benefits that is of use here. The relevance of the policy objectives to classification under CLP is, however, limited. A number of amendments have been made to the Regulation since its adoption, though impact assessments for these have not been identified. If the view that quantification of health impacts cannot be performed has persisted it is possible that any additional impact assessment material will not provide further insight of use here.

The removal of substances from cosmetics use requires manufacturers to either stop manufacture of a product line or reformulate. Reformulation in the industry will be done for a number of reasons unrelated to legislation, not least linked to changing fashions and behaviours. The view that reformulation costs are entirely attributable to legislative change is therefore often untrue. Costs can be very low, for example where a substitute is readily available, or significantly higher where it is not, or where reformulation involves significant change to the production process. In some cases costs may fall where an expensive ingredient is substituted by a cheaper one. Compliance periods are a significant determinant of cost, with short compliance periods adding to costs for a variety of reasons, linked to accelerated product development, and the need to scrap material if it can no longer be sold (White et al, 2002). Of course, a shorter compliance period will lead to greater protection of the public in the short term. Longer compliance periods also increase the possibility that manufacturers will be able to coordinate regulatory response with existing plans for reformulation.

White et al. estimate that this coordination will be limited to about 5% of manufacturers if reformulation is required within 12 months, compared to 40% if the compliance period extends to 4 years. Taking account of various factors through the product development phase, White et al. provide estimates of costs ranging from €12,000 to €920,000 per formula (inflated to 2015 prices). The range is broad, but analysis is presented in a disaggregated manner to enable the use of results for further calculations. These costs are of course non-recurring: once a substance has been phased out it is unlikely to return again. However, several manufacturers may need to reformulate when any substance is withdrawn from the market.

Analysis presented in the Background Document to the opinion of RAC and SEAC for proposed restrictions on D4 and D5 in wash-off products provides an estimate of €350,000 per product, broadly in line with the estimates of White et al. (RAC/SEAC, 2016). There is potential here for overestimation of costs given the large number of product lines estimated to be affected (>3,000): it is clearly to be expected that lessons learned from one case would be carried over to others. Sensitivity to the period permitted for change was noted.

Research by RPA (2007) generated a rather different range, based on a survey of companies potentially affected by the then Cosmetics Directive, with estimated costs of reformulation rather

evenly spread over a range from <€500 to >€100,000. Again, the time available for adaptation was regarded as a significant factor in determining costs. Further costs would be incurred for bringing new product to market, of a broadly similar magnitude to the costs of developing substitute formulations.

7.6.3 Toy Safety Directive

The first of the two Impact Assessments identified for the Toy Safety Directive [95] considered the range of concerns targeted by the Directive, including safety warnings, choking risk, suffocation risk, special requirements for toys in food and clarifying the general requirement for safety as well as 'new provisions on chemical requirements'. With respect to the latter, three policy options were considered:

1. Status quo + ban on allergenic fragrances;
2. Status quo + ban of allergenic fragrances and ban of all CMRs cat.1 and 2 unless authorised under REACH; and
3. Status quo + ban of allergenic substances and ban of all CMRs cat. 1, 2 and 3, unless authorised by dedicated comitology procedure.

The quantified costs and benefits of these options are shown in Table 7-6. The preferred option from the Impact Assessment is Option 3, although quantified costs exceed benefits. The logic given for this is that costs were considered likely to be overestimated and benefits underestimated, the latter because of the lack of account taken on impacts on health systems and productivity losses. Given the modest (<10%) difference in costs and benefits and associated uncertainties, the raw results of the CBA are not considered definitive. Given a desire for a strong level of protection for children, Option 1 (status quo) was then eliminated. Option 2 was also eliminated though on different grounds: that it would likely be challenged by WTO. This led to the recommendation for Option 3, as it was considered that it would circumvent the possible WTO problems.

A second impact assessment was carried out by Matrix Insight for DG Enterprise in 2012 and focused on children's exposure to lead from toys and on the benefits of reducing such exposure. The driver for this work at this time was that the migration limit for lead introduced in the 2009 Toy Safety Directive was to be enforceable from July 2013, reflecting a 4 year transition period. The study considered a number of lead related health impacts; kidney damage, hearing problems, behaviour and attention problems and slowed body growth. Economic analysis focused on behaviour and attention problems (ADHD), reduced IQ[96]. Two policy options were considered:

1. A set of migration limits for [dry, brittle, powder like or pliable substances; 4 mg/kg], [liquid or sticky substances; 1 mg/kg] and [scraped-off substances; 47 mg/kg].
2. The same set of migration limits for man-made materials, but a higher set for materials that naturally contain lead.

3. Overall health costs were calculated at €253 billion under the baseline scenario, with benefits of €32 billion for policy option 1, and €31 billion under policy option 2 (results inflated to 2015

[95] Directive 2009/48/EC on the safety of toys - Impact assessments. Available at: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_0038_en.pdf

[96] 'Slowed body growth' is also mentioned, but it is understood that analysis indicated that exposures were below a level at which impacts could reasonably be quantified.

prices). Roughly 40% of impacts were attributed to IQ loss and 60% to behaviour and attention problems.

Table 7-6: Costs and benefits of options for the Toy Safety Directive (millions €, 2015 prices), 2008-2051			
	Option 1	Option 2	Option 3
Costs			
NPV Financial costs Of which…	5,811	15,566	15,859
Administrative	563	1,507	1,536
Distributional	2,570	6,884	7,013
Manufacturing	2,678	7,174	7,309
Comitology			3
Other economic	Enforcement and compliance costs Costs of delay in innovation and in authorisation Administrative burden	Enforcement and compliance costs Costs of delay in innovation and in authorisation Administrative burden	Enforcement and compliance costs Costs of delay in innovation and in authorisation Administrative burden
Other social	Risks from substitutes 1,200 jobs lost	Risks from substitutes 3,000 jobs lost	Risks from substitutes 3,300 jobs lost
Other environmental	None	None	None
Benefits			
NPV financial benefits	14,362	14,755	14,833
Other economic			
Other social	Reduction in burden on health systems Reduction in productivity losses	Reduction in burden on health systems Reduction in productivity losses	Reduction in burden on health systems Reduction in productivity losses
Other environmental	None	None	None

Further assessments have been carried out under REACH concerning Restrictions on the use of lead in jewellery and consumer articles, with analysis provided on the ECHA website. Whilst neither is directly linked to the Toy Safety Directive, both were assessed relative to the potential for ingestion of lead by mouthing infants. It is of note that in both cases the magnitude of the benefits being discussed were orders of magnitude lower (although in the case of lead in consumer articles the assessment was based on a break-even analysis rather than a hard estimate of benefits).

Tris(2-chlorethyl)phosphate (TCEP) is used as a flame retardant plasticiser and viscosity regulator in polyurethanes, polyester resins, polyacrylates and other polymers. Its use in toys has been considered under Case Study 11. TCEP has been classified as a carcinogen Cat 2 and, on the basis of its effects on fertility, a Reprotoxin category 1B under CLP. As a result, TCEP should in theory be subject to the automatic ban on CMRs under the Toy Safety Directive, although specific concentration limits have been employed instead. It has been detected in polyurethane foam used in toys and its presence in toys imported into the EU and sold on the EU market was identified as an issue. In addition to the regulatory requirements set under the Toy Safety Directive, TCEP was also subject to authorisation under REACH. No applications for its continued use were submitted, suggesting that industry was able to move away from the substance. As a result, one must assume that industry found alternatives to the use of TCEP or to forego the need for it within some of the polymers.

Technopolis (2015) assessed the relevance of the Toy Safety Directive in addressing current needs, effectiveness and efficiency of its provisions, its coherence with the EU legislative framework and

the European added value. Overall, based on a largely qualitative assessment, compliance and administrative costs arising from the Directive were concluded to be proportionate relative to the Directive's objectives. Evidence was also collected to support the view that uniform legislation across Member States was of significant value to the industry.

7.6.4 Revision of Directive 2004/37/EC carcinogens or mutagens at work

In May 2016, the European Commission published a proposal to establish new or revised OELVs for a list of 13 priority chemical agents, together with an Impact Assessment that sets out the expected impacts of the proposed changes. The impact assessment presumes a 7% reduction in exposures using data from analysis by Cherrie et al. (2011). The 13 chemical agents, their carcinogenic effects and the proposed OELVs are described in Table 7-7. At the present time, OELVs exist for many chemical agents although these may differ between member states and may not be legally binding. The estimated number of deaths and estimated cancer cases for the period 2010-2069 if no further action is undertaken under the Carcinogens and Mutagens Directive are given in Table 7-8.

Table 7-7: Proposed OELVs for 13 chemical agents under the Carcinogens and Mutagens Directive

Chemical agent	Carcinogenic effect	Proposed OELV
1,2-Epoxypropane	Lymphopoietic cancer, haematopoietic cancer, increased risk of leukaemia	2.4 mg/m^3
1,3-Butadiene	Lymphohaematopoietic cancer	2.2 mg/m^3
2-Nitropropane	Liver tumours	18 mg/m^3
Acrylamide	Pancreatic cancer	0.1 mg/m^3
Bromoethylene	Liver cancer	4.4 mg/m^3
Chromium (VI) compounds	Lung cancer, sinonasal cancer	0.025 mg/m^3
Ethylene Oxide	Leukaemia	1.8 mg/m^3
Hardwood dusts	Sinonasal cancer, nasopharyngeal cancers	3 mg/m^3
Hydrazine	Lung cancer, colorectal cancer	0.013 mg/m^3
o-Toluidine	Bladder cancer	0.5 mg/m^3
Respirable Crystalline Silica	Lung cancer	0.1 mg/m^3
Refractory Ceramic Fibres	Possibly lung cancer	0.3 f/ml
Vinyl Chloride Monomer	Angiosarcoma, hepatocellular carcinomas	2.6 mg/m^3

Table 7-8: Estimated number of deaths, cancer cases and health costs for 2010-2069 with no action

Chemical agent	Estimated number of deaths	Estimated number of cancer cases	Estimated health costs (€ million)
1,2-Epoxypropane	-	-	2.8-11.8
1,3-Butadiene	100	160	45-180
2-Nitropropane	not assessed	not assessed	not assessed
Acrylamide	230	250	170-360
Bromoethylene	-	0	not assessed
Chromium (VI) compounds	17,000	24,000	9,500-30,000
Ethylene oxide	0	0	0
Hardwood dust	5,000	12,000	3,300-18,000
Hydrazine	710	2,500	600-3,300
o-Toluidine	150	490	95-770
Refractory ceramic fibres	50	60	36-91
Respirable crystalline silica	440,000	470,000	210,000-540,000
Vinyl chloride monomer	300	300	210-520

The results demonstrate the variation in impacts between substances, and hence the desirability of prioritising substances for action in order to gain the highest benefits over time. Results from the Commission's subsequent impact assessment are shown Table 7-9, where the figures in bold denote the OELs in the subsequent proposal from the European Commission[97].

Table 7-9: Avoided cases, compliance costs and benefit cost ratios for different OELVs in the Commission's Impact Assessment (not adjusted to 2015 prices for consistency with recently published Impact Assessment)

Chemical agent	OELV (mg/m^3)	Benefits, €	Compliance cost, €
1,2-Epoxypropane	12 **2.4**	No additional benefits **A few €k**	No significant impact **€1-2k**
1,3-Butadiene	11 **2.2** 1.1	€0-0.1 million **€0.2-0.6 million** €0.2-0.6 million	€0.7-4.4 million **€5.8-37.8 million** €9.2-59.9 million
2-Nitropropane	**18.25**	**Not possible to estimate impact**	**No significant additional costs**
Acrylamide	**0.1** 0.03	**No additional benefits** No additional benefits	**No additional costs** No additional costs
Bromoethylene	**4.4**	**n/a**	**No data**
Chromium (VI) compounds	0.05 **0.025**	€0.44- 1.3 billion **€0.591-1.7 billion**	€3.6-13 billion **€13.4-52.3 billion**
Ethylene oxide	**1.8**	**No health benefits**	**No significant cost**
Hardwood dust	**3** 1	**€12-54 million** €66-325 million	**No significant cost** €13-52 billion
Hydrazine	0.13 **0.013**	€0-0.02 million **€0.01-0.05 million**	€2-12 million **€5-32 million**
o-Toluidine	4.4 **0.5** 0.4	No change **not assessed** €0.2-1.3 million	Minimal **not assessed** €0.2-1.4 million
Refractory ceramic fibres	1 f/ml **0.3 f/l** 0.1 f/ml	€1.1-3 million **€1.1-3.4 million** €1.2-3.4 million	No significant costs **€1-6 million** €60-139 million
Respirable crystalline silica	0.2 **0.1** 0.05	€27.7-73.7 billion **€34-89 billion** €36.5-97.1 billion	€207 million **€3.5 billion** €15.7 billion
Vinyl chloride monomer	5.1 **2.6**	€1-2 million **€1-4 million**	<€1 million **€4-8 million**

The issue of proportionality was considered further in the Commission's Impact Assessment[98], where it is stated that: "*Generally speaking… even where it is estimated that current exposure levels are*

[97] European Commission (2016): Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016PC0248

[98] European Commission (2016): Commission Staff Working Document Impact Assessment – Accompanying the document Proposal for A Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: http://ec.europa.eu/transparency/regdoc/index.cfm;jsessionid=3EAB7C00BF4B14D59E2D411F4A3934A7.c

already very low, lack of EU OELs or too high EU OELs mean that it will still not be clear for employers and workers and enforcing authorities whether the achieved exposure level is satisfactory from the point of view of compliance with the minimisation principle of the CMD." This together with the desire to create a level playing field between member states was considered sufficient to justify the proportionality of proposals. In the case of CrVI, the fact that an OEL close to the figure recommended by ACSH (Advisory Committee on Safety and Health) is already adopted in France, where there are a high number of exposed workers, was considered to demonstrate that solutions are available to practically implement the recommended OEL.

Case Study 11 also looks at the impact of the Carcinogens and Mutagens Directive for other substances (formaldehyde, lead metal and gallium arsenide), although on a more qualitative basis. The formaldehyde case demonstrates the presence of some flexibility within the market, with alternatives available for some, perhaps many, users. The lead and GaAs examples demonstrate the flexibility that is present within the legislation and the desirability from a cost and feasibility perspective of recognising case-specific factors when developing the legislation.

7.6.5 The Seveso Directive

7.6.5.1 The Seveso III Impact Assessment

The Seveso III Directive (2012/18/EU) repealed the earlier Seveso II Directive, making the following changes:

- Updating and aligning the list of substances covered by the Directive to the EU legislation on the classification of dangerous substances;
- Strengthening citizens' rights on access to information, justice and on participation in decision-making;
- Improving the way information is collected, managed, made available and shared;
- Introducing stricter standards for inspections ensuring a more effective implementation and enforcement; and
- Clarifying and updating of provisions, including streamlining and simplification to reduce administrative burden.

The principal benefits relevant to this discussion can therefore be summarised as:

- Increasing protection of public health;
- Increasing protection of the environment;
- Increasing access to information, and the various benefits that brings (e.g. via transparency and participation in decision making), with a focus on the list of chemicals considered by European experts to be of most concern; and
- Strengthening the single market through more consistent implementation and enforcement.

The Impact Assessment of the Seveso III Directive provides some cost estimates; though these are restricted to administrative costs (see the note to the table). It also provides a qualitative indication of benefits as the following table, summarised from the Impact Assessment, shows. The reasons for uncertainty in benefit estimation relate in part to questions on the level of implementation.

fusion14601?fuseaction=list&n=10&adv=0&coteId=10102&year=2016&number=152&version=F&dateFrom=&dateTo=&serviceId=&documentType=&title=&titleLanguage=&titleSearch=EXACT&sortBy=NUMBER&sortOrder=DESC

Regarding the costs and benefits of Option 3e: Safeguard clause, it is stated that: *"The impacts will depend on how often such a clause is used. In any specific use of such a clause, the benefit will be an increased protection level for human health and the environment… The benefits of using delegated acts to effect changes to annex I from application of options (c) and (e) would be increased speed, flexibility and efficiency in amending Annex I. The protection level would remain the same or slightly increase."*

Table 7-10: Summary table of options considered in the Seveso III Impact Assessment (2015 prices)			
Policy issue	**Economic impact***	**Protection level**	**Other impacts**
1. Alignment of Annex 1	-4.2% to +0.3% (-€1.2M to +€5.39M)	Decrease through to small increase	Higher admin costs
2. Other technical amendments to Annex I			
2a/b/c Hydrogen, heavy fuel oil	Neutral or limited impact	Unchanged to slight decrease	
2d Aerosols, CLP approximation proposal	+€0.54M/year	Unchanged to slight increase	
2e Aerosols, higher threshold	-€3.2 to 4.3 M		
2f Sodium hypochlorite, accept LP reclassification for mixtures	€3.8 to 4.3 M/year	Increased	
2g Sodium hypochlorite exemption	Neutral or limited impact	Unchanged	
3. Procedure for changing Annex 1			
3b/c/d Allow Member States to grant derogations from some or all Seveso requirements based on harmonised criteria	Potential savings for industry and CAs	No or low impact (condition for derogation)	Potential risk of market distortion, allows flexibility in light of CLP
3e Introduce Safeguard clause	Potential increase in scope	Potential increase	Allows flexibility in light of CLP
4A. Type of information to the public, with different options offering various levels of information,	Costs ranging from €0.54-1.1M for set up + €54-110k per year, to set up costs of €22M + annual costs of up to €2.2M/year	Increase	Better access to information and associated benefits
4B Management of information through databases at Member State or EU level	Set up costs of €1.1M + €54-110k/year, up to 'substantial costs to adapt all existing systems to one database format	Increase	Better access to information
5. Land use planning, with options from minor clarifications to extending requirements	Potential savings up to one off costs of several hundred million or billion EUR	Limited impacts up to a significant increase	
6A. Closer coordination, integration of information and procedures	Cost savings of approximately €0.54M/year	Possible slight increase	Simplification, greater efficiency, more harmonised implementation
6B. Other improvements and clarifications, various measures	Most have a significant increase in costs, e.g. €27M for set up and €1.1M annually	Potential increase or increase	
Notes: **Economic impacts are administrative costs. Non-administrative compliance costs, for example related to such physical modifications have not been considered as they are very site specific and it has not been possible to quantify these.*			

7.6.5.2 Information from the stakeholder consultation

The targeted stakeholder data collection exercise and Case Study 13 also gathered information on the link between CLP and Seveso III. Interestingly, few industry respondents indicated that any of their facilities had been newly brought into the scope of the SEVESO III Directive. Amongst those that were affected, one formulator indicated that 30 sites newly fell under Seveso, while others noted, for example, that "*so far, two warehouses have changed requirements (H1 to H2)*", "*some plants now fall into scope*", "*9 sites, 7 now fall in scope*" and "*we now fall into scope due to heavy fuel oil inclusion*". One manufacturer noted: "*Not ours, but downstream users' plants yes, they have indicated to us that total cost of implementing changes could be up to 100,000,000 EUR (one hundred million EUR)*".

In response to the open public consultation, employers and manufacturers associations also raised concerns over the automatic links between CLP, REACH and Seveso. They highlighted that substances may fall into the Major Hazards regime if they come under one of the categories in Annex 1 of the Seveso III Directive regardless of whether or not they have major accident potential. CEEMET and EEF also indicate that the controls that companies have to introduce to comply with this Directive can reach up to €100,000.

7.6.5.3 UK estimates of avoided costs

The Seveso Directive[99] is concerned with the prevention of major industrial accidents and the establishment of emergency plans in the event that accidents occur (see also Case Study 13). The legislation was established in response to a number of serious accidents at chemical plant in the EU and elsewhere, including the Italian town of Seveso itself, and Flixborough in the UK.

Major industrial accidents are, fortunately, rare. This makes the assessment of the potential damage costs associated with an accident difficult (noting that costs avoided in this case concern not only health and environmental impacts, but also cost savings through avoiding accidents, the clean-up operations that would follow them, lost production and so on). Calculation of impacts is complicated by variability in numerous aspects, including the hazard posed by differing substances, the surrounding human population, weather conditions, the sensitivity of the receiving environment and so on. However, a recent study by HSE (2015) provides analysis of the economic impacts of accidents at major hazard sites. A driver for carrying out this analysis was the major fire at Hertfordshire Oil Storage Terminal at Buncefield just north of London, for which HSE estimates costs through injuries, damage to buildings, and impacts on business and the environment to be in the order of €1.3 billion[100] (value has been adjusted to 2015 €).

The HSE work performed modelling for all 1,700 major hazard sites in Great Britain for three main hazard types associated with overpressure, flammable and toxic effects. Analysis followed an impact pathway approach, and considered costs through harm to people, buildings and businesses, the costs of evacuation and costs for the emergency services. Averaged (mean and median) results per site are shown in Table 7-11, indicating a cost of €153 million (mean) and €36 million (median).

[99] The Seveso Directive (now Seveso-III, Directive 2012/18/EU), recognises the need to use large amounts of dangerous chemicals in certain industries, but aims at minimising associated risks and ensuring appropriate preparedness and response should accidents nevertheless happen.

[100] Despite this large figure, damage to human health could have been substantially greater had the accident not occurred early on a Sunday morning, when staffing levels on the site were very low.

Table 7-11: Average costs per site for major accidents in Great Britain (2015 prices, €million)		
	Mean per site	Median per site
Site count	1,725	
Population impact		
Non-financial human costs	95	20
Financial costs	41	8
Total population impact	**136**	**28**
Evacuation	0.24	0.008
Building damage	6.6	1.8
Business disruption	7.1	0.73
Business temporary relocation	0.48	0.13
Emergency services	2.9	0.73
Total cost	**153**	**36**
Note: The median cost components do not sum to the total median cost as they are calculated independently		

The authors of the HSE report adopt 'representative worst case' assumptions (in other words, not the absolute worst case, but the worst case of sufficient frequency to be relevant). However, there are reasons for considering these estimates to be conservative, including:

- The valuation of mortality uses a value for 'non-financial human costs' that is only one third of the value recommended by OECD (2012) from a meta-analysis of the international valuation literature. Including the higher estimate could double the overall estimate of damage from major accidents; and

- The analysis may omit some significant forms of impact through a focus on the local scale. The UK authorities were very ready to dismiss the potential for a public health impact of the plume of particulate matter generated by the Buncefield fire (based on analysis by AEA Technology, 2006). However, this position is in contradiction of the widely held view that there is no threshold at the population level for impacts of fine particles on health (see, e.g. WHO, 2013). Incremental exposures to these particles may thus have been low, but aggregated across a large population at the European scale, damage could be substantial.

In addition to the results shown in Table 7-11, the HSE study also provides a breakdown of mean costs by type of activity, demonstrating a high level of variability between sites, as may be expected.

Table 7-12: Average (mean) costs from major accidents, by type of activity (Source: HSE, 2015)			
	Number	% of sites	Mean cost per site, € million
Ammonium nitrate	170	10%	140
B1 - very toxic a	65	4%	168
B1 & B2 a	59	3%	252
B2 - toxic a	80	5%	130
B3 (oxidising)	14	1%	405
Chlorine	74	4%	391
Ethylene and propylene oxides	8	0.5%	82
Large scale petrol storage	38	2%	671
LPG bulk storage	428	25%	120
LPG cylinder storage	110	6%	17
Low volatility toxic	19	1%	4
Mixed substance	106	6%	266
Natural gas - high pressure	74	4%	46
Natural gas - low pressure	238	14%	182
Oxygen	15	1%	24

Table 7-12: Average (mean) costs from major accidents, by type of activity (Source: HSE, 2015)			
	Number	% of sites	Mean cost per site, € million
Refrigerated flammable liquids	19	1%	127
Various flammables	204	12%	41
Various toxic	4	0.2%	48
Total	**1725**	**100%**	**151 (average)**
Note a: Generic classifications where HSE used a single exemplar substance to represent the effects of substances within the group			

Consideration has also been given to the use of insurance data as a measure of benefits. However, no data were available. In any case, the interpretation of insurance data is complicated as it would require an understanding of the way that insurers estimate the risk of specific facilities, and other factors such as the expected magnitude of impacts. An important uncertainty in the assessment of the benefits of this legislation concerns the fact that major accidents are atypical events that cannot be easily predicted. Purely technical models have significant limitations in predicting interactions between risk factors[101]. They can also underestimate behavioural influences, particularly in industries that consider themselves to be 'very safe', with significant potential for habituation to the risks that are present.

7.6.3.4 Summary for Seveso III

The difficulties of estimating costs and benefits of modifications to Seveso are explicitly recognised in the impact assessment provided by the Commission. The cost estimates provided by the Commission are generally modest, though account for only part of the costs, possibly a small part. In contrast, some of the cost estimates provided in the stakeholder consultation are extremely large, but no further detail has been provided to substantiate these figures.

However, the Seveso Directives appear to be having a beneficial effect, with the number of major accidents broadly declining over the period 2000 – 2011 (AMEC-EU-VRi, 2013). That said, 2010 was the year with the highest recorded number of major accidents, though this appears to be an anomaly, given that numbers in surrounding years are low compared to the rest of the time series. The number of fatalities on and off site has fallen rather steadily across the time period, and also the number of injuries (though here, 2008 stands out as a bad year). These trends are evident despite an increase in the number of plant affected by the legislation over time.

7.7 Conclusions

Although it is possible to identify and describe a range of different costs and benefits associated with particular legislation in qualitative terms, quantitative data on the costs and benefits of the downstream legislation linked to CLP is very sparse. Where it does exist for specific legislation, it is also typically incomplete, particularly for environmental benefits. Additionally, there has been a lack of ex-post analysis of legislation previously (though it should be noted that the Commission has a series of studies that are ongoing that will help to fill this gap).

[101] For an example of risk factors interacting, see the Cullen Report into the Piper Alpha Disaster of July 1988, when 167 people died on a North Sea oil rig. Cullen W. D. (1990) The public inquiry into the Piper Alpha disaster. London: H.M. Stationery Office. ISBN 0101113102.

As a result, it is difficult to use the available evidence to conclude on the comparative efficiency of the different legislative approaches. The evidence for unnecessary burdens imposed on stakeholders is mixed.

The data show that there can be cases where the impacts associated with on-going exposures to a substance can be significant and clearly outweigh the impacts on industry of a ban on the use of that substance (the example given for toy safety and lead). This highlights the potential efficiency of the generic risk approach in such cases where there may be widespread, and on-going exposure of vulnerable populations. However, the Impact Assessment for the Toy Safety Directive found that the anticipated benefits were below the calculated costs of the preferred option, with this justified on the basis that benefits were likely to be underestimated and costs overestimated, the likely position of WTO, and Member State views on risk aversion for children.

The impact assessment for the Cosmetic Products Regulation clearly considered the adoption of a specific risk assessment approach, but instead concluded that a generic risk approach with a risk assessment based derogation should be adopted, even though there are cost-benefit calculations and the potential impacts for a substance in widespread use such as ethanol were recognised; as indeed was the fact that the automatic ban could result in an obvious inconsistency across the legislative framework. In this case, a factor appears to be concern over public perceptions regarding consumer safety. Although in this case the industry sector shares this concern at present, there may be cases in the future, such as ethanol, where industry will argue that feasibility and social interest should also be taken into account.

Such arguments are already being made with regard to plant protection products, although it is too soon in its implementation to establish what the actual impacts of the generic risk approach may be compared to a more specific risk approach for CMRs. The available studies highlight the importance of these parts of the chemicals sector for society, through information regarding the reduction of crop losses to pests and disease, and the prevalence of infections associated with healthcare. The potential for worsening problems linked to resistance to pesticides and biocides as the number of substances declines is noted. These cases demonstrate the need to strike the right balance in the legislation. The PPP example also highlights the need to properly understand the basis on which analysis has been performed: the Steward Redqueen report, for example, makes a number of worst case assumptions. An understanding of how impacts accumulate under worst case assumptions provides useful insight for optimising subsequent policy.

The impact assessment for the Biocidal Products Regulation foresees ways in which impacts may be mitigated. On the one hand there are additional costs under the regulation linked to extension to treated articles. On the other hand, a number of areas for cost saving were identified, which, together, substantially outweigh estimates of added cost from the actions proposed for the Regulation (although these are not linked to the automatic triggers within the legislation). The major question of course concerns the extent to which endocrine disrupting substances are linked to health impacts and the magnitude of any effects from biocidal (or plant protection) exposures. Whilst this is not currently known (and hence health benefits cannot be quantified) there is a logic for protecting public health and the environment by discouraging the widespread use of such substances. Although it is inherently difficult to reach the right balance with respect to precaution when data are unavailable, there may be longer term benefits to industry from giving a clear signal now, as this will inform the future selection of candidate biocides and pesticides, with the potential for avoiding regrettable investments. In the interim, however, the availability of derogations on the basis of risk, technical feasibility and economic grounds may be important to ensuring overall efficiency.

With respect to the Carcinogens and Mutagens Directive, analysis has been performed for all of the substances for which new EU OELs have been proposed recently by the Commission. In a number of cases there seems no argument about the proportionality of these OELs. Some appear more controversial, where estimated benefits are significantly lower than estimated costs. In this case, however, the specific risk assessment approach has been followed, so the trade-offs involved in the Commission's proposals are clear. The formaldehyde and gallium arsenide cases demonstrate the flexibility that is present within the legislation, and the desirability from a cost and feasibility perspective of recognising case-specific factors when developing the legislation.

Finally, the Seveso case illustrates how tailoring under the specific risk assessment approach can help improve the cost-effectiveness of actions by recognising that location-specific analysis has a role in some situations.

More generally, the Task 1 report gives annual costs of CLP implementation of €1.3 billion (on an annual basis this figure is broadly consistent with the results of Technopolis, 2016, though the Technopolis report is not specific to CLP legislation). Poison Centre reporting costs are additional to this (€1.7 billion per year). A partial analysis of benefits indicates that the average annual value of reductions in poisoning incidents, occupational skin and respiratory diseases and occupational cancers since 2000 is between €391 and €512 million per year and since 2008 between €217 and €338 million per year. Part of the quantified benefit is linked to a reduction in productivity losses, and hence provides a direct return to the affected industries.

RPA et al (2016) presents some good evidence that the exposure to substances that have been restricted by legislation has decreased over the years. A complete quantification of the actual benefits is, however, not possible, given uncertainty over the health impacts that would have occurred in the absence of legislation. As an illustration of the possible consequences of not having the chemical legislative framework in place, South Korea is currently working on a national law "imitating the European Biocidal Products Regulation"[102], following the death of 189 people and the long term lung injuries suffered by 506 people caused by the use of polyhexamethylene guanidine (PHMG) as a biocide in humidifier sanitiser products put on the Korean market by different companies. The companies involved face compensation expenses, loss in market shares and profits, as well as reputation damages in the order of hundreds of millions of euros[103].

[102] ChemicalWatch news on 1 June 2016. Available at: https://chemicalwatch.com/47729/work-on-south-korea-biocides-law-begins and CW news on 10 May 2016. Available at: https://chemicalwatch.com/biocideshub/47273/south-korea-begins-work-on-new-biocides-regulationglobal/

[103] Financial Times news article on 29 July 2016. Available at: https://www.ft.com/content/c0725ae4-5573-11e6-befd-2fc0c26b3c60

8 Implementation and Enforcement

8.1 Introduction

Key findings:

- Market restrictions are generally considered to be precise and clear, easy to implement (although search for alternatives may not be) and enforceable. The overall likelihood of compliance was assumed to be high by most stakeholders.
- Internet sales have been identified as resulting in illegal cross border trade of substances and products containing substances that are not permitted for use, this is highlighted through the use of the RAPEX system.
- With regard to illegal trade in PPPs, it has been found that Member States with third country land borders are generally those which are considered to have the highest level of illegal PPPs; large western European Member States may have higher than average levels of illegal PPPs; Nordic Member States (Denmark, Sweden and Finland) are generally considered to have the lowest level of illegal PPPs.
- It has been noted that it can be difficult to enforce the OSH legislation where substances/ mixtures do not fall under the scope of the CLP Regulation.
- The differences in enforcement regimes, sanctioning and availability of resources have been highlighted as the main reasons for inconsistencies in enforcement across the EU.
- A more harmonised approach has been sought through enforcement networks such as the REACH Annex XII and CLP (FORUM), biocidal products (CLEEN and BEG) and RoHS (RoHS Network), although the positive impact of these is yet to be established.

This section considers the consistency of implementation and enforcement activities with respect to the risk management of chemicals. This includes the likelihood of compliance and enforceability and consistency in national implementation. The relevant evaluation questions are set out in Table 8-1.

Table 8-1: Implementation and enforcement

Q #	Evaluation question
1.4.1.	Are the main elements of the EU legislative framework for the risk management of chemicals effectively and consistently implemented across all Member States? If there is a disparity in the way legislation is implemented, what are the consequences of such a disparity?
1.4.2.	To what extent is enforcement effective and consistent across all Member States? Are the frequency of controls, sanctions and liabilities consistent and comparable in different Member States?
1.4.3.	Are there other incentives to comply with the chemicals legislative framework (e.g. other market based incentives, consumer demands)?
1.4.4.	Are there any measures in place at EU level to support enforcement? Are these tools effective and sufficient?
1.4.5.	Do all actors including regulatory agencies (e.g. ECHA, EFSA) and the Commission consistently implement all aspects of the chemicals legislative framework in accordance with its objectives and intentions?
1.4.8.	Is the legislation and its original intentions properly reflected in interpretation and guidance documents and in implementing decisions taken by implementing institutions and authorities, including the Commission?

Table 8-1: Implementation and enforcement	
Q #	**Evaluation question**
1.4.9.	Are risk management measures imposed under the EU chemicals legislative framework designed in a way which makes it plausible that they are/will be complied with and to what degree are they enforceable?
2.1.5.	To what extent do duty holders, in particular SMEs, receive support in complying with the chemicals legislative framework? To what extent does this support improve the efficiency of the legal framework?
4.2.11.	Are there any national discrepancies in the implementation of chemicals legislation?
2.2.6.4	Are the risk management measures enforceable in practice or easily circumvented?
3.3.2.	To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?

8.2 Likelihood of compliance and enforceability

The likelihood of compliance is a difficult measure to judge and opinions vary. Member States have identified issues with enforcement with respect to the linkages between OSH legislation and other chemicals legislation (CLP and other). One authority has indicated that they have experienced difficulties when enforcing the OSH legislation with regards to the substances/mixtures not falling under the scope of the CLP Regulation. They gave the example of cosmetic products, where the hazards of such products are not apparent and it can be difficult for the inspector to provide the necessary evidence that the cosmetics falls under the OSH legislation definition of hazardous, which is required evidence in order to give an injunction.

For plant protection products, enforcement can be effectively implemented, for example 5m buffer zones, but this does not mean that it is. There is an issue with the implementation of testing methods as they are not always appropriate and are based on a nationalistic approach, e.g. testing of a plant protection product on both sides of the Rhine when the conditions are the same. Some stakeholders consider this problem to lie in the allowing industry to self-regulate.

Overall, it is considered that risk management measures are enforceable in theory but not necessarily in practice. Market restrictions are generally considered to be precise and clear, easy to implement (although search for alternatives may not be) and enforceable. The overall likelihood of compliance was assumed to be high by most stakeholders.

However, a report by the CLEEN network (Erdmann et al, 2016)[104] has highlighted issues regarding internet sales of hazardous substances. It found that "if inspectors detected products being in breach of law but being posted for sale on websites abroad, they could not act directly and immediately due to the lack of the legal basis. Instead, these cases had to be forwarded to the authorities in the country of origin". This point was corroborated by a Member State. Another conclusion reached by Erdmann et al. (2016) is that "private persons illegally offer dangerous chemical products on the internet to a large extent. Although a relevant minority of traders deliberately violates existing regulations, the obtained results indicate that it is reasonable to assume that private persons are usually not well informed on the legal restrictions concerning chemicals and use the online tools simply because they are available and accessible".

A response by UEAPME to the first stage consultation of the European social partners on the amendment of certain EC directives on health and safety at work as a result of adopting the CLP

[104] Erdmann. L., Frenzel. S. & Landauer. P (2016) Project e-commerce II – internet chemical trade: final report

Regulation, has suggested that "particular attention should focus on ensuring that references in the current directives also refer to the respective requirements in the annex of the CLP Regulation and hence allow compliance. For instance, regarding the Directive 2004/37 (the Carcinogens and Mutagens Directive) there should be a concrete reference to point 3.5 and 3.6 of the CLP annex"[105].

ECPA are of the opinion that realistic implementation timelines need to be defined based on testing capacity. They believe that a minimum of 12 months allows for proper preparation for the plant protection product sector.

Concern has been raised with enforcement of the Biocidal Products Regulation. One stakeholder has claimed that they "fail to see any real enforcement of risk management measures for biocides". The example given was that "there was a requirement under the Biocidal Products Regulation linked to all suppliers of active substances in Europe to be a part of the review programme and the Article 95 list. Products containing active substances from suppliers not on the Article 95 list should have been removed in September 2015. However, we have not yet seen any enforcement here".

The European Commission's Rapid Alert System (RAPEX) for non-food dangerous products allows for the rapid exchange of information between the national authorities of 31 countries and the European Commission on dangerous products found to be on the market[106]. The European Commission publishes the alerts in a weekly overview which includes information on the dangerous product, the risks identified and the measures taken to prevent or restrict their marketing or use. Differences in the number of products deemed dangerous between the countries that are reporting cannot be taken as the sole indication of national compliance, as it may be the case that some countries use RAPEX more than others, offering up a discrepancy. RAPEX notifications from 2012 to 2016 were examined for toys, cosmetics and chemical products. The number of notifications for chemical risks in toys increased between 2012 and 2014, then began to decrease between 2014 and 2016. The worst example of a breach of the rules on chemicals in toys was in the case of a male doll with accessory kit. This product contained 42% w/w of di(2-ethylhexyl)phthalate (DEHP). This substance is not permitted in toys above 0.1% by weight. The country of origin for this product was China, with the measures adopted being voluntary withdrawal from the market by the importer. This case highlights the issue that has been commented on by stakeholders, whereby risks of breaches in chemical safety are commonly found in products which have been imported into the EU from countries outside of the EEA.

8.3 National discrepancies in implementation

Availability of resources in Member States has been highlighted as one issue which can result in differences in compliance and enforceability. Countries which have greater resources at their disposal (workers available and financial input) are considered more likely to be able to undertake enforcement activities.

[105] UEAPME (2010) UEAPME response to the first-stage consultation of the European social partners on the amendment of certain EC directives in health and safety at work as a result of adoption of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

[106] European Commission (2016) Rapid Alert System – Weekly Notification Reports. Available at: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.listNotifications

A study carried out for DG SANTE (2015) highlighted a number of issues with the illegal trade of pesticides in the EU. It found that 10% of the EU PPP market is made up of illegal PPPs. The pattern observed is that (Agra CEAS Consulting, 2015)[107]:

- "Member States with third country land borders are generally those which are considered to have the highest level of illegal PPPs;
- Large western European Member States may have a higher than average levels of illegal PPPs;
- Nordic Member States (Denmark, Sweden and Finland) are generally considered to have the lowest level of illegal PPPs".

This study explains that "despite these differences, it should be noted that the perceived levels of illegal PPPs do not necessarily reflect the effectiveness of the control measures in place in the Member State. In some Member States, the level of PPPs may be considered to be low due to a lack of awareness of the problem and thus of regular enforcement. In other Member States, the perceived high level of PPPs may be due to greater detection resulting from higher levels of controls" (Agra CEAS Consulting, 2015).

Areas which could be the entry points for the illegal trade in PPPs were identified by the study, with Antwerp, Hamburg and Rotterdam identified as the main points of entry although illegal shipments have also been identified as passing through some Mediterranean ports. It was noted though that a lack of evidence of illegal shipments in other EU ports does not mean that they are not occurring; they may not be being detected due to the low level of controls (Agra CEAS Consulting, 2015). Ports are not the only point of entry for this illegal shipment, as smuggling across land borders with third countries has also been raised as an issue. It would appear that where this is occurring, the products are not being sent onwards for sale in other Member States.

This study for DG SANTE also considered the differences in national implementation and enforcement. Controls in Member States are considered to be complimentary measures for tackling the issue of illegal PPPs. Article 68 of the Plant Protection Products Regulation requires Member States to carry out official controls to ensure compliance with the regulation[108]. It has been noted that different Member States take different approaches to these required controls (Agra CEAS Consulting, 2015):

- "marketing – checks on retailers in all Member States, and other parts of the chain such as manufacturers, repackagers and wholesalers in some Member States;
- Composition – comparison of a PPPs composition as regards its technical specifications to that established in its authorisation;
- User controls – which involve one or more of the following: residue tests, examination of the register of use, water sample pollutant tests, controls of the method of application".

Article 67 of the Plant Protection Products Regulation theoretically allows for the traceability of PPPs through the system and requires producers, suppliers, distributors, importers and exporters of PPPs

[107] Consortium led by Agra CEAS Consulting (2015): Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU.

[108] The Plant Protection Products Regulation is not the only piece of legislation that requires Member States to carry out official controls to ensure compliance. The Prior Informed Consent Regulation (EU No. 649/2012) requires Member States to control the import of chemicals listed in Annex I, which too would contribute to preventing illegal trade,

to keep records for 5 years. This traceability differs between Member States. Some consider it possible to trace PPPs through the chain, while others consider it only partly possible or impossible to trace PPPs once they are on the market. The European Commission Food and Veterinary Office (FVO) has performed audits in 19 Member States, spanning 2012 to 2014, in order to check Member State compliance with relevant EU legislation in the area of PPPs, including controls and sanctions.

The results of these audits were:

- "Evidence of delays with re-authorisations of PPPs under Directive 91/414/EEC, and with mutual recognitions under Regulation (EC) No 1107/2009; many authorised PPPs had not been evaluated to EU standards, more than 15 years after the principles for evaluation had been established. Similarly, delays and problems with cooperation between Member States were identified for the zonal authorisation system under Regulation (EC) No 1107/2009. This highlights the difficulty of Member States to implement authorisation systems based on EU legislation;

- Emergency authorisations of PPPs under Regulation (EC) No 1107/2009: the report identifies problems with misuse of emergency authorisations for minor uses of PPPs, but also for other use extensions of approved PPPs. In addition, emergency authorisations for the same products have been granted for consecutive years, thus undermining the effectiveness of the strict criteria for regular authorisations established by EU legislation;

- Competent authorities were designated and their responsibilities were clearly defined;

- Significant delays of Member States in the evaluation or re-evaluation of PPPs highlight the difficulty to implement authorisation systems based on EU legislation, delays also observed in the evaluation for mutual recognition due to non-acceptance or lack of trust in assessments of reference Member States, misinterpretation or misuse of emergency use of authorisation was witnessed in one third of Member States audited;

- Systems in place for official control on the marketing of PPPs, with the exception of two Member States who had no systematic approach;

- In most Member States that were audited there was no systematic approach or strategy regarding counterfeit and illegal pesticides, this was in part due to the limited analytical scope of PPP quality controls and the weakness in labelling checks. Insufficient cooperation and coordination where more than one CA is involved in these activities was a contributing factor; and

- Overall, official controls on the use of PPPs are of better quality and more effective than controls on the marketing of PPPs[109].

The Agra CEAS Consulting (2015) study found it difficult to draw EU-wide conclusions due to the differences in control measures across Member States. They found that the lack of harmonisation played a significant role in national differences, whilst the awareness or interest of certain competent authorities and the resources available to them impact individual Member State measures and their effectiveness. They also noted that resources appear to be a significant factor in

[109] Food and Veterinary Office (2015) Overview report: Controls of plant protection products in Member States. Available at: http://ec.europa.eu/food/audits-analysis/overview_reports/ details.cfm?rep_id=79

the effectiveness of controls, recommending the development of a centralised EU database to gather information about all PPP authorisations. They also suggest the establishment of an EU Reference Laboratory for product composition as a step to ensuring a level playing field across the EU and improving the coordination of laboratory activities.

Member States have also highlighted issues with the consistency in enforcement between Member States. The differences in enforcement regimes, sanctioning and availability of resources have been highlighted as the main reasons for inconsistencies in enforcement across the EU. A more harmonised approach has been sought through enforcement networks such as the REACH Annex XII and CLP (FORUM), biocidal products (CLEEN and BEG) and RoHS (RoHS Network), although the positive impact of these is yet to be established. The ECHA FORUM is considered to be a good tool for facilitating discussion and should lead to greater cooperation. Another issue raised by a Member State is the different interpretation of legislation, guidance documents and borderline issues (such as medicines and treated articles under the Biocidal Products Regulation).

Discrepancies have also been identified in the authorisation of biocidal products and plant protection products at the national level. With regard to PBTs/vPvBs this may regard the depth and care with which other components of PPPs and biocidal products are assessed, as well as the interpretation and use of national derogations. In the targeted consultation, plant protection product manufacturers pointed out several differences in national approaches towards classification of products, which may extend also to other aspects of authorisation. These will affect the consistency of risk management under this legislation.

Risk management under the Water Framework Directive is partly carried out by the Member States. Apart from considering the substances in Annex X of the Water Framework Directive, Member States are also to develop lists of substances of priority concern in their own territory. Furthermore, risk management can be implemented using different legal instruments (e.g. installation permits, product authorisations) as well as measures developed and implemented as part of the River Basin Management Plans. This variety of options to manage risks from PBT/vPvB at national level under the Water Framework Directive leads to flexible approaches toward risk management in the Member States, which is intended by the legislator. However, it also means that there will inevitably be differences in approach to risk management.

It has been noted that there are inconsistencies between Member States in the implementation of the ban on CMRs in cosmetic products, due to confusion surrounding when the ban on CMR use should be enforced (entry into Annex VI of CLP or entry into Annex II CPR). This has now been clarified by the Working Group and Standing Committee on Cosmetic Products.

Findings from the 2015 evaluation of the Toy Safety Directive indicated that national differences in the implementation of the Directive hinder to some extent its effectiveness in ensuring the smooth functioning of the internal market. The major example of such inconsistencies is the German application of different chemical limit values. According to a Polish SME, this has an "*enormous impact on industry (especially SMEs) without improving toy safety*" (Technopolis et al., 2015).

Indeed, according to the majority of Member States, a relevant issue for the internal market of toys is the low consistency in the implementation of the Toy Safety Directive at national level. It should be noted that the Toy Safety Directive and its implementation is not solely concerned with chemicals and the Technopolis report reflects this. It should also be acknowledged that when the consultation for the Technopolis study was carried out, the chemical requirements under the Toy Safety Directive had stood for less than a year and so experience with the implementation of these was limited. The biggest problem relates to the adoption by Germany of different chemical rules (finding 12) than those established in the Directive (Technopolis et al., 2015). It is important to note that on the 9th

July 2015, the European Court of Justice rejected the German government's request to maintain different limits for arsenic, antimony and mercury in toys in its implementation of the Toy Safety Directive. This decision is based on the fact that Germany has not been able to provide evidence that a higher level of protection for public health would be granted by imposing different requirements (further details are provided in Case Study 8).

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Annex 1 - Legal Analysis of Key Legislation

A1.1 The Cosmetic Products Regulation

The Cosmetic Products Regulation follows a hazard-based approach regarding CMRs, but with greater flexibility than the approach taken in the former Cosmetics Directive (Directive 76/768/EC). Substances classified as CMRs 1A, 1B and 2 are in principle banned from cosmetic products on the basis of their hazard classification (Article 15). However, they can be authorised if the formulator can demonstrate within 15 months (for CMRs 1 A and 1 B) or at any time (for CMRs 2) that the substances have been found safe by the SCCS. Additional conditions apply to CMR 1A and 1B; the formulator must prove that substances 1) comply with food legislation (Regulation 178/2002), 2) that no suitable alternative is available and 3) that the application for derogation is made for a particular use of the product category with a known exposure. If the formulator is unable to meet these criteria within 15 months, then the substance will be prohibited indefinitely. According to stakeholders, no derogation has been granted for CMR substances yet, although one case is under consideration.

This approach taken in the Cosmetic Products Regulation has been proposed during the Impact Assessment as part of policy options in order to avoid inconsistencies between legislative regimes for different products. Under the repealed Cosmetics Directive, substances classified under CLP as CMR 1 and 2 based on their intrinsic properties were automatically banned in cosmetic products. The ban therefore depended on their hazard classification and did not consider exposure and use (Impact Assessment, p. 16). This was considered as leading to "incoherence between legislative regimes for different products". The Impact Assessment gave the example of ethanol, which was considered for classification as CMR 1 in 2006. If ethanol had been classified as CMR 1, perfumes in cosmetics would have automatically been banned, whereas ethanol-containing food and beverages would not have been affected by the classification (Impact Assessment, p.16).

The Impact Assessment identifies three possible options: no EU action, taking risk into consideration at the classification stage, and giving the possibility to allow, in exceptional cases, the use of a CMR 1, 2 substance provided that the substance is safe. The third option has been considered preferable, since the second option would have led to a significant revision of the regulatory systems for chemicals in the EU – as the classification system for chemicals in the EU is based on hazard. As a downside, the Impact Assessment mentions the increase in administrative costs for the submission of the safety files that would be incurred by manufacturers, which was, however, considered as justified by the benefits of the option.

A1.2 The Toy Safety Directive

Directive 88/378/EEC was revised in 2009 and replaced by Directive 2009/48/EC on toy safety (the Toy Safety Directive) on the basis of an Impact Assessment which identified problems in the application of safety requirements[110]. In particular, the Impact Assessment concluded that "the existing essential safety requirements of the Toy Safety Directive do not always correspond to the technical progress and are thus outdated", "do not respond fully to recently identified hazards", and generally need to be clarified (Impact Assessment, p. 11). More specifically regarding chemical

[110] European Commission (2008) Commission Staff Working Document Accompanying document to the Directive of the European Parliament and of the Council amending Directive 88/378/EEC on the safety of toys, Impact Assessment.

substances, the Impact Assessment identified a gap since at the time of the adoption of the Directive, the general knowledge on the use of chemicals in toys was limited. Market surveillance surveys have shown the presence of dangerous chemicals in toys (especially CMR), including chemicals not regulated at EU level such as allergens and nitrosamines (Impact Assessment, p.12). The 1988 Toy Safety Directive did not contain provisions regulating the use of dangerous substances like CMR or allergenic fragrances.

Exposure to chemicals was therefore a main focus of the revision of the Toy Safety Directive. Prohibitions of CMR substances, allergenic fragrances and migration limits for metals have been introduced as part of the revision of the Directive.

The general approach adopted, as mentioned in recital 21 of Directive 2009/48/EC on toy safety, considers specific risks related to children, which are a vulnerable group of consumers. The lack of provisions on CMR was in particular pointed out in the Impact Assessment since children can get in direct contact with toys by e.g. sucking. In comparison, the Impact Assessment points out that rules exist for cosmetic products that come into direct contact with the skin, with regard to the use of CMR chemicals and allergenic fragrances (Impact Assessment, p. 13). The approach chosen in the new Toy Safety Directive therefore also considered alignment with other chemical legislation, in particular REACH and the legislation on cosmetics.

The impact assessment recommends a risk-based approach, taking into account the characteristics of the toy to determine the exposure to CMR, and in particular whether the substance is accessible, for example in toys containing plastics as opposed to toys containing encapsulated chemical preparations or substances (Impact Assessment, p. 13).

The Toy Safety Directive indeed follows a risk-based approach concerning CMR substances. CMRs of categories 1A, 1B and 2 are not allowed in toys unless 1) they do not exceed the concentration limits established in CLP (category 1A/1B carcinogens and mutagens: 0.1%; toxic for reproduction: 0.3%; category 2 carcinogens and mutagens: 1%, toxic for reproduction: 3%) (Annex II.3 chemical properties, point 3), 2) they are inaccessible during use, 3) they are authorised after evaluation by the relevant Scientific Committee (Annex II.3 chemical properties, point 4 and 5).

This approach is close to what has been proposed in the Impact Assessment as the third regulatory option (considering accessibility and a limit of 0.1%). This approach is justified as ”workable in practice” as a ”content of 0% for any given chemical would be quasi-impossible to achieve”, and the 0.1 % is a well-established limit in chemicals legislation (Impact Assessment, p. 43).

The Toy Safety Directive also follows a risk-based approach regarding a number of metals listed in point 13 of part 3 of Annex II. Migration limits are based on assumed ingestion amounts and an allocation of a percentage of the Total Daily Intake to toys. In addition, “limit migration values must be applied to the elements listed except for toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin” (Annex II.3 chemical properties, point 13). These migration values have been set by the Scientific Committee on Health and Environmental Risks by calculating Tolerable Daily Intake, taking into account different exposure scenarios.

The same approach applies to nitrosamines and nitrosatable substances, which are prohibited for use in certain categories of toys: toys intended for use by children under 36 months or other toys intended to be placed in the mouth above a fixed migration limit (Annex II.3 chemical properties, point 8). Limit values have also been set for a number of chemicals in toys intended for use by children under 36 months or other toys intended to be placed in the mouth, such as TCEP, TCPP, TCDP and Bisphenol A (Appendix C to Annex II) (source: legal analysis)

However the Toy Safety Directive follows a hazard-based approach for allergens. A list of allergenic fragrances is prohibited in toys (Annex II.3 chemical properties, point 11). There are however exemptions for olfactory board games, cosmetic kits and gustative games provided that they are clearly labelled, contain safety warning and comply with relevant EU legislation (cosmetics, food) (source: legal analysis).

A1.3 The Biocidal Products Regulation

The Biocidal Products Regulation introduced hazard-based cut off criteria prohibiting the use of active substances with hazardous properties in biocidal products, including CMR 1A and 1B, CMR 2, other active substances with endocrine-disrupting properties pending the adoption of the Commission delegated act on the determination of endocrine disrupting properties, and active substances which meet the criteria for being PBT or vPvB according to REACH Annex XIII (exclusion criteria, Article 5(1)) (source: legal analysis).

However, exceptions are made if risks from exposure are negligible. Derogation from Article 5(1) can be granted if risks to humans, animals or the environment from exposure to the active substance is negligible – in particular if the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment (Article 5(2)). An active substance can also be permitted under Article 5(2) if it is essential to prevent or control a serious danger to human health, animal health or the environment; and if not approving the active substance would have a disproportionate negative impact on society compared to using it. In this case the authorisation is granted for five years (Article 4(1)). The authorisation can be renewed for 7 years (and not 15, as these substances are candidate for substitution under Article 10) if conditions for derogation are still valid (source: legal analysis)

The same approach applies to biocidal products: A biocidal product must not be authorised for making available on the market for use by the general public where (a) it meets the criteria for classification under Directive 1999/45/EC as toxic or very toxic or CMR category 1 or 2, (b) it meets the criteria for classification under CLP as acute oral toxicity category 1, 2 or 3, — acute dermal toxicity category 1, 2 or 3, acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3, acute inhalation toxicity (vapours) category 1 or 2, specific target organ toxicity by single or repeated exposure category 1, a category 1A or 1B carcinogen, a category 1A or 1B mutagen, or toxic for reproduction category 1A or 1B (Article 19(4)(b)). Exceptions can be made, although not on the basis of exposure or intended use.

A1.4 The Plant Protection Products Regulation

The Plant Protection Products Regulation introduced hazard based cut off criteria for CMR substances. It prohibits the use of substances as mutagen category 1A or 1B on the basis of higher tier genotoxicity testing and other data including review of the scientific literature; the use of substances classified as carcinogen or toxic for reproduction category 1A or 1B pursuant to the CLP Regulation, unless the exposure of humans, under realistic proposed conditions of use of the PPP, is negligible[111]; the use of substances considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans, under realistic proposed conditions of use of the PPP, is negligible. Pending the adoption of criteria by the Commission, substances that

[111] This is a key difference between the Biocidal Products Regulation and Plant Protection Products Regulation in their derogations. The Biocidal Products Regulation requires the **risk** to be deemed negligible, whereas the Plant Protection Products Regulation needs the **exposure** to be deemed negligible.

are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine disrupting properties.

The Plant Protection Products Regulation also introduces cut-off criteria for persistent chemicals. Active substances must not be approved if they fulfil the criteria to be considered as POPs, PBT or vPvB substances.

A1.5 The Chemical Agents Directive

The objective is to lay down minimum requirements for the protection of workers from risks to their safety and health, while allowing for sufficient flexibility to take into account circumstances at each workplace. At the same time, the Directive aims to avoid imposing unnecessary burdens on employers. For these reasons, the risk management approach is largely based on the assessment carried out by the employer. In general it seems that the balance has been appropriately struck; however, comparison with other OSH Directives and particularly the Carcinogens and Mutagens Directive raises some questions on whether some of the more fixed risk management measures and information duties could also be applicable in the context of chemicals other than carcinogens and mutagens (source: legal analysis).

A1.6 The Carcinogens and Mutagens Directive

The factors taken into account are largely the same as those under the Chemical Agents Directive. However, the consequences of exposure to carcinogens and mutagens are considered to be, as a general rule, more serious than exposure to most other chemicals, and also irreversible (source: stakeholder input). These considerations have led to the adoption of certain more fixed risk management measures, such as specified training requirements, more stringent substitution duties as well as a duty on the employer to regularly renew the risk assessment rather than just keep it up-to-date.

A1.7 The Pregnant and Breastfeeding Workers Directive

The particular vulnerability of pregnant and breastfeeding workers has led to the adoption of more stringently prescribed risk management measures at the EU level, leaving less scope for the situation specific assessment of employers. Pregnant and breastfeeding workers must be protected from exposure by way of adjusting the working conditions and/or the working hours. As the risk assessment is still carried out by the employer, it seems that sufficient flexibility is still allowed with respect to the individual circumstances of each workplace. The Commission has however provided additional guidelines for employers on the assessment of chemical agents and processes considered hazardous for pregnant and breastfeeding workers.

A1.8 The Young Workers Directive

The approach taken with regard to young workers is still theoretically risk-based, but in fact closely resembles a hazard-based approach, as young workers are to be completely prohibited from working in circumstances involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or which in any other way chronically affect human health. The aim behind this approach is to protect young workers from specific risks arising from chemical exposure, but due to the specific characteristics of young workers – namely, immaturity and inexperience – it is considered that normal risk management measures are not sufficient.

Annex 2 - Potentially self-standing national legislation with links to CLP

Table A2-1: Potentially self-standing national legislation with links to CLP	
France	
Name of the act[112]	**Link to CLP classification and requirements**
Arrêté du 6 mars 2013 fixant la liste des substances qui ne peuvent pas entrer dans la composition des produits de tatouage *(Order of 6 March 2013 establishing the list of substances prohibited in tattooing products)*	Substances classified as CMR 1A, 1B and 2 and sensitiser category 1 under the CLP Regulation are banned from tattooing products.
Arrêté du 26 octobre 2015 portant suspension de la mise sur le marché de jouets en mousse « tapis-puzzles » contenant du formamide[113] *(Order of 26 October 2015 suspending the placing on the market of foam toys 'puzzle matting' containing formamide)*	Importation and placing on the market of foam toys known as 'puzzle matting' containing over 200 mg/kg of formamide are suspended for a duration of one year. Similar Orders have been issued in previous years. The suspension is justified by the classification of formamide as a reprotoxic under the CLP Regulation.
Décision du 14 juin 2012 portant retrait et interdiction de la fabrication, de l'importation, de l'exportation, de la distribution en gros, de la mise sur le marché à titre gratuit ou onéreux, de la détention en vue de la vente ou de la distribution à titre gratuit et de l'utilisation de produits cosmétiques contenant la substance chloroacetamide *(Decision from 14 June 2012 prohibiting manufacturing, importation, exportation, bulk distribution, placing on the*	Manufacturing, importation, exportation, bulk distribution, placing on the market free of charge or against payment, holding for a purpose of sale or cost-free distribution and use of cosmetics products containing chloroacetamide are prohibited until measures are taken by the European Commission. The prohibition is justified on the basis of a recommendation of the European Scientific Committee on Consumer Safety and the

[112] The Ministry of Ecology, Sustainable Development and Energy has drafted a Decree which, once adopted, will amend the Environmental Code. Following the amendment, as of 1 January 2017 persons who place on the market 'chemical products liable to represent a significant health and environmental risk' must label the products with the crossed out wheeled bin symbol that is used under the WEEE Directive for waste electrical and electronic equipment to notify users that the waste and/or container is subject to special sorting instructions and must not be collected mixed with household. The list includes products of the following categories: pyrotechnics, extinguishers, products based on hydrocarbons, adhesion, sealing and repair products, surface treatment and coating of materials and surface preparation products, special maintenance and protection products, e.g. car polishers, common chemicals, solvents and thinners, household biocides and pesticides, and domestic fertilizers. However, no link to the CLP is made.

[113] The order does not transpose an EU legislative act. However, Directive 2015/2115 of November 2015 modifies Annex II, Appendice C of the Toys Directive in relation to formamide, following a recommendation of the French Food, Envrionmental and Occupational Safety Agency (ANSES). The Directive establishes an emission limit value of 20 µg/m3 after a maximum of 28 days from commencement of the emission testing for foam toy materials containing more than 200 mg/kg (cut-off limit based on content). This provision will enter into force by 24 May 2017.

Table A2-1: Potentially self-standing national legislation with links to CLP	
France	
market, holding for a purpose of sale or cost-free distribution and use of cosmetics products containing chloroacetamide)	classification of the substance as toxic for reproduction under the CLP Regulation. [A ban of chloroacetamide is being considered by the Commission. Public consultations have been held in 2015.]
Arrêté du 10 mars 2016 déterminant les phrases de risque visées au premier alinéa de l'article L. 253-7-1 du code rural et de la pêche maritime *(Order of 10 March 2016 defining risk phrases referred to in the first sub-paragraph of Article L. 253-7-1 of the Rural and maritime fisheries Code)*	Plant protection products cannot be used near schools and hospitals, with the exception of low-risk products, and products which have been exclusively classified as toxic for the aquatic environment or Hazardous to the ozone layer (H400, H410, H411, H412, H413, H059) under the CLP Regulation.
Arrêté du 12 juin 2015 modifiant l'arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L. 253-1 du code rural *(Order of 12 june 2015 on the placing on the market and use of phytopharmaceutical products referred to in Article L253-1 of the Rural and maritime fisheries Code)*	The order modifies rules on preharvest intervals and waiting periods aimed at protecting agricultural workers and consumers. Plant protection products classified as causing severe eye damage or irritation and causing skin irritation have a waiting period extended to 24 hours (instead of 6 or 8); products classified as causing allergy, asthma symptoms or breathing difficulties if inhaled and causing allergic skin reaction have a waiting period extended to 48 hours. [This order is a national risk management measure as stated in an Opinion from the Food, Envrionmental and Occupational Safety Agency (ANSES): Avis de l'ANSES concernant l'«application de la réglementation européenne relative à la classification, l'étiquetage et à l'emballage des substances et des produits phytopharmaceutiques», Saisine n° 2015-SA-0067]
Arrêté du 12 juin 2015 modifiant l'arrêté du 7 avril 2010 relatif à l'utilisation des mélanges extemporanés de produits visés à l'article L. 253-1 du code rural et de la pêche maritime *(Order of 12 June 2015 modifying the Order of 7 April 2010 on the use of unprepared blends of phytopharmaceutical products referred to in Article L253-1 of the Rural and maritime fisheries Code)*	The Order specifies which mixtures of plant protection products are, based on the CLP classification, subjected to prior evaluation by the French Food, Envrionmental and Occupational Safety Agency (ANSES). These products are those classified as acutely toxic, CMRs, toxics for organs after single or repeated exposure. [The 2015 Order modifies the 2010 Order to adapt it the hazard categories of the CLP Regulation] [This order is a national risk management measure as stated in an Opinion from the Food, Envrionmental and Occupational Safety Agency (ANSES): Avis de l'ANSES concernant l'«application de la réglementation européenne relative à la classification, l'étiquetage et à l'emballage des substances et des produits phytopharmaceutiques», Saisine n° 2015-SA-0067]

Table A2-1: Potentially self-standing national legislation with links to CLP	
France	
Arrêté du 30 décembre 2010 interdisant l'emploi de certains produits phytopharmaceutiques par des utilisateurs non professionnels *(Order of 30 December 2010 prohibiting the use of certain phytopharmaceutical products to non-professional users)*	Products classified as explosives, acutely toxic, toxic for organs, CMRs category 1 and 2, and products containing active substances classified as CMRs 1A and 1B, cannot be granted a marketing authorisation allowing their use by non-professional users. [This order is part of the national regulatory framework complementing the PPP Regulation. This is stated in an Opinion from the Food, Envrionmental and Occupational Safety Agency (ANSES): Avis de l'ANSES relatif à la « modification ou à l'apport de précision de l'arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels», Saisine n° « 2013-SA-0128 »]
Arrêté du 5 mars 2014 définissant les modalités d'application du chapitre V du titre V du livre V du code de l'environnement et portant règlement de la sécurité des canalisations de transport de gaz naturel ou assimilé, d'hydrocarbures et de produits chimiques *(Order of 5 March 2014 defining the application of chapter V of Title V of Book V of the Environmental Code and regulating the safety of natural gas, hydrocarbons and chemical products)*	Inflammable, harmful and toxic fluids are defined based on Annex I of the CLP Regulation. Risk management measures (surveillance and maintenance) are defined for these categories of fluids.
Germany	
Name of the act	**Link to CLP classification and requirements**
Packaging Ordinance of 21 August 1998 (VerpackungsVO) BGBl. I 2379	The German Packaging Ordinance provides that manufacturers and distributors of sales packaging of hazardous contents are obligated to ensure that the used and emptied packaging can be returned free of charge within a reasonable distance from the final user. They must inform the final user by clearly visible and legible signs at the point of sale and, in case of internet purchases by other appropriate means, of the possibility to return the packaging. If the final user is not a private household derogations can be made. If technically possible and economically reasonable, the packaging waste should be reused or recovered, pursuant to Section 8(1) and (2) Packaging Ordinance. 'Hazardous contents' are defined under the Packaging Ordinance, inter alia, as 'substances and mixtures' that, if distributed by a retailer, could not be purchased via self-service, as defined under Section 4(1) of the Chemicals Prohibition Ordinance. Under latter, the self-service ban applies to substances and mixtures that must be labelled with the hazard symbols T (poisonous), T+ (very poisonous) or F+ (highly flammable) or with the R-phrases R 40, R 62, R 63 or R68, according to the Hazardous Substances Ordinance. The term 'hazardous contents' is hence

Germany	
	linked to the classification under the Dangerous Substances Directive and Dangerous Preparations Directive. However, no direct reference is made.
Chemicals Act of 28 August 2013/ Chemikaliengesetz (BGBl. I S. 3498, 3991)	Pursuant to Section 16e (2) of the Chemicals Act, a physician who suspects that the disease of his patient has been caused by an exposition to hazardous substances or mixtures or articles containing or releasing such chemicals is obligated to inform the Federal Institute for Risk Assessment. The information needs to contain the name of the substance or mixture, age and sex of the patient, exposition route, the quantity that was taken in, and the identified symptoms. Regarding the classification as 'hazardous', the Chemicals Act also refers to the CLP.
Greece	
None identified.	
Italy	
None identified	
Latvia	
Regulation No 1117 of 14 December 2010 'The quality requirements for bio-oils and the utilisation and control procedures for bio-oils to be used for oiling cutting tools used in forestry operations' (*Ministru kabineta 2010.gada 14.decembra noteikumi Nr.1117 'Bioeļļas kvalitātes prasības un mežizstrādes darbos izmantojamo griezējinstrumentu eļļošanai lietojamās bioeļļas izmantošanas un kontroles kārtība'*) LV, 200 (4392), 17.12.2010.	According to Point 5 of Regulation No 1117, bio-oils must not contain any mineral oils or any toxic, carcinogenic, mutagenic, teratogenic or other additives that are dangerous to the environment. The Regulation does not contain definitions of these terms and also makes no explicit reference to measures implementing/transposing EU legislation. Nevertheless, to interpret these terms, one would use the definitions of hazardous substances and mixtures as laid down in the legislation implementing/transposing EU law such as the Chemical Substances Law, which implements the CLP Regulation.

Netherlands	
Name of the act	**Link to CLP classification and requirements**
Governmental Decree of 14 August 2003 on establishing rules concerning the safety of tattooing dyes (Commodities Act Decree on tattooing dyes) (*Besluit van 14 augustus 2003 tot het stellen van regels betreffende de veiligheid van tatoeagekleurstoffen* (*Warenwetbesluit tatoeagekleurstoffen*[114]))	The Commodities Act Decree on tattooing dyes finds its legal basis in Art. 4(1-3), 5(1-2) and 14 of the Commodities act (*Warenwet*[115]). In addition, the Commodities Act Decree on tattooing dyes defines Regulation 1223/2009 on cosmetic products. Art. 4(1)(e) of the Commodities Act Decree on tattooing dyes regulates that tattooing dyes can only be sold if, amongst others, it does not contain substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1A, 1B and 2 in Part 3 of Annex VI to Regulation (EC) No. 1272/2008.
Poland	
Name of the act	**Link to CLP classification and requirements**
The Act on packaging and waste packaging / Ustawa z dnia 13 czerwca 2013 r. o gospodarce opakowaniami i odpadami opakowaniowymi (Dz. U. z 2013 r., Poz. 888)	According to this Act, the person who places on the market hazardous substances/mixtures in packaging is obliged to organise the system of collection and ensure recovery, including recycling of waste packaging. In addition, pursuant to Article 18(2) of this Act, the person who places on the market a plant protection product which meets the definition of dangerous substance/mixture according to this act is obliged to finance the costs of collection performed by retailer or wholesaler and to receive from him, at his own expense, waste packaging. For the purpose of the Act, dangerous substance/mixture cover some of hazard classes from CLP Regulation for example substances and mixtures classified as toxic category 1, 2, 3 and as carcinogenic, toxic for reproduction, mutagenic category 1A and 1B or substances/mixtures classified for environmental hazard – category 1 for acute aquatic hazard and category 1 and 2 for chronic aquatic hazard. The definition includes also plant protection products classified, according to CLP, as toxic category 1, 2, 3 and hazardous to the environment – category 1 for acute aquatic hazard and category 1 and 2 for chronic aquatic hazard. To this end, Article 18(2) makes direct reference to the CLP. While the treatment of the packaging of pesticides is also subject to EU legislation, namely Article 13 of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides, a

[114] http://wetten.overheid.nl/BWBR0015471/2013-07-11.

[115] http://wetten.overheid.nl/BWBR0001969/2016-08-01#Artikel14.

	specific obligation of the person who places the product on the market as regards collection and financing thereof is not foreseen under the Directive. Arguably, therefore, Article 18(2) of the Polish Act on packaging and waste packaging could still be considered as 'self-standing legislation'.
Regulation on restrictions on the manufacturing, placing on the market or use of dangerous or hazardous substances and mixtures and the placing on the market or use of articles containing such substances or mixtures / Rozporządzenie Ministra Gospodarki z dnia 25 września 2013 r. w sprawie ograniczeń produkcji, obrotu lub stosowania substancji i mieszanin niebezpiecznych lub stwarzających zagrożenie oraz wprowadzania do obrotu lub stosowania wyrobów zawierających takie substancje lub mieszaniny (Dz. U. z 2013 r., Poz. 1173)	According to this Regulation, methanol and mixtures containing methanol in concentration equal or higher than 3% cannot be sold to the consumers. According to the Polish CARACAL, the value of 3% was established based on the specific concentration limit established in Annex I to Directive 67/548/EEC for methanol for acute toxicity. However, the Regulation does not refer explicitly to the Dangerous Substances Directive.
Spain	
Royal Decree 138/2011, of 4 February, adopting the safety regulation for refrigeration installations and their complementary technical instructions	This RD establishes the requirements for companies selling refrigeration installations that because they use certain pressurised gases and substances that can be considered to be included under the category of flammable gases under the CLP. These companies must be registered with the Industrial Register; they have to fulfil the information obligations of suppliers and the obligations regarding claims. These companies have to hold an insurance scheme and will be subject to periodic inspections.
Sweden	
Chemical Products and Biotechnical Organisms Regulations / Kemikalieinspektionens föreskrifter (KIFS 2008:2) om kemiska produkter och biotekniska organismer	Chapter 3 of the KIFS 2008:2 regulations contains a duty, applicable to those who professionally manufacture or import to Sweden chemical products or biotechnical organisms falling within the scope of Regulation 2008:245 on chemical products and biotechnical organisms, to notify certain information to the product registry. The information that must be notified includes e.g. information on the product's classification under the CLP. For products within the hazard classes of carcinogenic 1A or 1B, mutagenic 1A or 1B, toxic to reproduction 1A or 1B, or skin or airway sensitising in category 1, the packaging must include information on the name of the substance and the contained components that have been classified. According to Chapter 4 of the Regulations, chemical products that fall under certain CLP hazard classes are considered to be 'particularly dangerous'. According to 3§, those who professionally supply particularly dangerous chemical products must note down information on: 1. the sale date, 2. the name and volume of the product,

	3. the name or firm name of the buyer and their address, 4. whether the product has been supplied for professional purposes or such private use that requires a permit under 7§ of Regulation 2008:245. In the latter case, information on how the buyer demonstrated their eligibility. The information must be kept in a specific book or handled in another way to allow for it to be easily checked. It must be kept for at least three years.
The Pesticides Ordinance / Förordning (2014:425) om bekämpningsmedel	Chapter 2, 5§ contains a duty to inform the Chemicals Agency of changes to the classification or marking of a pesticide under the CLP or the regulations issued by the Chemicals Agency.
United Kingdom	
The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013	Under these Regulations, where a conveyor of flammable gas through a fixed pipe distribution system receives notification of the death, loss of consciousness or taking to hospital of a person because of an injury arising in connection with that gas, that person must (a) notify the Executive of the incident without delay; and (b) send a report of the incident to the Executive in an approved manner within 14 days of the incident, pursuant to section 11 (1). 'Flammable gas' is defined in the interpretation section as having the meaning associated with this hazard class under the CLP.
The Pipelines Safety Regulations 1996 as amended by The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015	These Regulations, which are applicable in England, Scotland and Wales but not in Northern Ireland, regulate the safe construction, installation, operation and maintenance of pipelines. Schedule 2 defines 'dangerous fluids' referring to certain hazard classes under the CLP.
The Pipelines Safety Regulations (Northern Ireland) 1997	These Regulations, which apply in Northern Ireland, regulate the safe construction, installation, operation and maintenance of pipelines. Schedule 2 defines 'dangerous fluids' in the same way as in the above-mentioned Pipelines Safety Regulations 1996 as amended by The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015.

Annex 3 - Information on the Costs and Benefits of Legislation from the Open Public Consultation

Table A1-1: Direct costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
Direct compliance cost	Administrative burdens	Generic to chemical legislation framework	• Costs associated with addressing internal EU market barriers
		Directive 98/24/EC on chemical agents at work	• assessment and the resulting changes which may need to be made to processes to meet risk management measures
		Directive 92/85/EEC on pregnant workers	• Increased assessment requiring extra resources (cost).
		Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• Mutual recognition between Member States for substances used as food contact materials does not always function well
		Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Chemical data needs to be reported to numerous authorities because of numerous regulatory requirements. This leads to costs both for companies and authorities
		Directive 2008/98/EC on waste	• The use of CLP classification criteria for the classification of waste is not at all straightforward because the heterogeneous nature of waste makes it difficult to check its composition
Hassle costs	Annoyance	Generic to chemical legislation framework	• continuously changing guidance documents and legal requirements
		Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• REACH tends to be reasonably transparent, while systems that involve EFSA – including pesticides and food contact chemicals – tend to be rather less transparent
		Regulation (EC) No 1107/2009 on plant protection products	• The dual roles of ECHA and Efsa lead to confusion and frustration and delays
		Regulation (EU) No 528/2012 biocidal products	• technical/regulatory guidelines or agreements on interpretation between competent authorities are constantly changing and their applicability can be immediate – with companies having to react within very tight deadlines
		Directive 2008/98/EC on waste	• The application of CLP has led to unpredicted burden for waste management. Inconsistent application of CLP-requirements to waste materials and waste products, which are not chemicals
		Directive 2000/53/EC on end-of life vehicles	• The revised Annex II of the End-of-Life Vehicles Directive was published in May 2016 with a phase out date of 1 January 2016 for lead in particular

Table A1-1: Direct costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
			applications (exemption 8h). A publication date after a phase out date is makes it extremely difficult for OEMs and impossible for suppliers to adjust processes accordingly
	Waiting time	Generic to chemical legislation framework	• not allowing sufficient time for primary producers and food business operators in general to adapt, can entail economic costs in terms of supply contracts that can no longer be honoured
		Regulation (EC) No 1223/2009 on cosmetic products	• New interpretation of Article 15 since 2010 results in substances classified as CMR2 being automatically banned. The only exception is for industry to obtain a positive opinion from SCCS. However, the timeline available to submit a dossier, for SCCS to evaluate it and for annexes of the CPR to be amended is not workable
		Regulation (EU) No 528/2012 biocidal products	• Differences in the transitional period between the different member states The time to adapt to new regulations is often too short because a chemical is often involved in several processes and the evaluation of alternative substances, when available, and the subsequent changes of the affected processes is a time-intensive procedure
Direct compliance costs	Compliance costs	Generic to chemical legislation framework	• Implementation of adaption of classification and labelling requirements
		Generic to chemical legislation framework	• Testing costs
		Generic to chemical legislation framework	• Reporting of chemical data to authorities
		Generic to chemical legislation framework	• Software
		Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• Migration limits and testing methods have been developed from the packaging approach/applications, thus being very challenging for household appliance industry to apply the testing methods, consequently to show compliance
		Regulation (EC) No 1107/2009 on plant protection products	• Chemicals may be borderline or used for multiple purposes (e.g. reach and Plant Protection Products or Biocides legislations), and may be required to be tested under the requirements of each legislation resulting in duplicate testing • Recent changes to the Biocidal Products Regulations have required operators of electrochlorination plants who produce active chlorine solely for their own consumption to submit a dossier under the Biocidal Products Regulation to register as a producer in the same manner as a major chemical supplier

Table A1-1: Direct costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
		Regulation (EU) No 528/2012 biocidal products	• When there is a change in alcohol denaturation, the complete biocidal products/medical device procedure has to be redone • national fees are very disparate and generally very expensive
		Regulation (EC) No 1223/2009 on cosmetic products	• Cost of risk assessment is incurred by industry and by SCCS for nanomaterials
		Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)	• ELVs need to be complied with, type of RMM is flexible.
			• Monitoring obligations must be implemented
		Directive 2004/35/CE on environmental liability	• Implementation to prevent and remediate damage from hazardous substances
		Directive 92/85/EEC on pregnant workers	• Increased assessment requiring extra resources (cost)
		Directive 94/33/EC on young people at work	• Increased assessment requiring extra resources (cost)Extra costs for implementing risk management to cover young workers
		Directive 2008/98/EC on waste (Decision 2000/532)	• Industries must classify their wastes accordingly
		Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Need to implement specific measures on-site to prevent accidents • Despite an ECJ Decision, Seveso requirements are still applicable because an appeal has been lodged by the Commission. Before any decision is taken at Court level, the provisions of Seveso will have to be implemented with significant consequences in terms of costs • Make and update notifications to the competent authorities • Prepare and submit the MAPP (major accident prevention policy) • Produce a safety report for upper-tier establishments and submit to the competent authorities • Provide information to the public in general and to the public likely to be affected by a major accident in particular • Provide documents and assessments to the competent authorities to determine if proposed modifications to the establishment are 'significant' • Host 1-3 days of annual inspections by the competent authorities and provide the necessary assistance and information • Assist the competent authorities in its preparation and testing of the external emergency plan
		Directive 1999/31/EC on the landfill of waste	• landfill operators need to ensure acceptance procedures, documentation

Table A1-1: Direct costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
		Directive 2009/48/EC on the safety of toys	and measurements of leachate • Dossiers for exemption
		Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• Costs associated with dossier submission for entry into the Union list
		Regulation (EC) No 1107/2009 on plant protection products	• The standard 6-12 month grace period when an active substance is withdrawn from the market may be insufficient to allow the product to be used without incurring disposal costs for the supply chain
		Directive 2000/53/EC on end-of life vehicles	• Vehicle producers should create an inventory of hazardous substances in vehicles and derive relevant dismantling information. Information collection and provision in the automotive industry works via a specific IT-system (IMDS and for dismantling IDIS)
		Regulation (EC) No 1013/2006 on shipments of waste	• Waste export options are limited to some countries, documentation requirements must be implemented and wastes classified

Table A1-2: Enforcement costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
Enforcement costs	One-off adaptation costs	Generic to chemical legislation framework	• Training/education of staff
	Information costs	Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Chemical data needs to be reported to numerous authorities because of numerous regulatory requirements. This leads to costs both for companies and authorities
	Monitoring	Generic to chemical legislation framework	• Continuous monitoring
	Enforcement	Generic to chemical legislation framework	• Enforcement costs
		Directive 2009/48/EC on the safety of toys	• Exhaustive market surveillance to stop the majority of dangerous toys entering the EU market would be very costly for authorities, especially in relation to online toy sales which requires authorities to check internet channels
		Regulation (EC) No 1107/2009 on plant protection products	• The so-called "unless-clause" in the uniform principles has led to considerable increase in the expenditure of competent authorities in risk

Table A1-2: Enforcement costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
			assessment
	Adjudication	Regulation (EU) No 528/2012 biocidal products	• Even when the legislation foresees a system of mutual recognition between member states, member states are re-evaluating the first evaluation performed by the lead member state. These costs are charged back to industry through a system of fees

Table A1-3: Indirect costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
Other indirect costs	Reduced efficiency	Relevant to legislation that is hazard based	• Defensive research, obliging companies to find alternative for 'stigmatised' substances, rather than enabling investment in R&D
		Directive 92/85/EEC on pregnant workers	• Increased costs associated with employing cover for a worker who cannot be given a different job role and requires paid leave • Lost man hours for a process which a worker normally occupies but has had to be removed from
		Directive 2009/48/EC on the safety of toys	• If products cannot be reformulated or materials substituted then products may have to be removed from the market
		Regulation (EC) No 1223/2009 on cosmetic products	• Loss of ingredients (including preservatives and perfumes) without any evidence of health issues related to the use of the substance in cosmetic products
Other indirect costs	Competitiveness	Regulation (EC) No 1107/2009 on plant protection products	• The inclusion in the Prior Informed Consent Regulation leads for greater export restriction and places European manufacturers at a global disadvantage • Reduced innovation capacity following banning of substances
		Regulation (EU) No 528/2012 biocidal products	• products with improved human health or environment profiles, will likely be competitive only in the EU - not globally - when these new substances/products lead to higher costs or inferior performance • Reduced innovation capacity following banning of substances
		Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• the provisions of Seveso will have to be implemented with significant consequences in terms of competitiveness
		Directive 2008/98/EC on waste	• CLP classification can trigger different waste related requirements at the national level

Table A1-3: Indirect costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
		Directive 98/24/EC chemical agents at work	• overlaps between CLP, chemical agents and REACH makes this anti-competitive legislation

Table A1-3: Indirect costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
Other indirect costs	Substitution effects	Regulation (EC) No 1107/2009 on plant protection products	• Higher cost or inferior performance of alternatives
		Regulation (EU) No 528/2012 biocidal products	• There should always be a socio-economic analysis when regulatory measures are considered, as it might be that the substance in question is necessary to save lives or protect the environment • Higher cost or inferior performance of alternatives
Other indirect costs	Transaction costs	Generic to chemical legislation framework	• agreements with other parties on data sharing
		Directive 2008/98/EC on waste	• the impact of having a hazardous classification of waste has far-reaching consequences for e.g. transport (Basel Convention)
Other indirect costs	Innovation	Regulation (EC) No 66/2010 on the EU Ecolabel	• The label can be obtained only if hazardous (classified) substances are not used or used in minimum concentrations thus manufacturers are encouraged to reformulate hazardous mixtures or redesign of articles
		Regulation (EC) No 1223/2009 on cosmetic products Directive 2009/48/EC on the safety of toys	• Need for reformulation of products if exception is not granted or applied for
		Regulation (EC) No 1107/2009 on plant protection products	• Need for reformulation of products which contain CMR substances if exemption is not applied for and granted
		Regulation (EC) No 450/2009 on active and intelligent materials Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• Reformulation costs as a result of not being allowed to use certain substances
Other indirect costs	Reduced market access	Generic to chemical legislation framework	• relocation of chemical suppliers in extra-EU for servicing a market without restrictions
		Regulation (EU) No 528/2012 biocidal products	• Under the Biocidal Product Directive it was possible to have risk mitigation measures e.g. for treated wood within the authorization of a product. Now, under the Regulation, it is not possible to consider risk reduction measures for treated articles
		Directive 2008/98/EC on waste	• The current leaching limit value for molybdenum applied to inert waste in the Waste Acceptance Criteria for is jeopardizing valuable uses of ferro-molybdenum slags in road construction

Table A1-3: Indirect costs with examples			
Type of cost	**Details**	**Relevant legislation**	**Example costs**
Other indirect costs	Uncertainty	Generic to chemical legislation framework	• limited time frame of 18 months which is difficult to meet for substitution as the process for finding an alternative can take years
		Generic to chemical legislation framework	• lack of planning certainty due to an increasing number of chosen substitutes to be regulated after substitution as well which leads to continuous substitution of substitutes
		Regulation (EC) No 1223/2009 on cosmetic products	• Legal uncertainty due to substance being banned under CLP but allowed in annexes of CPR
		Directive 2009/48/EC on the safety of toys	• Different requirements across Member States reduces predictability
		Regulation (EC) No 1107/2009 on plant protection products	• Several paragraphs relate to human data but are worded differently and can be interpreted in markedly different ways
		Regulation (EU) No 528/2012 biocidal products	• There are missing explanatory documents, which affect interpretation and application of the regulations • The timelines for the approval of active substances and the authorization of biocidal products in the Biocidal Products Regulation are not predictable and the outcomes of the scientific evaluations linked to the data submitted are not easy to predict
		Directive 2008/98/EC on waste	• The use of terms such as harmful (waste framework directive) creates uncertainty about which substances are covered by different regulations
		Directive 98/24/EC chemical agents at work	• whenever a binding OEL value (BOELV) exists under Annex III of the Carcinogens and Mutagens Directive and the requirement to eliminate or reduce exposure "as low as technically possible" applies, the existence and validity of the BOELV may be questioned. It is unclear how far below the OEL the exposure needs to be reduced

Table A1-4: Direct benefits with examples			
Type of benefit	**Details**	**Relevant legislation**	**Example benefits**
Improved well-being	Health	Directive 92/85/EEC on pregnant workers	• Reduced number of occupational cancer cases • Endocrine disrupting substances are not specifically identified as "agents" in Annex I, or Annex II therefore there is no obligation on employers to reduce exposure
		Directive 94/33/EC on young people at work	• Reduced number of occupational cancer cases • Endocrine disrupting substances are not specifically identified as "agents" in Annex I, or Annex II therefore there is no obligation on employers to reduce exposure
		Directive 2004/37/EC on carcinogens or mutagens at work	• Reduced number of occupational cancer cases • obligation is to protect workers from exposure
		Regulation (EC) No 1223/2009 on cosmetic products	• Reduced exposure to CMR substances reducing health care costs, using risk-based approach allowing exceptions where all conditions in Article 15.2 are fulfilled
		Directive 2009/48/EC on the safety of toys	• Reduced exposure to CMR substances reducing health care costs, based on hazard associated with category 1A, 1B or 2 substances • EU toy safety requirements are the strictest in the world
		Regulation (EC) No 450/2009 on active and intelligent materials	• Reduced exposure to CMR substances reducing health care costs
		Directive 98/24/EC on chemical agents at work	• Reduced exposure to other hazardous substances reducing health care costs • employers have an obligation to eliminate exposure through substitution • vulnerable groups are a grey area in the risk management
		Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Reduced exposure to other hazardous substances reducing health care costs
		Directive 92/85/EEC on pregnant workers	• Prevention of harmful effects on babies which may lead to developmental problems, relieving pressure on health care services
		Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) Directive 2000/53/EC on end-of life vehicles	• Reduced exposure to other hazardous substances via the environment reducing health care costs • Knowledge and availability of data on emissions is still very patchy
	Safety	Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• increased installation safety, quick reaction to accidents by operators

Table A1-4: Direct benefits with examples			
Type of benefit	**Details**	**Relevant legislation**	**Example benefits**
		Generic to chemical legislation framework	• Reduced risk of accidents and injury from accidents
	Environment	Regulation (EC) No 1223/2009 on cosmetic products	• List of ingredients on packaging of cosmetics does not provide information on which are environmentally hazardous
		Directive 2009/48/EC on the safety of toys	• Lack of environmental aspects included in toys directive. As a result substances restricted in biocide are present in finger paints for children
		Regulation (EC) No 1107/2009 on plant protection products	• The criteria for allowing derogations across chemical legislation should be consistent to guarantee a high level of protection to health and the environment, as well as ensuring legal certainty and predictability
		Regulation (EC) No 1013/2006 on shipments of waste	• Ensuring that EU standards are applied in the treatment of hazardous wastes should result in reduced environmental exposure as compared to treatment in countries, with lower standards
		Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)	• Prevention / reduction of exposure
		Regulation (EC) No 66/2010 on the EU Ecolabel	• Less exposure of the environment to hazardous substances, if consumers buy products with an ecolabel rather than products without one
		Directive 2008/98/EC on waste	• Less exposure from hazardous substances due to appropriate waste treatment processes and controls of operators
		Directive 2000/53/EC on end-of life vehicles	• Less exposure to substances from waste treatment of end-of-life vehicles
		Directive 1999/31/EC on the landfill of waste	• Risks from hazardous substances in hazardous wastes are controlled
		Regulation (EC) No 1107/2009 on plant protection products	• Greater concern given to human health criteria than to environmental. The only preventative measure for an environmental classification is that of aquatic toxicity where simplified authorisation will not be granted
		Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Prevention of exposure to hazardous substances and higher likelihood of quick mitigation of impacts
		Directive 2004/35/CE on environmental liability	• Implementation to prevent and remediate damage from hazardous substances. If operators also have to fulfil SEVESO and/or Industrial Emissions Directive respective obligations are not expected to cause additional work

Table A1-4: Direct benefits with examples			
Type of benefit	**Details**	**Relevant legislation**	**Example benefits**
Market efficiency	Cost savings	Generic to chemical legislation framework	• Loss prevention from reduced illness/impacts on staff
		Generic to chemical legislation framework	• Reduced health care costs (exposure at work)
	Improved information	Generic to chemical legislation framework	• Better marketing opportunities for consumer products that do not contain hazardous substances of concern
		Generic to chemical legislation framework	• Better informed decision-making in relation to use of/exposure to hazardous substances
		Regulation (EC) No 1223/2009 on cosmetic products	• Lack of information on which ingredients are environmentally hazardous on packaging means consumers cannot make an informed choice when they purchase cosmetic products
		Directive 2009/48/EC on the safety of toys	• No labels for non-perfume allergens in toys
		Regulation (EC) No 66/2010 on the EU Ecolabel	• Consumers are informed which products are without or with minimum content of hazardous substances and push the market to greener consumption, Possibility to reduce exposure to hazardous substances by better informed decision making
		Regulation (EU) No 528/2012 biocidal products	• The very detailed and technical information is intended to be addressed to consumers via the label. This flow of technical and very detailed information would flood consumers' capacity to discern relevant information for the intended use
	Wider range of products/services	Regulation (EU) No 528/2012 biocidal products	• The potential benefits for society are not normally considered for biocidal products e.g. need to control a serious danger, economic or social impact, i.e. lost business, reduced innovation capacity etc.

Table A1-5: Comments from the open public consultation highlighting efficiency and effectiveness concerns		
Impact	**Relevant legislation**	**Key points from comment**
Efficiency	Regulation (EC) No 1223/2009 on cosmetic products	• Move to Regulation has led to an improvement but there are still differences between interpretation of the regulations as well as enforcement • Need for consideration of use of electronic methods to make information available to consumers to avoid the need for increased packaging, with impacts on industry in terms of cost and the environment in terms of raw materials and waste • Risk assessment of the ingredient is done twice for nanomaterials (by company notifying

Table A1-5: Comments from the open public consultation highlighting efficiency and effectiveness concerns		
Impact	**Relevant legislation**	**Key points from comment**
		and then by SCCS) • Animal testing ban in CPR is in conflict with testing requirements of REACH • Borderline issue between CPR and Toys Directive where there are cosmetic toys, especially with regard to additional safety factor
	Directive 2009/48/EC on the safety of toys	• Borderline issue between CPR and Toys Directive where there are cosmetic toys, especially with regard to additional safety factor
	Regulation (EC) No 66/2010 on the EU Ecolabel	• There are some overlaps, e.g. for furniture products with Green Public Procurement (GPP) criteria requirements • Ecolabel uses its own criteria rather than following the biocides legislation
	Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• There are overlaps between food contact materials and biocides
	Regulation (EC) No 1107/2009 on plant protection products	• The evaluation process for active substances in PPP and the CLH process seem not to be totally coherent and should be re-examined • The consequences of fulfilling the PBT/vPvB criteria are very different. For REACH no immediate consequences (candidate listing and maybe subsequent inclusion in the authorisation list). For PPP, however fulfilling the PBT/vPvB criteria leads to non-authorisation • Under the Plant Protection Products Regulation, an EDC or PBT substance may be approved if it is 'necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, not exceeding five years' (Article 4(7)). The Biocidal Products Regulation however, also permits the approval of an EDC or PBT substance based on socio-economic considerations (Article 5(2)(c)). • There is inconsistency between plant protection products and biocides where the legislation places restrictions on availability to the general public of products classified as skin sensitizing. Similarly classified products can be purchased as general consumer products
	Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances	• Changes in classification impact across Seveso and cause additional costs which can take more than 18 months to filter through
	Directive 2008/98/EC on waste	• Waste legislation sets aims (recycling & recovering) that are in conflict with REACH regulation when this regulation restrict the use of some dangerous substances
	Directive 2000/53/EC on end-of life vehicles	• contradictions and double-regulation regarding the battery directive and the End-of-Life Vehicles Directive

Table A1-5: Comments from the open public consultation highlighting efficiency and effectiveness concerns		
Impact	**Relevant legislation**	**Key points from comment**
		• Exemptions for legacy spare parts granted under the End-of-Life Vehicles Directive but still not granted under the EU POP Regulation • End-of-Life Vehicles Directive and RoHS Directive covers different final product categories, but many of their covered applications (parts) and supply chain are common
	Directive 98/24/EC chemical agents at work	• There are overlaps between Directive 98/24/EC-Chemical Agents and CLP Regulation, in terms of exposure information and there are missing links for Risk Assessment aspects which could be better linked so that recommendations for workplace risk assessment can come together under the same regulatory document • Reach overlaps the chemical agents directive instead of just supporting the implementation. The obligation to develop a DNEL when there is an OEL leads to inconsistent obligations for the employer.
	Directive 2004/37/EC carcinogens or mutagens at work	• When CMR is also subject to the authorization process under REACH, whereas it is not accessible to the consumer, there is unnecessary duplication
Effectiveness	Regulation (EC) No 1223/2009 on cosmetic products	• Interpretation of article 15 is unworkable for industry and competent authorities • Some substances, e.g. trichloroacetic acid are banned in cosmetics but allowed in injectable medical devices • No criteria in relation to identify or restrict endocrine disruptors or PBT substances with deadline to set criteria not being met
	Directive 2009/48/EC on the safety of toys	• RAPEX statistics show that 96% of RAPEX notifications for toys come from rogue traders who will always try to circumvent the rules
	Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	• Substances on the REACH candidate list (SVHC) and in Annex XIV are still allowed in food contact materials • There are gaps in relation to colorants, solvents and printing inks
	Directive 92/85/EEC pregnant workers	• Certain chemicals show “non-monotonic dose responses” which means that a smaller dose can have a much higher detrimental impact than a higher exposure depending on the stage of the embryonic development. EU chemicals legislation needs to be adapted to take these issues into account.
Notes: Group 1: citizens; Group 2: industry; Group 3: Government/public authority; Group 4: NGOs and others		

Annex V: Consultation summary (Task 4 Report)

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1 Introduction to Consultation Activities

1.1 Introduction

This report describes the consultation actions undertaken in support of the study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, which is one of the key studies in support of the European Commission's fitness check on chemicals legislation (excluding REACH).

Five different consultative activities were undertaken to support the study. These are:

1) targeted stakeholder consultation to gather information on specific evaluation issues from key stakeholder groups;
2) a stakeholder workshop to provide an early check on preliminary study findings, identify potential gaps and opportunities for further investigation and to collect ideas and information from stakeholders;
3) an SME Panel survey among the members of the Enterprise Europe Network (EEN) to ensure that the study captures information on the issues affecting small and medium sized enterprises;
4) an Open Public Consultation, to gather views on the chemicals legislative framework from across stakeholders and civil society; and
5) consultation (via interviews and written correspondence) of industry, Member States, NGOs, research institutes/academic experts and professionals (e.g. toxicologists), agency/scientific body representatives and the Commission services as part of the case study work.

A separate report has already been published on the conclusions of the stakeholder workshop and can be found available on the Commission's website[1].

The sections below provide an overview of the activities carried out as part of the targeted consultation, and presents the analyses of the responses to the SME Panel survey and the Open Public Consultation (OPC).

The findings from consultation for the case studies (and main task evaluations) via interviews and written correspondence with the range of stakeholders are reported on in the case studies and main evaluations.

1.2 Targeted data collection – industry

1.2.1 Introduction

Targeted data collection has been conducted in support of the three main tasks of the study, which are reported in Annexes II, III and IV. The broad aim of the work under Task 1 is to assess the effectiveness, efficiency, relevance and the EU added value of the classification, labelling, packaging and other requirements under the CLP Regulation and their implementation; in the process of doing

[1] http://ec.europa.eu/growth/sectors/chemicals/ec-support_en

this, clear conclusions need to be drawn on where and how the CLP Regulation is performing appropriately against its objectives. The Task 1 findings should also provide an indication of the coherence of the CLP Regulation with GHS and, in particular, the adoption of the building blocks within the GHS and associated transition times, the harmonised classification process, the timing of implementation of adaptations to technical progress (ATPs), and costs and benefits of classification, labelling and packaging requirements.

In order to assist in the collection of information on the above aspects of CLP implementation, a series of targeted questionnaires were developed by the study team. The questionnaires developed for companies were mainly focused on gathering data for Task 1, rather than data to feed into the Task 2 or Task 3 evaluations (the focus of surveys for other (non-industry) stakeholders, such as NGOs and trade unions, has been more even across the tasks). In part, this is due to feedback from the main industry associations that many companies (especially SMEs) would have trouble answering questions about legislative overlaps, inconsistencies and gaps.

Targeted questionnaires were developed for the following company types:

- Manufacturers and importers of chemicals
- Distributors of substances and mixtures
- Formulators:
    - Industrial chemicals
    - Plant protection products
    - Detergents, and
    - Cosmetics (with this including some questions on cosmetic toys).

Draft surveys were reviewed by Cefic, FECC, AISE and ECPA prior to their finalisation, with the aim of making sure that companies would understand the questions being asked. This also led to some questions being removed from the questionnaires in order to reduce the burden of completing each. In each case, an electronic version was developed to enable on-line completion; pdf versions were also produced and, in a few cases, word versions have also been made available.

Links to the on-line versions of the targeted questionnaires were then distributed via the industry associations listed in Table 1-1 to their members, where this included industry sector groups, national associations, and individual corporate members. Links to the questionnaires were also made available on RPA's website, to provide companies with the ability to verify who was undertaking the information collection exercise and to contact RPA should they have any difficulties.

Table 1-1: Associations contacted for targeted data collection

AISE	European Bulk Oil Traders' Association
Cefic	European Domestic Glass Association
CEEMET	EurEau
CEPE	Eurometaux
Concawe	European Solvent Industry Group
Cosmetics Europe	FECC
ECPA	Fertilisers Europe
EEF	FEICA
European Aerosols Federation	ECCA
European Federation of Pharmaceutical industries and Associations	Plastics Europe
European Federation for Construction	Toy Industries Europe

Table 1-1: Associations contacted for targeted data collection
Chemicals
UEAPME

These questionnaires were developed and made available, while the consultants were awaiting final approval of the fitness check evaluation questions, case studies and the OPC survey instrument.

The consultants were approached by the German Chambers of Commerce to ask if they could also make the targeted questionnaires available to their members. This issue was discussed with DG GROW due to concern that such an action would mean that the data collection was no longer as "targeted" as initially intended. In the event, the German Chambers of Commerce were encouraged to direct their members to respond to the OPC.

Key statistics from the targeted industry consultation are provided below. The additional data collected through the consultation is reported on in the Task 1 to 3 reports as appropriate, using a range of tabular and graphical data as well as qualitative statements of respondents' experiences and views. These data are considered to be an important source of information for Task 1 and Task 3 in particular.

1.2.2 Numbers of industry respondents

Manufacturers

There were a total of 91 useable responses to the consultation, from companies across the EU, as well as from the US, Switzerland, and Norway. The responses came from 16 different countries, with most responses coming from France followed by the Netherlands and the UK. In terms of the corporate nature of the respondents (n=88):

- 53% represented a single company
- 23% represented a group of EU companies
- 24% represented a global group of companies.

Unsurprisingly, given the above, 66% of respondents represented a large enterprise, with the remainder comprised of 16.5% medium enterprises, 7% small enterprises and 11% microenterprises (n=91).

Importers

There were a total of 23 meaningful responses to the consultation, from companies across the EU, as well as from the US, Switzerland and Norway. The responses came from 12 different countries. In terms of the corporate nature of the respondents (n=88):

- 70% represented a single company
- 4% (1 respondent) represented a group of EU companies
- 26% represented a global group of companies.

65% of respondents represented a large enterprise, with the remainder comprised of 17% medium enterprises, 13% small enterprises and 4%% micro enterprises.

Distributors

There were a total of 11 meaningful responses to the consultation, from companies located in six EU MS, with the majority located in the Netherlands. Most responses came from France followed by the Netherlands and the UK. In terms of the corporate nature of the respondents (n=11):

- 73% represented a single company
- 27% represented a group of EU companies, none represented a global group of companies.

64% of respondents represented a medium enterprise, with the remainder comprised of 18% small enterprises and 18% large enterprises (no micro enterprises).

Formulators

There were a total of 72 meaningful responses to the consultation, from companies across the EU, as well as from Switzerland and Japan. The responses came from 17 different countries, with most responses coming from France followed by the Netherlands and the UK. In terms of the corporate nature of the respondents (n=71):

- 69% represented a single company
- 10% represented a group of EU companies
- 21% represented a global group of companies.

Unsurprisingly, given the above, 49% of respondents represented a large enterprise, with the remainder comprised of 22% medium enterprises, 21% small enterprises and 8% microenterprises (n=91).

Plant protection products

There were a total of 17 responses, but two of these were duplicates reducing the number of individual responses to 16. The duplicate response has been removed from the analysis below.

Eleven of the sixteen respondents (69%) indicated that they were a single company with three (19%) responding that they were a global group of companies. The remaining two respondents (13%) identified themselves as a group of EU companies. Eight of the respondents stated that they are large enterprises, four are medium enterprises and the remaining four are small enterprises (staff <50, turnover <€10 million, balance sheet total <€2 million).

Cosmetic products

There were a total of 5 responses to the targeted consultation of cosmetics companies, with all five being multi-nationals. Two of the five respondents (40%) indicated that they were a single company with the remaining three (60%) responding that they were a global group of companies.

Detergent sector organisations

There were a total of 45 useable responses for the detergents sector:

- 11 large (non-SME) companies
- 23 SME companies and
- 11 national associations

The majority of non-SMEs and SMEs who answered this question, indicated that they were answering on the behalf of their company (N=30), two indicated that they were answering on behalf of a global group of companies and one answered on behalf of a group of EU companies.

Totals across all groups of general chemical industry respondents

- 250 companies in total provided responses
- 62% were single company, 16% a group of EU companies, and 22% represented a global group of companies
- 12% micro enterprises, 13% small, 21% medium, 54% large

Finally, as there is considerable overlap in many of the questions asked across the different surveys, it is possible to combine the results to provide more representative data. However, not all responses were full responses. In addition, it was necessary to "clean" the data to remove duplicate responses or cases where the survey was opened and non-meaningful responses were given (e.g. letters entered into a cell for a numeric).

1.2.3 Characteristics of industry respondents

1.2.3.1 Geographic markets

Respondents from the general chemicals sector place their products on all EU markets and EEA markets listed in the survey, with the relative distribution as illustrated in Figure 1-1.

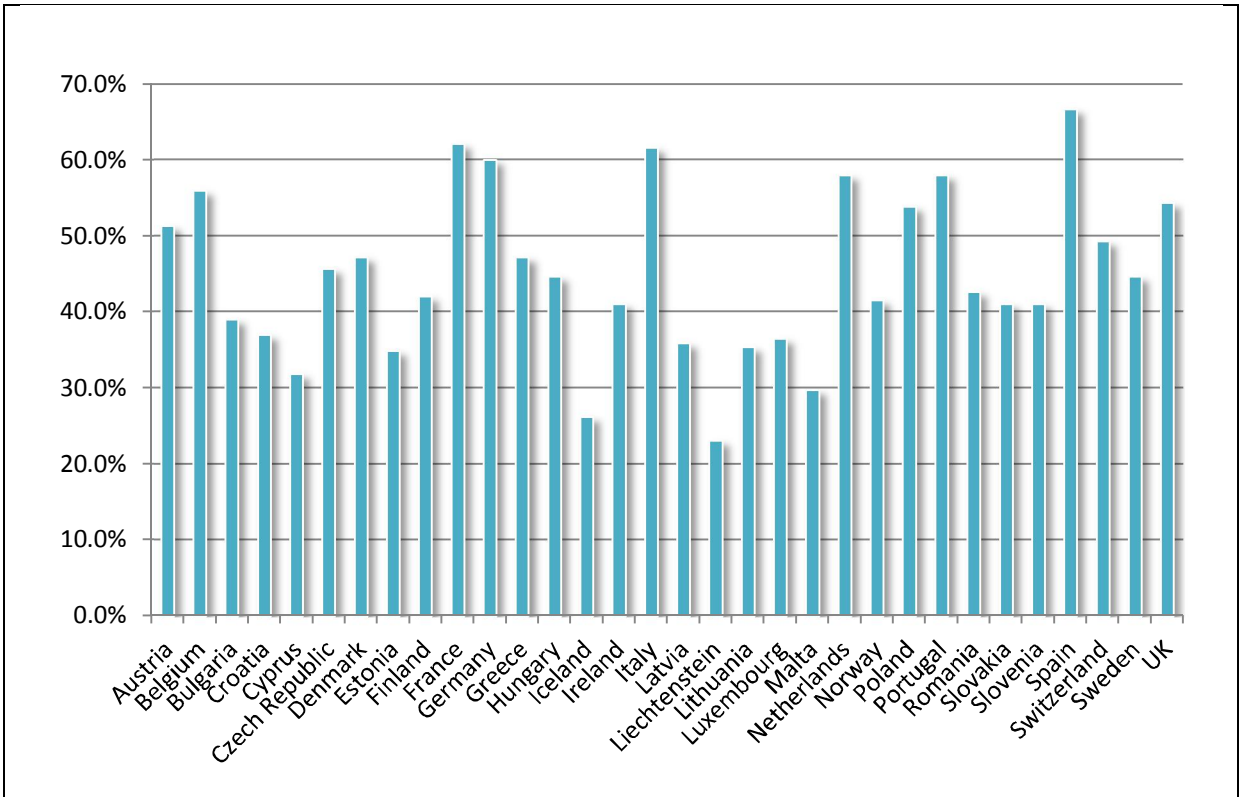

Figure 1-1: Countries where responding SMEs and Non-SMEs place their products on the market (n=195)

The picture is similar for the other sectors. For example, all five companies from the cosmetics sector indicated that they place their products in all 32 of the countries listed in Figure 1-1. With

respect to the plant protection products sector respondents, 15 place their products in all of the listed countries; the most common market is France (73%), followed by Belgium, Greece, Italy, Slovenia and Spain (all at 67%).

Similarly, the detergent sector respondents place their products across the EU, and the national detergents sector associations that responded represent members in 13 countries.

1.2.3.2 Numbers of substances and mixtures in portfolios

120 of the general chemical respondents (from manufacturers, importers and distributors) provided information on the number of substances within their product portfolio. As can be seen from Table 1-2, the majority of respondents at just over 32% have less than 25 substances within their product portfolio, although over 46% have more than 100 substances within their portfolio (with a significant proportion of these (25%) having over 500). The pattern is similar for mixtures, with over 34% producing less than 50 mixtures, but around 29% of the respondents producing over 1500 mixtures (and 48% producing greater than 500).

Table 1-2: Number of substances and mixtures within product portfolio (n=120 for substances, n=187 for mixtures including formulators)

Number of substances	Response Percentage
<25	32.5%
25 to50	10.0%
50 to 100	11.7%
100 to 250	15.0%
250 to 500	5.8%
>500	25.0%
Total number of responses	**120**
Number of mixtures	**Response Percentage**
<50	34.2%
50 to100	8.6%
100 to 250	9.6%
250 to 500	8.0%
500 to 1500	10.2%
>1500	29.4%
Total number of responses	**187**

All five of the cosmetics respondents said that they had more than 500 mixtures in their portfolio, with 4 of the 5 respondents having more than 1500 mixtures.

For plant protection products, a range for potential responses of between <10 to >90 active substances was provided for establishing sizes of portfolios. The most common response was 30 to 50, with five respondents indicating that they had this many active substances in their portfolio. Based on the responses, a weighted average of around 40 active substances can be estimated as the mean number per company. However, this is highly variable with four respondents (27%) having fewer than 10 active substances and two respondents (13%) having more than 90. Perhaps not surprisingly, it is the large enterprises that also have the highest number of active substances with four of the eight large enterprises (50%) have 70 or more active substances. Of the four respondents with fewer than 10 active substances, two were small enterprises (50% of the four small enterprises) and two are medium enterprises (50% of the four medium enterprises; one other medium enterprise did not answer this question). With respect to mixtures (plant protection products), the answers range from <50 to >1500. A total of five respondents (31%) answered that

they had <50 mixtures (formulations). Using the results, a weighted average number of mixtures (formulations) across all respondents can be estimated at around 330. As with the number of active substances (Q5), it is the large enterprises that have the highest number of mixtures (formulations). There are no small or medium enterprises among the respondents that have more than 100 mixtures (formulations) currently in their portfolio. There is one large enterprise that has fewer than 50 mixtures (formulations) but all other large enterprises have at least 100 mixtures.

With respect to the detergents sector, all twenty-three SME respondents answered a question regarding the number of mixtures within their product portfolio; ten non-SMEs also answered the question. The SME responses covered the full range of having <50 to >1500 mixtures in their portfolio, more than 50% of SME responders had either 50 to 100 or 100 to 250 mixtures in their portfolio. Non-SME responses indicated that on average they have a larger range of mixtures in their portfolio, 40% had between 250 to 500 mixtures in their portfolio.

1.2.3.3 Product markets

Figure 1-2 summarises the sectors relevant to general chemicals manufacturers, importers and distributors. As can be seen from the responses, a broad range of sectors are supplied by the respondents. As might be expected, inorganic and speciality chemicals represent the biggest downstream sectors, with over 45% of respondents supplying these sectors, followed by polymers, paints and inks and plastics.

The picture varies for formulators, who were also asked to respond across a larger number of downstream sectors. Figure 1-3 presents their responses, and illustrates the importance of paints, inks and coatings (with 44% of respondents supplying this sector), detergents (relevant to 31% of respondents) and cosmetics (relevant to 25% of respondents).

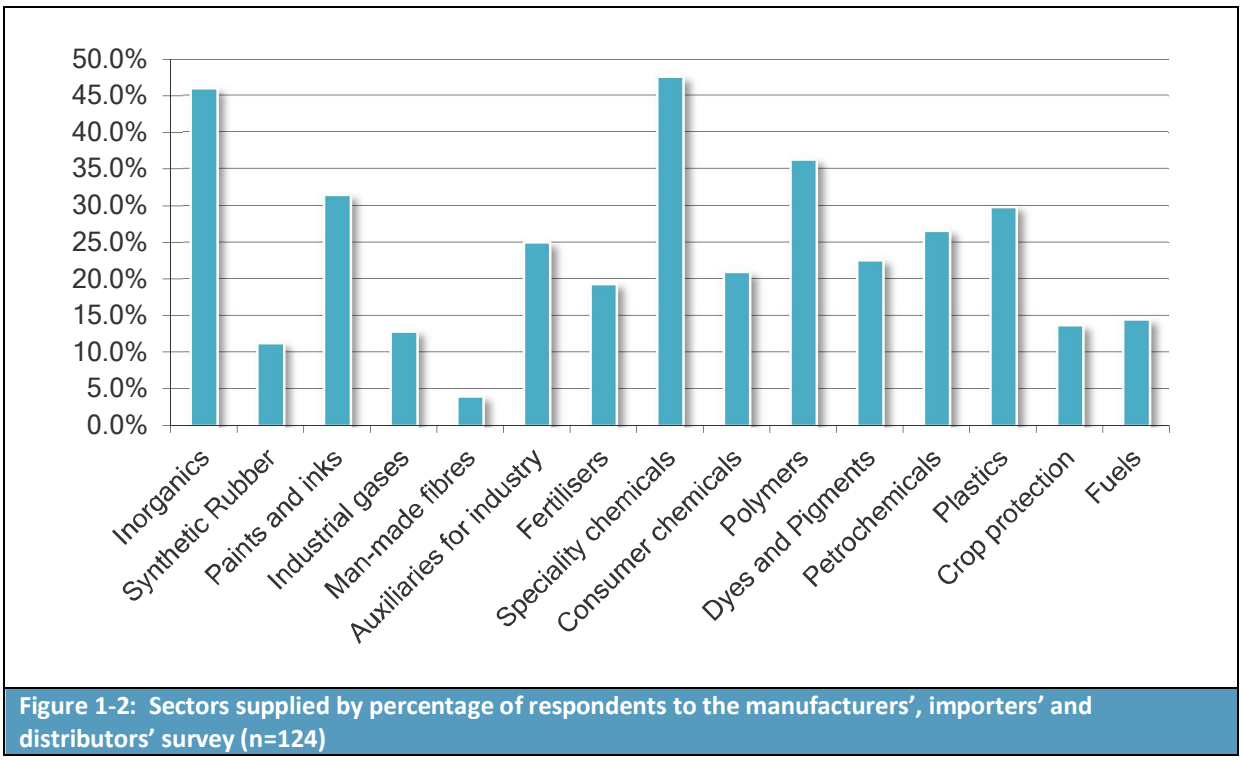

Figure 1-2: Sectors supplied by percentage of respondents to the manufacturers', importers' and distributors' survey (n=124)

With respect to cosmetic products, all five respondents indicated that they produce: rinse-off products, face products, leave-on products, hair products, skin products and eye products.

44 of the detergents sector respondents provided information on their product portfolio, with national associations responding on behalf of their members. Members of National Associations were linked to most of the different product types. Most non-SMEs produce household disinfectants and surface care products, the least commonly produced product type is building care products for professional cleaning & hygiene. Most SMEs produce household laundry and surface care products and Kitchen and catering professional cleaning & hygiene products. The least commonly produced product types indicated by SMEs are household maintenance and bleach products and professional cleaning & hygiene health care and food, beverage and agricultural products. Overall household laundry care products were indicated as being the most common produced product type.

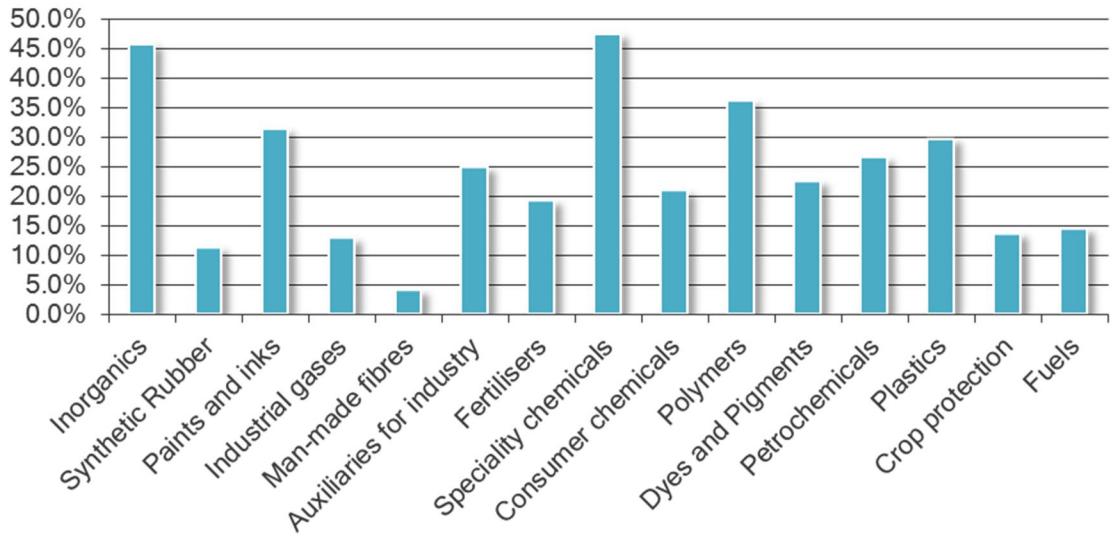

Figure 1-3: Sectors supplied by percentage of respondents to the formulators' survey (n=70)

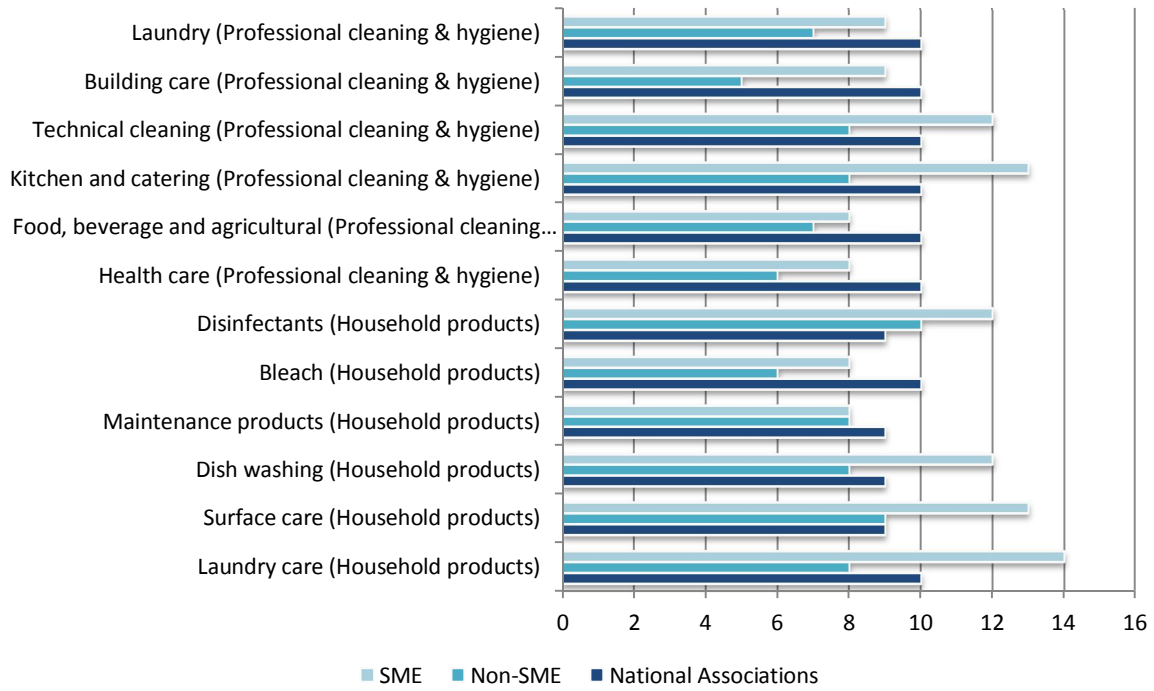

Figure 1-4: Product types produced by detergents sector non-SME, SME and members of National Associations

1.2.3.4 Import or export

In total 170 respondents provided information on the countries that they either imported to or substances and mixtures from or exported to outside the EU. The relative importance of different countries as a trading partner is presented in Figure 1-5. As can be seen from this figure, exports are important for over 50% of respondents for Turkey, Russia, South and Central America and North America, with China and the rest of Asia of slightly lower (but still significant) importance. In terms of imports, China and North America dominate supply sources (45% and 34% respectively).

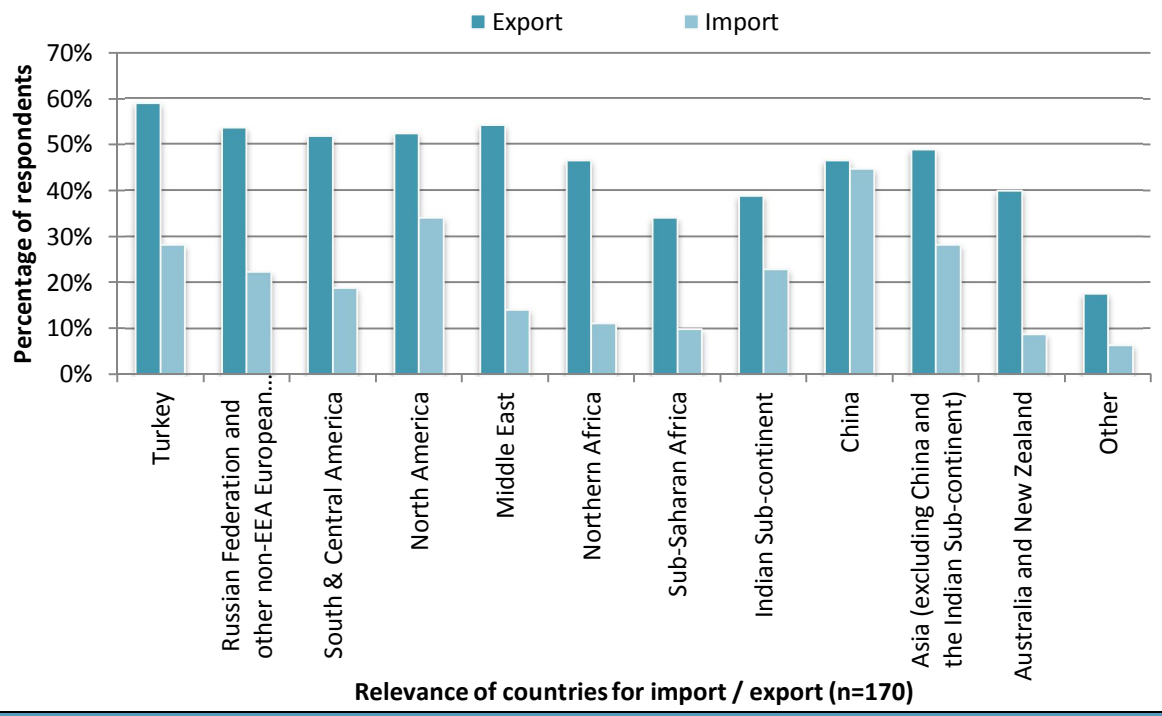

Figure 1-5: Countries traded with – imports and exports

At the company level, it is clear from the graph that a far larger percentage are exporting substances and/or mixtures than are also importing into the EU. It is also clear that the range of export markets appear to be important, rather than just one or two to any given company.

To try and gain a feel for how important imports and exports are to individual respondents, they were asked to indicate what % of their turnover was linked to both intra-EU and extra-EU import and export activities (and for substances and mixtures separately). As anticipated, this question was difficult for many companies to answer, and the total number of responses fell from over 80 to 64.

The figures presented in Table 1-3 exclude importers and exclude substance export for formulators. The reflect counts of the number of respondents out of a total 127 providing an indication of the importance of exports or imports to their activities (total response counts are less than 127 for any given row due to intra or extra EU import or export not being relevant to all respondents).

As can be seen from the table, imports and exports generally account for less than 20% by value of a given company's turnover, with there being numerous exceptions where import or export of substances and the export of mixtures accounts for >60% of turnover by value. In this respect, the data suggest that harmonisation of classification and labelling at the global level is of great importance for only a relatively small percentage of companies (i.e. linked to >60% of turnover). This does not mean that imports and exports are not also important for those with between 20% and 60% of turnover linked to these activities; some companies may have a small percentage of turnover represented by imports due to the high added value of the products, however, these imports may be crucial. Similarly, the data highlight the importance of the internal market to EU manufacturers.

Table 1-3: Relative importance of import and export as a percentage of annual turnover for manufacturers and formulators (n=127)				
Answer Options	**<20% by value (€)**	**<60% by value (€)**	**>60% by value (€)**	**Response Count**
% turnover related to the export of substances (intra-EU)	34	14	18	66
% turnover related to the import of substances (intra-EU)	49	19	20	88
% turnover related to the export of substances (extra-EU)	34	17	3	54
% turnover related to the import of substances (extra-EU)	52	24	2	78
% turnover related to the export of mixtures (intra-EU)	51	27	17	95
% turnover related to the import of mixtures (intra-EU)	66	15	6	87
% turnover related to the export of mixtures (extra-EU)	53	18	7	78
% turnover related to the import of mixtures (extra-EU)	56	10	1	67

In terms of exporting, all of the five of the cosmetics respondents export to all but two geographical blocks. The only exceptions are Asia (excluding China and the Indian sub-continent) which four (80%) of the respondents export to and 'Other' (not specified) which three (60%) of the respondents export to. The pattern is much more variable in terms of imports, with the most important geographical blocks being North America and Asia (excluding China and the Indian sub-continent) from where four (80%) of the respondents import. This reduces to three (60%) in terms of imports from China and then to two (40%) for imports from Turkey, the Russian Federation and other non-EEA European countries, and the Middle East. At least one of the five respondents imports from each of the geographical blocks. The full results are summarised in Table 1-4. These respondents were less willing to provide information on turnover, so that which was reported cannot be provided here for commercial sensitivity reasons.

Table 1-4: Geographical blocks cosmetics respondents import from and/or export to (n=5)		
Geographical block	**Import**	**Export**
Turkey	2 (40%)	5 (100%)
Russian Federation and other non-EEA European countries	2 (40%)	5 (100%)
South & Central America	1 (20%)	5 (100%)
North America	4 (80%)	5 (100%)
Middle East	2 (40%)	5 (100%)
Northern Africa	1 (20%)	5 (100%)
Sub-Saharan Africa	1 (20%)	5 (100%)
Indian Sub-continent	1 (20%)	5 (100%)
China	3 (60%)	5 (100%)
Asia (excluding China and the Indian Sub-continent)	4 (80%)	4 (80%)
Australia and New Zealand	1 (20%)	5 (100%)
Other	1 (20%)	3 (60%)

Eleven of the sixteen plant protection respondents also provided an answer to this question. Only one of the eleven respondents (9%) imports from all the listed groups of countries (except other) whereas five of the eleven respondents (45%) export to all the listed groups of countries (excluding other). Overall, the most common groups of countries for export are Turkey and Northern Africa with eight respondents (73%) identifying that they export here. This reduces to seven respondents

(64%) for the Middle East and Sub-Saharan Africa. The minimum number of respondents exporting to any one group of countries is five (45%) to North America, Indian Sub-Continent, China, and Australia and New Zealand. In terms of imports, the maximum number of respondents is five (45%) from the Indian Sub-Continent and China, followed by South & Central America, North America and Asia (excluding China and the Indian Sub-Continent) all with four (36%). The minimum number is one (9%) from Sub-Saharan Africa and for other (but the actual countries are not specified). The full results are summarised in Table 1-5. These respondents were less willing to provide information on turnover, so that which was reported cannot be provided here for commercial sensitivity reasons.

Table 1-5: Groups of countries that plant protection respondents import from and/or export to (n=11) (Q7)

Geographical block	Import	Export
Turkey	3 (27%)	8 (73%)
Russian Federation and other non-EEA European countries	3 (27%)	6 (55%)
South & Central America	4 (36%)	6 (55%)
North America	4 (36%)	5 (45%)
Middle East	2 (18%)	7 (64%)
Northern Africa	2 (18%)	8 (73%)
Sub-Saharan Africa	1 (9%)	7 (64%)
Indian Sub-continent	5 (45%)	5 (45%)
China	5 (45%)	5 (45%)
Asia (excluding China and the Indian Sub-continent)	4 (36%)	6 (55%)
Australia and New Zealand	3 (27%)	5 (45%)
Other	1 (9%)	3 (27%)

For the detergents sector, the most important import regions indicated by non-SMEs and SMEs are China (five) and North America (four), the most important export regions indicated by non-SMEs and SMEs are the Russian Federation and other non-EEA European countries (fourteen), the Middle East (twelve) and Turkey (ten).

1.3 Targeted data collection – non-industry stakeholders

1.3.1 Non-governmental organisations (NGOs)

In addition to targeted data collection from industry, questionnaires have been distributed to non-industry stakeholders, including trade union/worker representative organisations, consumer associations, environmental NGOs and health-related NGOs. The full list of such stakeholders is given in Table 1-6 below, with this list developed together with the Commission.

Three separate targeted data collection surveys were developed for information gathering from these stakeholders. These include surveys focused at: trade unions and other organisations representing workers; consumer associations, and environmental and public health non-governmental organisations. When sending out the surveys, recipients were encouraged to also send the links to national associations (e.g. national consumer associations, national trade unions) to gather a broader range of information than just that of the EU-level organisation.

Table 1-6: Non-industry stakeholders contacted for targeted data collection	
ANEC	Food and Water Europe
BEUC	HEAL
Centre for International Environmental Law	Health Care without Harm
Chemsec	IndustriALL Europe
Client Earth	PAN
EEB (European Environment Bureau)	PETA
EFFATT	Uni Europa/ Uni Global
ETUC / ETUI	Women in Europe for a common future
Chemtrust	Women's Environment Network
European Public Health Alliance	

These questionnaires were sent out the first week in March, with a completion deadline of the end of April. Key statistics are as follows:

- Although nine separate IP addresses opened the questionnaire for health and environmental NGOs, only four provided substantive responses, and none of these answered all of the questions. However, NGOs did provide additional supporting position papers and documents to the consultants. They also contributed to the OPC and more detailed consultation and interviews were held with this group as part of the case study work;
- With respect to consumer groups, five separate IP addresses opened the questionnaire, with two providing substantive responses. More detailed consultation was held with these groups as part of case study and more detailed task work (e.g. on toy safety, generic versus specific risk assessment, etc.);
- Five separate IP addresses opened the workers association questionnaire, with only one organisation providing substantive responses. Follow-up consultation was undertaken with the other two organisations as part of case study and more detailed task related work.

Only seven of the NGOs listed in Table 1-6 responded to the OPC. In total, 26 NGOs responded to the OPC and there are only a few of these that did not also respond to the targeted consultation and that operate at the EU level.

1.3.2 Targeted data collection – Authorities and Expert Groups

A questionnaire for targeted data collection from Member State (MS) authorities was also distributed on the 26th April with a request for responses by the 31st May, although responses were also accepted after this date (indeed into August).

Responses were submitted by 14 authorities from 11 different MS (although it is of note that MS not responding to this data collection exercise did respond to the OPC, with 47 in total responding to the OPC). It is important to note that in some cases one respondent replied on behalf of a country, covering all relevant authorities to the legislation falling into the scope of the Fitness Check. In any event, across all respondents there were at least two authorities that indicated any single piece of legislation fell within their remit.

All of these respondents provided substantive information, with some also submitting position papers or additional comments. All position papers were forwarded to the European Commission, and all additional comments have been taken into account in the work on Tasks 1 to 3.

In addition, a separate questionnaire was developed and submitted to the Expert Group on Toy Safety. In total there were 10 responses to the questionnaire sent to the toy safety expert group (outlined below), and a further two additional consultation responses. These included responses from EU authorities, a market surveillance authority, a health and environmental NGO, national and EU industry representatives and a consumer organisation.

1.4 The SME Panel survey

The SME Panel survey was carried out from May to July 2016. In total there were 246 usable responses[2]. Some of the responses were from companies or groups who report that they have 250 employees or more, which is not considered to be a SME. The analysis of the SME panel survey focuses just on those responses from SMEs (i.e. without responses from those with 250 or more employees), but any differences between SMEs and larger responses are identified where particularly noticeable. There were a total of 209 responses from companies with fewer than 250 employees. The analysis of the responses to the questions is provided in Section 2 of this report, in the order of the questions from the survey.

The questions asked of the SME Panel were developed along the same lines as the OPC and the industry stakeholder targeted consultation to the extent appropriate to ensure some consistency. The survey included four main sections:

1. a section that collected data on the characteristics of the survey respondents;
2. a section focusing on the impacts of CLP implementation on respondents' activities;
3. questions regarding hazard classification and communication; and
4. questions regarding the regulatory fitness of the EU chemicals legislative framework.

This survey relied to a greater extent on closed questions than the OPC, in order to simplify the data being requested.

1.5 The Open Public Consultation

This Open Public Consultation was carried out via Survey Monkey and hosted on RPA's website with a link to the Commission's webpages (with links from these webpages to the survey also created). The OPC ran from the 4th of March to the 27th of May 2016, with questionnaires available in three languages: English, French and German.

The questions were provided to the consultants by the Commission[3], and some minor changes were made to the language used in a small number of questions and in some cases to adapt open-ended questions to close-ended questions with comment boxes.

The final survey instrument contained 34 separate questions, with the first 8 of these mandatory and more "administrative" in nature. Most of the remaining 26 questions were designed to gain more than just a "yes" or "no" response, with the aim of ensuring that meaningful information is collected on the different issues covered by the survey. As indicated above, key questions were also

[2] 247 responses were received, but one of these only provided contact details.

[3] The Consultants provided an early draft of proposed questions in 2015 for consideration.

accompanied by prompts for respondents to provide further explanation, depending on their response to the close-ended part of the question.

Once the OPC was launched, RPA sent out e-mails notifying all industry and non-industry stakeholders being contacted for various parts of the study that the consultation was open. We also asked Chemical Watch to announce that the public consultation was open, and sent out posts via LinkedIn (with such postings made by a number of study team members).

Analysis of the OPC is organised by the type of respondent with these organised into four groups:

- Group 1: Citizens
- Group 2: Industry association/business
- Group 3: Government or public authority
- Group 4: NGOs and others, comprising non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other.

Other comprised a range of different respondents including consultants, trade unions, employees, employers' association, Chambers of Commerce and an economic development association, and national associations.

Table 1-7 shows the total number of responses by each of these organisations, broken down into the sub-organisations where appropriate. There were 378 responses in total.

Table 1-7: Number of responses to OPC by type of organisation

Group of organisations		Sub-organisations	No. of responses	% of all responses
1	Citizen	-	**63**	**17%**
2	Industry association/business	***Total***	***210***	***56%***
		Industry association	105	28%
		Business	105	28%
3	Government or public authority	-	**49**	**13%**
4	NGOs and others	***Total***	***56***	***15%***
		Non-governmental organisation (NGO)	26	7%
		Consumer association	5	1%
		Trade union	6	2%
		Academia or a research or educational institute	1	0.3%
		Other	18	5%

1.6 Scope and organisation of the report

The remainder of this report presents the detailed analysis for the SME Panel survey and the on-line open public consultation.

- Section 2 presents the results from the SME Panel survey; while
- Section 3 presents the results from the on-line public consultation.

Copies of the surveys themselves are not presented here as all questions are given in full.

2 SME Panel Results

2.1 Introduction

This section provides the analysis of the responses to the SME panel consultation, focused on legislation governing the risk management of chemicals (excluding REACH), in particular CLP and related legislation.

The analysis looks at the answers across all respondents and then by different types of respondent, including company size, activities and sectors where there are particular differences between types of respondent.

2.2 Summary of results

Consultation was undertaken through the SME panel among the members of the Enterprise Europe Network (EEN) to ensure that the impacts and opinions of small and medium-sized enterprises are represented within the analysis. The survey was very similar to that of the OPC to provide consistency. There were 245 responses from the SME panel in total, of which 209 were from companies with fewer than 250 employees. It is the responses from these 209 companies that provide the main focus of the analysis. The most common activity undertaken by SMEs due to implementation of the CLP Regulation was training (Q6). In total 89% of all SMEs undertook some training. This is likely linked to the need for staff to understand the new pictograms and hazard and precautionary statements (Q8), with this identified as the training need for 65% of all respondents. In addition, 50% of all respondents reported a short-term increase in costs due to implementation of CLP (Q7). However, a significant proportion of respondents (31%) reported that they had not incurred any short-term costs (they had also not seen any benefits from implementation of CLP).

Some 60% of all SME respondents identified that they incurred significant costs on an annual basis in complying with the CLP Regulation or other chemicals legislation (other than REACH) (Q10). The most common response was training of staff to ensure compliance with legal requirements, with 48% of SMEs identifying that they incurred this cost on an annual basis. This may be linked to the 45% of respondents who identified a cost associated with understanding and keeping up-to-date with changes in legal requirements.

Opinions of SMEs on the EU chemicals legislation overall (Q15) are generally positive in terms of harmonisation of chemicals legislation across Member States for the proper functioning of the internal market and on coherence of the legislative framework, with 98 (of 202) agreeing or strongly agreeing with the first statement and 93 (of 204) agreeing or strongly agreeing with the second. There are some negative opinions on the extent to which EU chemicals legislation is consistently enforced by Member States. More manufacturers, importers[4] and formulators disagreed or strongly disagreed with this statement than agreed or strongly agreed with it.

[4] This is a small sample size of 30 where 9 disagreed/strongly disagreed compared with 8 who agreed (there were no respondents who strongly agreed).

2.3 Section 1.1: You and your company

2.3.1 Q1: In which country are you based?

There were 245 responses to this question[5]. Table 2-1 shows the number of responses received from each country, together with the percentage that this represents of the 208 responses from SMEs and from the total of 245 responses (SMEs and non-SMEs). There were responses from 16 Member States in total, with no responses being received from Belgium, Croatia, Czech Republic, Finland, Greece, Ireland, Luxembourg, Malta, Portugal, Slovakia, Sweden, or United Kingdom. Figure 2-1 presents the information in graphical form, clearly showing that the largest numbers of responses are from SMEs in Italy (63 or 26%), Romania (28 or 11%) and Poland (27 or 11%).

Table 2-1: Number and percentage of responses by country (n=245)

Country	SMEs only (n=208)		All responses (n=245)	
	Number of responses	Percent of all responses	Number of responses	Percent of all responses
Austria	5	2%	10	4%
Bulgaria	3	1%	3	1%
Cyprus	9	4%	9	4%
Denmark	2	1%	2	1%
Estonia	1	0%	2	1%
France	16	7%	16	7%
Germany	13	5%	20	8%
Hungary	15	6%	15	6%
Italy	63	26%	67	27%
Latvia	5	2%	6	2%
Lithuania	4	2%	5	2%
Netherlands	0	0%	1	0%
Poland	27	11%	31	13%
Romania	28	11%	33	13%
Slovenia	10	4%	14	6%
Spain	7	3%	11	4%

[5] There was also one response which did not give the country but did answer the majority of the rest of the questions

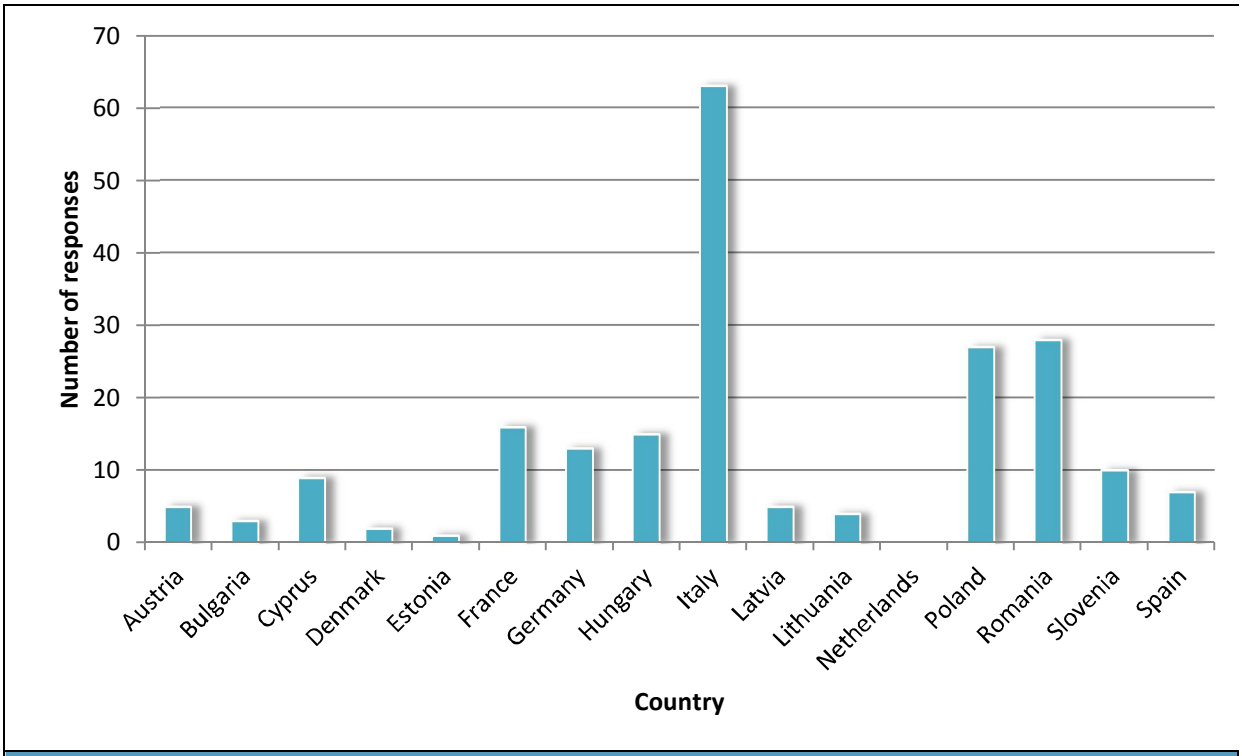

Figure 2-1: Number of responses by country (SMEs only) (n=208)

2.3.2 Q2: Apart from the country in which your company is based, in how many countries of the EU do you regularly sell products and/or services?

There were 242 responses to this question (in total, SMEs plus non-SMEs), with the results summarised in Table 2-2. The largest number of respondents, 114 (47%), sell their products and/or services in 5 or more countries, while 19% only sell their products in their home market.

Table 2-2: Number and percentage of responses by number of other countries in which their products or services are sold (n=242)

Number of other countries	Number of responses	Percent of all responses
None	45	19%
1	25	10%
2	20	8%
3	24	10%
4	14	6%
5 or more	114	47%

Some of the responses are from companies or groups who report that they have 250 employees or more, which is not considered to be an SME. Those companies with 250 or more employees and those who only answered for a group with 250 or more employees have also been removed leaving the analysis for companies and groups with fewer than 250 employees, plus those who responded for a company with fewer than 250 employees but are in a group with 250 or more employees. The analysis focuses on responses from SMEs (i.e. without responses from those with 250 or more employees), but any differences between SMEs and larger responses are identified where particularly noticeable. There are 194 responses from SMEs to this question.

When companies or groups with 250 employees or more are removed, the breakdown changes to that shown in Table 2-3. The results show that 41 of the 45 respondents (91%) that sell their products in their home market only are SMEs, whereas only 82 of the 114 respondents (72%) that sell their products in 5 or more other countries are SMEs. While the largest individual response is still '5 or more', this has reduced to 40% of all responses from companies (82 responses) compared to 47% when >250 employee companies are included.

Table 2-3: Number and percentage of responses by number of other countries in which their products or services are sold EXCLUDING companies with 250 or more employees and groups (n=194)

Number of other countries	Number of responses	Percentage of all responses
None	41	20%
1	25	12%
2	21	10%
3	24	12%
4	13	6%
5 or more	82	40%

2.3.3 Q3: Indicate which of the following best describes the size of your company/your group of companies

There were 209 responses to this question from companies/groups with fewer than 250 employees. Table 2-4 shows the number and percentage of responses by company and group size (note some respondents identified themselves as both a company and a group, giving 225 answers in total). Figure 2-2 presents the results (as percentages). Both the table and figure show that company sizes are smaller than group sizes. The mode (most common) company size is 10-49 employees, but for groups this is 250 or more employees (reflecting the number of respondents who also included the group size in their response). The mean company size is 50-249 employees when based on an estimate of the weighted mean[6].

Table 2-4: Number and percentage of responses by number of other countries in which their products or services are sold EXCLUDING companies and groups with 250 or more employees (n=209)

Number of employees	Company (n=197)		Group (n=28)	
	Number	Percentage	Number	Percentage
Self-employed	1	1%	0	0%
1-9 employees	42	21%	0	0%
10-49 employees	82	42%	3	11%
50-249 employees	72	37%	10	36%
250 or more employees (non-SMEs)	0	0%	14	50%

[6] Assumed 1 employee for self-employed, and mid-points of 5 for 1-9 employees, 30 for 10-49 employees, and 150 for 50-249 employees gives a weighted mean of 68.

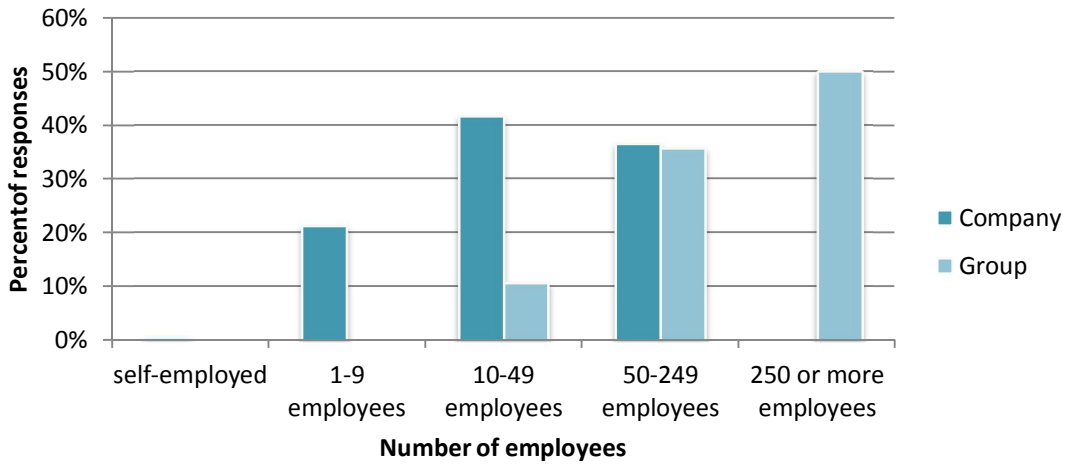

Figure 2-2: Percentage of responses by company and group size (n=209)

The size of a company can also be compared against the number of countries in which products and/or services are sold. These figures are presented in Table 2-5. The table presents figures for companies only (hence it excludes the 28 groups included in Table 2-4, above). The table shows that the numbers of countries in which products/services are sold generally increases as the number of employees increases. Given the very small number of responses from 'self-employed' (one), the remaining analysis only considers breakdown by those companies with 1-9, 10-49 and 50-249 employees.

Table 2-5: Number and percentage of responses by number of other countries in which their products or services are sold EXCLUDING companies with 250 or more employees and groups (n=194)

Number of other countries	Self-employed (n=1)		1-9 employees (n=41)		10-49 employees (n=80)		50-249 employees (n=72)	
	No.	%	No.	%	No.	%	No.	%
None	0	0%	19	46%	16	20%	5	7%
1	0	0%	6	15%	14	18%	5	7%
2	0	0%	4	10%	9	11%	7	10%
3	1	100%	3	7%	13	16%	6	8%
4	0	0%	0	0%	8	10%	5	7%
5 or more	0	0%	9	22%	20	25%	44	61%
Weighted mean	4.0		2.7		3.5		4.8	

2.3.4 Q4: Indicate the term that best describes your company and its activities

There were 205 responses to this question from companies with fewer than 250 employees. Table 2-6 presents the results showing all those who indicated that they undertook each of the activities (each respondent could indicate more than one choice; hence, the total exceeds the 205 responses). Subsequent analyses report variations between responses by those undertaking the different activities where these are particularly notable.

Table 2-6: Number and percentage of responses by activity (n=205)								
Activity	Total number of companies indicating this activity (n=205)		Number of respondents undertaking this activity only (n=158)		Number of respondents undertaking two activities (n=32)		Number of respondents undertaking three or more activities (n=15)	
	No.	%[1]	No.	%	No.[2]	%[1]	No.[2]	%[1]
Manufacturer	103	50%	70	44%	20	63%	13	87%
Importer	31	15%	9	6%	12	38%	10	67%
Formulator	42	20%	19	12%	10	31%	10	67%
Other downstream user	50	24%	41	26%	3	9%	6	40%
Distributor	46	22%	19	12%	16	50%	11	73%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of activities indicated to show the proportion of responses where this activity was undertaken by their company
[2] Number includes counts of companies for each activity indicated, e.g. a manufacturer and importer is counted under both categories, hence exceeds the number of responses (n)

The number of companies undertaking each activity can also be considered by size. The results are presented in Table 2-7. The table shows that importers has the highest percentage of companies with 1-9 employees (32% or 10) while the lowest percentage is for formulators (14% or 6). The highest percentage for companies with 10-49 employees is distributors (57% or 26) and the lowest is other downstream users (28% or 14). For companies with 50-249 employees, it is other downstream users that has the highest proportion (52% or 26) while distributors has the lowest (15% or 7). There are 58% of manufacturers and 57% of formulators with 49 employees or fewer. This increases to 74% of importers and 83% of distributors. Only "other downstream user" shows the majority of companies having 50-249 employees (52%).

Table 2-7: Number and percentage of responses by activity and by size of company (n=205)										
Size	Manufacturer (n=103)		Importer (n=31)		Formulator (n=42)		Other downstream user (n=50)		Distributor (n=46)	
	No.	%[1]	No.	%	No.	%[1]	No.	%[1]	No.	%[1]
1-9 employees	20	19%	10	32%	6	14%	10	20%	12	26%
10-49 employees	40	39%	13	42%	18	43%	14	28%	26	57%
50-249 employees	41	40%	8	26%	18	43%	26	52%	7	15%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of activities indicated to show the proportion of responses where this activity was undertaken by their company

2.3.5 Q5: With which sectors are you involved?

There were 204 responses to this question from companies with fewer than 250 employees. As with the activities, each respondent could indicate as many sectors as were relevant so the number of sectors indicated (493) greatly exceeds the number of individual responses. Table 2-8 presents the results showing the number of sectors indicated. The percentage is calculated based on the number of individual responses (204) to show the relative importance of each sector. The table is ordered by number of companies involved with each sector. The table shows that there is a good mix of sectors covered by the respondents with only 'toys' not represented at all.

It is not appropriate to compare responses by sector because of the large number of sectors and a small number of responses per sector.

Table 2-8: Number and percentage of responses by sectors in which companies are involved (n=204)		
Sector	**Number of companies involved in this sector**	**Percentage of responses**
Formulation of chemical products	30	15%
Other	29	14%
Biocidal products	28	14%
Speciality chemicals	28	14%
Paints, inks and coatings	26	13%
Basic chemicals	25	12%
Detergents and cleaning products	24	12%
Adhesives and glues	23	11%
Other manufacturing	23	11%
Polymers	20	10%
Plastics	19	9%
Auxiliaries for industry	18	9%
Dyes and Pigments	17	8%
Fertilisers	17	8%
Lubricants, oils and related products	17	8%
Aerosols	15	7%
Food	14	7%
Plant protection products	14	7%
Cosmetics	13	6%
Automotive	12	6%
Other chemicals production activities	12	6%
Packaging	12	6%
Retail	11	5%
Electronics	7	3%
Metals and metal alloys	7	3%
Textiles	7	3%
Personal care products	6	3%
Synthetic Rubber	6	3%
Paper and pulp	5	2%
Aerospace and Defence	4	2%
Furniture	4	2%
Toys	0	0%

2.4 Section 1.2: Impact of CLP implementation on SMEs

2.4.1 Q6: Did you have to undertake any of the following activities as a result of implementation of the CLP Regulation?

The remaining questions focus specifically on the impact of CLP implementation on SMEs. Therefore, the remainder of the analysis only considers responses from those companies with fewer than 250 employees.

There were six possible options available to respondents and 134 responses were received to this question (with this limited to manufacturers, importers and formulators). Table 2-9 presents the

responses, across all respondents and then by manufacturers, importers and formulators. The total number of responses across manufacturers, importers and formulators exceeds 134 as some respondents indicated that they undertook more than one of these activities. Figure 2-3 presents these results graphically to more clearly show the patterns between the different types of activity.

Table 2-9: Number and percentage of responses by activities required due to implementation of the CLP Regulation by activity (n=134)

Activity	Total across all types of activities (n=134)		Activities of manufacturers (n=76)		Activities of importers (n=30)		Activities of formulators (n=42)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
Training	119	89%	67	88%	25	83%	39	93%
Purchase of new IT and software	42	31%	19	25%	9	30%	26	62%
Re-classification of substances	57	43%	32	42%	13	43%	24	57%
Re-classification of mixtures	78	58%	43	57%	12	40%	38	90%
Re-labelling of products	89	66%	47	62%	19	63%	35	83%
Re-packaging of products	30	22%	17	22%	5	17%	12	29%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of activities indicated to show the proportion of responses where this activity was undertaken by their company

Figure 2-3 shows that the most common activity was training, with similar levels of respondents indicating that this was required in response to implementation of the CLP Regulation (range from 83% (25) of importers to 93% (39) of formulators). Overall, formulators undertook more activities than manufacturers and importers, with 90% (38) reporting that they had to undertake re-classification of mixtures. This compares with 58% (78) of all respondents, 57% (43) of manufacturers and 40% (12) of importers. Formulators were also more likely to undertake re-labelling of products with 83% (35) highlighting that they had undertaken this activity. This compares with 66% (89) overall, 62% (47) of manufacturers, and 63% (19) of importers. Formulators were also more likely to have purchased new IT and software with this activity undertaken by 62% (26) of formulators but just 31% (42) overall and 25% (19) of manufacturers and 30% (9) of importers.

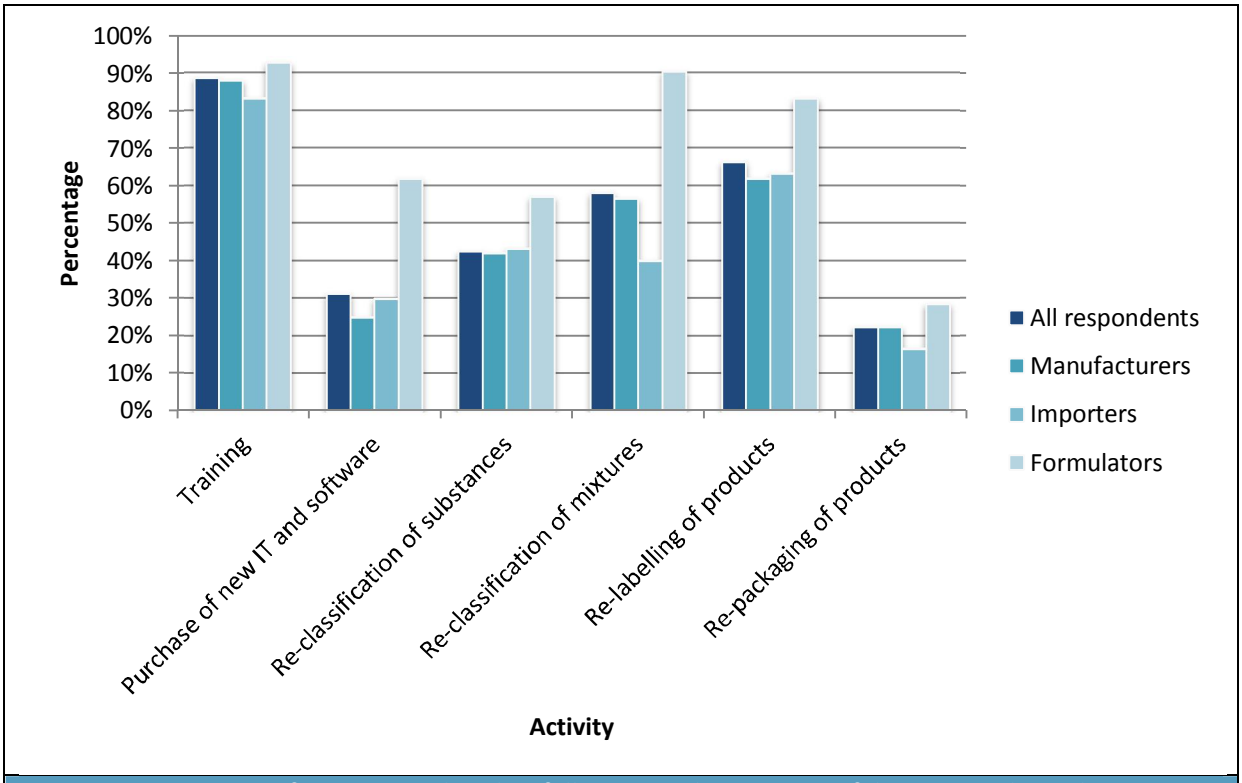

Figure 2-3: Percentage of activities undertaken following implementation of the CLP Regulation by activity (n=134 all respondents, 76 for manufacturers, 30 for importers and 42 for formulators)

These results can be compared with responses by company size, with Table 2-10 presenting a summary of activities undertaken by company size and Figure 2-4 presenting a chart that can be compared with Figure 2-3. The pattern of activities is similar across all company sizes, although those with 1-9 employees appear to have undertaken less re-classification of substances (31% or 8) than those with more than 10 employees (10-40 employees is 46% (28) and 50-249 employees is 45% (21)). Companies with 1-9 employees also undertook less re-classification of mixtures at 35% (9) compared with 64% (39) of those with 10-49 employees and 64% (30) of those with 50-249 employees. Almost all (98% or 46) of companies with 5-249 employees undertook training.

Table 2-10: Number and percentage of responses by activities required due to implementation of the CLP Regulation by company size (n=134)

Activity	Total across all types of activities (n=134)		1-9 employees (n=26)		10-49 employees (n=61)		50-249 employees (n=47)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
Training	119	89%	23	88%	50	82%	46	98%
Purchase of new IT and software	42	31%	9	35%	18	30%	15	32%
Re-classification of substances	57	43%	8	31%	28	46%	21	45%
Re-classification of mixtures	78	58%	9	35%	39	64%	30	64%
Re-labelling of products	89	66%	15	58%	45	74%	29	62%
Re-packaging of products	30	22%	6	23%	16	26%	8	17%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of activities indicated to show the proportion of responses where this activity was undertaken by their company

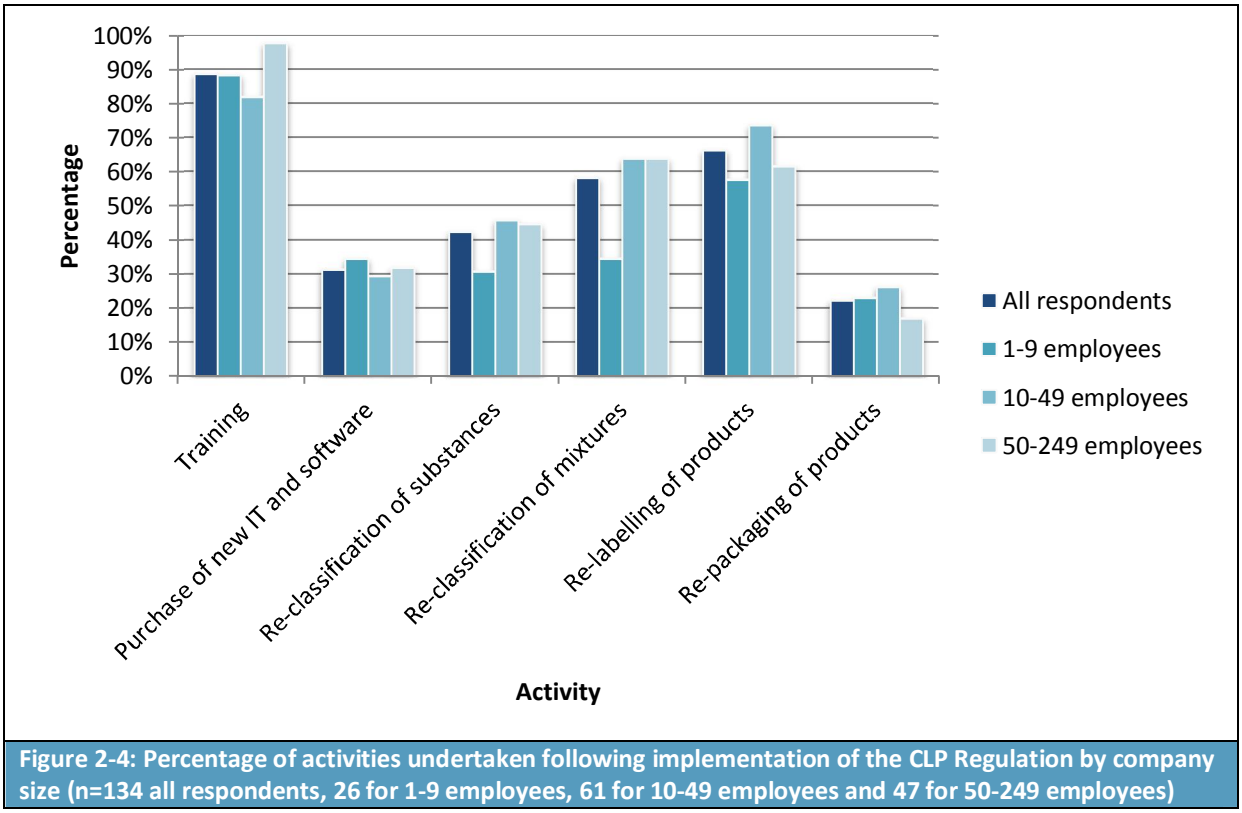

Figure 2-4: Percentage of activities undertaken following implementation of the CLP Regulation by company size (n=134 all respondents, 26 for 1-9 employees, 61 for 10-49 employees and 47 for 50-249 employees)

2.4.2 Q7: Did implementation of the CLP Regulation impact your business in any of the following ways?

There were a total of 145 responses to this question, with the results shown in Table 2-11. The results are given across all manufacturers, distributors and formulators and by each activity separately. The patterns of responses can be more easily seen in Figure 2-5 for negative impacts and Figure 2-6 for positive impacts. Both figures are shown with the same scale on the vertical (y) axis to give a clear indication of the variation in percentage of respondents agreeing that each impact had affected their business.

Table 2-11: Number and percentage of responses by impacts on the business due to implementation of the CLP Regulation by activity (n=145)

Impact	Total across all types of activities (n=145)		Activities of manufacturers (n=82)		Activities of formulators (n=42)		Activities of distributors (n=40)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
Negative impacts for the business								
Required the employment of new staff to meet classification and labelling requirements	27	19%	14	17%	11	26%	11	28%
Led to a short term increase in costs	73	50%	39	48%	25	60%	26	65%
Led to a decrease in sales due to increased competition in the EU market	7	5%	6	7%	0	0%	2	5%
Positive impacts for the business								

Table 2-11: Number and percentage of responses by impacts on the business due to implementation of the CLP Regulation by activity (n=145)								
Impact	Total across all types of activities (n=145)		Activities of manufacturers (n=82)		Activities of formulators (n=42)		Activities of distributors (n=40)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
Increased our customer base due to greater harmonisation across the EU	7	5%	5	6%	0	0%	1	3%
Increased our import of products from outside the EU	9	6%	4	5%	2	5%	1	3%
Led to an increase in our ability to export due to greater harmonisation globally	4	3%	4	5%	1	2%	1	3%
Other responses								
None of the above	45	31%	26	32%	11	26%	9	23%
Don't know	15	10%	7	9%	3	7%	6	15%
Other impacts	11	8%	9	11%	3	7%	3	8%
Notes: [1] Percentage is calculated over the number of responses (n) rather than the total number of impacts indicated to show the proportion of responses where this impact was felt by their company								

A comparison of Figure 2-5 and Figure 2-6 shows that there were many more respondents that agreed with the negative impacts for businesses than with the positive ones. The most common negative impact identified by the SMEs responding to the survey was 'led to an increase in short-term costs' with this indicated by 50% (73) of all respondents, 48% (39) of manufacturers, 60% (25) of formulators and 65% (26) of distributors. In contrast, 45 of the respondents (31%), 26 manufacturers (32%), 11 formulators (26%) and 9 distributors (23%), replied that 'none of the above' applied to them, with this representing a larger number of respondents than for many of the negative impacts on businesses. The pattern across type of activity is reasonably similar across both negative and positive impacts, although formulators and distributors do appear slightly more likely to suggest negative impacts than manufacturers. Manufacturers also indicated that they had experienced all three of the positive impacts (not the same manufacturers), but these were at very low levels (6% and lower across the three positive types of impact).

The short-term increase in costs could, perhaps, be associated with the types of activities required that were identified in Q6. This shows that 88% of manufacturers, 83% of importers and 93% of formulators undertook training following implementation of the CLP Regulation. Other sources of costs could come from the need to re-label products, with this undertaken by 62% of manufacturers, 63% of importers and 83% of formulators. (However, it should also be noted that only 48% of manufacturers indicated a short-term increase in costs, although all undertook training; this is likely to be due to the fact that training in relation to health and safety may be obligatory).

Manufacturers were most likely to have experienced no stated impacts at 32% (26) compared with 26% (11) of formulators and 23% (9) of distributors.

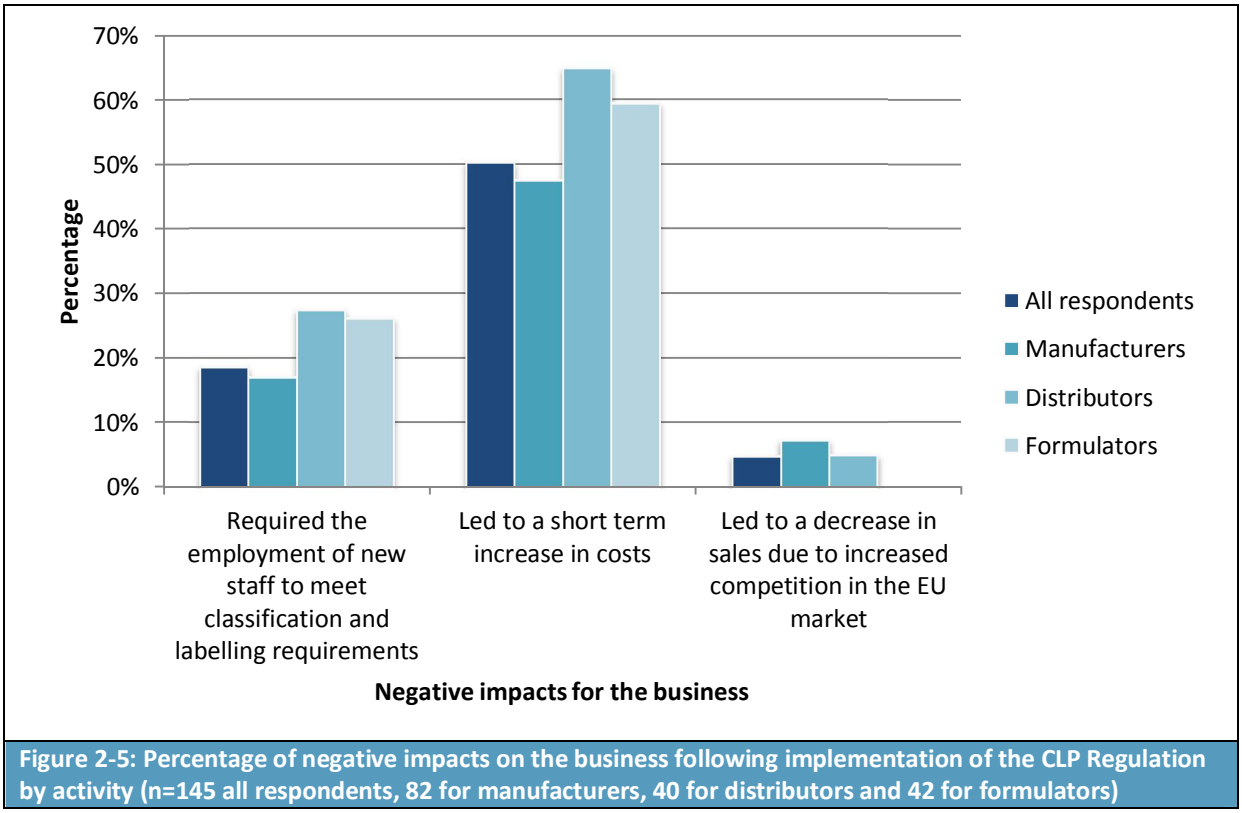

Figure 2-5: Percentage of negative impacts on the business following implementation of the CLP Regulation by activity (n=145 all respondents, 82 for manufacturers, 40 for distributors and 42 for formulators)

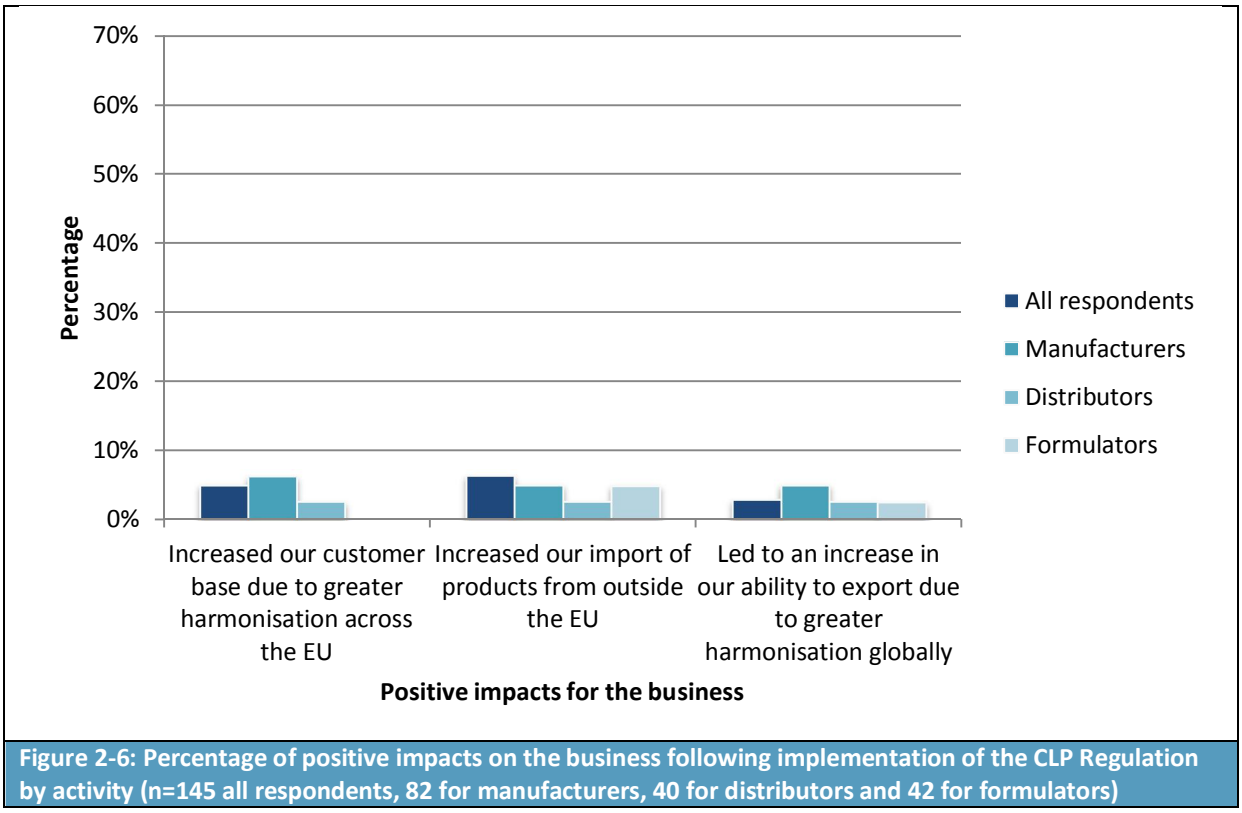

Figure 2-6: Percentage of positive impacts on the business following implementation of the CLP Regulation by activity (n=145 all respondents, 82 for manufacturers, 40 for distributors and 42 for formulators)

Table 2-12 and Figure 2-7 and Figure 2-8 present the breakdown of impacts by company size. These show that fewer companies with 1-9 employees identified that their business had been impacted by

implementation of the CLP Regulation than larger companies. Just 37% (11) of companies with 1-9 employees stated that there had been a short term increase in costs compared with 62% (40) of companies with 10-49 employees and 44% (21) of companies with 50-249 employees. Similarly, just 7% (2) of companies with 1-9 employees highlighted that they had had to employ new staff to meet classification and labelling requirements. This compares with 22% (14) of those with 10-49 employees and 21% (10) of those with 50-249 employees. The levels of positive impact are all at a low level, with the most responses (10% or 3) being from companies with 1-9 employees who said that they had increased import of products from outside the EU. This compares with 4% (2) of companies with 50-249 employees and 5% (3) with 10-49 employees.

Table 2-12: Number and percentage of responses by impacts on the business due to implementation of the CLP Regulation by company size (n=145)

Impact	Total across all types of activities (n=145)		1-9 employees (n=30)		10-49 employees (n=65)		50-249 employees (n=48)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
Negative impacts for the business								
Required the employment of new staff to meet classification and labelling requirements	27	19%	2	7%	14	22%	10	21%
Led to a short term increase in costs	73	50%	11	37%	40	62%	21	44%
Led to a decrease in sales due to increased competition in the EU market	7	5%	0	0%	5	8%	2	4%
Positive impacts for the business								
Increased our customer base due to greater harmonisation across the EU	7	5%	0	0%	2	3%	5	10%
Increased our import of products from outside the EU	9	6%	3	10%	3	5%	2	4%
Led to an increase in our ability to export due to greater harmonisation globally	4	3%	1	3%	1	2%	2	4%
Other responses								
None of the above	45	31%	11	37%	15	23%	19	40%
Don't know	15	10%	4	13%	10	15%	1	2%
Other impacts	11	8%	4	13%	1	2%	6	13%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of impacts indicated to show the proportion of responses where this impact was felt by their company

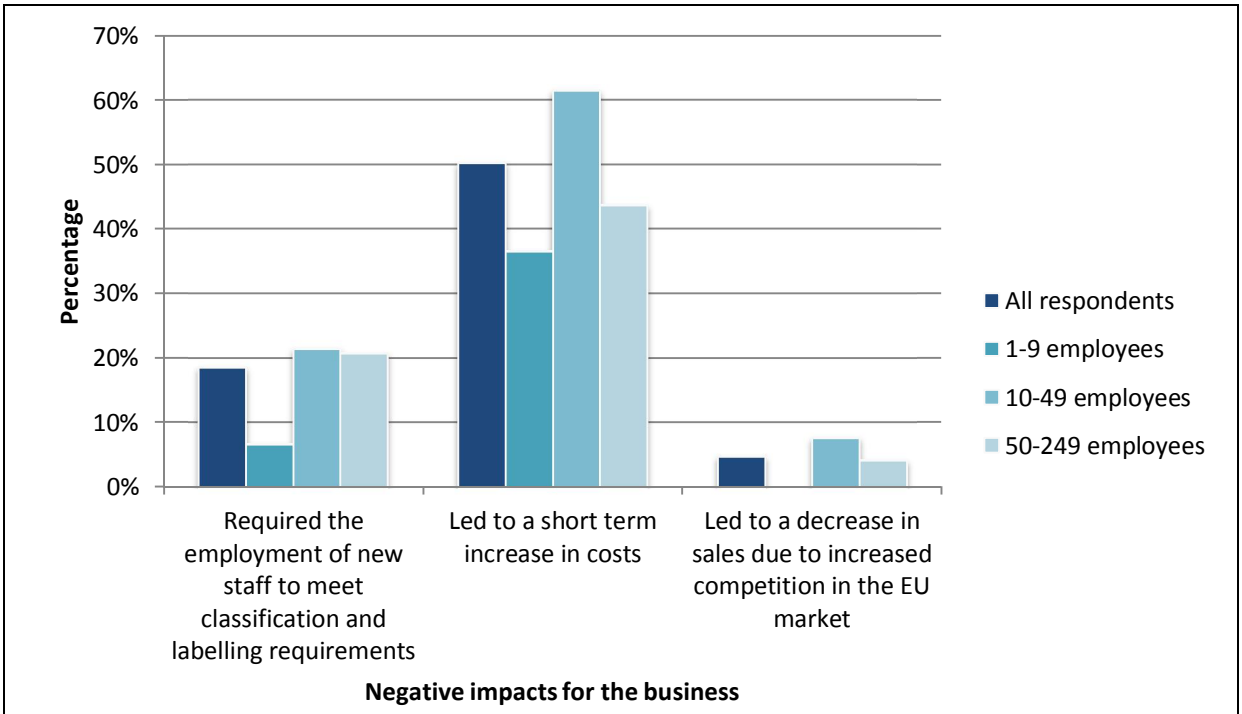

Figure 2-7: Percentage of negative impacts on the business following implementation of the CLP Regulation by company size (n=145 all respondents, 30 for 1-9 employees, 65 for 10-49 employees and 48 for 50-249 employees)

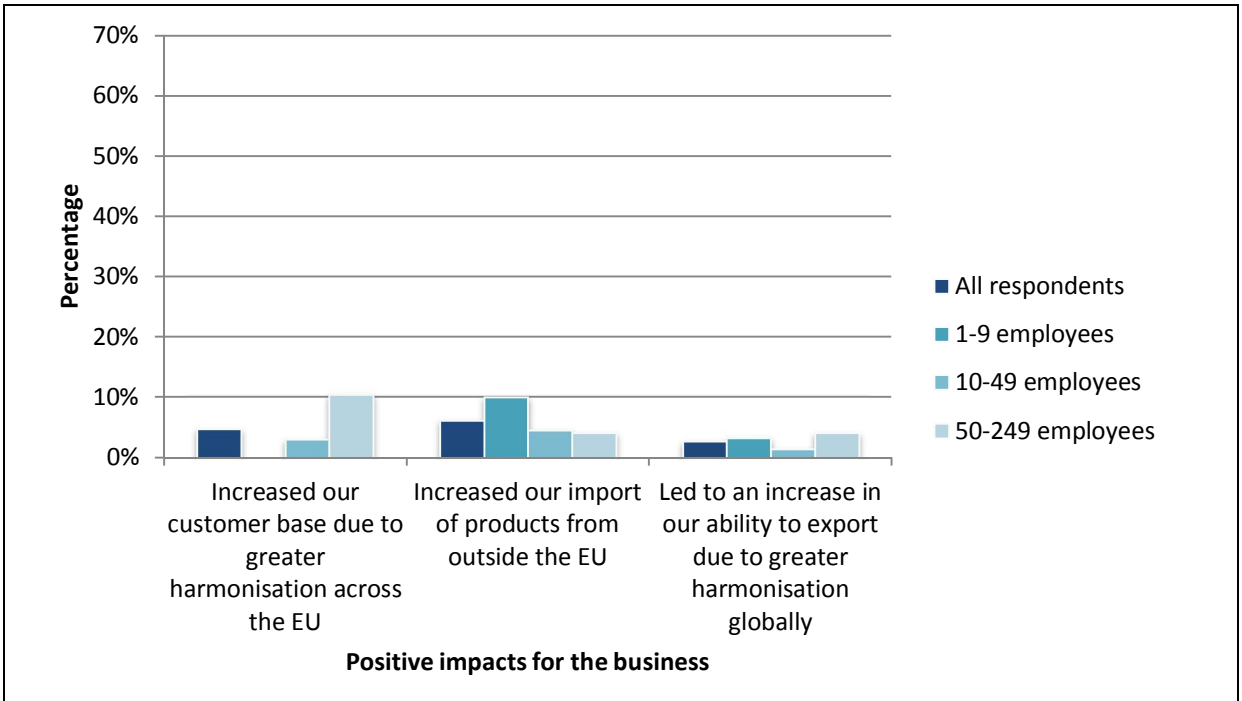

Figure 2-8: Percentage of positive impacts on the business following implementation of the CLP Regulation by company size (n=145 all respondents, 30 for 1-9 employees, 65 for 10-49 employees and 48 for 50-249 employees)

Some of those who identified that they had experienced other impacts provided further detail on what these impacts were:

- *There has been a general increase of costs as it now takes more time under CLP compared to DPD;*
- *New label printers had to be purchased, new Labels cause higher costs;*
- *Extra administration, uncertainty because of the permanent changes;*
- *Selection of suppliers;*
- *Management / disposal of packaging / labels for classification changes; and*
- *Non-productive implementation period [durée de mise en œuvre non productive], e.g. due to inspections conducted by the relevant authorities, which stopped a production.*

Three of the comments relate to time (two that more time is needed), while two refer to non-productive periods, during implementation and inspections. Also, two respondents not quoted above indicated that they rely upon external service providers.

2.4.3 Q8: If you are a downstream user of chemicals did implementation of the CLP impact on your business in any of the following ways?

There were 167 responses to this question, although many of these were by manufacturers and importers and thus have been removed from the analysis, leaving 79 formulators and downstream users. The results are summarised in Table 2-13 for all respondents and then by type of activity (manufacturers, importers, formulators, other downstream users and distributors).

Table 2-13: Number and percentage of downstream users of chemicals impacted due to implementation of the CLP Regulation by activity (n=168)

Impact	Total across all types of activities (n=167)		Activities of formulators (n=31)		Activities of other downstream users (n=48)	
	No.	%[1]	No.	%[1]	No.	%[1]
Required training of staff to ensure they understood the new pictograms and hazard & precautionary statements	109	65%	25	81%	31	65%
Increased the number of suppliers placing chemicals products on the EU market	6	4%	1	3%	1	2%
Decreased the price of chemical products due to increased competition	3	2%	1	3%	0	0%
Required a review of your risk assessments under the Chemical Agents Directive	79	47%	18	58%	30	63%
Required a re-labelling of your products	53	32%	16	52%	9	19%
Results in actions under other legislation	22	13%	5	16%	11	23%
None of the above	20	12%	0	0%	7	15%
Other	2	1%	0	0%	1	2%
Don't know	18	11%	2	6%	0	0%

Notes:
[1] Percentage is calculated over the number of responses (n) rather than the total number of impacts indicated to show the proportion of responses where this impact was felt by their company

Both the table and the figure show that training of staff was the most commonly mentioned impact on downstream users. This was mentioned by 81% of formulators and 65% of downstream users, who were more affected by this impact than the other activities. Other key activities include re-labelling and reviews of OSH risk assessments.

2.4.4 Q9: Have you ever submitted a proposal to ECHA or participated in a public consultation by ECHA?

There were 190 responses to this question, with results presented in Table 2-14 for all respondents and then by type of activity for submission of a proposal and Table 2-15 for participation in a consultation by ECHA.

Table 2-14 shows that the vast majority of all respondents had not submitted a proposal (95% or 180) nor responded to a public consultation by ECHA (93% or 176). There is very little variation between types of activities from a low of 92% (33) of formulators saying 'no' up to 98% of both other downstream users (48) and distributors (41) saying 'no' to submission of a proposal. The number of respondents reporting that they had submitted a proposal increases by company size, from 0% for companies with 1-9 employees to 5% (4) for those with 10-49 employees and to 7% (5) for those with 50-249 employees.

The range for not participating in a public consultation shown in Table 2-15 is from 83% (25) for importers to 98% (44) for other downstream users. Although the percentage of 'no' responses to participation in a public consultation by importers appears lower (83%), this is a small sample size with only 5 respondents (17%) saying 'yes' that they had participated in a public consultation by ECHA. The percentages involved by company size are all low with the maximum being 9% (6) for companies with 50-249 employees, decreasing to 5% (2) for those with 1-9 employees and 6% (5) for those with 10-49 employees.

Table 2-14: Number and percentage of respondents who had and had not submitted a proposal to ECHA by activity and by company size (n=190)

Impact	Total across all types of activities (n=190)		Activities of manufacturers (n=97)		Activities of importers (n=29)	
	No.	%	No.	%	No.	%
No	180	95%	90	93%	27	93%
Yes	10	5%	7	7%	2	7%
Impact	**Activities of formulators (n=36)**		**Activities of other downstream users (n=49)**		**Activities of distributors (n=42)**	
	No.	**%**	**No.**	**%**	**No.**	**%**
No	33	92%	48	98%	41	98%
Yes	3	8%	1	2%	1	2%
Impact	**1-9 employees (n=38)**		**10-49 employees (n=77)**		**50-249 employees (n=73)**	
	No.	**%**	**No.**	**%**	**No.**	**%**
No	38	100%	73	95%	68	93%
Yes	0	0%	4	5%	5	7%

Table 2-15: Number and percentage of respondents who had and had not participated in a public consultation by ECHA (n=189)						
Impact	Total across all types of activities (n=189)		Activities of manufacturers (n=92)		Activities of importers (n=30)	
	No.	%	No.	%	No.	%
No	176	93%	87	95%	25	83%
Yes	13	7%	5	5%	5	17%
Impact	Activities of formulators (n=39)		Activities of other downstream users (n=45)		Activities of distributors (n=43)	
	No.	%	No.	%	No.	%
No	38	97%	44	98%	41	95%
Yes	1	3%	1	2%	2	5%
Impact	1-9 employees (n=39)		10-49 employees (n=79)		50-249 employees (n=69)	
	No.	%	No.	%	No.	%
No	37	95%	74	94%	63	91%
Yes	2	5%	5	6%	6	9%

2.4.5 Q10: Does your company incur significant costs on an annual basis in complying with the CLP Regulation or other chemicals legislation (other than REACH)?

There are two elements to this question. First, respondents were asked to identify which types of costs they incur on an annual basis. Second, they were asked to rank those costs from most significant (1) to least significant (10).

2.4.5.1 Types of costs incurred by respondents

There were 192 responses to the types of costs that were incurred. The results for all respondents and then by type of activity are provided in Table 2-16. A graphical representation of the results is provided in Figure 2-9.

Table 2-16: Number and percentage of respondents that had incurred costs on an annual basis in complying with the CLP Regulation or other chemicals legislation by activity (other than REACH) by company size (n=192)						
Impact	Total across all types of activities (n=192)		Activities of manufacturers (n=94)		Activities of importers (n=31)	
	No.	%	No.	%	No.	%
CLP classification requirements for substances and mixtures	60	31%	36	38%	14	45%
Complying with CLP labelling and packaging requirements	81	42%	46	49%	21	68%
Complying with other chemicals legislation (other than CLP or REACH)	60	31%	30	32%	12	39%
Laboratory testing required to comply with chemicals legislation (other than REACH)	43	22%	28	30%	8	26%

Table 2-16: Number and percentage of respondents that had incurred costs on an annual basis in complying with the CLP Regulation or other chemicals legislation by activity (other than REACH) by company size (n=192)						
Understanding and keeping up-to-date with changes in legal requirements	87	45%	44	47%	17	55%
Training staff to ensure compliance with legal requirements	93	48%	44	47%	18	58%
Inspections or audits by authorities and related administrative requirements	54	28%	30	32%	10	32%
Other (please describe in box below)	4	2%	3	3%	2	6%
We do not incur significant costs	56	29%	23	24%	9	29%
Don't know	20	10%	10	11%	1	3%

Impact	Activities of formulators (n=40)		Activities of other downstream users (n=46)		Activities of distributors (n=41)	
	No.	%	No.	%	No.	%
CLP classification requirements for substances and mixtures	24	60%	13	28%	16	39%
Complying with CLP labelling and packaging requirements	30	75%	11	24%	25	61%
Complying with other chemicals legislation (other than CLP or REACH)	16	40%	12	26%	16	39%
Laboratory testing required to comply with chemicals legislation (other than REACH)	9	23%	11	24%	4	10%
Understanding and keeping up-to-date with changes in legal requirements	26	65%	18	39%	20	49%
Training staff to ensure compliance with legal requirements	30	75%	22	48%	24	59%
Inspections or audits by authorities and related administrative requirements	14	35%	11	24%	12	29%
Other (please describe in box below)	1	3%	2	4%	1	2%
We do not incur significant costs	9	23%	14	30%	12	29%
Don't know	1	3%	8	17%	4	10%

In total, just over 60% of all respondents stated that they incurred costs on an annual basis in complying with the CLP Regulation. A further 29% of all respondents noted that they did not incur significant costs[7], while 10% did not know. The proportion of respondents replying that they did not incur significant costs varies slightly by activity, with the highest proportion coming from downstream users at 30%, followed by importers and distributors at 29%, manufacturers at 24% and formulators at 23%.

There is considerable variation across the different cost types with a minimum of 22% (43) of all respondents (total respondents) reporting that they undertake laboratory testing to comply with chemicals legislation (other than REACH) up to a maximum of 48% (93) of all respondents who undertake training of staff to ensure compliance with legal requirements.

There is also variation across activities. The largest range is for costs associated of complying with CLP labelling and packaging requirements, where the minimum percentage incurring these costs is 26% (12) for other downstream users and the maximum is 75% (30) of formulators. The lowest percentage of any activity for any cost type is for distributors and laboratory testing where just 10% (4) incurred these costs. The highest is 75% for formulators to comply with CLP labelling and packaging requirements (as noted above) and also for formulators to train staff to ensure compliance, again at 75% (30).

The most common costs for manufacturers are associated with complying with CLP labelling and packaging requirements (49% or 46) and understanding and keeping up-to-date with changes in legal requirements and training of staff, both with 47% (44). The most common cost for importers is also complying with CLP labelling and packaging requirements (68% or 21). For other downstream users, the most common cost type is training of staff (48% or 22) and for distributors it is complying with CLP labelling and packaging requirements (61% or 25). Thus, complying with CLP labelling and packaging costs is the most common cost type for manufacturers, importers, formulators (equal top), and distributors.

The incidence of costs can also be broken down by company size, with the results presented in Table 2-17 and in Figure 2-10. There is reasonable consistency in terms of costs incurred across the different company sizes. The largest difference is for inspections or audits by authorities and associated administrative requirements. Here there is a clear pattern with smaller companies being more likely to incur these costs annually. A total of 45% (14) of respondents with 1-9 employees reported that they incurred such costs compared with 32% (24) of companies with 10-49 employees and 23% (15) of companies with 50-249 employees.

[7] The definition of what was considered significant was left to the respondent to determine. There may, therefore, be some inconsistency between what each individual respondent considers to be significant. However, the key objective of this question was to identify what proportion of respondents felt they incurred significant costs, hence, it is their interpretation of what is significant that is considered to be the most relevant.

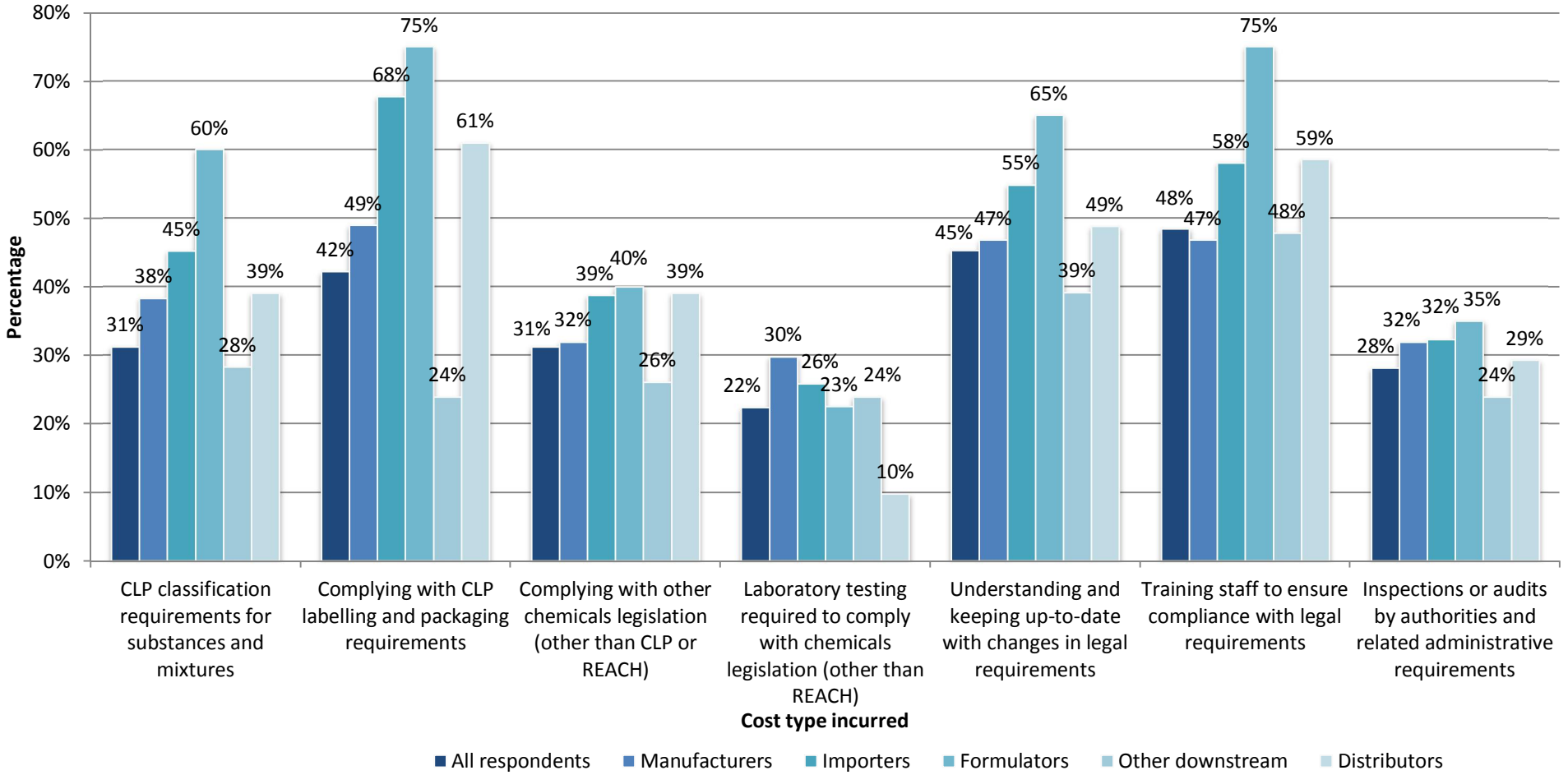

Figure 2-9: Percentage of respondents incurring annual costs in complying with CLP by type of cost by activity (n=192 all respondents, 94 for manufacturers, 31 for importers, 40 for formulators, 46 for other downstream users and 41 for distributors)

Table 2-17: Number and percentage of respondents that had incurred costs on an annual basis in complying with the CLP Regulation or other chemicals legislation (other than REACH) by company size (n=192)								
Impact	Total across all types of activities (n=192)		1-9 employees (n=31)		10-49 employees (n=76)		50-249 employees (n=66)	
	No.	%	No.	%	No.	%	No.	%
CLP classification requirements for substances and mixtures	59	31%	11	30%	29	37%	18	25%
Complying with CLP labelling and packaging requirements	80	42%	15	41%	40	51%	24	33%
Complying with other chemicals legislation (other than CLP or REACH)	59	31%	12	32%	25	32%	22	30%
Laboratory testing required to comply with chemicals legislation (other than REACH)	42	22%	7	19%	17	22%	18	25%
Understanding and keeping up-to-date with changes in legal requirements	85	45%	16	43%	39	49%	30	41%
Training staff to ensure compliance with legal requirements	92	48%	18	49%	40	51%	33	45%
Inspections or audits by authorities and related administrative requirements	53	28%	14	38%	24	30%	15	21%
Other (please describe in box below)	4	2%	1	3%	1	1%	2	3%
We do not incur significant costs	56	29%	9	24%	22	28%	24	33%
Don't know	20	11%	7	19%	4	5%	8	11%
Notes: the total across all activities is not always the sum of responses across the three bands of employees due to one response from 'self-employed'.								

There were seven respondents who provided further details on the nature of the significant costs that they incur. These are as follows with some being one-off costs and others being annual costs:

- *"*Other: Biocide register, such as tax, laboratory testing, risk assessments"*
- *"især udskiftning af etiketter har været meget dyr.[especially the replacement of labels has been very expensive]*
- *We inform our customers when public consultations on certain substances are open.*
- *achat logiciel [software purchase]*
- *3000€ per year*
- *Topics "Understanding and keeping..." and "Training staff" are carried out by service provider*

Each response gives a different type of cost or comment. The comment '*3000€ per year*' relates to costs associated with training of staff to ensure compliance with legal requirements as this was the only cost type selected by that respondent.

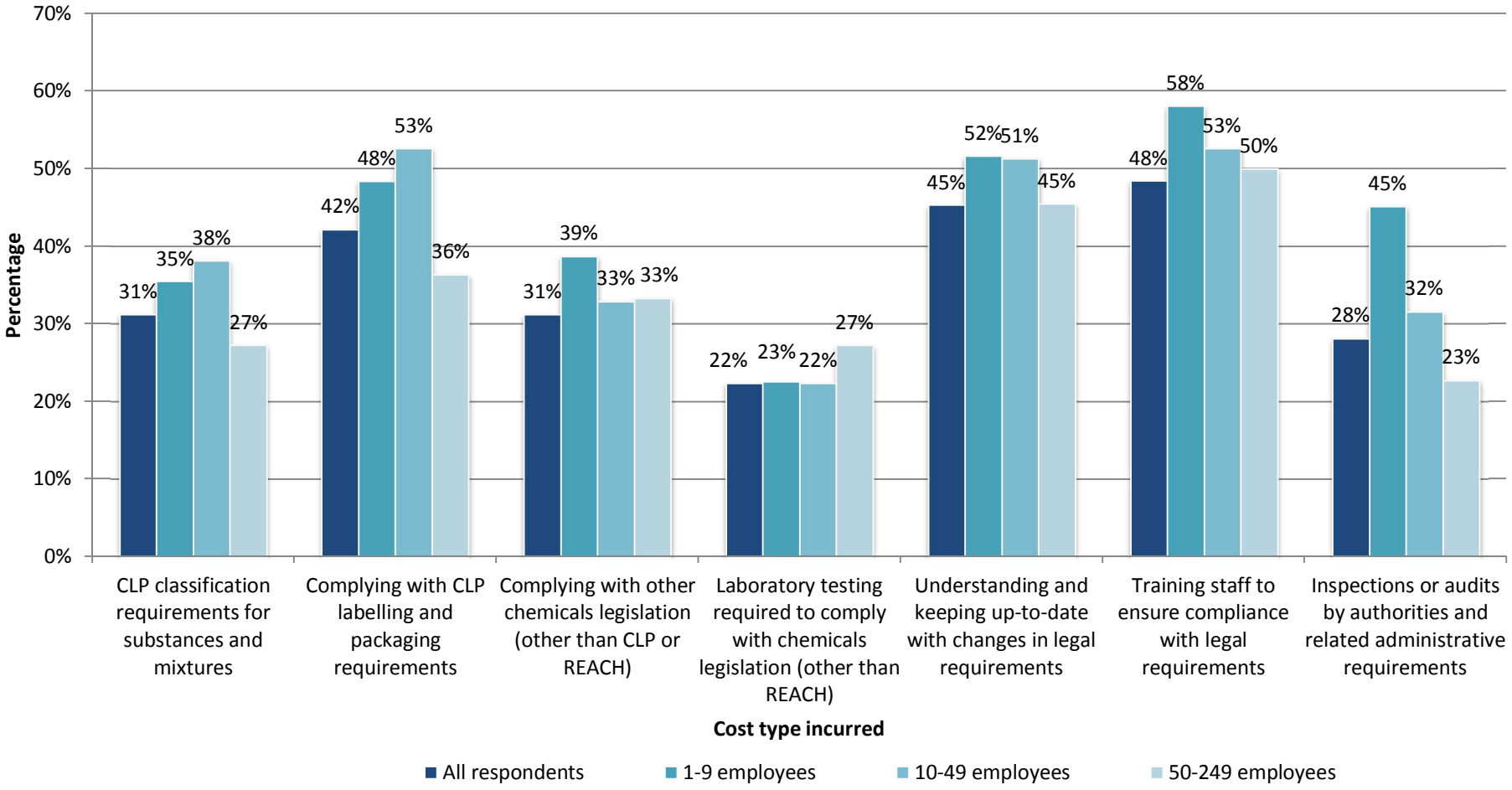

Figure 2-10: Percentage of respondents incurring annual costs in complying with CLP by type of cost by company size (n=192 all respondents, 31 for 1-9 employees, 76 for 10-49 employees and 66 for 50-249 employees)

2.4.5.2 Ranking of costs from most to least significant

As part of question 10, respondents were asked to rank the costs from most to least significant, with most significant assigned a rating of 1 and the least significant assigned a rating of 10.

The number of respondents varies by cost type from 55 (for laboratory testing) to 86 (for understanding and keeping up-to-date with changes in legal requirements and training staff to ensure compliance with legal requirements). Table 2-18 presents the number of scores assigned to each cost type by activity, where 1 is most significant and 10 is least significant. The scores are colour coded to give a visual presentation of where the most common responses were (darker shading) to the least common responses (light shading).

The table shows that the most significant costs are identified as being associated with complying with CLP labelling and packaging requirements (with 24 respondents scoring this 1, most significant and 20 scoring it a 2).

'Other' scores very highly for companies with 50-249 employees. However, none of the companies of this size who score 'other' as most significant provided further comments to explain their responses.

Table 2-18: Number of respondents assigning each score relating to the most (1) to least significant (10) cost types (n=55 to 86, depending on cost type, excluding other where n=10)

Cost type	Score assigned (1 = most significant, 10 = least significant)									
	1	2	3	4	5	6	7	8	9	10
CLP classification requirements for substances and mixtures	20	7	12	10	7	6	1	1	0	0
Complying with CLP labelling and packaging requirements	24	20	17	8	6	1	0	1	0	0
Complying with other chemicals legislation (other than CLP or REACH)	11	12	13	8	11	4	3	2	0	0
Laboratory testing required to comply with chemicals legislation (other than REACH)	14	11	14	6	1	3	3	3	0	0
Understanding and keeping up-to-date with changes in legal requirements	19	24	13	13	3	8	4	2	0	0
Training staff to ensure compliance with legal requirements	16	28	16	10	5	7	3	1	0	0
Inspections or audits by authorities and related administrative requirements	11	9	14	6	9	0	5	2	0	0
Other	4	0	2	1	0	0	0	3	0	0

2.5 Section 1.3: Hazard classification and communication

2.5.1 Q11: Indicate the extent to which you agree with the following statements relating to hazard communication measures enforced by CLP

Question 11 asked respondents to indicate whether they strongly disagree, disagree, agree or strongly agree with twelve different statements. The number of responses by impact is presented in Table 2-19 for all respondents.

Table 2-19: Number of responses and level of agreement with statements related to hazard communication measures enforced by CLP (n=147 to 199 depending on statement)

Impact	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Don't know
CLP hazard pictograms are generally representative of the actual hazard (n=199)	2	21	20	135	21	0
Employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=196)	4	29	35	112	16	0
The CLP classification of a chemical product influences the choice of employers to buy it for use by their workers (n=186)	8	37	38	72	31	0
Workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=197)	1	31	39	111	15	0
Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals (n=157)	17	47	48	43	2	0
Workers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products) (n=171)	8	31	53	67	12	0
CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals (n=182)	5	31	35	83	28	0
Consumers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products) (n=147)	9	49	52	36	1	0

Table 2-19: Number of responses and level of agreement with statements related to hazard communication measures enforced by CLP (n=147 to 199 depending on statement)						
Impact	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**	**Don't know**
Consumers generally do not look beyond the label for hazard information and information on safe use (n=169)	9	31	23	88	18	0
The information currently required to be included on labels is necessary and appropriate (n=195)	6	11	30	114	34	0
The hazard classification of a chemical product influences the choice of a consumer (n=176)	9	33	39	77	18	0
Providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites (n=168)	5	26	35	60	42	0

The results following application of a rating of -2 to strongly disagree, -1 to disagree, 0 to neither agree not disagree, 1 to agree and 2 to strongly agree are presented in Table 2-20 by activity and in Table 2-21 by company size. In this way, a weighted score can be determined that shows the extent to which all respondents agree or otherwise to each statement. The same information is presented for each type of activity. Where scores are greater than 0, this shows that respondents overall are in agreement with the statement. The higher the score, the more the strongly that respondents agree with the statement. Conversely, negative scores mean respondents overall disagree with the statement. The more negative the score, the more strongly they disagree.

Table 2-20: Weighted scores by agreement with statements related to hazard communication measures enforced by CLP by activity (n=147 to 199 depending on statement)						
Impact	**All activities (n=147 to 199)**	**Manufacturers (n=76 to 97)**	**Importers (n=20 to 30)**	**Formulators (n=26 to 42)**	**Other downstream users (n=32 to 49)**	**Distributors (n=33 to 46)**
CLP hazard pictograms are generally representative of the actual hazard	0.8	0.8	0.8	0.6	0.8	0.7*
Employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	0.5	0.6	0.7	0.5	0.7	0.5
The CLP classification of a chemical product influences the choice of employers to buy it for use by their workers	0.4	0.6	0.4	0.5	0.4	0.2

Table 2-20: Weighted scores by agreement with statements related to hazard communication measures enforced by CLP by activity (n=147 to 199 depending on statement)						
Impact	All activities (n=147 to 199)	Manufacturers (n=76 to 97)	Importers (n=20 to 30)	Formulators (n=26 to 42)	Other downstream users (n=32 to 49)	Distributors (n=33 to 46)
Workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	0.5	0.6	0.7	0.6	0.5	0.4
Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	-0.2	-0.2	0.2	-0.4	-0.2	-0.4
Workers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products)	0.3	0.2	0.4	0.3	0.3	-0.1
CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals	0.5	0.4	0.5	0.5	0.7	0.5
Consumers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products)	-0.2	-0.1	-0.1	-0.2	-0.3	-0.2
Consumers generally do not look beyond the label for hazard information and information on safe use	0.4	0.4	0.2	0.1	0.8	0.4
The information currently required to be included on labels is necessary and appropriate	0.8	0.8	0.9	0.7	0.8	0.8
The hazard classification of a chemical product influences the choice of a consumer	0.4	0.4	0.3	0.3	0.2	0.1
Providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites	0.6	0.5	0.3	0.8	0.8	0.4
*Note that of the 19 distributors answering this question,						

Table 2-21: Weighted scores by agreement with statements related to hazard communication measures enforced by CLP by company size (n=192)				
Impact	All activities (n=147 to 199)	1-9 employees (n=26 to 40)	10-49 employees (n=65 to 82)	50-249 employees (n=54 to 76)
CLP hazard pictograms are generally representative of the actual hazard	0.8	0.8	0.7	0.8
Employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	0.5	0.8	0.4	0.6
The CLP classification of a chemical product influences the choice of employers to buy it for use by their workers	0.4	0.4	0.3	0.6
Workers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	0.5	0.5	0.4	0.7
Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals	-0.2	-0.1	-0.4	-0.1
Workers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products)	0.3	0.4	0.1	0.4
CLP labelling requirements should be complemented by voluntary industry initiatives to promote the safe use of chemicals	0.5	0.5	0.6	0.6
Consumers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products)	-0.2	-0.1	-0.3	-0.1
Consumers generally do not look beyond the label for hazard information and information on safe use	0.4	0.6	0.4	0.4
The information currently required to be included on labels is necessary and appropriate	0.8	0.9	0.7	0.8
The hazard classification of a chemical product influences the choice of a consumer	0.4	0.4	0.3	0.4
Providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites	0.6	0.4	0.7	0.8

Table 2-20 shows that there is general agreement across activities in terms of the level of agreement and disagreement to each statement. The two statements most strongly agreed with are:

- CLP hazard pictograms are generally representative of the actual hazard: all respondents = 0.8 (n=199); range of activities from 0.6 for formulators (n=41) to 0.8 for manufacturers (97), importers (30) and other downstream users (49);
- The information currently required to be included on labels is necessary and appropriate: all respondents = 0.8 (n=195); range of activities from 0.7 for formulators (n=42) to 0.9 for importers (30). Manufacturers (95), other downstream users (48) and distributors (41) all score 0.8.

The statements with the lowest level of agreement, and overall slight disagreement are:

- Consumers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals: all respondents = -0.2 (n=157); range of activities from -0.4 for formulators (n=31) and distributors (33) to -0.2 for manufacturers (84) and other downstream users (35). Responses from importers result in an overall score of +0.2 (n=24) and is the only activity to agree (slightly) with this statement. The overall range for this statement from low to high is 0.7;
- Consumers understand the additional voluntary safe use icons that are included on certain products (e.g. cleaning products): all respondents = -0.2 (n=147); the scores across activities range from -0.3 for other downstream users (32) to -0.1 for manufacturers (76) and importers (20). Formulators (26) and distributors (33) to both have a score of -0.2. All activities disagree (slightly) with this statement.

The largest difference in scores is for the statement: Consumers generally do not look beyond the label for hazard information and information on safe use with a low score of 0.1 for formulators (n=32) and a high score of 0.8 for other downstream users (n=38). The score across all respondents is 0.4 (n=169), with this also the score for distributors (n=37) and manufacturers (n=85). The overall score for importers is 0.2 (n=23).

Table 2-21 shows that there is also general agreement across the statements by company size. The largest range by company size is 0.4, for two statements:

- Employers understand the CLP pictograms and information provided on labels regarding the safe use of chemicals, with a high score of 0.8 (companies with 1-9 employees) and a low score of 0.4 (companies with 10-49 employees). Responses from companies with 50-249 employees give a score of 0.6;
- Providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites. Here there is a trend with companies with 1-9 employees only scoring this statement at 0.4, with the score increasing by company size up to 0.7 (10-49 employees) and then to 0.8 (50-249 employees). This is the only statement where there appears to be a trend, with larger companies more likely to agree with the statement than smaller companies.

2.5.2 Q12: Could tools and mechanisms used for communicating the hazards of substances and mixtures be simplified and/or improved?

There were 94 responses to this question, with 58 of all respondents (33%) answering 'yes' and 36 (21%) replying 'no'. There were also 81 'don't know' answers to this question (46%). Table 2-22 also provides a summary of the responses by activity and by company size. Note that the question could

be considered as a leading one, in that responses will tend to reflect the fact that activities can always be improved.

Table 2-22: Responses to whether tools and mechanisms for communicating the hazards of substances and mixtures could be simplified and/or improved (n=175)							
Response	**Number/%**	**All activities (n=175)**	**Manufacturers (n=92)**	**Importers (n=29)**	**Formulators (n=37)**	**Other downstream users (n=38)**	**Distributors (n=40)**
Yes	Number	58	30	9	15	16	14
	%	33%	33%	31%	41%	42%	35%
No	Number	36	20	8	11	5	4
	%	21%	22%	28%	30%	13%	10%
Don't know	Number	81	42	12	11	17	22
	%	46%	46%	41%	30%	45%	55%

Response	**Number/%**	**All activities (n=175)**	**1-9 employees (n=38)**	**10-49 employees (n=72)**	**50-249 employees (n=64)**
Yes	Number	58	10	21	26
	%	33%	26%	29%	41%
No	Number	36	7	15	14
	%	21%	18%	21%	22%
Don't know	Number	81	21	36	24
	%	46%	55%	50%	38%

The table shows that the 'yes' responses across all activities outnumber 'no' responses. However, the highest response for all activities except formulators is 'don't know', where the range is from 45% for other downstream users (n=17) to 55% for distributors (n=22). A total of 41% (15) of formulators replied 'yes', compared with 30% (11) who said 'no' and 30% (11) who said 'don't know'. The highest proportion of 'yes' responses come from other downstream users at 42% (16). Responses from both manufacturers and importers resemble those of all responses more closely.

The responses show that larger companies are more likely to reply 'yes', that tools and mechanisms used for communicating hazards of substances and mixtures could be simplified and/or improved. In total, 41% (26) of companies with 50-249 employees replied 'yes' compared with 29% (21) of companies with 10-49 employees and 26% (10) with 1-10 employees. It is the number of 'don't know' responses that reduces with company size, from 55% (21) for 1-10 employees to 50% (36) for 10-49 employees and 38% (24) for 50-249 employees. The proportion of 'no' responses increases slightly with company size from 18% (7) for 1-10 employees through 21% (15) for 10-49 employees to 22% for companies with 50-249 employees.

There were 49 suggestions as to what these simplifications and/or improvements could involve. The comments have been grouped into four main types of comments: issues and problems, suggested solutions, more general comments, and other. Table 2-23 presents the key themes from the comments.

Table 2-23: Key themes from comments on how to simplify/improve the tools and mechanisms (n=49)	
Issues and problems	**Recommendations from respondents**
• Pictogram are not clear or informative enough • There is too much text • CLP has made attaining warning more	• Hazard and precautionary statement should be made clearer and simpler • Pictograms should be made instinctively

Table 2-23: Key themes from comments on how to simplify/improve the tools and mechanisms (n=49)	
Issues and problems	**Recommendations from respondents**
complicated than before • There are too many H and P sentences and they are not clear • Long chemical names are not meaningful to non-professional users	comprehensible • Pictograms should be extended and more accurately show the risks • Add product composition • Use QR codes • Number of risk indications should be reduced • Amount of text should be reduced • A traffic light system should be used • Type of hazard and to whom it is toxic should be indicated • An explanatory leaflet explaining pictograms should be included • Information should be better disseminated • More attention should be given to hazards of mixtures
General comments	**Other**
• Safety data sheets should be provided for every delivery of chemicals • Technical characteristics of PPE must be better specified in safety data sheets • Instruments and mechanisms are appropriate but classification should be simplified • Should be more simplification	• Advertising in media • The permanent change of the rules is not necessary. The most important is predictability. Or if a change is needed the cost should be borne by the legislature • The harmonization of the ADR and KRESZ(rule of the road) • easy collection

2.5.3 Q13: Indicate the extent of the impacts of the CLP Regulation and other EU hazard communication requirements

This question asks respondents to identify the extent of impact (from large negative to large positive) for eight different statements. The number of responses by level of impact across all respondents is set out in Table 2-24.

Table 2-24: Number of responses by level of impacts of the CLP Regulation and other EU hazard communication requirements (n=200 to 203)

Impact	Large negative impact	Low negative impact	Neutral / No change	Low positive impact	Large positive impact	Don't know
Increased access to classification data for substances (n=203)	3	5	48	68	61	18
More consistent hazard classifications across substances (n=202)	2	8	43	75	59	15
Safe use of chemicals by workers (n=203)	2	7	60	73	54	7
Safe use of chemicals by consumers (n=203)	3	7	70	47	47	29
Changes in packaging requirements (n=203)	5	16	81	48	23	30
Preparedness for industrial	1	2	66	62	44	26

Table 2-24: Number of responses by level of impacts of the CLP Regulation and other EU hazard communication requirements (n=200 to 203)						
Impact	Large negative impact	Low negative impact	Neutral / No change	Low positive impact	Large positive impact	Don't know
accidents (n=201)						
Increased awareness of the potential health impacts of chemical products (n=203)	2	3	54	68	65	11
Increased awareness of the potential environmental impacts of chemical products (n=200)	2	5	55	73	60	5

The table shows that the majority of comments suggest a positive impact (low to large) across almost all of the statements. The only exception is 'changes in packaging requirements' where 81 responses were neutral/no change compared with 71 for a positive impact (low plus large). This is also the statement with the largest number of negative responses (21). In all cases, these ignore 'don't know' responses.

Differences between the activities can also be presented. This is most easily expressed when a score is assigned to each of the choices from -2 for a large negative impact to +2 for a large positive impact. Table 2-25 presents the results for all respondents and then by activity, with the breakdown of results by company size given in Table 2-26.

Table 2-25: Weighted scores by agreement with statements related to extent of impacts of the CLP Regulation and other EU hazard communication requirements by activity (n=200 to 203)						
Impact	All activities (n=200 to 203)	Manufacturers (n=101 to 102)	Importers (n=27 to 29)	Formulators (n=40 to 41)	Other downstream users (n=48 to 49)	Distributors (n=43 to 45)
Increased access to classification data for substances	1.0	0.9	1.0	1.1	1.1	0.9
More consistent hazard classifications across substances	1.0	1.0	1.2	0.9	0.9	0.9
Safe use of chemicals by workers	0.9	0.9	0.7	0.7	1.1	0.6
Safe use of chemicals by consumers	0.7	0.8	0.6	0.6	0.9	0.5
Changes in packaging requirements	0.4	0.4	0.3	0.3	0.5	0.3
Preparedness for industrial accidents	0.8	0.9	0.7	0.6	0.9	0.8
Increased awareness of the potential health impacts of chemical products	1.0	0.9	1.0	0.8	1.1	0.8
Increased awareness of the potential environmental impacts of chemical products	0.9	0.9	0.9	0.8	1.0	0.8

Table 2-26: Weighted scores by agreement with statements related to extent of impacts of the CLP Regulation and other EU hazard communication requirements by company size (n=200 to 203)				
Impact	**All activities (n=200 to 203)**	**1-9 employees (n=40 to 41)**	**10-49 employees (n=81 to 83)**	**50-249 employees (n=75 to 76)**
Increased access to classification data for substances	1.0	0.6	1.1	1.1
More consistent hazard classifications across substances	1.0	0.5	1.1	1.1
Safe use of chemicals by workers	0.9	0.6	0.9	1.0
Safe use of chemicals by consumers	0.7	0.7	0.7	0.8
Changes in packaging requirements	0.4	0.4	0.3	0.6
Preparedness for industrial accidents	0.8	0.7	0.9	0.9
Increased awareness of the potential health impacts of chemical products	1.0	0.7	1.0	1.2
Increased awareness of the potential environmental impacts of chemical products	0.9	0.6	0.9	1.1

Table 2-27 shows that there is general agreement across all activities with the range of scores not exceeding 0.5 for any of the impacts. The highest scores are attributed to[8]:

- More consistent hazard classifications across substances: with a highest score of 1.2 from importers (n=26). The lowest score for this impact is 0.9 from formulators (n=40), other downstream users (n=44) and distributors (n=42). Manufacturers assigned this impact a score of 1.0 (n=94);
- Increased access to classification data for substances: the highest score here is 1.1 from formulators (n=40) and other downstream users (n=45). The lowest score is 0.9 from both manufacturers (n=93) and distributors (n=40) with importers assigning an overall score of 1.0 (n=26); and
- Increased awareness of the potential environmental impacts of chemical products: the high score is 1.1 from other downstream users (n=46) with the lowest score of 0.8 from both formulators (n=41) and distributors (n=42). Manufacturers (100) and importers (27) both assigned an overall score of 0.9.

The lowest score based on the responses is for changes in packaging requirements. This was assigned responses giving a score of 0.3 from importers (26), formulators (38) and distributors (39).

[8] Number of responses excludes 'don't know' as these have not been included when estimating a score for each statement

The responses resulting in the highest score were from other downstream users with a score of 0.5 (39) while responses from manufacturers result in a score of 0.4 (90).

The impact with the greatest range in score across the activities is safe use of chemicals by workers. The score based on all responses is 0.9 (196) but this declines to 0.6 for distributors (40) and increases to 1.1 for other downstream users (43). Responses from importers (27) and formulators (36) both result in a score of 0.7 while responses from manufacturers (99) give a score of 0.8.

There is again a clear distinction between the responses from companies with 1-9 employees and the larger companies (10-49 and 50-249 employees). For all statements except changes in packaging requirements, the score estimated from the responses from companies with 1-9 employees is consistently lower than that for larger companies. A review of responses shows that companies with 1-9 employees are much less likely to assign a score of 'large positive impact' than companies with 1-49 or 50-249 employees. Taking the statement with the largest range in scores (more consistent hazard classifications across substances), it can be seen that:

- Responses from companies with 1-9 employees result in a score of 0.5, compared with scores of 1.1 for companies with 10-49 employees and with 50-249 employees
- Only 16% (6) of companies with 1-9 employees identified that this statement has a large positive impact compared with 37% (28) of companies with 10-49 employees and 32% (23) of companies with 50-249 employees
- Conversely, 5% (2) of companies with 1-9 employees indicated that this statement resulted in a large negative impact, compared with 0% of both companies with 10-49 and 50-249 employees. In fact, none of the 75-76 respondents from companies with 50-249 employees assigned 'large negative impact' to any of the statements.

2.5.4 Q14: Are you aware of any other legal requirements under other legislation that were triggered by a CLP classification and that have affected your business?

There were 179 responses to this question, with 49 of all respondents (27%) answering 'yes' and 74 (41%) replying 'no'. A further 56 (31%) replied 'don't know'. Table 2-27 provides a summary of the responses by activity and by company size.

The table shows some differences in opinion across activities. For example, 51% (20) of other downstream users replied 'no' while 46% (16) of formulators answered 'yes' and just 29% (10) answered 'no'. For distributors the most common response was 'don't know' at 45% (18). Excluding 'don't know' responses, the overall response from each activity would be:

- Yes: formulators (46%)
- No: manufacturers (37%), importers (41%), other downstream users (51%), distributors (35%)

Table 2-27: Whether respondents are aware of other legal requirements under other legislation that were triggered by a CLP classification and that have affected their business by activity and company size (n=179)							
Response	**Number/%**	**All activities (n=179)**	**Manufacturers (n=89)**	**Importers (n=27)**	**Formulators (n=35)**	**Other downstream users (n=39)**	**Distributors (n=40)**
Yes	Number	49	30	8	16	9	8
	%	27%	34%	30%	46%	23%	20%
No	Number	74	33	11	10	20	14
	%	41%	37%	41%	29%	51%	35%
Don't know	Number	56	26	8	9	10	18
	%	31%	29%	30%	26%	26%	45%

Response	**Number/%**	**All activities (n=179)**	**1-9 employees (n=37)**	**10-49 employees (n=71)**	**50-249 employees (n=69)**
Yes	Number	58	5	17	27
	%	33%	14%	24%	39%
No	Number	36	16	29	29
	%	21%	43%	41%	42%
Don't know	Number	81	16	25	13
	%	46%	43%	35%	19%

There is a clearer pattern from the responses by company size, with the number of 'yes' responses increasing as company size increases. A total of 14% (5) of respondents from companies with 1-9 employees replied 'yes', increasing to 24% (17) for companies with 10-49 employees and to 39% for companies with 50-249 responses. The number of 'no' responses remains roughly constant from 43% (16) for companies with 1-9 employees through 42% (29) for companies with 50-249 employees to 41% (29) for companies with 10-49 employees. It is the number of 'don't know' responses that declines, suggesting larger companies are better able to identify other legal requirements under other legislation that are triggered by a CLP classification that may impact on their business.

Those answering 'yes' were asked to provide further explanation. A total of 39 additional comments were provided. Table 2-28 presents a summary of the responses, based on the number of times other legislation was suggested.

Table 2-28: Comments on other legislation triggered by a CLP classification (n=49)	
Legislation/legislative area	**Number of mentions**
Seveso	8
Waste	8
Biocides	6
Transport	6
REACH	4
Health and safety at work	3
RoHS	2
Cosmetics	1
Requirement to notify the Chemicals Inspector on hazardous mixtures brought to Poland	1
Dangerous goods	1
Aerosols	1
Water legislation	1

2.6 Section 1.4: Regulatory fitness of the chemicals legalisation framework (excluding REACH)

2.6.1 Q15: Indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

Respondents to this question were asked to indicate the extent to which they agreed or disagreed with five statements. The number of responses varies between 200 and 204 depending on the statements. Table 2-29 presents the results across all respondents.

Table 2-29: Number of responses agreeing with statements relating to the EU chemicals legislation framework overall (n=200 to 204)

Impact	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	I don't know
Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market (n=202)	8	23	32	93	5	41
The EU chemicals legislation framework is coherent (n=204)	5	22	47	89	4	37
The EU chemicals legislation framework contains gaps (n=201)	2	29	53	44	11	62
The EU chemicals legislation framework has overlaps (n=202)	0	17	65	36	8	76
The EU chemicals legislation framework is consistently enforced by Member States (n=200)	8	35	39	49	5	64

The table shows that there is a spread of opinion from strongly disagree to strongly agree on almost all of the statements. The number of agree and strongly agree responses outweigh other responses (including neutral but excluding don't know) for two of the statements:

- Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market: 98 agree or strongly agree compared with 32 neutral and 31 who disagree/strongly disagree (there are also 41 don't know responses)
- The EU chemicals legislation framework is coherent: 93 agree or strongly agree compared with 47 neutral and 27 who disagree/strongly disagree (there are also 37 don't know responses).

Using a scoring systems of +2 or strongly agree to -2 for strongly disagree allows differences between the responses from the activities to be identified. Table 2-30 presents the results from applying such a scoring system with the breakdown by company size presented in Table 2-31.

Table 2-30: Weighted scores by agreement with statements related to EU chemicals legislative framework overall and by activity (n=200 to 204)						
Impact	All activities (n=200 to 204)	Manufacturers (n=99 to 100)	Importers (n=29 to 31)	Formulators (n=40 to 41)	Other downstream users (n=49)	Distributors (n=43 to 46)
Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market	0.4	0.4	0.3	0.5	0.4	0.2
The EU chemicals legislation framework is coherent	0.4	0.5	0.2	0.4	0.4	0.2
The EU chemicals legislation framework contains gaps	0.2	0.2	0.3	0.1	0.5	0.3
The EU chemicals legislation framework has overlaps	0.3	0.2	0.6	0.3	0.4	0.3
The EU chemicals legislation framework is consistently enforced by Member States	0.1	-0.1	-0.2	-0.1	0.2	0.0

Table 2-31: Weighted scores by agreement with statements related to EU chemicals legislative framework overall and by company size (n=200 to 204)				
Impact	All activities (n=200 to 204)	1-9 employees (n=10 to 41)	10-49 employees (n=81 to 83)	50-249 employees (n=75 to 77)
Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market	0.3	0.0	0.4	0.6
The EU chemicals legislation framework is coherent	0.3	0.1	0.3	0.6
The EU chemicals legislation framework contains gaps	0.2	0.3	0.4	0.1
The EU chemicals legislation framework has overlaps	0.2	0.3	0.3	0.3
The EU chemicals legislation framework is consistently enforced by Member States	0.0	0.3	0.0	0.1

The table shows that there is reasonable similarity across activities with the results being that the answers result in scores that are closer to neutral (0) than to agree (1) with the exception of the following where the responses are closer to agree (1) than to neutral (0):

- Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market: formulators responses result in a score of 0.5 (n=41). This is also the statement with the largest range with a lowest score of 0.2 (distributors, 44). Responses from manufacturers (99) and other downstream users (49) result in a score of 0.4, while importers have a score of 0.3 (30). The score over all responses is 0.4 (202);

- The EU chemicals legislation framework has overlaps: importers responses result in a score of 0.6 (n=30) with all responses resulting in a score of 0.3 (n=202). The other activities scores are 0.2 for manufacturers (100) and 0.3 for formulators (30) and other downstream users (49).

The EU chemicals legislation framework is consistently enforced by Member States is the only statement with negative scores across some activities. Responses from manufacturers (n=99), and formulators (n=41) result in a score of -0.1 while results from importers (30) result in a score of -0.2. Responses from other downstream users result in a score of 0.2 (n=49) and is the only positive (agree) score across all activities against this statement, with the score from distributors being neutral (n=44). The overall score for this statement is 0.1 (slightly positive). This occurs due to the majority of respondents who are involved in two or more activities being more likely to give a negative response for this statement. This means that the individual activity scores tend to be more negative than the overall score.

Unlike in previous questions, there is no clear pattern where smaller companies are less likely to disagree with the statements than larger companies. There is an increase in agreement with company size for two of the statements:

- Chemicals legislation is sufficiently harmonised across Member States for the proper functioning of the European single market with a neutral score (0) for companies with 1-9 employees (41) increasing to 0.4 for companies with 10-49 employees (81) and then to 0.6 for companies with 50-249 employees (77);
- The EU chemicals legislation framework is coherent with a score of (0.1) for companies with 1-9 employees (41) increasing to 0.3 for companies with 10-49 employees (83) and then to 0.6 for companies with 50-249 employees (77).

For the statement 'The EU chemicals legislation framework is consistently enforced by Member States', it is companies with 1-9 employees who give the highest score of 0.3 (40) compared with 0.1 for companies with 50-249 employees (75) and a neutral score (0) for companies with 10-49 employees (82).

2.6.2 Q16: Please indicate any specific cases of incoherence between different pieces of chemicals or chemicals-related legislation

There were 20 responses to this question that provided specific comments. They have been grouped into key themes in Table 2-32. Full comments are provided in Table B in Annex 1.

Table 2-32: Themes on specific cases of incoherence between different pieces of chemicals and chemicals-related legalisation (n=20)

Legislation/legislative area	Comments
Safety data sheets	• Preparations and mixtures do not always declare all components • WEA rules are not harmonised • Norway's interpretation of SDS is strange • Requirements for under 18s are too precautionary (e.g. cannot work with certain hand dishwashing detergents)
CLP and biocides/plant protection products	• There is an inconsistency between CLP and biocides • Plant protection products are allowed in some Member States but not others • Overlaps between regulations can only be understood by experts when same substance is used for different purposes

Table 2-32: Themes on specific cases of incoherence between different pieces of chemicals and chemicals-related legalisation (n=20)	
Legislation/legislative area	**Comments**
Waste	• End of Waste not yet standardised with incoherence with REACH • Confusion between hazardous waste to the environment arising from non-hazardous substances • Regulations are too complicated • No proper alignment with legislation on waste classification
Transport	• Partially inconsistent with ADR • Products that do not match pictograms of CLP label with those of transport • Definition of flammable substance in APQ (up to 55°C) compared with ADR and CLP (up to 60 °C)
Cosmetics	• No indication in Cosmetics Regulation if SDS has to be made available • Cosmetics legislation prohibits use of raw materials that have been tested on animals, but CLP and REACH requires DDL tests on animals to be indicated
Food	• Food does not fall under scope of CLP but aromas are dangerous mix that must be labelled
REACH	• Overlap between REACH and notifies ISS
Other	• The deviancy of the special authority's opinion within the country • VOC • See Point 18. There is no easy access to legislation of different countries in relation to thresholds of professional expositions, contact information of Poison centres and Rescue services • WGK (engl. WHC, Water Hazard Class) is a German obligation

2.6.3 Q17: How do you keep up-to-date with changes in regulatory requirements under EU chemicals legislation?

This question allowed respondents to select one of six possible statements. There were 205 responses to this question. Table 2-35 presents the results across all respondents and then by each activity, with the breakdown of results by company size provided in Table 2-33. Figure 2-11 provides a visual representation of the results by activity with the results by company size in Figure 2-12.

Table 2-33: Percentage of respondents using each approach to keep up-to-date with changes in regulatory requirements under EU chemicals legislations by activity (n=205)						
Impact	**All activities (n=205)**	**Manufacturers (n=102)**	**Importers (n=30)**	**Formulators (n=42)**	**Other downstream users (n=49)**	**Distributors (n=45)**
My company monitors the conclusions of ATPs	25%	26%	23%	45%	20%	27%
We rely on an external service provider to tell us of changes introduced by ATPs	23%	23%	17%	24%	29%	20%
We rely on our national association to tell us of changes introduced by ATPs	16%	20%	20%	7%	16%	18%
We rely on our suppliers to inform us of any changes that impact on us	27%	22%	33%	17%	33%	24%
None of the above / other (please describe below)	3%	1%	3%	7%	2%	2%

Table 2-33: Percentage of respondents using each approach to keep up-to-date with changes in regulatory requirements under EU chemicals legislations by activity (n=205)						
Impact	All activities (n=205)	Manufacturers (n=102)	Importers (n=30)	Formulators (n=42)	Other downstream users (n=49)	Distributors (n=45)
Don't know	5%	9%	3%	0%	0%	9%

Table 2-34: Percentage of respondents using each approach to keep up-to-date with changes in regulatory requirements under EU chemicals legislations by company size (n=205)				
Impact	All activities (n=205)	1-9 employees (n=42)	10-49 employees (n=83)	50-249 employees (n=77)
My company monitors the conclusions of ATPs	25%	19%	20%	34%
We rely on an external service provider to tell us of changes introduced by ATPs	23%	19%	24%	25%
We rely on our national association to tell us of changes introduced by ATPs	16%	12%	18%	16%
We rely on our suppliers to inform us of any changes that impact on us	27%	33%	31%	19%
None of the above / other (please describe below)	3%	2%	2%	4%
Don't know	5%	14%	4%	3%

The most common approach across all respondents is to rely on suppliers (27% or 55), followed by the company monitoring the conclusions of ATPs themselves (25% or 52) and rely on external service providers (23% or 48). Reliance on national associations is lower at 16% (33).

The table and figure show that there is reasonable consistency in terms of the approaches used by companies undertaking different activities. There are some differences though, for example:

- many more formulators monitor the conclusions of ATP themselves (45% or 19) than for other activities, for other downstream users this is just 20% (10), 23% for importers (7), 26% for manufacturers (27) and 27% for distributors (12).
- Other activities rely more on national associations, with only 7% (3) formulators using this approach compared with 20% of manufacturers (20) and importers (6), 18% of distributors (8) and 16% of other downstream users (8)
- other downstream users rely more on an external service provider (29% or 14) compared with importers (17% or 6), distributors (20% or 9), manufacturers (23% or 23) and formulators (24% or 10)
- importers (10) and other downstream users (16) rely more on suppliers with both at 33%. This compares with 17% (7) of formulators, 22% (22) of manufacturers and 24% (11) of distributors.

The results by company size show some difference in approach:

- larger companies (50-249 employees) are much more likely (34% or 26) to monitor the conclusions of ATPs than companies with 1-49 employees (20% or 17) or companies with 1-9 employees (19% or 8)
- smaller companies with 1-9 employees (33% or 14) or 10-49 employees (31% or 26) are more likely to rely on suppliers than companies with 50-249 employees (19% or 15)
- companies with 1-9 employees were much more likely to answer 'don't know' to this question with this accounting for 14% of responses (6) compared with just 4% from companies with 10-49 employees (3) and 3% for companies with 50-249 employees (2).

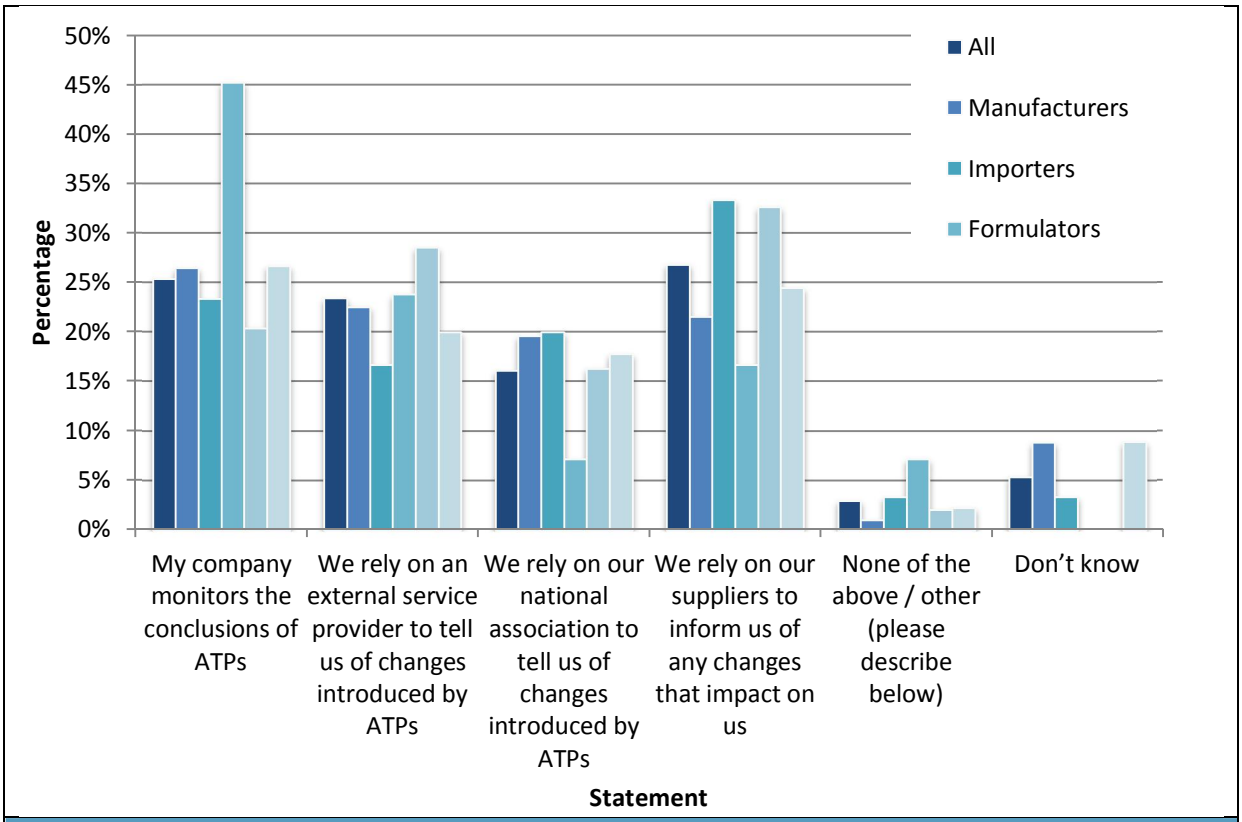

Figure 2-11: Percentage of respondents using each approach to keep up-to-date with changes in regulatory requirements under EU chemicals legislations by activity (n=205 all respondents, 102 for manufacturers, 30 for importers, 42 for formulators, 49 for other downstream users and 45 for distributors)

Two respondents (one manufacturer and formulator, and one formulator) provided further details:

- "Vi er tilknyttet en national sammenslutning, der fortæller os om ændringer i tilpasninger til den tekniske udvikling. [We are affiliated with a national association that tells us about changes in adaptation to technical progress"]
- "Vi er tilknyttet en ekstern tjenesteyder, der fortæller os om ændringer i tilpasninger til den tekniske udvikling. [We are affiliated with an external service provider who tells us about the changes in adaptations to technical progress].

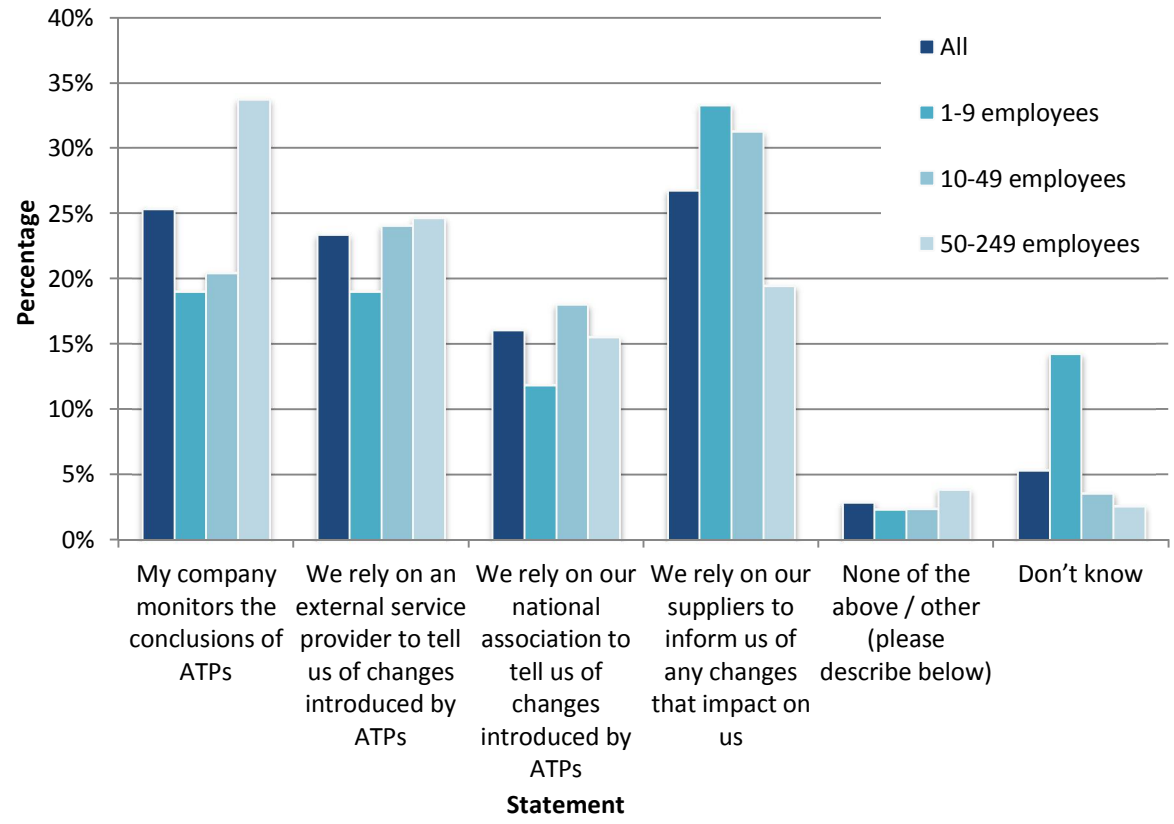

Figure 2-12: Percentage of respondents using each approach to keep up-to-date with changes in regulatory requirements under EU chemicals legislations by company size (n=205 all respondents, 42 for 1-9 employees, 83 for 10-49 employees and 77 for 50-249 employees)

2.6.4 Q18: Do you have any final comments you wish to make about the implementation of chemicals legislation including REACH?

There were 17 comments provided to question 18. The key themes extracted from these comments are presented in Table 2-35, with full comments under each of these themes provided in Table C (Annex 1).

Table 2-35: Key themes from final comments on the implementation of chemicals legislation excluding REACH (n=17)

Issues with costs	Issues with knowledge and understanding
• Biocides legislation involves expensive costs for companies if you wish to sell in several countries you have to pay fees • Changes require large amount of time and human resources	• Users do not always have the knowledge need to prevent emergency situations • Pictograms do not show serious risks • It can be difficult to get information on human health and environmental safety because information is not translated
Wider issues for SMEs	**Issues with sources of information**
• Move to more single entrepreneurs without employees • SMEs are at the mercy of big companies who hold the decisions behind labelling	• Information can be downloaded from lots of different places • Having SDS in language of each country is difficult but understandable, but this is disproportionate for exposition scenes

Table 2-35: Key themes from final comments on the implementation of chemicals legislation excluding REACH (n=17)	
Issues with costs	**Issues with knowledge and understanding**
• Inspectors are not sufficiently aware of the problems of the industrial world	• More training and informative events are required
Issues with classification	**Other issues**
• Classification is too complicated and unclear • Classification has not resulted in harmonised labelling	• Chaos of past three years has made it almost impossible for SMEs to work • Human and environmental protection is not complete as too many substances are not covered by REACH and CLP

3 Open Public Consultation Results

3.1 Introduction

3.1.1 Overview

This section of the report provides a summary of the analysis of responses to the Open Public Consultation (OPC) but also incorporates a selection of responses received in the form of position papers from organisations outside the OPC (non-questionnaire responses).

As discussed below, position papers submitted by one organisation from within each of the key stakeholder groups were reviewed prior to undertaking the analysis of the open-ended questionnaire responses. The aim of this was to use the detailed position papers to help identify the themes that one would also expect to come out of responses to the OPC open ended questions, and to enable a comparison of the two. This provided a validation check to ensure that the Task 4 analysis covered the range of issues being identified by stakeholders, and as a minimum the most important ones identified by key stakeholders. There are obviously additional issues identified from respondents from the OPC that were not raised in the position papers, and these should be captured by the approach to the analysis as described below.

It is important to note that these position papers, together with the other position papers submitted to the OPC and the consultants separately, have been used to inform the evaluations carried out under Tasks 1 to 3. Similarly, key findings from the OPC have been integrated into the evaluation work.

The following overview of the analysis is organised in the order that the questions were asked and covers both the closed and open questions (where applicable).

3.1.2 Analysis methodology of responses to the Open Public Consultation

Analysis of the OPC is organised by the type of respondent with these organised into four groups. These four groups are:

- Group 1: Citizens – 57 responses;
- Group 2: Industry association/business – 199 responses;
- Group 3: Government or public authority – 46 responses; and
- Group 4: NGOs and others, comprising non-governmental organisation (NGO), consumer association, trade union, academia or a research or educational institute, other – 54 responses.

Analysis of responses to the closed questions has been undertaken using Excel. The number and percentage of responses is broken down by group, allowing a comparison of the views of the four groups. All of the responses are included in the analysis. Some questions focused on particular groups or those who had assigned a particular response to a previous question. Here, the analysis focuses on those responses that meet the specific requests in the question. Where a large number of responses were also provided by other groups or from those who had given different responses to previous questions, these are also included in the analysis. This also gives an opportunity to compare perspectives.

There were sixteen questions with open-text boxes where respondents could provide further details to support or explain their response to the closed element of the question. The maximum number of open text responses to any one of these questions was 209 and the minimum was 59. In total, there were 2,221 written responses across the sixteen open-text boxes. Of these, more than 1,650 were in English (74%), 172 were in French (8%) and around 400 were in German (18%). Some of the German responses were very long (e.g. one comment to Q35 contains 16,950 characters).

Analysis of the open-text responses involves reviewing each comment, identifying the key points that are being made, recording these key points as 'themes' and then comparing other comments to see if they make the same point. Where a new point is being a made, a new theme is identified until all comments have been reviewed. The advantage of this approach is that each comment is reviewed in detail with consideration given to the specific points it is making and the extent to which those points are reflected in other comments or are unique. Due to the number of open-text responses received, it was necessary to start by taking a sample of the responses when applying this approach in order to ensure that the comments could be given the attention required to ensure that the implications of each reviewed comment is fully considered.

Any approach that requires a sample to be taken results in a trade-off between all of the comments being read (albeit at a high level without any analysis being applied) or some comments being analysed in detail. Providing an appropriate sample size is taken, research has found that sampling and detailed analysis will pick up the vast majority of the key points that are being made across the comments as a whole. Clearly, there is a risk that some specific points may be missed, hence, it is ensured that all comments are read by using software to review all of the comments. However, it is estimated to take, on average, five minutes per comment to review, analyse to identify themes and highlight key points to expand upon the theme. Without the use of sampling, the review of all the comments in detail would take an estimated 25 days. Therefore, a sampling approach in line with the suggestions of DG Secretariat-General for a resource efficient approach has been adopted here.

However, wherever the reviewed comments were repetitive of themes already identified then additional responses from within the same group from the sample were read with the aim of identifying new themes. In addition, the manual analysis of the open text responses to the OPC for each group was supported by automated analysis using NVivo software to ensure that all comments have been taken into account. All of the comments were read via the NVivo analysis. Further details on the approach to the analysis are provided below for both the manual component and the NVivo analysis.

In addition to these formal analyses for the purposes of reporting on the OPC, the study team searched responses using a series of different key words to pull out responses to feed into the Task 1 to 3 evaluation work. This included identifying search terms relevant to each task and then carrying out searches of the aggregated data file. For example, in relation to Task 1, terms such as harmonised classification, labelling, packaging, poison centre, etc. were used as part of this search. For Task 2, the names and acronyms for the different legislation with horizontal links to CLP acted as the basis for one step in the search, with other terms such as allergen, PBT etc. then used in a second step of searching. This provided a second level check to ensure that relevant responses were captured in the evaluation.

3.1.2.1 Overview of the manual analysis of responses

The manual review is based on the detailed analysis of a random selection of $\sqrt{N} + 2$ responses (based on a suggested approach developed by RPA in work for SecGen and which is to be included in the Better Regulation Toolbox #50). The approach used here has been applied to ensure that comments from as many respondents as possible are included in the detailed analysis, while

maintaining a resource efficient approach. The results of the following approach are that comments from 88% of all responses are included in the sample for at least one of the open-text questions. Specifically:

1. The sample is taken based on the number of responses to each question, with a different sample taken each time. This gives coverage of a greater number of responses overall. In total, 39 of the 44 responses that provided at least one written comment (89%) from NGOs and others were sampled. Similarly, 18 of 19 responses (95%) with open text comments from citizens and 30 out of 32 responses (94%) from government or public authority respondents were sampled.

2. Due to the difference in number of responses received by the different groups of organisations, the number of comments from industry that have been reviewed has been doubled. This then ensures that the percentage of total comments that are included in the detailed analysis of the open text responses is similar to that for the 'others' group. This is considered to give a better balance across the four groups. In total, 143 of the 172 responses from industry associations/businesses that provided written comments have been captured in at least one sample (83%).

3. During the analysis, if two sampled comments within the same group/type of organisation were found to be identical or almost identical[9] then another comment was included. This ensures that the widest range of comments is considered when developing the themes from the OPC. This was quite commonly found in the responses from industry and NGOs and others. For example, four identical comments were included in the initial sample of 28 industry responses for Question 14. These were replaced with unique comments such that 32 comments were actually reviewed. For some questions, there were a large number of comments that were very similar making it difficult to take a random sample that comprised unique responses. In such cases, the comments were not replaced as the repetitive nature of the responses was considered to give a better indication of the overall views. This was particularly true for responses from industry.

   It is important to note that manual checking found that three of the responses from NGOs and others not included in at least one sample were duplicate responses reducing the percentage not captured to just 5% (2 responses). Five of those not included in the industry association/business samples provided duplicate responses meaning that there are just 24 responses (14%) that are not captured in the sample for this group. There were no duplicate responses associated with those comments that were not sampled for citizens or government/public authorities.

4. Comments such as 'N/a' or 'see response to Qx' were also not included in the sample and were replaced by a more detailed comment. This ensures that the sample only considers comments that provide an opinion or view in direct response to the question. One of the responses from the NGOs and others group that was not captured in the sample included a non-useful response. This reduced the number not captured to just one response (2%). There were no such responses from industry association/business or government/public authorities. One response from citizens was non-useful (dghgd), resulting in all usable

[9] Almost identical is defined as differing by just a few words or where the entirety of one comment is contained in the other. If the latter, the longer comment is retained and the shorter one is replaced.

responses being included in at least one sample. It is important to note that the non-sampled responses from government/public authorities just provided one comment (i.e. in one of the sixteen open text boxes).

The actual number of responses that is the basis for the sample varies by question, as shown in Table 3-1. The total number of responses by type of organisation to the open-text part of each question is shown in Table 3-2. Due to the adjustments described above, the actual number of comments reviewed and/or represented by the detailed analysis is actually significantly greater than those shown in Table 3-1.

3.1.2.2 Overview of application of NVivo

The NVivo software has been used to ensure that all comments received on the OPC have been reviewed. The specific steps taken to ensure that any further key points not captured in the sample are included in the analysis and review of the OPC are:

- Data was cleaned in the answers to each open question in order to retain the unique identifier, the open response and stakeholder type fields only;
- A 'language' column was created so that the data can be analysed in NVivo (software analyses in one language at a time);
- A 'word frequency' query was carried out in NVivo in order to identify the 100 most common words in open responses;
- The most commonly used words that do not indicate any new themes, such as 'legislation', were removed;
- The subsequent 100 most common words and identify 'impact' words (e.g. prolonged, cost) and key 'aspect' words (e.g. competitiveness, innovation) were reviewed;
- Any new themes using word trees were identified through the use of NVivo to check whether all themes associated with each of the 100 top words have been captured. An additional eight themes were identified across the 16 open text questions from the NVivo analysis on top of the 650 themes that had already been identified through the manual analysis. An example word tree is shown below in Figure 3-1; and
- Using the word trees, any comments that made specific points, provided more detail or an example to illustrate a theme have been added to the example comments in the report.

3.1.3 Analysis methodology of responses from sample of non-questionnaire responses

As indicated in Section 3.1.1, an analysis has been made of position papers received from five organisations representing different stakeholder interests based on nine word and/or pdf documents that were submitted (CEEMET, Cefic, CHEM Trust, Royal Society of Chemicals and Swedish Chemicals Agency). Not all of these position papers were in direct response to the OPC, hence, they consider wider issues than were covered by the questions in the OPC. However, to the extent possible, the responses received have been mapped onto the survey questions that provided the opportunity for an open-text response. A set of key themes has been identified using these responses. This enables the comments from these other documents to be considered alongside those from the questionnaire itself.

21 position papers in total were submitted to the OPC and to the consultants separately. These have been analysed with the information from them feeding into the analysis undertaken as part of Tasks 1 to 3.

Table 3-1: Number of responses considered in sample by type of organisation by question																		
Group of organisations	Number of responses by open-text question (excludes duplicates which have been reviewed but replaced)																	
	Q14	Q15	Q16	Q17	Q18	Q21	Q22	Q24	Q26[1]			Q27	Q30	Q31	Q32	Q33	Q34	Q35
									Gaps	Over	Inco							
Citizen	5	5	5	5	1[2]	3	2	3	5	5	4	4	3	3	4	2	4	4
Government or public authority	6	7	6	6	4	5	6	6	6	6	6	6	2	5	5	3	4	4
Industry association/business	28	28	26	26	16	20	18	22	20	22	24	26	18	16	22	20	20	18
NGOs and others	8	8	8	8	7	7	6	8	8	6	7	7	6	5	7	6	6	7
Notes: [1] Q26 includes three opportunities to comment: on gaps or missing links, on overlaps and on inconsistencies. [2] only one proper response was received in the open-text boxes hence the sample is reduced from 2. All non-sampled responses have been reviewed using NVivo, with this leading to manual reading of additional responses and the identification of a small number of additional themes.																		

Table 3-2: Total number of responses to survey by type of organisation by question																		
Group of organisations	Number of responses by open-text question (excludes duplicates which have been reviewed but replaced)																	
	Q14	Q15	Q16	Q17	Q18	Q21	Q22	Q24	Q26[1]			Q27	Q30	Q31	Q32	Q33	Q34	Q35
									Gaps	Over	Inco							
Citizen	10	10	8	7	2	3	2	3	7	8	6	5	3	3	4	2	5	6
Government or public authority	13	25	17	20	6	9	20	18	17	13	15	19	2	7	10	3	5	6
Industry association/business	137	136	127	113	38	66	44	77	59	89	97	115	54	37	78	61	63	50
NGOs and others	34	38	33	36	27	27	20	32	35	15	27	21	18	12	28	15	19	24
Notes: [1] Q26 includes three opportunities to comment: on gaps or missing links, on overlaps and on inconsistencies.																		

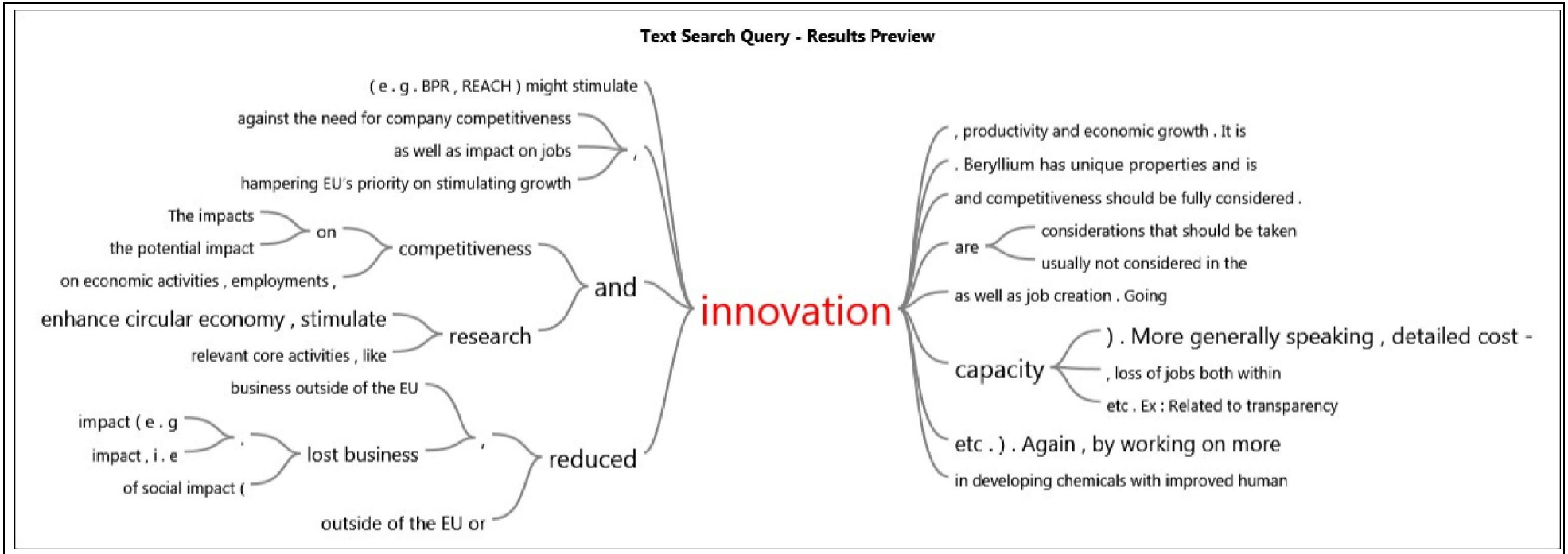

Figure 3-1: Word tree associated with key word 'innovation'

3.2 Summary of key points arising from the OPC

Table 3-3 shows the total number of responses by each of the groups, broken down into sub-grouping where appropriate. While 378 responses were received, 22 responses were disregarded as they did not contain any responses to the fitness check questions (from question 9 onwards). Therefore, there were 356 valid responses in total.

Table 3-3: Number of responses to OPC by type of organisation

Group of organisations		Sub-organisations	No. of responses	% of all responses
1	Citizen	-	***57***	***16.0%***
2	Industry association/business	***Total***	***199***	***55.9%***
		Industry association	103	28.9%
		Business	96	27.0%
3	Government or public authority	-	***46***	***12.9%***
4	NGOs and others	***Total***	***54***	***15.2%***
		Non-governmental organisation (NGO)	26	7.3%
		Consumer association	5	1.4%
		Trade union	5	1.4%
		Academia or a research or educational institute	1	0.3%
		Other	17	4.8%

Table 3-4 provides an overview of the overall responses to Questions 9, 10, 11 and 12 which asked respondents to identify the importance (Q9) and effectiveness (Q10) of the EU chemical legislation to four objectives, what the main reason was for low effectiveness scores (Q11) and what level of value added was provided by the chemical legislation as a whole.

Table 3-4: Summary of the views of respondents by group to Question 9, 10, 11 and 12

Group	Rating	a) Protecting human health	b) Protecting the environment	c) Ensuring a well-functioning internal market	d) Stimulating competitiveness and innovation
Group 1 (citizens)	Importance	Important	Very important	Very important	Very important
	Effectiveness	Moderately effective	Mostly effective	Mostly effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake
	Value added	Moderate level of value added			
Group 2 (industry)	Importance	Important	Very important	Very important	Important
	Effectiveness	Moderately effective	Mostly effective	Mostly effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake	Legislation is not adapted to issues at stake	Legislation is not effectively implemented	Legislation is not adapted to issues at stake
	Value added	High level of value added			
Group 3 (public authority)	Importance	Moderately important	Important	Important	Important
	Effectiveness	Moderately	Moderately	Mostly effective	Mostly effective

Table 3-4: Summary of the views of respondents by group to Question 9, 10, 11 and 12					
Group	**Rating**	**a) Protecting human health**	**b) Protecting the environment**	**c) Ensuring a well-functioning internal market**	**d) Stimulating competitiveness and innovation**
		effective	effective		
	Main reason for lower effectiveness	Legislation is not adapted to issues at stake = Legislation is not effectively implemented	Legislation is not adapted to issues at stake = Legislation is not effectively implemented at stake	Legislation is not adapted to issues at stake = Legislation is not effectively implemented	Legislation is not adapted to issues at stake
	Value added	High level of value added			
Group 4 (NGO/ others)	Importance	Moderately important	Moderately important	Important	Important
	Effectiveness	Moderately effective	Slightly effective	Moderately effective	Moderately effective
	Main reason for lower effectiveness	Legislation is not effectively implemented	Legislation is not effectively implemented	Legislation is not adapted to issues at stake	Legislation is not effectively implemented
	Value added	High level of value added			
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not important/effective, 2 = slightly important/effective; 3 = moderately important/effective; 4 = important/mostly effective; 5 = very important/effective. The main reason to explain why respondents thought the legislation is ineffective is based on the most common response (excluding no opinion). Value added is based on score of 1=no value added, 2= slight, 3=moderate, 4=high, 5=very high.					

Question 13 showed that the legislation that most commonly regulates affected activities within each group is Classification, Labelling and Packaging Regulation (CLP) affecting 92% of Group 2, followed by REACH (78%) and Waste Framework Directive (73%).

Question 14 found differences of opinion amongst the groups in terms of whether risk assessment should be based on generic or specific risk considerations. Group 2 was strongly in favour of specific risk assessment (72%). Other groups were less clear with 41% of Group 4 in favour of generic risk considerations but 25% preferring specific risk assessment, while 37% of Group 3 was in favour of staying with the current approach. Comments supporting specific risk assessment to the open text questions also generally came from Group 2 and included suggestions that '*specific risk assessment is…more appropriate to define the most effective risk management measure whilst preserving social benefits*' (Group 2). Opposition to specific risk considerations included that '*the unknown factors are usually far too many and impossible to foresee. The unforeseeable cannot be predicted nor assessed*' (Group 3).

Question 15 asked if all relevant considerations are taken into account in regulatory decision-making on risk assessment. In total 85% of Group 4, 72% of Group 2, 71% of Group 3 and 45% of Group 1 all said 'no'. Only 4% of Group 4, 18% of Group 2, 25% of Group 3 and 29% of Group 1 said yes. Respondents to the open text question gave consideration that they thought should be taken into account but were not. These include:

- '*impact assessment should be systematic and better address employment and competitiveness issues across the industry chain*' (Group 2)

- '*the combined effects and vulnerable groups are mentioned in occupational safety and health legislation but it is not very clear how to enforce them*' (Group 3)
- '*risk assessments… do not take into account the specific risk that chemical substances… pose to women and children*' (Group 4)

Question 16 asked respondents to identify their level of satisfaction with twelve different elements of the overall EU legislative framework. There was considerable variation amongst the groups as shown in Table 3-5.

Table 3-5: Summary of the views of respondents by group to Question 16

Group	Highest score	Score	Lowest score	Score
Group 1* (citizens)	Stability of the legal framework	Moderately satisfied	International collaboration and harmonisation	Slightly satisfied
Group 2 (industry)	Speed with which hazards/risks are assessed = speed with which identified risks are addressed	Moderately satisfied	Predictability of the outcomes	Slightly satisfied
Group 3 (public authority)	Time to allow duty holders to adapt	Mostly satisfied	Speed with which identified risks are addressed	Moderately satisfied
Group 4 (NGO/ others)	Stability of the legal framework	Mostly satisfied	Speed with which identified risks are addressed = public awareness and outreach	Slightly satisfied
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not satisfied, 2 = slightly satisfied; 3 = moderately satisfied; 4 = mostly satisfied; 5 = very satisfied				

Open text responses to Question 16 were predominantly negative, including '*the impression is that the regulatory framework is not sufficiently thought through*' (Group 1) and '*the interlinkages between the CLP Regulation…and other EU sectoral legislation…can in some cases trigger automatic risk management measure(s)…This can have unintended consequences and create further uncertainty and unpredictability*' (Group 2).

Question 17 asked respondents to indicate their satisfaction with six elements of risk management. The elements that achieved the highest and lowest levels of satisfaction by group are shown in Table 3-6.

Table 3-6: Summary of the views of respondents by group to Question 17

Group	Highest score	Score	Lowest score	Score
Group 1* (citizens)	Hazard and risk communication to workers	Moderately satisfied	Risk assessment and characterisation	Slightly satisfied
Group 2 (industry)	Hazard and risk communication to workers = risk managements measures regulating the safe use of chemicals	Mostly satisfied	Risk management measures restricting or banning the use of chemicals	Moderately satisfied
Group 3 (public authority)	Hazard identification criteria	Mostly satisfied	Hazard and risk communication to consumers = Risk management measures restricting or banning the use of chemicals	Mostly satisfied

Table 3-6: Summary of the views of respondents by group to Question 17				
Group	**Highest score**	**Score**	**Lowest score**	**Score**
Group 4 (NGO/ others)	Hazard and risk communication to workers	Moderately satisfied	Risk assessment and characterisation = Risk management measures restricting or banning the use of chemicals = Risk management measures regulating the safe use of chemicals	Slightly satisfied
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not satisfied, 2 = slightly satisfied; 3 = moderately satisfied; 4 = mostly satisfied; 5 = very satisfied				

Open text responses to Question 17 included comments on the hazard classification criteria, risk management in general and hazard/risk communication. These highlighted specific gaps and issues such as '*we see many substances being targeted for ban multiple times via different EU legislation*' (Group 2) and '*risk management…process is so slow that substances of very high concern can still be widely used*' (Group 4).

Question 18 found that 63% of Group 2, 51% of Group 3 and 41% of Group 1 thought that the quality requirements for safety data for chemicals were appropriate. However, 44% of Group 4 thought that they were not compared with 31% from Group 4 who thought that they were appropriate. Comments from the open text responses included '*GLP…does not guarantee the reliability and relevance of the study results for the risk assessment*' (Group 3) and '*physico-chemical data requirements need improvement*' (Group 2).

Question 19 asked respondents to identify where they thought the EU chemical legislation had generated significant benefits. Table 3-7 highlights those benefit types that were most commonly identified by group.

Table 3-7: Summary of the views of respondents by group to Question 19			
Group	**Benefits identified by largest proportion of respondents by group**		
	Top ranked	**Second ranked**	**Third ranked**
Group 1 (citizens)	Reducing the damage to the environment and to eco-systems (58%)	Reducing the exposure of consumers and citizens in general to toxic chemicals (54%)	Reducing the exposure of workers to toxic chemicals (54%) [equal second ranked]
Group 2 (industry)	Reducing the exposure of workers to toxic chemicals (85%)	Reducing the damage to the environment and to eco-systems (84%)	Reducing the exposure of consumers and citizens in general to toxic chemicals (79%)
Group 3 (public authority)	Reducing the exposure of consumers and citizens in general to toxic chemicals (95%)	Reducing the exposure of workers to toxic chemicals (92%)	Reducing the damage to the environment and to eco-systems (89%)
Group 4 (NGO/ others)	Reducing the exposure of workers to toxic chemicals (91%)	Reducing the exposure of consumers and citizens in general to toxic chemicals (80%)	Reducing the damage to the environment and to eco-systems (70%) = encouraging research and innovation, generating jobs and improving competitiveness (70%)

Question 20 found that most respondents from Group 2 (89%), Group 3 (64%) and Group 4 (70%) thought that there were significant costs for small and medium enterprises due to EU chemical legislation. This reduces to 31% from Group 1. In addition, 72% of Group 2 thought that there were significant costs for large enterprises. Group 4 respondents were the most likely to indicate that there were significant costs for national authorities (42%) and authorities at EU level (40%). This compares with just 33% of Group 3 responses who thought there were significant costs for national authorities and 25% who indicated significant costs for authorities at EU level.

Question 21 asked respondents to identify the types of costs they thought were incurred by companies. Table 3-8 identifies the cost types that were most commonly identified by each group. Open text responses provided some details on what these costs might be. They include: '*increasing complexity…and constant changes in legislation…imply very often the need for external consultancy and legal advice*' (Group 2) and *'large cost burdens arising from…ongoing adjustments to labelling and packaging requirements, loss of starting materials and resulting conversion products*' (Group 2).

Table 3-8: Summary of the views of respondents by group to Question 21

Group	Cost types to companies identified by largest proportion of respondents by group		
	Top ranked	Second ranked	Third ranked
Group 1* (citizens)	Classification requirements for substances and mixtures (25%)	Chemical labelling and packaging requirements (25%) [equal top rank]	Understanding and keeping up-to-date with changes in legal requirements (21%)
Group 2 (industry)	Understanding and keeping up-to-date with changes in legal requirements (84%)	Risk management measures under different legislation (73%)	Training staff to ensure compliance with legal requirements (61%)
Group 3 (public authority)	Risk management measures under different legislation (42%)	Classification requirements for substances and mixtures (36%)	Understanding and keeping up-to-date with changes in legal requirements (27%)
Group 4 (NGO/ others)	Risk management measures under different legislation (42%)	Understanding and keeping up-to-date with changes in legal requirements (42%) [equal top rank]	Chemical labelling and packaging requirements (24%) = Training staff to ensure compliance with legal requirements (24%) = inspections and administrative requirements (24%)
Notes: * don't know was the most common response from Group 1 at 54%			

Question 22 asked respondents if they thought that there were specific requirements in the EU legislative framework that lead to significant costs for authorities. Most respondents from Group 1 (61%) and Group 2 (70%) replied 'don't know'. A total of 56% of respondents from Group 3 and 38% from Group 4 said 'yes'. Open text responses identified costs with implementation and compliance and market surveillance but also identified the potential for cost savings.

Question 23 asked respondents to identify the extent to which the EU legislative framework has contributed to a reduction in use of hazardous chemicals and/or substitution with safer alternatives. Question 24 required respondents to identify the extent to which the EU legislative framework sufficiently addresses emerging areas of concern. Question 25 then asked respondents to identify the extent to which they agreed or disagreed with statements concerning the EU legislative framework. Question 28 asked respondents to identify the level of effectiveness of hazard communication with CLP labels for workers and consumers. Table 3-9 shows the results by group across all of these questions.

Table 3-9: Summary of the views of respondents by group to Questions 23, 24, 25 and 28				
Aspect	**Group 1 (citizens)**	**Group 2 (industry)**	**Group 3 (public authority)**	**Group 4 (NGO/others)**
Extent of contribution (Q23)	Moderate contribution	Moderate contribution	Significant contribution	Moderate contribution
Level of satisfaction (Q24)	Moderately sufficiently	Mostly sufficiently	Moderately sufficiently	Slightly sufficiently
The EU chemicals legislation framework contains gaps and missing links (Q25)	Agree	Neither agree nor disagree	Agree	Agree
The EU chemicals legislation framework has overlaps (Q25)	Agree	Agree	Agree	Neither agree nor disagree
The EU chemicals legislation framework is internally inconsistent (Q25)	Neither agree nor disagree	Agree	Neither agree nor disagree	Agree
Effectiveness of CLP labels in communicating hazards to workers (Q28)	Moderately effective	Mostly effective	Mostly effective	Mostly effective
Effectiveness of CLP labels in communicating hazards to consumers (Q28)	Moderately effective	Moderately effective	Mostly effective	Moderately effective
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = no contribution/not sufficiently/not effective, 2 = slight contribution/slightly sufficiently/slightly effective; 3 = moderate contribution/moderately sufficiently/moderately effective; 4 = significant contribution/mostly sufficiently/mostly effective; 5 = large contribution/sufficiently/very effective Agreement/disagreement is based on scores of -2 for strongly disagree, -1 for disagree, 0 for neither agree nor disagree, +1 for agree, +2 for strongly agree				

Open text responses to Question 24 provided conflicting views that the existing framework could address emerging areas of concern but also that it could not. For example, '*emerging areas of concern could easily be addressed through modification of existing legislative frameworks*' (Group 2) but also '*the process takes too long…is politicised and scientific studies are excluded from…decision-making*' (Group 4).

Open text responses to Question 26 identify where there are gaps, omissions, overlaps, duplications, inconsistencies and conflicts between legislation that is under the scope of the fitness check. Numerous areas are mentioned including food contact materials, chemicals in consumer articles, CLP and Plant Protection/Biocidal Products Regulations, notification of the same substances under Biocidal Products Regulation, Cosmetic Products Regulation and REACH, nanomaterials, burden for waste management, and treatment of glass. Question 27 focuses on inconsistencies between legislation covered by the scope of this fitness check and other legislation. This includes inconsistencies with REACH, RoHS[10], OSH[11], EQS[12], and the Biocidal Products Regulation, and CLP

[10] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

[11] Occupational Safety and Health legislation.

[12] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy.

with the Detergents Regulation and Seveso. Others mentioned include the Drinking Water Directive, Construction Products Regulations, and the Common Agricultural Policy.

Question 29 asked respondents if the hazard classes in the CLP Regulation for environmental, physical and human health risks cover all relevant hazards. There was a clear 'yes' response from Group 2 with 82% saying 'yes' for environmental risks, 85% for physical risks and 86% for human health risks. Group 3 also largely agreed with 71% saying 'yes' for physical risks and 63% for human health risks. However, only 44% said 'yes' to environmental risks with 34% saying 'no'. Group 4 also agreed with physical risks (70%) but less so for human health (35% 'yes' and 53% 'no') and environment (21% 'yes' and 56% 'no'). Responses from Group 1 were mostly 'don't know', although there were 45% that agreed with physical risks compared with just 9% that said 'no'. Open text responses provided potential additional hazard categories, including covering other environmental endpoints such as '*one simple way of including other compartments could be to…broaden the class…to "hazardous to the environment"*' (Group 3).

Question 30 asked respondents to identify the effectiveness of support provided to companies through guidance and helpdesks. The results are summarised in Table 3-10. Open text responses identified potential areas where more guidance is needed and the need for guidance to be translated into more languages. Comments on helpdesks included '*helpdesks are highly appreciated and effective*' (Group 3) to '*helpdesks rarely give useful information*' (Group 2).

Table 3-10: Summary of the views of respondents by group to Question 30

Type of support	Group 1 (citizens)	Group 2 (industry)	Group 3 (public authority)	Group 4 (NGO/others)
Guidance documents	Moderately effective	Moderately effective	Mostly effective	Moderately effective
Helpdesks	Slightly effective	Moderately effective	Mostly effective	Moderately effective
Industry association guidance and materials	Moderately effective	Mostly effective	Mostly effective	Moderately effective
Other (training, conferences, etc.)	Moderately effective	Mostly effective	Mostly effective	Mostly effective

Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = no not effective, 2 = slightly effective; 3 = moderately effective; 4 = mostly effective; 5 = very effective

Question 31 asked respondents to identify the extent to which CLP is enforced across Member States. Most respondents from Group 1 (59%), Group 3 (58%) and Group 4 (63%) answered 'don't know'. The most common response from Group 2 was that enforcement is not harmonised across Member States (40%). Open text responses identified issues with '*differences in levels of enforcement*' (Group 2) and '*enforcement…seems mediocre, particularly concerning provision of CLP compliance [sic] SDS*' (Group 2).

Question 32 asked respondents to identify the extent to which the current elements relating to CLP classification criteria are satisfactory. The results, based on the weighted scores, are provided in Table 3-11. Open text responses focused on harmonisation, coverage of classification criteria, issues with interpretation of data and divergent classifications, mixtures and communication of hazards to consumers. For example '*stronger harmonisation would reduce the risk of misinterpretation*' (Group 2), '*hazard categories for endocrine disruption, neurotoxicity, allergenic properties, nanoforms/nanomaterials, biodegradation PBTs/vPvBs should be added*' (Group 4) and '*additivity method for classification of mixtures does not seem to be appropriate*' (Group 2).

Table 3-11: Summary of the views of respondents by group to Question 32				
Element	**Group 1 (citizens)**	**Group 2 (industry)**	**Group 3 (public authority)**	**Group 4 (NGO/others)**
Ease of implementation for duty holders	Moderately satisfactory	Moderately satisfactory	Moderately satisfactory	Moderately satisfactory
Appropriateness of classification criteria and methods for substances	Moderately satisfactory	Mostly satisfactory	Mostly satisfactory	Moderately satisfactory
Appropriateness of classification criteria and methods for mixtures	Moderately satisfactory	Moderately satisfactory	Moderately satisfactory	Moderately satisfactory
International harmonisation through the Globally Harmonised System	Moderately satisfactory	Moderately satisfactory	Mostly satisfactory	Moderately satisfactory
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not satisfactory, 2 = slightly satisfactory; 3 = moderately satisfactory; 4 = mostly satisfactory; 5 = very satisfactory				

Question 33 asked respondents to indicate if transitional periods allow sufficient time to implement new or revised classification criteria. A total of 63% of Group 3 respondents replied that the transition time is sufficient, with this also selected by 38% of respondents from Group 4 and 43% from Group 2. A further 41% of Group 2 respondents answered that the transition period is too short. Open text responses include '*transition period may be sufficient in the case of some substances, but it is often too short in the case of mixtures*' (Group 2).

Question 34 asked respondents to what extent the current elements of the procedures for harmonised classification and labelling (CLH) are satisfactory. The results, again using the weighted scores, are presented in Table 3-12.

Table 3-12: Summary of the views of respondents by group to Question 34				
Element	**Group 1 (citizens)**	**Group 2 (industry)**	**Group 3 (public authority)**	**Group 4 (NGO/others)**
Transparency of the procedures	Slightly satisfactory	Moderately satisfactory	Mostly satisfactory	Mostly satisfactory
Involvement of stakeholders	Slightly satisfactory	Moderately satisfactory	Mostly satisfactory	Moderately satisfactory
Quality of scientific data and related information	Moderately satisfactory	Moderately satisfactory	Mostly satisfactory	Slightly satisfactory
Speed of the procedure	Slightly satisfactory	Moderately satisfactory	Mostly satisfactory	Slightly satisfactory
Notes: based on weighted scores calculated from responses rounded to closest whole number, where 1 = not satisfactory, 2 = slightly satisfactory; 3 = moderately satisfactory; 4 = mostly satisfactory; 5 = very satisfactory				

Open text responses on CLH include '*CLH timeline of 45 days is too short…because evaluation of the published data…needs longer*' (Group 2) and '*industry should…be allowed to submit CLH proposals or changes to existing CLH*' (Group 2). Comments on decision-making include '*there is too little discussion with RAC and too little stakeholder engagement*' (Group 2) and '*the lack of capacity and resources within CSO and SMEs hinder their capacity to participate in the CLH process*' (Group 4).

Comments to Question 35 cover additional points that respondents wished to make. These include:

- '*If a substance can be used safely then is should not be substituted automatically based on hazard alone*' (Group 2);
- '*Hazards indicated by CLP labelling are understood as risks…communication of risks…is better understood*' (Group 2);
- '*A well-functioning circular economy can only work efficiently by using a risk-based approach*' (Group 2);
- '*Better synergies between chemical legislation and worker safety legislation should be sought*' (Group 2);
- *'It would be desirable to substitute directives that need local implementing acts with regulations, straight forward applicable at the same way in all EU Member States' (Group 1);*
- *'Directives vs. Regulations: Most of the chemical related legislation is highly technical and some of it is subject to continuous amendments. It creates a lot of work in the Member States to implement changes in directives in their national legislation. The Commission should, therefore, consider the difference and the choice to be made between regulations and directives in accordance with the statements made in the interinstitutional agreement on better regulation (Art. 25)' (Group 3);*
- *'Animal welfare is an essential part under many of the chemical legislations. More efforts should be made to properly implement these measures to avoid animal testing' (Group 4);*
- *'Adequate chemical provisions are (almost) non-existent for many products consumers come into contact with, such as non-plastics food contact materials, materials in contact with drinking water, products releasing emissions to the indoor air, clothing and other consumer textiles, child use and care articles, other articles for children, tattoo inks, personal protective equipment, furniture, sports and playground surfaces and equipment, car interiors etc.' (Group 4);*
- *'Under previous legislation, the harsher product types carried a more significant labelling and were distinctly recognisable by their label. For instance, CHIP labelling of hydrochloric acid toilet cleaners carried a corrosive classification. Very few other household products were corrosive. Now, however, under CLP, many products carry a corrosive classification – even ones such as non-biological laundry detergents. If a consumer swallowed a hydrochloric acid toilet cleaner, compared with a non-biological laundry detergent, the effects would be far more severe. However, the CLP classification of both does not distinguish this from a consumer's perspective. There is a danger, as more and more products become corrosive, that customers will fail to identify those which genuinely need the most care' (Group 1).*

The sections that follow provide the more detailed question by question analysis of the responses. Note that these start from question 5, as the questions before this related to gathering contact details and other essential information related to the transparency register.

3.3 Detailed analysis

3.3.1 Question 5: Nature of people providing responses

The respondents were grouped into four categories:

- Group 1: Citizens
- Group 2: Industry, business
- Group 3: Government or public authority, and intergovernmental organisations
- Group 4: NGOs, consumer associations, trade unions, academia and other

Figure 3-2 shows that the majority of respondents (56%) belonged to Group 2, followed by Group 1, Group 4 and Group 3 respectively.

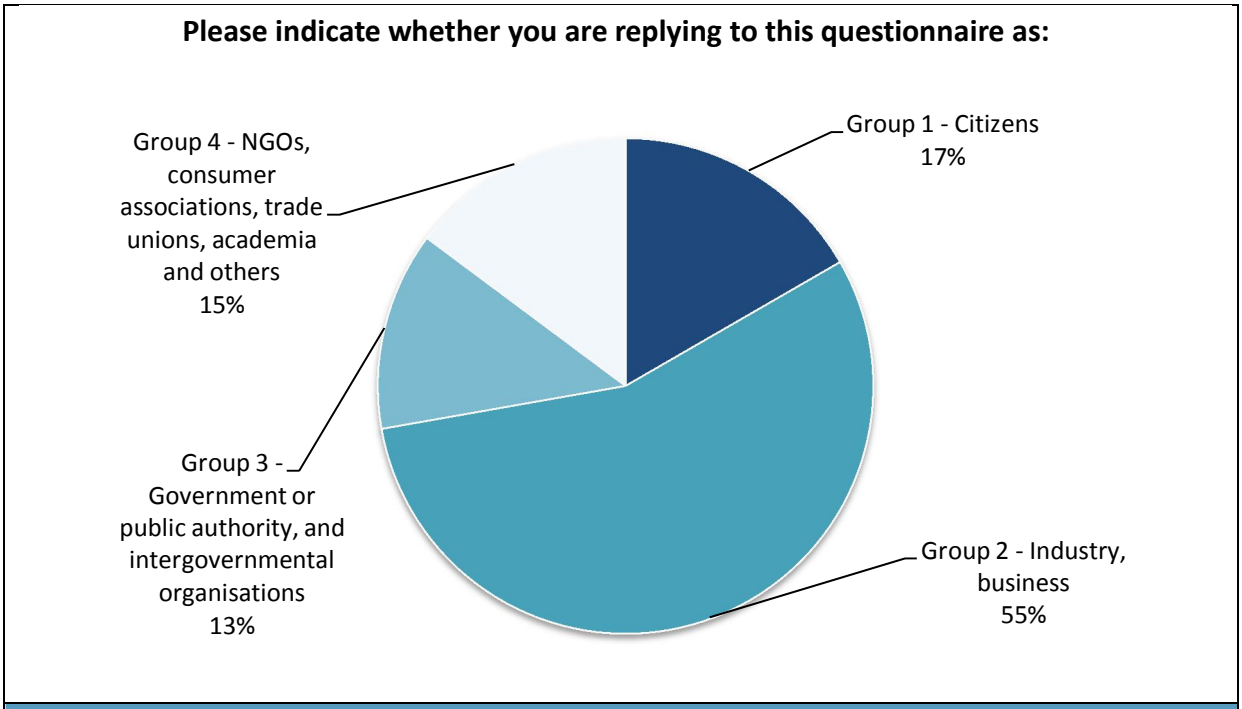

Figure 3-2: Chart showing the proportion of responses by group (n=378)

3.3.2 Question 6: Field of interest or activity

Question 6 provided respondents with a choice of 39 fields of interest or activity. Although the question was focused on industry and business, some respondents from the other groups also replied. Table 3-13 summarises the responses. There were 253 responses to this question, suggesting that 125 respondents did not indicate a field of interest or activity. Of the 210 responses from industry associations and businesses, though, 208 did respond (99% response rate from Group 2). The percentages shown for Groups 1, 3 and 4 are based on the number of respondents to the question, not the total number of respondents to the questionnaire as a whole.

Table 3-13: Number and percentage of responses by field of interest or activity (n=253)

Field of interest or activity	Group 1 (citizens) (n=22)		Group 2 (industry) (n=208)		Group 3 (public authority) (n=5)		Group 4 (NGO/others) (n=18)	
	No.	%	No.	%	No.	%	No.	%
Agriculture, forestry and fishing (A)	7	32%	**8**	**4%**	0	0%	2	11%
Mining and quarrying (B)	2	9%	**5**	**2%**	0	0%	3	17%
Manufacture of food products (C10)	0	0%	**14**	**7%**	0	0%	1	6%
Manufacture of beverages (C11)	0	0%	**7**	**3%**	0	0%	2	11%
Manufacture of tobacco products (C12)	1	5%	**2**	**1%**	0	0%	1	6%
Manufacture of textiles (C13)	0	0%	**9**	**4%**	0	0%	1	6%
Manufacture of wearing apparel (C14)	1	5%	**10**	**5%**	0	0%	1	6%
Manufacture of leather and related	1	5%	**8**	**4%**	0	0%	1	6%

Table 3-13: Number and percentage of responses by field of interest or activity (n=253)								
Field of interest or activity	Group 1 (citizens) (n=22)		Group 2 (industry) (n=208)		Group 3 (public authority) (n=5)		Group 4 (NGO/others) (n=18)	
	No.	%	No.	%	No.	%	No.	%
products (C15)								
Manufacture of wood and of products of wood and cork except furniture (C16)	0	0%	**3**	**1%**	0	0%	1	6%
Manufacture of paper and paper products (C17)	0	0%	**5**	**2%**	0	0%	1	6%
Printing and reproduction of recorded media (C18)	0	0%	**4**	**2%**	0	0%	1	6%
Manufacture of coke and refined petroleum products (C19)	0	0%	**7**	**3%**	0	0%	1	6%
Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)	1	5%	**34**	**16%**	0	0%	2	11%
Manufacture of pesticides and other agrochemical products (C20.2)	1	5%	**18**	**9%**	0	0%	3	17%
Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)	0	0%	**35**	**17%**	1	20%	2	11%
Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)	0	0%	**50**	**24%**	0	0%	2	11%
Manufacture of other chemical products (C20.5)	2	9%	**65**	**31%**	0	0%	3	17%
Manufacture of man-made fibres (C20.6)	0	0%	**13**	**6%**	0	0%	2	11%
Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)	0	0%	**20**	**10%**	0	0%	2	11%
Manufacture of rubber and plastic products (C22)	0	0%	**26**	**12%**	0	0%	2	11%
Manufacture of other non-metallic mineral products (C23)	0	0%	**11**	**5%**	0	0%	1	6%
Manufacture of basic metals (C24)	0	0%	**19**	**9%**	0	0%	3	17%
Manufacture of fabricated metal products, except machinery and equipment (C25)	0	0%	**18**	**9%**	0	0%	3	17%
Manufacture of computer, electronic and optical products (C26)	0	0%	**9**	**4%**	0	0%	1	6%
Manufacture of electrical equipment (C27)	1	5%	**24**	**11%**	0	0%	1	6%
Manufacture of machinery and equipment (C28)	0	0%	**25**	**12%**	0	0%	1	6%
Manufacture of motor vehicles, trailers and semi-trailers (C29)	0	0%	**6**	**3%**	0	0%	1	6%
Manufacture of other transport equipment (C30)	1	5%	**4**	**2%**	0	0%	1	6%
Manufacture of furniture (C31)	1	5%	**8**	**4%**	0	0%	1	6%
Manufacture of games and toys	1	5%	**15**	**7%**	0	0%	1	6%

Table 3-13: Number and percentage of responses by field of interest or activity (n=253)								
Field of interest or activity	Group 1 (citizens) (n=22)		Group 2 (industry) (n=208)		Group 3 (public authority) (n=5)		Group 4 (NGO/others) (n=18)	
	No.	%	No.	%	No.	%	No.	%
(C32.4)								
Manufacture of medical and dental instruments and supplies (C32.5)	0	0%	**11**	**5%**	0	0%	1	6%
Other manufacturing(excluding manufacturing of toys or medical and dental instruments) (C32)	1	5%	**8**	**4%**	0	0%	1	6%
Electricity, gas, steam and air conditioning supply (D)	0	0%	**5**	**2%**	0	0%	1	6%
Water supply; sewerage; waste management and remediation activities (E)	1	5%	**13**	**6%**	1	20%	3	17%
Construction (F)	0	0%	**7**	**3%**	0	0%	1	6%
Wholesale and retail trade (G)	0	0%	**18**	**9%**	0	0%	2	11%
Transporting and storage (H)	0	0%	**9**	**4%**	0	0%	1	6%
Professional, scientific and technical activities (M)	2	9%	**11**	**5%**	0	0%	1	6%
Other	2	9%	**19**	**9%**	1	20%	3	17%

Considering Group 2 only, the top four fields of interest or activities represent at least 15% each of all responses from Group 2. These are:

- Manufacture of other chemical products (C20.5): 65 responses or 31% of all Group 2 responses;
- Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4): 50 responses or 24% of all Group 2 responses;
- Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3): 35 responses or 17% of all Group 2 responses; and
- Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1): 34 responses or 16% of all Group 2 responses.

3.3.3 Question 7: Size of the business

Group 2 respondents were asked to identify the size of their business. In total there were 132 industry/businesses that responded to this question, with the breakdown of responses shown in Table 3-14. The table shows that almost half (48% or 64) of business responses were from large companies. There were also 78 Group 2 respondents that did not answer this question (37% of all Group 2 responses to the OPC overall).

Table 3-14: Number and percentage of industry/business responses by size (n=132)			
Group	Type	Number	Percentage
Group 2 - Industry, business	Large company (250 employees or more)	64	48%
	Medium-sized enterprise (under 250 employees)	22	17%
	Small enterprise (under 50 employees)	23	17%
	Micro-enterprise (under 10 employees)	17	13%
	Self-employed	6	5%

3.3.4 Question 8: Level at which the organisation is active

Respondents from Groups 2, 3 and 4 were asked whether their organisation acts at the local, national, regional, EU or global scale. The results are shown in Table 3-15.

Table 3-15: Number and percentage of responses by level of activity (n=315)			
Group	**Type**	**Number**	**Percentage**
Group 2 - Industry, business	Local	4	2%
	National	7	3%
	Regional (e.g. Scandinavia)	47	22%
	EU	71	34%
	Global	77	37%
Group 3 – Government or public authority	Local	7	14%
	National	4	8%
	Regional (e.g. Scandinavia)	25	51%
	EU	5	10%
	Global	1	2%
Group 4 – NGOs, consumer association, trade unions, academia or a research or educational institute, other	Local	6	11%
	National	2	4%
	Regional (e.g. Scandinavia)	16	29%
	EU	20	36%
	Global	6	11%

Table 3-15 shows that the majority of businesses (71% in total) operate at the EU (34% or 71) or global (37% or 77) levels. There were also 22% (47) responses from Group 2 who operate at the regional level. Group 3 responses were mainly from those operating at a regional level (51% or 25), with just 8% at the national level (4) and 14% at the local level (7). The highest number of responses from Group 4 was from those who operate at the EU level (36% or 20), followed by the regional level (29% or 16).

3.3.5 Question 9: How important is it that there is chemical and chemical-related legislation at EU-level?

Respondents were asked to identify importance in achieving four objectives:

a) Protecting human health;
b) Protecting the environment;
c) Ensuring a well-functioning internal market; and
d) Stimulating competitiveness and innovation.

In total there were between 346 and 350 responses (depending on the objective), with the results presented by group in Table 3-16.

Table 3-16: Number and percentage of respondents identifying level of importance of chemical legislation to achieving objectives (n=346 to 350)									
Group	Importance score	Objective a: protecting human health (n=350)		Objective b: protecting the environment (n=346)		Objective c: ensuring a well-functioning internal market (n=346)		Objective d: stimulating competitiveness and innovation (n=347)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=53 to 56)	1	7	13%	4	8%	4	7%	5	9%
	2	1	2%	2	4%	5	9%	7	13%
	3	5	9%	5	9%	18	33%	17	31%
	4	6	11%	4	8%	4	7%	5	9%
	5	26	46%	28	53%	10	19%	8	15%
	I don't know	11	20%	10	19%	13	24%	12	22%
2 (industry) (n=198)	1	5	3%	4	2%	4	2%	10	5%
	2	3	2%	4	2%	5	3%	25	13%
	3	5	3%	5	3%	22	11%	64	32%
	4	38	19%	48	24%	46	23%	29	15%
	5	142	72%	132	67%	111	56%	60	30%
	I don't know	5	3%	5	3%	10	5%	10	5%
3 (public authority) (n=43 to 44)	1	1	2%	1	2%	0	0%	1	2%
	2	0	0%	0	0%	1	2%	1	2%
	3	1	2%	2	5%	2	5%	8	19%
	4	7	16%	6	14%	11	26%	7	16%
	5	32	73%	33	75%	24	56%	20	47%
	I don't know	3	7%	2	5%	5	12%	6	14%
4 (NGO/ others) (n=51 to 52)	1	3	6%	3	6%	3	6%	4	8%
	2	1	2%	1	2%	4	8%	5	10%
	3	3	6%	3	6%	5	10%	9	17%
	4	5	10%	5	10%	4	8%	4	8%
	5	40	77%	39	76%	33	65%	28	54%
	I don't know	0	0%	0	0%	2	4%	2	4%

Table 3-16 shows that more than 70% of respondents from Group 2 (72% or 142), Group 3 (73% or 32) and Group 4 (77% or 40) assigned a score of 5 (very important) to the objective of protecting human health. The majority of Group 1 did assign a score of 4 (11% or 6) or 5 (46% or 26), but the responses were considerably lower than for other groups. Respondents from Group 1 (citizens) also gave the highest number of scores of 1 (not important) at 13% (7).

More than 70% of Groups 3 and 4 also assigned a score of 5 (very important) to the objective of protecting the environment: Group 3 (75% or 33) and Group 4 (76% or 39). Group 2 also assigned a high score of the objective of protecting the environment with 67% (132) assigning a score of 5 and 24% (48) assigning a score of 4. The majority of respondents from Group 1 did assign a score of 5 (53% or 28) but again it is Group 1 that has the highest level of 'not important' scores at 8% (4).

For the objective of ensuring a well-functioning internal market, the majority of responses from Groups 2, 3 and 4 are again 'very important' (5) with this score assigned by 65% (33) from Group 4, 56% (24) from Group 3 and 56% (111) from Group 2. Just 19% (10) of Group 1 respondents assigned a score of 'very important' (5). Here, the most common response was a score of 3 from 33% (18) of respondents. None of the respondents from Group 3 (out of 43) assigned a score of 'not important' (1) for chemical legislation in relation to this objective.

A total of 54% (28) of respondents from Group 4 assigned a score of 'very important' to the objective of stimulating competitiveness and innovation. This compares with 47% (20) from Group 3, 30% (60) from Group 2 and 15% (8) from Group 1.

Figures 3-3 to 3-6 present charts comparing the responses across the groups by objective. The shading varies from dark to light for scores of 1 to 5, where 1=not important and 5=very important. Comparison across the groups clearly shows that Groups 2, 3 and 4 feel that chemical legislation is more important than Group 1 in achieving all four objectives. The proportion of scores of 4 and 5 also declines across all groups for objective c (ensuring a well-functioning internal market) and d (stimulating competitiveness and innovation) when compared with objectives a (protecting human health) and b (protecting the environment).

Note that as part of this question, the following definition was provided (see ** in Figures below): *"The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals."*

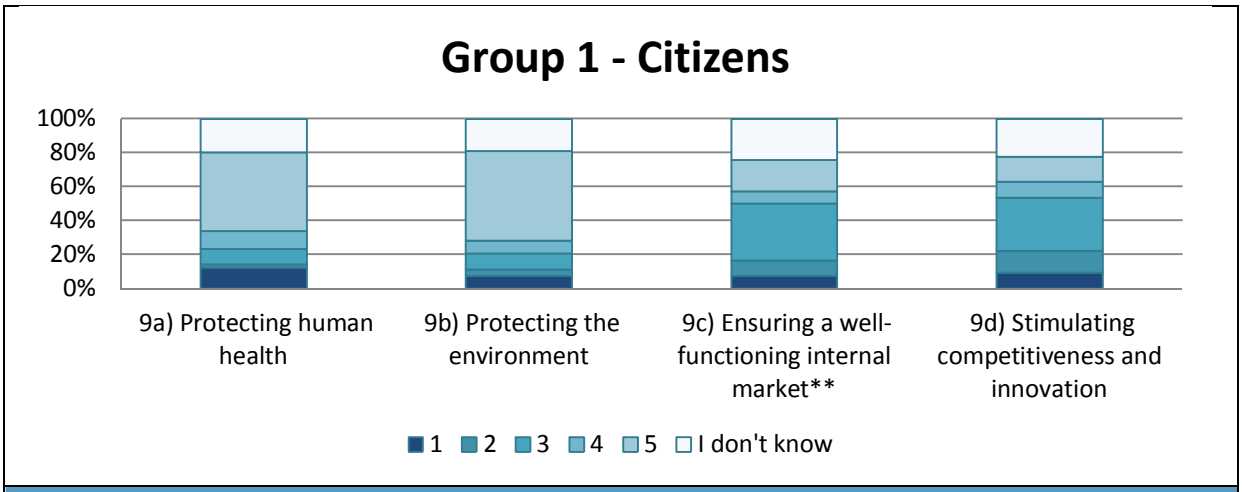

Figure 3-3: Chart showing proportion of scores assigned by Group 1 respondents by objective (n=53 to 56)

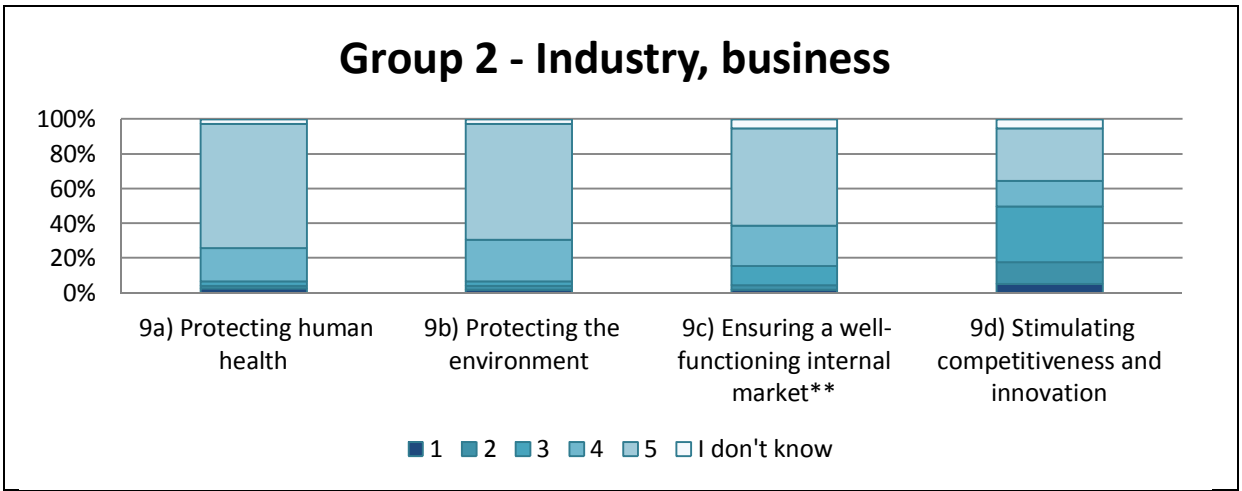

Figure 3-4: Chart showing proportion of scores assigned by Group 2 respondents by objective (n=198)

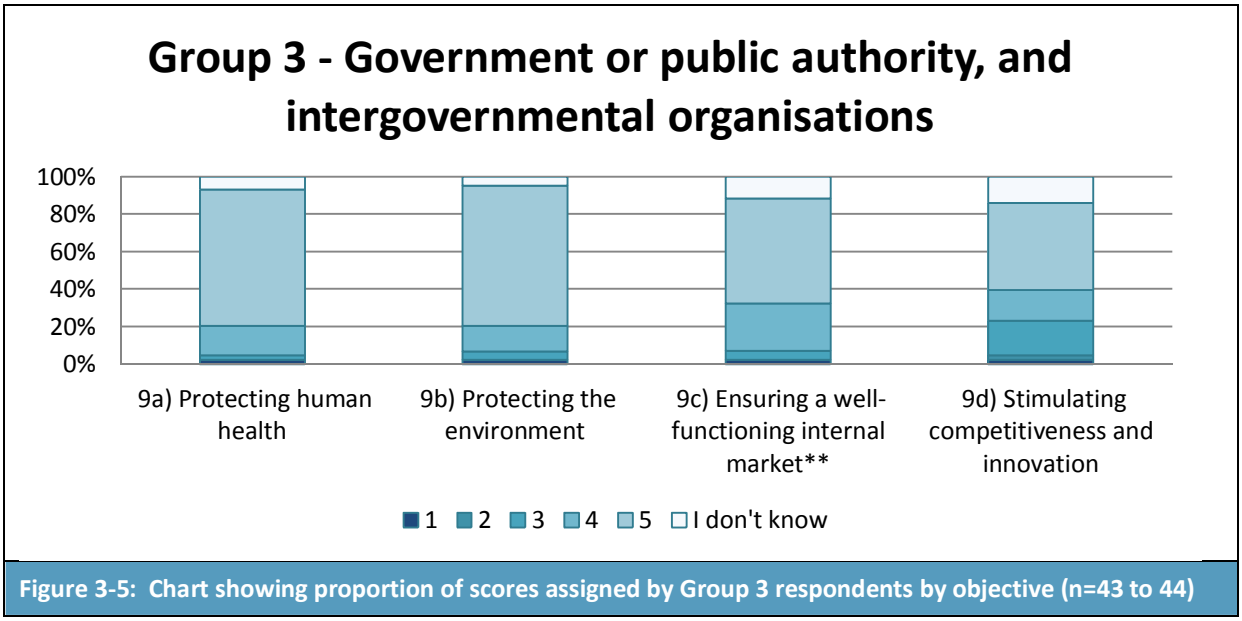

Figure 3-5: Chart showing proportion of scores assigned by Group 3 respondents by objective (n=43 to 44)

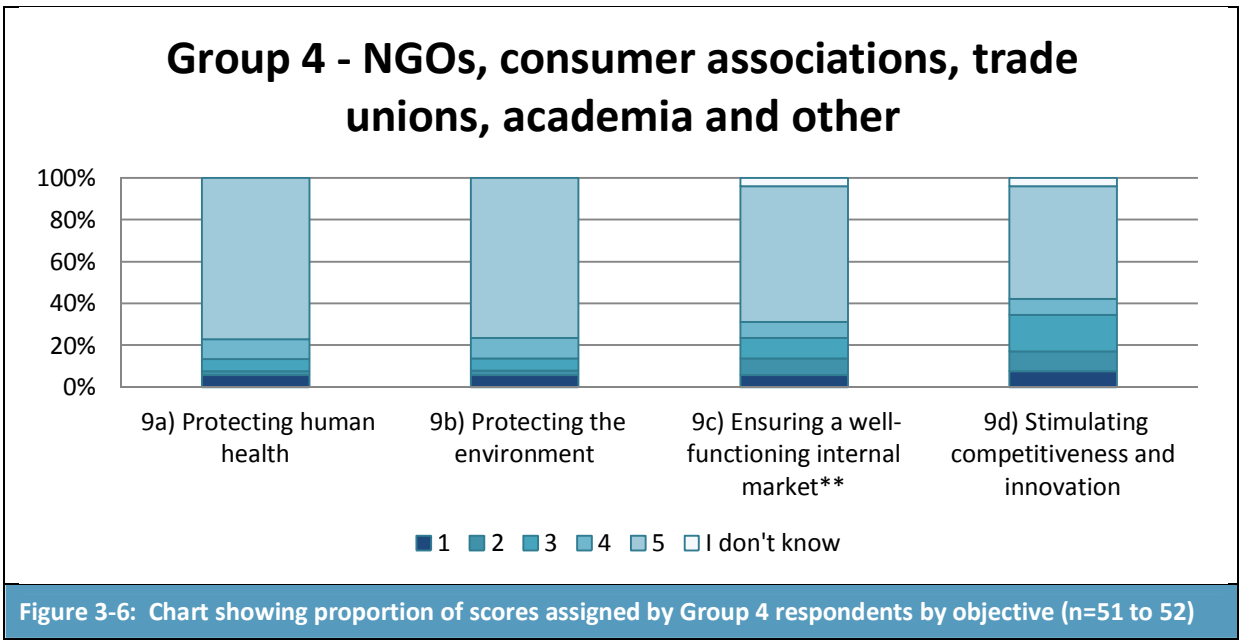

Figure 3-6: Chart showing proportion of scores assigned by Group 4 respondents by objective (n=51 to 52)

The results can also be presented as a weighted score giving an indication of the overall extent to which each group considers that the chemical legislation enables each objective to be achieved. The results are presented in Table 3-17. The table further emphasises the difference between the responses from Group 1 and those from the other groups. There is a noticeable (between 0.3 and 0.8) difference in weighted score across the objectives. The table also shows how the overall importance of chemical legislation at EU level is perceived to decrease from objectives a and b to objectives c and d. For Groups 2, 3 and 4 scores of 3.5, 3.9 and 3.8, respectively suggest that they still consider EU chemical legislation important in achieving objective d but a score of 3.1 from Group 1 suggests that this group considers importance to be moderate.

Table 3-17: Weighted scores based on number and percentage of respondents identifying level of importance of chemical legislation to achieving objectives (n=346 to 350)				
Group	Objective a: protecting human health (n=350)	Objective b: protecting the environment (n=346)	Objective c: ensuring a well-functioning internal market (n=346)	Objective d: stimulating competitiveness and innovation (n=347)
1 (citizens) (n=53 to 56)	4.0	4.2	3.3	3.1
2 (industry) (n=198)	4.6	4.6	4.2	3.5
3 (public authority) (n=43 to 44)	4.7	4.8	4.3	3.9
4 (NGO/others) (n=51 to 52)	4.5	4.5	4.1	3.8
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the importance placed by each group as a whole on the importance of chemical legislation in achieving the objective. The calculation excludes don't know responses				

3.3.6 Question 10: Do you think the EU chemical and chemical-related legislation has been effective?

Respondents were asked to score effectiveness from 1 (not effective) to 5 (effective) for the same four objectives that were considered in Question 9. Table 3-18 presents the results by group with the total number of responses varying between 344 and 352 depending upon the objective.

Table 3-18: Number and percentage of respondents identifying effectiveness of chemical legislation in achieving objectives (n=344 to 352)									
Group	Effectiveness score	Objective a: protecting human health (n=352)		Objective b: protecting the environment (n=344)		Objective c: ensuring a well-functioning internal market (n=345)		Objective d: stimulating competitiveness and innovation (n=346)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=52 to 58)	1	7	12%	7	13%	5	9%	10	19%
	2	6	10%	8	15%	7	13%	8	15%
	3	21	36%	17	33%	12	23%	10	19%
	4	7	12%	3	6%	8	15%	5	9%
	5	4	7%	4	8%	5	9%	4	8%
	Don't know	13	22%	13	25%	16	30%	16	30%
2 (industry) (n=198)	1	5	3%	6	3%	12	6%	70	35%
	2	10	5%	14	7%	60	30%	49	25%
	3	62	31%	58	29%	82	41%	52	26%
	4	63	32%	65	33%	14	7%	6	3%
	5	51	26%	47	24%	13	7%	6	3%
	Don't know	7	4%	8	4%	17	9%	15	8%
3 (public authority)	1	1	2%	1	2%	2	5%	2	5%
	2	4	9%	3	7%	1	2%	8	19%

Table 3-18: Number and percentage of respondents identifying effectiveness of chemical legislation in achieving objectives (n=344 to 352)									
Group	Effectiveness score	Objective a: protecting human health (n=352)		Objective b: protecting the environment (n=344)		Objective c: ensuring a well-functioning internal market (n=345)		Objective d: stimulating competitiveness and innovation (n=346)	
		No.	%	No.	%	No.	%	No.	%
(n=43 to 44)	3	12	27%	12	28%	10	23%	8	19%
	4	16	36%	12	28%	12	28%	8	19%
	5	8	18%	9	21%	6	14%	3	7%
	Don't know	3	7%	6	14%	12	28%	14	33%
4 (NGO/ others) (n=51 to 52)	1	2	4%	3	6%	2	4%	3	6%
	2	3	6%	2	4%	5	10%	5	10%
	3	31	60%	32	63%	13	25%	26	50%
	4	7	13%	7	14%	12	24%	8	15%
	5	7	13%	5	10%	12	24%	1	2%
	Don't know	2	4%	2	4%	7	14%	9	17%
Notes: a score of 1 = not effective and a score of 5 = very effective									

Table 3-18 and Figures 3-7 to 3-10 show the pattern of responses from each group. The key patterns are:

- Group 1 (citizens): responses from this group are concentrated around a score of 3 for objectives on protecting human health and protecting the environment, but are tending towards lower scores (i.e. less effective) for objectives on ensuring a well-functioning internal market and stimulating competitiveness and innovation. There is also a high proportion of 'don't know' responses ranging from 22% (13) for the objective on protecting human health to 30% (16) for objectives on ensuring a well-functioning internal market and stimulating competitiveness and innovation.

- Group 2 (industry): responses from this group tend towards higher scores for the objectives to protect human health and the environment. There is a considerable difference, however, with the scores assigned to the objectives on ensuring a well-functioning internal market and stimulating competitiveness and innovation with most scores being 2 or 3.

- Group 3 (public authority): responses from this group tend towards higher scores across all objectives, with only the objective on stimulating competitiveness and innovation receiving the same proportion of responses (19% or 8) for a score of 2 as for scores of 3 and 4. There is also a high proportion of 'don't know' responses to objective c (28% or 12) and objective d (33% or 14).

- Group 4 (NGO/others): the majority of responses from this group are given as 3 for objectives on protecting human health (60% or 31), protecting the environment (63% or 32) and stimulating competitiveness and innovation (50% or 26). A score of 3 for the objective on ensuring a well-functioning internal market is still the highest in terms of any individual score at 25% (13) but almost equal numbers of scores 4 and 5 are also assigned (each with 24% or 12).

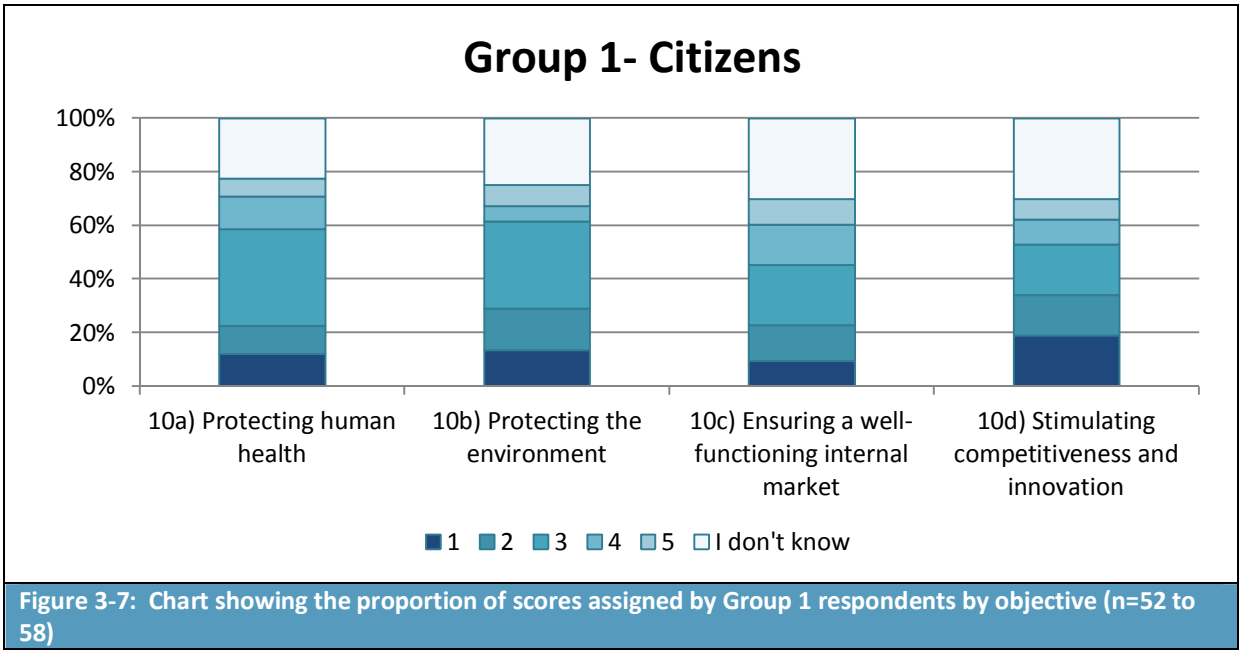

Figure 3-7: Chart showing the proportion of scores assigned by Group 1 respondents by objective (n=52 to 58)

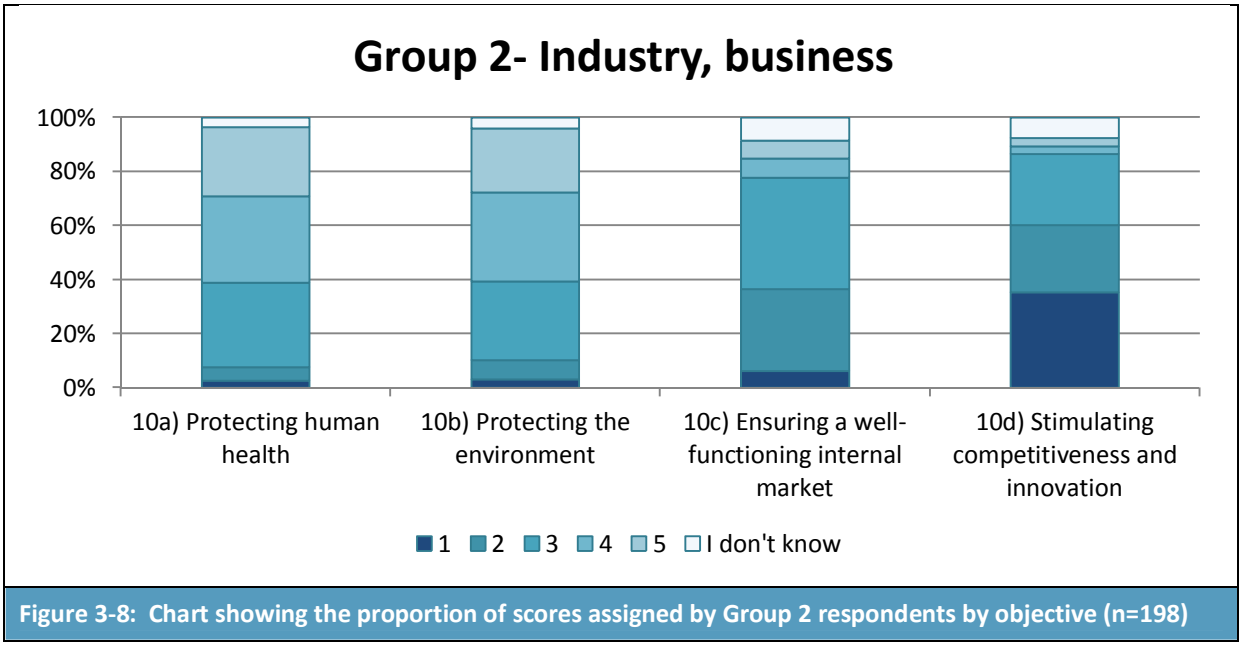

Figure 3-8: Chart showing the proportion of scores assigned by Group 2 respondents by objective (n=198)

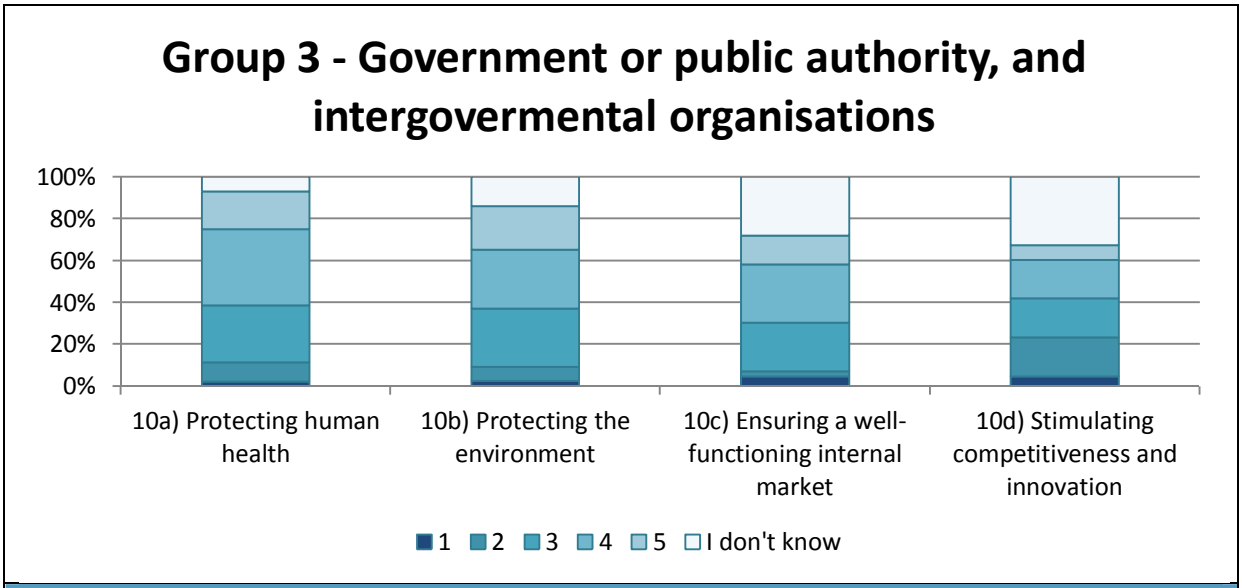

Figure 3-9: Chart showing the proportion of scores assigned by Group 3 respondents by objective (n=43 to 44)

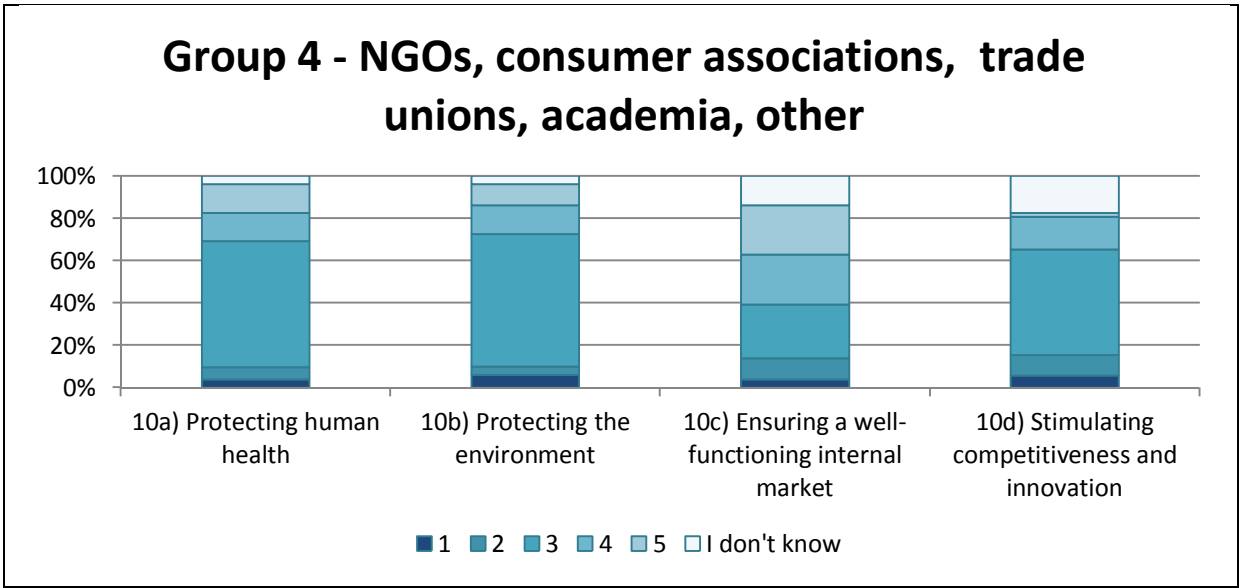

Figure 3-10: Chart showing the proportion of scores assigned by Group 4 respondents by objective (n=51 to 52)

Table 3-19 presents weighted scores based on responses to the effectiveness of EU chemical legislation in achieving the objectives. The table shows that there is again (as with Question 9) a difference between the scores assigned by Group 1 and those from Groups 2, 3 and 4 for the objectives on protecting human health (a) and protecting the environment (b). The difference is around one point to the scores of Groups 2 and 3, but closer to the scores from Group 4 (difference of 0.4 for objective a and 0.5 for objective b). Group 1 does not have the overall lowest score for objectives c and d, with this instead coming from Group 2. Group 3 has the highest scores for objectives c (3.6) and d (3.1). Overall, all the scores for effectiveness of EU chemical legislation are lower than the scores for importance of EU chemical legislation from Question 9.

Table 3-19: Weighted scores based on number and percentage of respondents identifying level of effectiveness of chemical legislation to achieving objectives (n=344 to 352)				
Group	**Objective a: protecting human health (n=352)**	**Objective b: protecting the environment (n=344)**	**Objective c: ensuring a well-functioning internal market (n=345)**	**Objective d: stimulating competitiveness and innovation (n=346)**
1 (citizens) (n=52 to 58)	2.9	2.7	3.0	2.6
2 (industry) (n=198)	3.8	3.7	2.8	2.1
3 (public authority) (n=43 to 44)	3.6	3.7	3.6	3.1
4 (NGO/ others) (n=51 to 52)	3.3	3.2	3.6	3.0
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the importance placed by each group as a whole on the effectiveness of chemical legislation in achieving the objective. The calculation excludes don't know responses				

3.3.7 Question 11: If you think the EU chemical legislation is not effective (1) or only somewhat effective (2, 3), please indicate what you believe are the main reasons why

Respondents were given four possible options to explain why they thought the EU chemical legislation and chemical-related legislation are not effective or only somewhat effective in achieving each of the four objectives. Table 3-20 presents the results by group for those who answered 1, 2 or 3 to question 10[13]. Figures 3-7 to 3-10 present charts comparing the results by group and objective. Since respondents could select more than one of the possible responses, the percentages shown in the Table and the Figures relate to the percentage of *respondents* who selected at least one explanation.

Table 3-20 and Figures 3-11 to 3-14 show that the most commonly cited reason for scoring EU chemical legislation as not effective (1) or only somewhat effective (2 or 3) for protecting human health, protecting the environment and for stimulating competitiveness and innovation is that the legislation is not adapted to the issues at stake. For protecting human health, this is the reason reported by the majority of respondents from Group 1 (56% or 19), Group 2 (70% or 53) and Group 3 (65% or 11). For Group 4, the most common response is the legislation is not effectively implemented (50% or 18). This reason was also selected by 65% (11) respondents from Group 3 as a reason for low effectiveness in protecting human health, making it equal top.

[13] In undertaking this analysis, there were four responses where respondents had identified a score for one objective but then provided their explanation under another objective. These responses have been adjusted to ensure that the explanation relates to the objective for which a score was given. This then ensures that the number of responses in total, and for those who scored 1, 2 or 3 plus those who scored 4 or 5 sum up correctly.

Table 3-20: Number and percentage of respondents identifying reasons why they assigned a score of 1, 2 or 3 to effectiveness of chemical legislation to achieving objectives (n=161 to 250)									
Group	Importance score	Objective a: protecting human health (n=163)		Objective b: protecting the environment (n=161)		Objective c: ensuring a well-functioning internal market (n=208)		Objective d: stimulating competitiveness and innovation (n=250)	
		No.	%	No.	%	No.	%	No.	%
1 (citizen) (n=24 to 34)	The legislation is unclear	11	32%	8	25%	8	33%	7	26%
	The legislation is not adapted to the issues at stake	19	56%	17	53%	12	50%	14	52%
	The legislation is not effectively implemented	9	26%	16	50%	3	13%	4	15%
	No opinion or not applicable	1	3%	1	3%	3	13%	3	11%
2 (industry) (n=76 to 171)	The legislation is unclear	16	21%	12	16%	36	24%	31	18%
	The legislation is not adapted to the issues at stake	53	70%	50	65%	58	38%	119	70%
	The legislation is not effectively implemented	18	24%	17	22%	73	48%	43	25%
	No opinion or not applicable	6	8%	9	12%	14	9%	22	13%
3 (public authority) (n=13 to 18)	The legislation is unclear	6	35%	4	25%	6	46%	4	22%
	The legislation is not adapted to the issues at stake	11	65%	10	63%	5	38%	11	61%
	The legislation is not effectively implemented	11	65%	10	63%	5	38%	4	22%
	No opinion or not applicable	0	0%	1	6%	3	23%	2	11%
4 (NGO/ others) (n=19 to 36)	The legislation is unclear	4	11%	4	11%	5	26%	4	12%
	The legislation is not adapted to the issues at stake	14	39%	15	42%	7	37%	5	15%
	The legislation is not effectively implemented	18	50%	17	47%	6	32%	14	41%
	No opinion or not applicable	4	11%	4	11%	2	11%	11	32%

Lack of effective implementation is also a common choice to explain why EU chemical legislation is not or only somewhat effective in protecting the environment, with 50% (16) of Group 1, 63% (10) of Group 3 and 47% (17) of Group 4 selecting this reason. For Group 2, though, only 22% (17) identified a lack of effective implementation as one of the main reasons why EU chemical legislation

is not or only somewhat effective in protecting the environment. The main reason selected by Group 2 respondents was that the legislation is not adapted to the issues at stake (65% or 50), with this reason also selected by 63% (10) of Group 3, 53% (17) of Group 1 and 42% (15) of Group 4.

The legislation not being adapted to the issues at stake is still seen as a main reason for the EU chemical legislation not being effective for ensuring a well-functioning internal market by 50% (12) of Group 1, 38% (58) of Group 2 and Group 3 (5) and 37% of Group 4 (7). This reason is still, therefore, important but not to the same degree as for the other objectives. Also, responses from Group 4 are much more in line with those from the other groups for objective c. For Group 2, the most common response is that the legislation is not effectively implemented (48% or 73) and for Group 3, the most common response is that the legislation is unclear (46% or 6).

For stimulating competitiveness and innovation, the legislation not being adapted to the issues at stake is indicated by 70% (119) of Group 2, 61% (11) of Group 3 and 52% (14) of Group 1. However, this explanation is only considered to be one of the main reasons for lack of effectiveness by 15% (5) of Group 4. For Group 4, the most common choice is that the legislation is not effectively implemented (41% or 14); although there are also 32% (11) respondents who responded that they had no opinion.

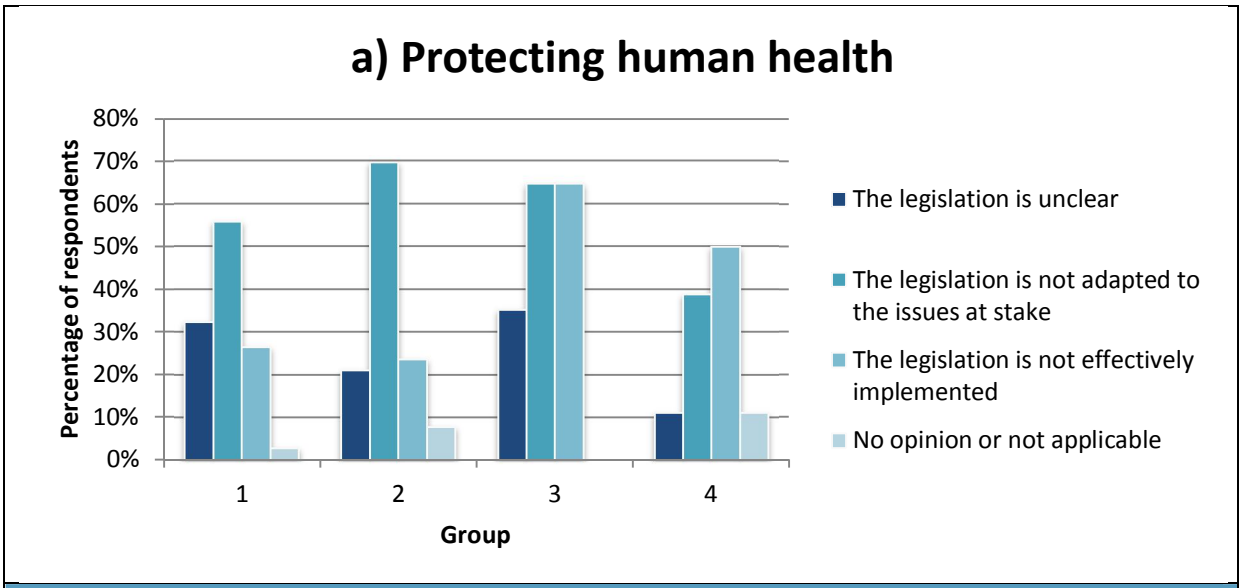

Figure 3-11: Chart showing explanation provided by respondents as reasons why they scored effectiveness of chemical legislation as 1, 2 or 3 (where 1 is not effective) for objective a (Group 1 (citizens): n=34, Group 2 (industry): n=76, Group 3 (public authority): n=17, Group 4 (NGO/others): n=36)

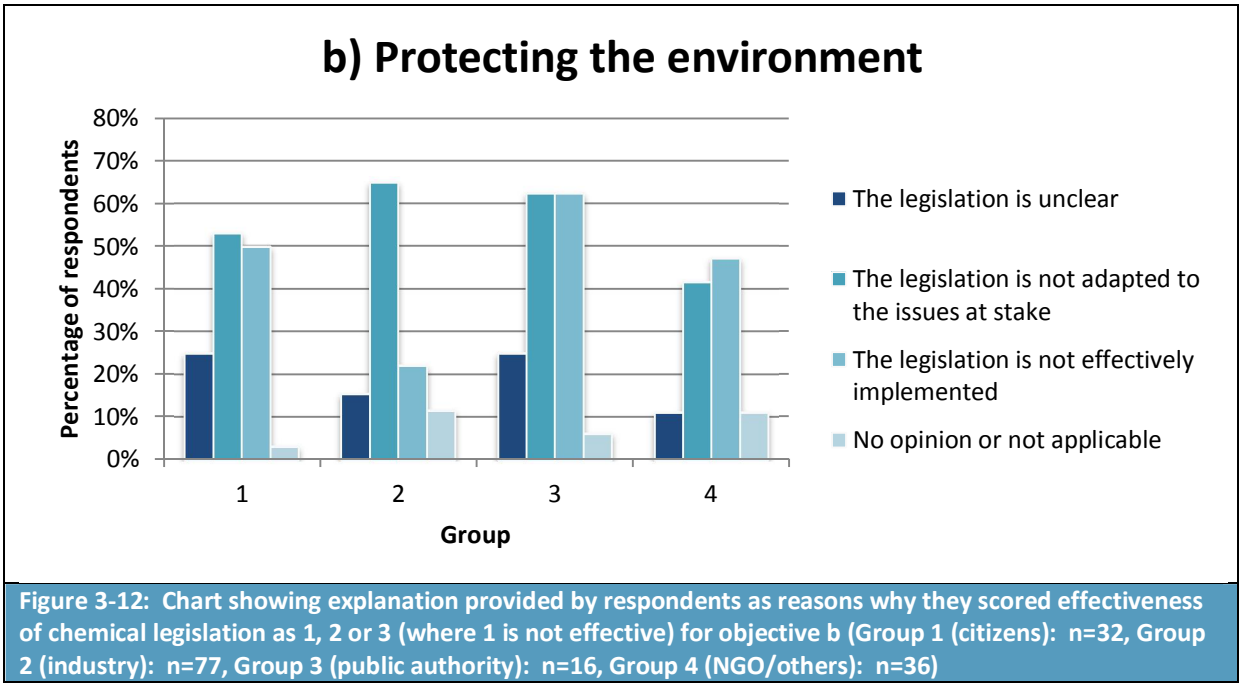

Figure 3-12: Chart showing explanation provided by respondents as reasons why they scored effectiveness of chemical legislation as 1, 2 or 3 (where 1 is not effective) for objective b (Group 1 (citizens): n=32, Group 2 (industry): n=77, Group 3 (public authority): n=16, Group 4 (NGO/others): n=36)

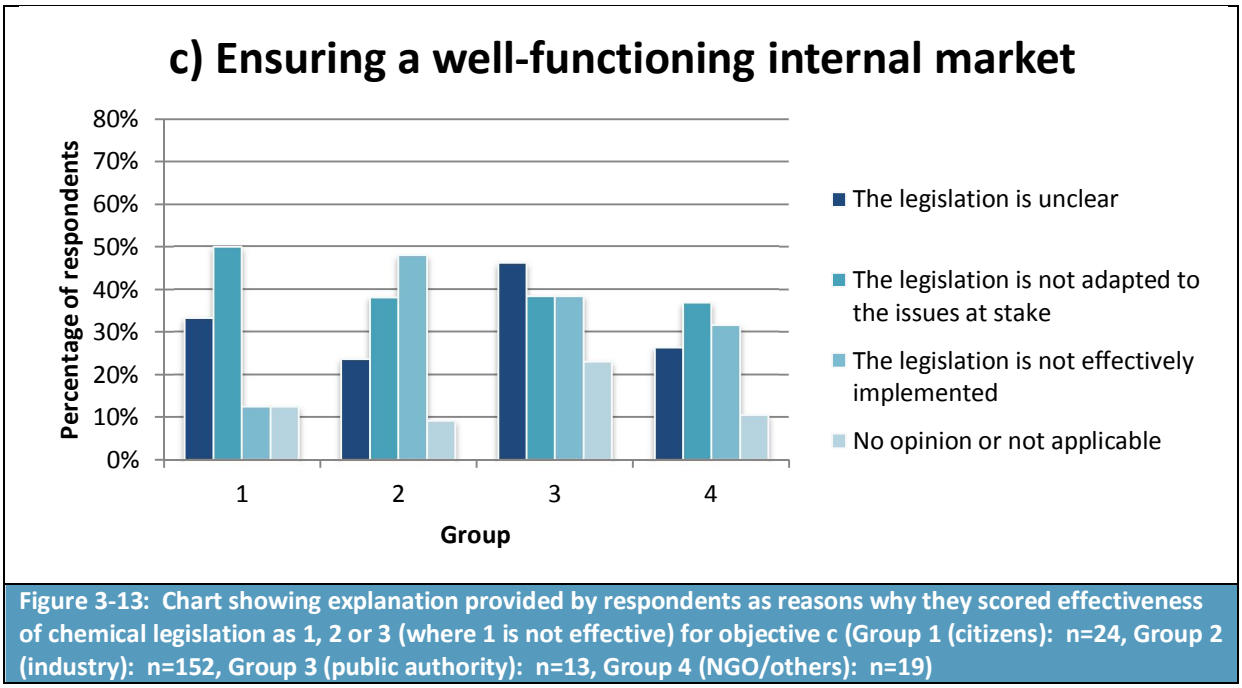

Figure 3-13: Chart showing explanation provided by respondents as reasons why they scored effectiveness of chemical legislation as 1, 2 or 3 (where 1 is not effective) for objective c (Group 1 (citizens): n=24, Group 2 (industry): n=152, Group 3 (public authority): n=13, Group 4 (NGO/others): n=19)

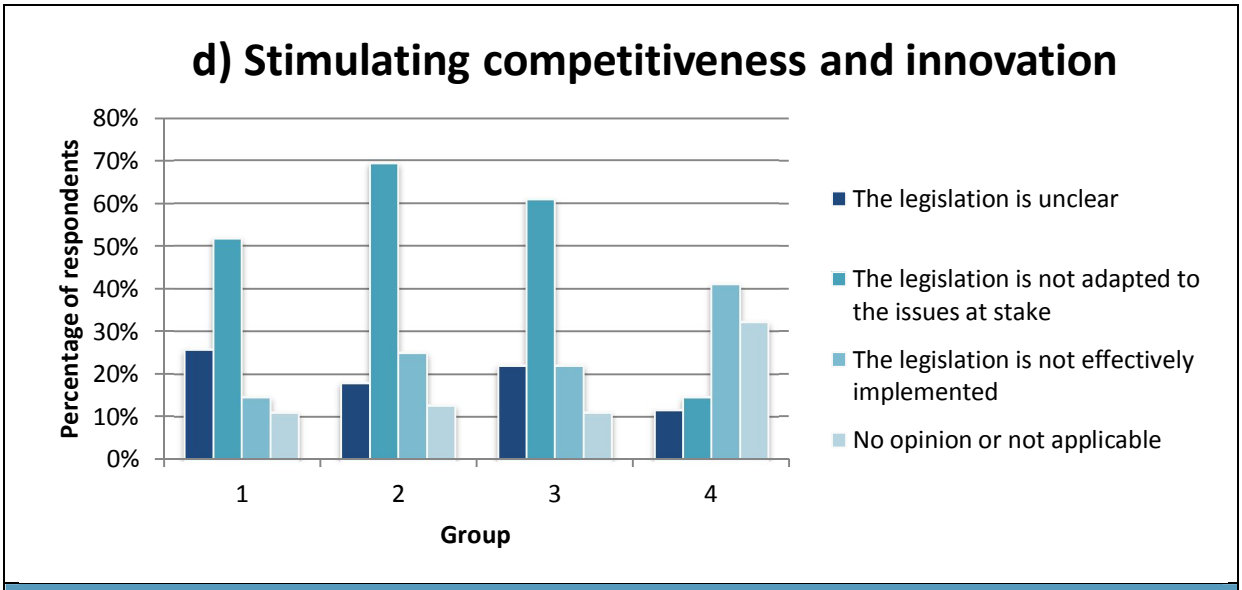

Figure 3-14: Chart showing explanation provided by respondents as reasons why they scored effectiveness of chemical legislation as 1, 2 or 3 (where 1 is not effective) for objective d (Group 1 (citizens): n=27, Group 2 (industry): n=171, Group 3 (public authority): n=18, Group 4 (NGO/others): n=34)

There were also 101 responses to objective a, 96 responses to objective b, 53 responses to objective c and 31 responses to objective b from those who answered 4 or 5 to Question 10 but who also provided an explanation. The majority of these respondents answered 'no opinion or not applicable' meaning that the number of responses selecting one of the reasons is low. The maximum number of responses relates to the legislation not being effectively implemented, which was selected by 7 respondents (11%) from Group 2 for the objective of protecting the environment.

3.3.8 Question 12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level

Respondents were asked to assign a score from 1 (no value) to 5 (very high added value). There were 355 responses to this question in total, with the breakdown by groups presented in Table 3-21 and in Figure 3-15.

Table 3-22 and Figure 3-15 show that there are a high proportion of respondents who place a high added value on EU chemicals legislation. The most common response from Groups 2, 3 and 4 are all for a score of 5: Group 2 with 42% (84) of responses, Group 3 with 37% (17) of responses and Group 4 with 40% (21) of responses. The most common response for Group 1 is a score of 4 at 22% (13) of responses but there are also 16% (9) responses that assigned a score of 5. Group 1 also has the highest level of 'don't know' responses at 24% (10).

The weighted scores (also shown in Table 3-21) give an indication of the overall score from each Group. These show that Groups 2, 3 and 4 are equally the most positive about the added value of the EU chemicals legislation with scores of 4.0. There is then a difference of 0.7 to Group 1 with a weighted score of 3.3.

Table 3-21: Scores assigned to value added of EU level chemical legislation above what could have been achieved through action at a national level (n=355)								
Score	Group 1 (citizens) (n=58)		Group 2 (industry) (n=198)		Group 3 (public authority) (n=46)		Group 4 (NGO/others) (n=53)	
	No.	%	No.	%	No.	%	No.	%
1	4	7%	14	7%	1	2%	0	0%
2	8	14%	9	5%	3	7%	7	13%
3	10	17%	30	15%	6	13%	7	13%
4	13	22%	50	25%	15	33%	17	32%
5	9	16%	84	42%	17	37%	21	40%
I don't know	14	24%	11	6%	4	9%	1	2%
Weighted score	3.3		4.0		4.0		4.0	
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the added value placed by each group as a whole on EU chemical legislation. The calculation excludes don't know responses								

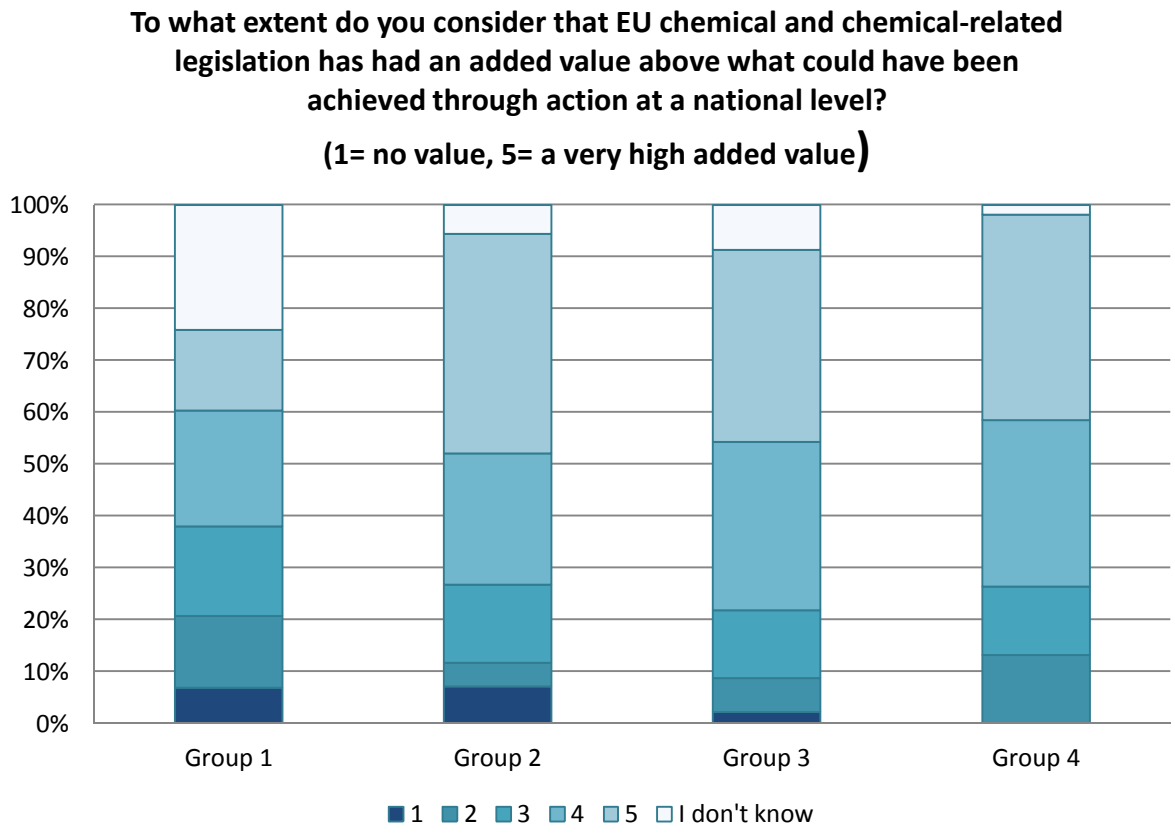

Figure 3-15: Chart showing scores assigned to value added of EU level chemical legislation above what could have been achieved through action at a national level (n=355)

3.3.9 Question 13: Please select the legislation that regulates or otherwise affects your sector's or your company's activities

This question was targeted at business and industry associations, but respondents from all groups provided answers as can be seen from Table 3-22. The table is ordered from the legislation that regulates or affects the highest proportion of businesses/industry associations (Group 2) to that which affects the lowest. The percentage reflects the number of respondents to Question 13 that indicated that they were affected by each piece of legislation.

Table 3-22: Number and percentage of responses by legislation that regulates or otherwise affects your sector or company activities (n=324)

Legislation	Group 1 (citizens) (n=44)		Group 2 (industry) (n=192)		Group 3 (public authority) (n=39)		Group 4 (NGO/others) (n=49)	
	No.	%	No.	%	No.	%	No.	%
Classification, labelling and packaging (Regulation No (EC) 1272/2008)	20	45%	**177**	**92%**	25	64%	37	76%
REACH, Annex XIII (Regulation (EC) No 1907/2006)	11	25%	**150**	**78%**	16	41%	26	53%
Waste framework (Directive 2008/98/EC) and List of Waste	9	20%	**141**	**73%**	22	56%	28	57%
Chemical Agents (Directive 98/24/EC)	5	11%	**135**	**70%**	25	64%	36	73%
Inland transport of dangerous goods (Directive 2008/68/EC)	7	16%	**127**	**66%**	3	8%	10	20%
Carcinogens and mutagens at work (Directive 2004/37/EC)	7	16%	**124**	**65%**	13	33%	16	33%
Biocidal products (Regulation (EU) No 528/2012)	13	30%	**122**	**64%**	11	28%	8	16%
Packaging and Packaging Waste (Directive 94/62/EC)	5	11%	**120**	**63%**	12	31%	19	39%
Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)	9	20%	**117**	**61%**	7	18%	13	27%
Pregnant workers (Directive 1992/85/EEC)	5	11%	**114**	**59%**	8	21%	14	29%
Young people at work (Directive 1994/33/EC)	4	9%	**106**	**55%**	8	21%	9	18%
Water Framework (Directive 2000/60/EC)	7	16%	**103**	**54%**	7	18%	12	24%
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)	6	14%	**101**	**53%**	7	18%	25	51%
General Product Safety (Directive 2001/95/EC)	1	2%	**100**	**52%**	6	15%	5	10%
EU Ecolabel (Regulation (EC) 66/2010)	6	14%	**96**	**50%**	10	26%	14	29%
Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)	5	11%	**95**	**49%**	7	18%	21	43%
Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)	2	5%	**95**	**49%**	5	13%	5	10%
Export and import of hazardous chemicals (Regulation No 649/2012)	6	14%	**94**	**49%**	5	13%	5	10%
Signs at work (Directive 92/58/EEC)	1	2%	**87**	**45%**	7	18%	18	37%
Persistent organic pollutants (Regulation (EC) 850/2004)	6	14%	**83**	**43%**	6	15%	10	20%

Table 3-22: Number and percentage of responses by legislation that regulates or otherwise affects your sector or company activities (n=324)								
Legislation	Group 1 (citizens) (n=44)		Group 2 (industry) (n=192)		Group 3 (public authority) (n=39)		Group 4 (NGO/others) (n=49)	
	No.	%	No.	%	No.	%	No.	%
Test methods (Regulation (EC) No 440/2008)	2	5%	**76**	**40%**	5	13%	10	20%
Cosmetic products (Regulation (EC) No 1223/2009)	6	14%	**67**	**35%**	5	13%	15	31%
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)	1	2%	**66**	**34%**	11	28%	11	22%
Detergents (Regulation (EC) No 648/2004)	6	14%	**62**	**32%**	13	33%	18	37%
Drinking Water (Directive 98/83/EC)	3	7%	**61**	**32%**	4	10%	10	20%
Waste shipments (Regulation (EC) No 1013/2006)	3	7%	**59**	**31%**	8	21%	15	31%
Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)	2	5%	**51**	**27%**	4	10%	17	35%
Safety of toys (Directive 2009/48/EC)	5	11%	**49**	**26%**	10	26%	16	33%
Batteries (Directive 2006/66/EC)	1	2%	**47**	**24%**	12	31%	22	45%
Aerosol dispensers (Directive 75/324/EEC)	2	5%	**47**	**24%**	13	33%	13	27%
Asbestos (Directive 2009/148/EC)	4	9%	**44**	**23%**	8	21%	15	31%
Pressure equipment (Directive 2014/68/EU)	0	0%	**40**	**21%**	8	21%	12	24%
Plant protection products (Regulation (EC) No 1107/2009)	10	23%	**39**	**20%**	5	13%	10	20%
End of life vehicles (Directive 2000/53/EC)	1	2%	**38**	**20%**	3	8%	8	16%
Urban Waste Water (Directive 91/271/EEC)	4	9%	**35**	**18%**	4	10%	5	10%
Protection of animals used for scientific purposes (Directive 2010/63/EU)	3	7%	**35**	**18%**	3	8%	7	14%
Explosives (Directive 93/15/EEC)	1	2%	**33**	**17%**	7	18%	17	35%
Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)	1	2%	**24**	**13%**	5	13%	13	27%
Residues of pesticides (Regulation (EC) No 396/2005)	6	14%	**24**	**13%**	9	23%	13	27%
Fertilisers (Regulation (EC) No 2003/2003)	2	5%	**19**	**10%**	9	23%	16	33%
Marine Strategy Framework (Directive 2008/56/EC)	2	5%	**16**	**8%**	2	5%	6	12%
I am not familiar with any of the pieces of legislation listed above	3	7%	**1**	**1%**	0	0%	1	2%
Other	-	-	**-**	**-**	-	-	-	-

Table 3-22 shows that 92% of Group 2 respondents (177) are regulated by or affected by the CLP Regulation, with this being considerably higher than the second ranked legislation: REACH at 78% (150). The pattern across other groups is reasonably similar, although Plant Protection Products affects a similar level of Group 1 (23% or 10) and Group 4 (20% or 26) as Group 2 (20% or 39) and this proportion is much higher than for much of the other legislation. Group 3 is affected more by the Fertilisers Regulation (23% or 8) than Group 2 (10% or 19), and Group 1 (5% or 2) but less than Group 4 (33% or 16). There is also a high proportion of respondents from Group 4 affected by the

Explosives Directive (35% or 17) compared with 18% from Group 3 (4), 17% from Group 2 (33) and just 2% (1) from Group 1.

Table 3-23 lists the top ten ranked legislation affecting or regulating each group. The table shows that there are 19 pieces of legislation that rank in the top ten for at least one of the groups. The CLP Regulation is ranked one for all groups, with the REACH Regulation being the only other that is ranked in the top ten across all four groups. Legislation such as the Carcinogens and Mutagens at Work Directive, Biocidal Products Directive and Packaging and Packaging Waste Directive all rank in the top ten for three of the four groups. The Plant Protection Products Regulation ranks 1= (with CLP Regulation) for Group 3 but is only in the top ten for one other group: Group 1 where it ranks fourth.

There were also 37 comments provided as other pieces of relevant legislation[14]. These are summarised in Table 3-24.

Table 3-23: Rank of those pieces of legislation that regulate or otherwise affects your sector or company activities that fall within the top ten for each group (n=324)

Legislation	Group 1 (citizens) (n=44)		Group 2 (industry) (n=192)		Group 3 (public authority) (n=39)		Group 4 (NGO/others) (n=49)	
	Rank	%	Rank	%	Rank	%	Rank	%
Classification, labelling and packaging (Regulation No (EC) 1272/2008)	1	45%	**1**	**92%**	1=	64%	1	76%
REACH, Annex XIII (Regulation (EC) No 1907/2006)	3	25%	**2**	**78%**	4	41%	4	53%
Waste framework (Directive 2008/98/EC) and List of Waste	5=	20%	**3**	**73%**	-	-	3	57%
Chemical Agents (Directive 98/24/EC)	-	-	**4**	**70%**	-	-	2	73%
Inland transport of dangerous goods (Directive 2008/68/EC)	7=	16%	**5**	**66%**	-	-	-	-
Carcinogens and mutagens at work (Directive 2004/37/EC)	7=	16%	**6**	**65%**	8=	31%	-	-
Biocidal products (Regulation (EU) No 528/2012)	2	30%	**7**	**64%**	3	56%	-	-
Packaging and Packaging Waste (Directive 94/62/EC)	-	-	**8**	**63%**	8=	31%	8	39%
Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)	5=	20%	**9**	**61%**	-	-	-	-
Pregnant workers (Directive 1992/85/EEC)	-	-	**10**	**59%**	-	-	-	-
Plant protection products (Regulation (EC) No 1107/2009)	4	23%	-	-	1=	64%	-	-
Water Framework (Directive 2000/60/EC)	7=	16%	-	-	5=	33%	-	-
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)	10	14%	-	-	-	-	5	51%
General Product Safety (Directive 2001/95/EC)	-	-	-	-	5=	33%	-	-

[14] One comment concerned hybrid and electric cars and seemed to be irrelevant to this question.

Table 3-23: Rank of those pieces of legislation that regulate or otherwise affects your sector or company activities that fall within the top ten for each group (n=324)								
Legislation	Group 1 (citizens) (n=44)		Group 2 (industry) (n=192)		Group 3 (public authority) (n=39)		Group 4 (NGO/others) (n=49)	
	Rank	%	Rank	%	Rank	%	Rank	%
Persistent organic pollutants (Regulation (EC) 850/2004)	-	-	-	-	5=	33%	-	-
Detergents (Regulation (EC) No 648/2004)	-	-	-	-	10	28%	9=	37%
Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)	-	-	-	-	-	-	7	43%
Signs at work (Directive 92/58/EEC)	-	-	-	-	-	-	9=	37%
Batteries (Directive 2006/66/EC)	-	-	-	-	-	-	6	45%
Notes: Rank is based on number/percentage of respondents who indicated that each piece of legislation regulates or affects them. Where the number/percentage is the same across two or more pieces of legislation they are shown as =, e.g. waste framework directive and industrial emission directive were both identified by the same number of respondents from Group 1 and are ranked 5=								

Table 3-24: Other comments (n=37)	
Type of legislation	Specific comments
Adhesives	Adhesives 1895/2005
Birds and habitats	Birds and Habitats Directives
Ceramics	Ceramics (84/500/EEC, 2005/31/EC, 333/2007); FCM (1935/2004)
Construction	Construction legislation (emissions from building materials) Construction Products Regulation
Detergents	Detergents Regulation (EC) No. 648/2004 (and all following adaptations)
Emissions from air conditioning systems in motor vehicles	Richtlinie 2006/40/EG zu Emissionen aus Pkw-Klimaanlagen
Explosives	The ATEX Directive Règlement 98/2013 sur les précurseurs d'explosifs Verordnung (EG) Nr. 98/2013
Fluorinated greenhouse gases	Fluorinated greenhouse Gases Regulation Regulation 517/2014 on fluorinated greenhouse gases Fluorinated greenhouse gases regulation (517/2014/EU) EU F-Gas Regulation 517/2014 Verordnung über fluorierte Treibhausgase (EU) Nr. 517/2014 inkl. Durchführungsverordnungen VO 517/2014
Food	Food contact materials Regulation 2004/1935 EC 470/2009 (MRL and residues in meat) Règlement (CE) 1935/2004 du Parlement européen et du Conseil du 27 octobre 2004 concernant les matériaux et objets destinés à entrer en contact avec des denrées alimentaires reglement 1935/2004 contact alimentaire
Indoor air quality	Indoor Air quality
Inland transport	Inland transport of dangerous goods (2008/68)
Landfill	Landfill Directive There are several pieces of EU legislation missing that refer to hazardous substances (e.g. landfill directive, regulations on ozone depleting substances etc.)
Medical	Good Manufacturing Practice (for Medical)
Medicinal products	Medicinal products (Directive 2001/83/EC)

Table 3-24: Other comments (n=37)	
Type of legislation	**Specific comments**
	medicinal products (Dir 2001/83/EC)
Metals and alloys	CoE Guide on Metals and Alloys in FCM & FCA [CM/Res(2013)9], GMP 2023/2006
Ozone depleting substances	EU ODS Regulation 1005/2009 Verordnung über Stoffe, die zum Abbau der Ozonschicht führen (EG) Nr. 1005/2009 VO 1005/2009
Pesticides	Directive-cadre Pesticides 2009/128/CE (non reprise dans la liste visée par cette enquête)
Physical agents	Physical Agents Directive 2013/35
Seveso	Directive SEVESO III 2012/18
Sewage sludge	Sewage Sludge Directive 86/278/EEC Sludge Directive 86/278/EEC
Veterinary medicines	Directive 2001/82/EC (on Veterinary medicinal products)
VOCs in paints	Richtlinie 2004/42/EG
Waste electrical and electronic equipment	Waste electrical and electronic equipment (Directive 2012/19/EU)
Worker exposure	Protection des travailleurs contre les risques liés à l'exposition à des agents Protection des travailleurs contre les risques liés à l'exposition à des agents Protection des travailleurs contre les risques liés à l'exposition à des agents Protection des travailleurs contre les risques liés à l'exposition à des agents

3.3.10 Question 14: To what extent do you agree with the following statements relating to the EU chemicals legislation framework overall

3.3.10.1 Analysis of closed question responses

This question asked respondents to indicate the extent to which they agreed with four statements. The results, by group, are provided in Table 3-26. The preferences of the different groups vary quite considerably with 72% (151) from Group 2 (business/industry) being in favour of specific risk assessment. The most common response from Group 4 was for generic risk considerations (41% or 23), but there were also 25% (14) who agreed that there should be more orientation towards specific risk assessment and 16% (9) who thought the legislation should remain as it is. The most common response from Group 3 was that it should remain as it is (37% or 18) but 29% (14) provided no answer. Responses from Group 1 were also mixed with almost half stating (49% or 31) 'I don't know'; the next most common response is 17% (11) for both specific risk assessment and generic risk considerations.

Table 3-25: Extent to which respondents agreed with statements relating to the extent that EU chemical and chemical-related legislation should… (n=296)								
Chemicals legislation framework overall should …	**Group 1 (citizens) (n=32)**		**Group 2 (industry) (n=182)**		**Group 3 (public authority) (n=35)**		**Group 4 (NGO/others) (n=47)**	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged	11	17%	151	72%	6	12%	14	25%

Table 3-25: Extent to which respondents agreed with statements relating to the extent that EU chemical and chemical-related legislation should… (n=296)								
Chemicals legislation framework overall should …	Group 1 (citizens) (n=32)		Group 2 (industry) (n=182)		Group 3 (public authority) (n=35)		Group 4 (NGO/others) (n=47)	
	No.	%	No.	%	No.	%	No.	%
discussions and implementation delays)								
b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted)	11	17%	5	2%	7	14%	23	41%
c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)	3	5%	23	11%	18	37%	9	16%
d. I don't know	7	11%	3	1%	4	8%	1	2%
No answer	31	49%	28	13%	14	29%	9	16%

3.3.10.2 Analysis of open text responses

Respondents were also asked to provide comments if they answered 'yes' to statements a (specific risk assessment) or b (generic risk considerations). In total 47 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-26. The table also shows which groups the comments were from.

Table 3-26: Q14: specific versus generic risk assessments themes from OPC responses (n=47; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Themes for specific risk assessment	
Specific risk assessment is more appropriate to define most effective risk management	Group 2 (industry) Group 4 (NGO/others)
Specific risk assessment allows the benefits of uses to be considered	Group 2 (industry)
Risk assessment is central to risk management	Group 2 (industry)
Risk assessments should consider the specific characteristics of each individual substance	Group 3 (public authority) Group 2 (industry)
Risk-based approach is needed justifying legislative action and intervention	Group 3 (public authority)
Applying risk management to specific uses would reduce obstacles leading to prolonged discussions and implementation difficulties	Group 2 (industry) Group 4 (NGO/others)
Use of specific or tailored management measures would allow more focused use of risk management	Group 2 (industry) Group 4 (NGO/others)
Themes against specific risk assessment	
Hazard based exclusion criteria can override specific risk assessments	Group 3 (public authority)
Risk assessment can take years to finalise	Group 3 (public authority) Group 4 (NGO/others)
Specific risk assessments are not suitable for all uses of hazardous substances	Group 4 (NGO/others)
Risk-based assessment requires access to more data and is time consuming	Group 2 (industry) Group 4 (NGO/others)

Table 3-26: Q14: specific versus generic risk assessments themes from OPC responses (n=47; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Consideration of specific cases opens the way to non-authorised uses	Group 1 (citizen)
Themes for generic risk considerations	
Risk management should be based on generic risk considerations	Group 1 (citizen) Group 3 (public authority) Group 4 (NGO/others)
Burden of proof lies with producers and users	Group 3 (public authority)
Precautionary principle should be applied	Group 1 (citizen)
Hazard identification reduces costs for regulators	Group 3 (public authority)
Use of a hazard based approach to risk management results in a predictable legislative framework	Group 4 (NGO/others)
Hazard based approach should be used for all consumer relevant chemicals legislation	Group 4 (NGO/others)
Hazard based approach allows certain groups of chemicals to be banned on their harmful properties, speeding up implementation of legislation	Group 4 (NGO/others)
Themes against generic risk considerations	
Generic risk considerations result in properly controlled chemical use being prohibited	Group 2 (industry)
Regulation should target specific risks instead of generic ones to be more efficient, to increase security where it is necessary, and to not create disincentives for manufacturers who already appropriately control risks	Group 2 (industry)
Hazard-based approaches result in companies having to take action where none is necessary	Group 2 (industry)
Hazard based decisions give rise to excessive management burdens	Group 2 (industry)
Other themes on hazard and risk based approaches	
The cocktail effect is not evaluated	Group 3 (public authority)
Risk assessments should be based on the weight of all available evidence	Group 2 (industry)
Consideration should be given to the full range of scientific studies	Group 2 (industry)
Precaution needs to be taken considering the populations at risk	Group 2 (industry)
Intrinsic properties are easy to communicate throughout the supply chain	Group 3 (public authority)
Information on intrinsic properties is official	Group 3 (public authority)
If a study has proved "safe use", this should be communicated along with inherent toxicity	Group 2 (industry)
Hazard identification helps prioritisation	Group 3 (public authority) Group 4 (NGO/others)
Hazard-based cut-off can be too blunt an instrument	Group 3 (public authority)
Cut-off criteria give clear guidance to industry	Group 4 (NGO/others)
Cut-off criteria result in the loss of important PPP substances for no valid scientific reason	Group 2 (industry)
Exposure assessments need to be updated on a regular basis; hazard based assessments consider intrinsic properties so do not change over time	Group 4 (NGO/others)
Implementation even with the help of ECHA guidance within a reasonable amount of time is hardly possible	Group 1 (citizen)
Chemical policies have to be better linked to other Directives and strategies	Group 3 (public authority)
EU chemical policies need to be stricter and better linked in order to protect European waters	Group 3 (public authority)

Table 3-26: Q14: specific versus generic risk assessments themes from OPC responses (n=47; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
The EU needs to give a clear position on endocrine disruptors	Group 3 (public authority)
Restrictions have been made too late	Group 3 (public authority)
Exposures that have not yet been measured or are risks that are poorly controlled should be limited	Group 2 (industry)
BPR[1] is too general to consider specific needs	Group 2 (industry)
Classification should not lead to an elimination of established and safely used controlled substances	Group 2 (industry)
Linkages between legislation means that tightening of the CLP Regulation leads to tightening in other areas	Group 2 (industry)
Research should focus on limits for no effect	Group 4 (NGO/others)
Resources needed for compliance are overwhelmed reducing opportunities for innovation	Group 2 (industry)
The public should be educated about the scientific basis of no effect limits	Group 4 (NGO/others)
Registration is an excessive requirement for production for own consumption on site	Group 2 (industry)
REACH should be risk focused so a full exemption of medical devices is appropriate	Group 2 (industry)
There should be a greater focus on personal responsibility for management of chemical safety	Group 2 (industry)
Notes: [1] BPR = Biocidal Products Regulation	

3.3.10.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-27 provides a summary of the themes from these non-questionnaire responses.

Table 3-27: Q14: specific risk assessment versus generic risk consideration themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes for specific risk assessment	
Specific risk assessment is needed	Group 2 (industry)
Chemical-related legislation should be oriented towards specific risk assessments	Group 2 (industry)
Themes against specific risk assessment	
Specific risk assessment methods are burdensome	Group 3 (public authority)
Specific risk assessment methods are unpredictable	Group 3 (public authority)
Themes for generic risk considerations	
Generic risk considerations are more economical	Group 3 (public authority)
Generic approaches provide greater predictability	Group 3 (public authority)
Support generic risk management approach	Group 3 (public authority)
Legislation should be oriented towards generic risk considerations	Group 3 (public authority)
Range of uses covered by generic risk considerations should be widened	Group 4 (NGO/others)
Additional generic risk considerations should lead to the implementation	Group 4 (NGO/others)

Table 3-27: Q14: specific risk assessment versus generic risk consideration themes from non-questionnaire responses (n=9)	
Theme	**By**
of 'hazard based' cut off or bans	
Themes against generic risk considerations	
Restricting chemicals based on their hazardous properties could deny major benefits	Group 2 (industry)
In-depth risk assessment is needed	Group 2 (industry)
Chemical substitution decisions should be the result of comparative risk assessment and evaluation	Group 2 (industry)
Risk assessment should consider exposure and risk mitigation measures	Group 2 (industry)
Needs to be a move towards risk-based approaches	Group 2 (industry)
Other themes on generic considerations versus specific risk assessment	
The balance between generic and specific risk considerations should be decided at the level of downstream legislation	Group 3 (public authority)
Single substance risk assessment is not adequate	Group 4 (NGO/others)
Cumulative risk assessment approach should be undertaken addressing the cumulative effects from combined exposures	Group 4 (NGO/others)
Risk assessment should be based on weight of evidence	Group 2 (industry)
Risk assessments ignore mixtures and do not adequately consider chemicals from multiple sources	Group 4 (NGO/others)
Risk assessment tends to look at one chemical at a time and at one route of exposure at a time	Group 4 (NGO/others)
The methods for environmental risk assessment are complex and resource-intensive for both Governments and businesses, and the trend is that the complexity is increasing	Group 3 (public authority)
It is important to analyse how risk assessments can be simplified such that the scientific quality remains high	Group 3 (public authority)
Divergent MS rules and risk assessment would hinder functioning of the internal market	Group 4 (NGO/others)
Issue of recycler not having to develop a separate risk assessment needs to be reviewed	Group 4 (NGO/others)
Themes on hazard classification	
Classification needs to be hazard based	Group 3 (public authority)
Classification must remain based on intrinsic hazardous properties	Group 3 (public authority)
A hazard-based approach is important: The hazard-based classification system is a key part of the chemical legislation in the EU and it is, in our view, essential that it remains hazard-based and that it is only based on intrinsic hazardous properties	Group 3 (public authority)
Classification system should remain hazard based	Group 3 (public authority)
Hazard based identification and classification should be used	Group 4 (NGO/others)
Hazard based identification and classification is the appropriate base for taking measures for consumer and environmental protection	Group 4 (NGO/others)
Other themes	
Assessment processes under BPR[1] focus on worst case scenarios	Group 2 (industry)
Studies that are outliers are used instead of weight of evidence	Group 2 (industry)
Socioeconomics and exposure considerations should only be considered where hazard is known	Group 3 (public authority)
Classification according to CLP provides a good approach	Group 3 (public authority)

Table 3-27: Q14: specific risk assessment versus generic risk consideration themes from non-questionnaire responses (n=9)	
Theme	**By**
Derogations should be for lawmakers to decide	Group 3 (public authority)
Risk management divergences between worker protection H&S and REACH/CLP	Group 2 (industry)
Risk management divergences need to be rationalised to simplify compliance requirements	Group 2 (industry)
Scope of substitution for SVHC[2] is broader than under H&S Directives adding further complexity	Group 2 (industry)
Serious concerns with proposed use of Threshold of Toxicological Concern for NIAS[3]	Group 4 (NGO/others)
There is a need for development of classification criteria for alternative test methods	Group 3 (public authority)
Additional uncertainty factors are needed	Group 4 (NGO/others)
Notes: [1] BPR = Biocidal Products Regulation. [2] SVHC = Substances of Very High Concern. [3] Non-Intentionally Added Substances (NIAS)	

3.3.10.4 Comparison of themes

The comparison of themes for and against specific risk assessment versus generic risk considerations are summarised in the table below. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-28: Comparison of responses on relevant considerations taken into account in regulatory decision-making			
Non-questionnaire responses		**OPC responses**	
For	**Against**	**For**	**Against**
Specific risk assessment			
Group 2 (2)	Group 3 (2)	Group 2 (6) Group 3 (2) Group 4 (3)	Group 1 (1) Group 2 (1) Group 3 (2) Group 4 (3)
Generic risk considerations			
Group 3 (4) Group 4 (2)	-	Group 1 (1) Group 3 (2) Group 4 (1)	Group 2 (4)
Key: others captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from question 5 of the OPC			

The table shows that specific risk assessment is favoured by Group 2 (industry associations and businesses) but may be opposed by some in the other groups (although see also Table 3-25 on the percentages indicating for and against specific risk assessment, or in favour of the current system). Some of the comments associated with positive and negative themes are:

- Support for specific risk assessment:
  - The risk associated with each chemical is dependent on the specific use for which it is intended, as well as the conditions for use (e.g. amount, containment, personal protection measures, packaging, and awareness of user). Therefore a specific risk

assessment is in general more appropriate to define the most effective risk management measure whilst preserving societal benefits (Group 2).

- Support for generic risk considerations:
  - Generic risk considerations are especially important in regards to substances that are not controlled and cannot be easily traced. Endocrine Disrupting Chemicals (EDCs) and Persistent, Bioaccumulative and Toxic (PBT) substances require a hazard-based approach due to the uncertainty in predicting exposure and effects. For example, in relation to EDCs, substances can have delayed effects at very low doses making it difficult to calculate no-effect of exposure. Moreover, for PBTs, it may not be possible to calculate "safe" levels due to their persistence and the potential to accumulate in the environment, hence risk assessments are not reliable in managing the risks as long-term toxicity is difficult to predict (Group 4);
  - A generic approach is more convenient to maintain innovation and competitiveness for a sustainable risk management. However the generic approach has to be proportionate and should not overuse the "precaution principle" or overestimate exposure (Group 2);
  - For nanomaterials, a more cautious approach is needed, given the high level of uncertainty due to poor and little scientific information. A more generic risk-oriented approach, giving more weight to hazard profiles of substances, would better ensure adequate protection, while encouraging developers (of substances, nano-particles, and products containing them) to improve scientific information prior to placing products on the market (Group 4).

- Opposition to specific risk assessment:
  - The basis for risk assessment is the un-scientific belief that risk can be foreseen and controlled. In an infinitely complex system, such as chemicals, the risk is simply impossible to anticipate. The unknown factors are usually far too many and impossible to foresee. The unforeseeable cannot be predicted nor assessed (Group 3);
  - Due to the enormous limitation of exposure assessment for chemicals with a widespread exposure, risk management measures should be taken based on the identified hazard classification using generic risk considerations. This is because specific risk assessments are not suitable for all uses of hazardous substances. Secondly, generic risk considerations will not generally result in an automatic ban. In most cases generic risk considerations will lead to a reversal of proof on the economic operator to establish that the intrinsic hazard of the substance can be managed, or the socio-economic benefits outweigh a ban. Positive examples of chemical legislation that are based on generic risk considerations are the Plant Protection Products Regulation (Regulation (EC) 1107/2009) (PPPR) and the Biocidal Products Regulation (Regulation No 528/2012) (BPR). The PPPR and the BPR provide an effective way to regulate the manufacture and use of EDC and PBT substances by ensuring that substances are not put on the market, unless the economic operator can prove that a specific exception applies (Group 4);
  - Directive 98/83/EC (Drinking Water Directive) sets quality standards for pesticides applicable to water intended for human consumption at a maximum of 0.1µg/l. This standard takes no account of the variation in chemical properties of the 484 substances currently approved as pesticides in the EU. An individual standard for each pesticide based on its hazard would be more scientific and present cost savings for water treatment across the EU (Group 4);

- Advocate widening the range of uses that are covered by generic risk assessments (or hazard based exclusion provisions), particularly focussing on situations where there is exposure of the general public and the environment. Important areas for extension include, but are not limited to, food contact materials, toys, furniture and certain construction materials (Group 3).

- Opposition to generic risk considerations:
  - Where a more generic approach is adopted, situations develop whereby properly controlled chemical use is prohibited. This leads to the unfortunate scenario where processes that do use hazardous chemicals are prohibited from happening in Europe and they end up being relocated to other jurisdictions where the level of national control is much lower. This has two very serious consequences; loss of competitiveness for Europe and greater level of exposure to less developed jurisdictions (Group 2);
  - A blanket ban, i.e. hazard-based prohibition of CMR 1A and 1B substances in cosmetic products would lead to absurd situations, for example with ethanol (alcohol). Ethanol is widely used in cosmetic products, and its classification as CMR of category 1 has been proposed several times over the past years. Without an exemption from the terms of Art. 15.2 based on risk assessment, such classification would result in the prohibition of the use of ethanol in cosmetic products, whilst alcohol-containing food and beverages would not be affected by this classification, and consumers could continue to use such products and expose themselves to much higher quantities of ethanol than through the application of perfumes and other ethanol-containing cosmetics on the skin (Group 2);

Support for hazard-based risk management (risk management based on generic risk considerations) tends to come from parts of Group 4 and a sub-set of Group 3. There were six themes from the non-questionnaire responses that support generic risk considerations (four from Group 3 and two from Group 4). There were nine positive themes from the OPC responses (four from Group 3 and six from Group 4[15]). In contrast, there were three negative themes from the non-questionnaire responses (from Group 2) and two negative themes from the OPC responses (three Group 2 responses commented on these themes). The negative themes include: 'restricting chemicals based on their hazardous properties could deny major benefits' with this related to the comments that 'chemical substitution decisions should be the result of comparative risk assessment and that risk assessment should consider exposure and risk mitigation measures'; 'hazard-based approaches result in companies having to take action where none is necessary'; and 'Hazard based decisions give rise to excessive management burdens'.

In terms of other comments, there are some common themes as follows:

- Comments on assessment of cumulative effects and mixtures:
  - Single substance risk assessment is not adequate (Group 4);
  - Risk assessments ignore mixtures and do not adequately consider chemicals for multiple sources (Group 4);
  - Risk assessment tends to look at one chemical at a time and at one route of exposure at a time (Group 4);

[15] One positive theme was agreed with by two 'other' respondents.

- Cumulative risk assessment approach should be undertaken addressing the cumulative effects from combined exposures (Group 4);
- The cocktail effect is not evaluated (Group 3).

- Comments on information used in risk assessment:
  - Risk assessment should be based on weight of evidence (Group 2);
  - Risk assessment should be based on the weight of all available evidence (Group 2);
  - Consideration should be given to the full range of scientific studies (Group 2);
  - Risk assessment requires access to more data and is time consuming (Group 2; Group 4).

- Comments on Biocidal Products Regulation:
  - Assessment processes under BPR focus on worst case scenarios (Group 2); and
  - BPR is too general to consider specific needs (Group 2).

There is also a conflict between two themes related to cut-off criteria. The theme from Group 4 states that 'Cut-off criteria give clear guidance to industry'. The theme from Group 2 comments that 'Cut-off criteria result in the loss of important PPP substances for no valid scientific reason'.

3.3.11 Question 15: Are all relevant considerations taken into account in regulatory decision-making on risk management?

3.3.11.1 Analysis of closed question responses

Respondents were asked to identify if they thought that all relevant considerations are taken into account, including combined effects of chemicals, impacts on vulnerable groups, impacts on jobs and competitiveness, etc. In total, there were 296 responses to this question. The results are presented in Table 3-29. The table shows that the vast majority of Group 2 (72% or 130), Group 3 (71% or 27) and Group 4 (85% or 39) replied 'no', that they did not think all relevant considerations are taken into account in regulatory decision-making on risk management. No was the most common response for Group 1 but with a much lower percentage (45% or 14 respondents). Group 1 had the highest percentage that answered 'yes', at 29% (9) followed by Group 3 at 24% (9) and Group 2 at 18% (32). Only 4% (2) of Group 4 answered 'yes', with this lower than the proportion of respondents who replied 'don't know'.

Table 3-29: Extent to which respondents agreed that all relevant considerations are taken into account (n=296)

Response	Group 1 (citizens) (n=31)		Group 2 (industry) (n=181)		Group 3 (public authority) (n=38)		Group 4 (NGO/others) (n=46)	
	No.	%	No.	%	No.	%	No.	%
Yes	9	29%	32	18%	9	24%	2	4%
No	14	45%	130	72%	27	71%	39	85%
I don't know	8	26%	19	10%	2	5%	5	11%

3.3.11.2 Analysis of open text responses

Respondents were then asked to explain their answer using an open text box. In total 48 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-30. The table also shows which groups the comments were from.

Table 3-30: Q15: considerations taken into account in regulatory decision making themes from OPC responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Themes on impacts that are and are not considered	
Relevant considerations are taken into account for human health	Group 3 (1)
More guidance is needed	Group 3 (1)
Emphasis should be on risk not hazard	Group 2 (1)
Unintended consequences of risk management decisions do not receive sufficient consideration	Group 2 (1)
Technical feasibility should be taken into account in regulatory decision-making	Group 2 (2)
Exposure from different sources is not taken into account	Group 4 (1)
Chemicals' exposure pathways are unclear and not sufficiently assessed in regulatory decision making	Group 3
Themes on analyses that are and are not undertaken	
In general risk assessment fail to take into account the specific risk that chemicals pose to women and children	Group 4 (1)
Not clear how to take account of vulnerable groups / vulnerable groups are not sufficiently taken into account	Group 3 (1) Group 4 (1)
Concept of vulnerable groups is considered in standards	Group 2 (1)
Poor quality impact assessments undermine EU legislation	Group 2 (1)
Themes in relation to impact assessment an socio-economic impacts	
Specific adverse effects on minor economic activities or particular products are not considered	Group 2 (1)
Socio-economic analysis is needed in regulatory decision-making on risk management	Group 3 (1) Group 2 (7)
Impacts on jobs and competitiveness do not seem to be taken into consideration	Group 2 (10)
Poor quality impact assessments undermine EU legislation	Group 2 (1)
Where cost-benefit analysis has been undertaken this is often not considered during final voting stage	Group 2 (1)
Economic effects are taken into account during risk assessment but legislation is not foreseen at this point	Group 2 (1)
Limit values of substances insufficiently consider the socio-economic impacts	Group 2 (1)
Themes in relation to combination effects	
Knowledge on effects of mixtures is incomplete	Group 1 (1)
Addressing the toxicity of single substances through risk management measures also controls any risks when they are in combination with other substances	Group 2 (1)
There is a lack of adequate exposure information	Group 4 (1)
Themes in relation to taking account of new science and data	
Knowledge and data availability on emissions is patchy	Group 1 (1)
The physical/chemical limit of substitution needs to be recognised	Group 2 (1)
The software for calculation within CLP may not be correct; outcomes do not correspond with tests	Group 2 (1)
More emphasis is needed on developing and implementing non-animal test strategies	Group 4 (1)

Table 3-30: Q15: considerations taken into account in regulatory decision making themes from OPC responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Commission should stimulate cooperation between European universities to strengthen knowledge in toxicology, ecotoxicology and risk management	Group 4 (1)
Themes on difficulties and complexities of legislation	
Difficult to implement obligation for employers to assess the risk of combination of all present chemical agents	Group 3 (1)
It is unclear if it is the substance or the active substances that should be the basis for classification of trace elements	Group 2 (1)
A deeper understanding is needed of how chemicals are used and which legislation to apply	Group 2 (1)
The high volume of legislation and updates makes it difficult to gather and make connections	Group 2 (1)
Risk management decisions can come from different pieces of legislation for a substance or mixture	Group 2 (1)
Themes on gaps	
Precise listing of materials targeted is needed not generic references	Group 2 (1)
Uncertainties are not adequately dealt with	Group 4 (1)
There is a lack of information on hazardous properties of most chemicals	Group 4 (2)
The Commission has not set scientific criteria for endocrine disruptors	Group 4 (1)
EU is late and reluctant to regulate nanomaterials	Group 4 (1)
Themes on grouping of substances	
No specific comments received	
Themes on consistency of interpretation, implementation, etc.	
Specific uses should be regulated, rather than substances	Group 3 (1)
Certain Directives are not homogenously implemented across Europe	Group 2 (2)
Risk management can be too political or driven by poorly informed committees	Group 2 (1)
Risk management should be based on scientific facts	Group 2 (1)
Sufficient risk management is achieved through national regulation on top of EU level legislation	Group 2 (1)
Commission rulings are not adhered to and there is no mechanism to impose such rulings on Member States	Group 2 (1)
Decisions are not based on the precautionary principle	Group 4 (1)
Other themes	
Often there is no major risk for accidents for products classified as dangerous under Seveso III Directive	Group 2 (1)
Bioavailability is not considered in Seveso III Directive*	Group 2 (1)
Labelling/restriction should be favoured as a valid regulatory alternative to a ban	Group 2 (1)
There are no established limits or measurement equipment for level of odour for some chemicals	Group 2 (1)
It is the responsibility of the chemical manufacturer to give advice and recommendations for use for product safety	Group 2 (1)
Current legislation favours large enterprises over SMEs	Group 4 (1)
*This comment is not correct as bioavailability should be taken into account in the hazard classification of	

Table 3-30: Q15: considerations taken into account in regulatory decision making themes from OPC responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
substances. Also this is an aspect that could be considered in the safety report.	

3.3.11.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-31 provides a summary of the themes from these non-questionnaire responses.

Table 3-31: Q15: considerations taken into account in regulatory decision making themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on impacts that are and are not considered	
Impacts on competitiveness are not considered in the context of regulatory decision making	Group 2 (industry)
Societal benefits of products are insufficiently considered under BPR[1]	Group 2 (industry)
Themes on analyses that are and are not undertaken	
Detailed cost-benefit analyses (CBA) are not conducted during approvals process	Group 2 (industry)
Where CBA has been undertaken these are not always considered during final voting stage of new legislation	Group 2 (industry)
Themes on treatment of combination effects	
The chemical legislation does not in general take into account the exposure to multiple substances	Group 3 (public authority)
Additional uncertainty factors are needed to address risks from cumulative exposures for some substance groups.	Group 4 (NGO/others)
Mixture/combination effects and the impact of chemicals on vulnerable groups are part of risk assessment not risk management, whereas impact on competitiveness relates to risk management decisions	Group 2 (industry)
Wildlife and humans are now exposed to many different substances from a whole range of consumer and other products. Many of these chemicals will have additive action at specific endpoints. Single substance risk assessment is not adequately protective to account for possible mixture effects	Group 4 (NGO/others)
Themes in relation to taking account of new science and data	
Provision of the chemicals legislation are not sufficiently updated in relation to new scientific data	Group 3 (public authority)
Some chemicals have not been re-tested using up to date methods.	Group 4 (NGO/others)
Themes on difficulties and complexities of legislation	
Methods of legislating in complex areas such as articles need to be reassessed	Group 3 (public authority)
Themes on gaps	
Not all chemicals used in food contact materials are covered in EU laws	Group 4 (NGO/others)
Regulation of non-harmonised materials is dependent on national legislation	Group 4 (NGO/others)
There is a need to provide specific regulations for nanomaterials	Group 3 (public authority)

Table 3-31: Q15: considerations taken into account in regulatory decision making themes from non-questionnaire responses (n=9)	
Theme	**By**
For industrial chemicals the information requirements below 100 tpa are not sufficient to allow for classification of all endpoints, in particular for suspected SVHC[2] properties	Group 4 (NGO/others)
Themes on grouping of substances	
The grouping of substances facilitates prioritization and later a regulation of substances for a better protection of human health and the environment.	Group 3 (public authority)
Requirements and procedures for the evaluation of groups of substances should be developed by taking into account lessons learnt from relevant evaluations	Group 3 (public authority)
Themes on consistency of interpretation, implementation, etc.	
Risk management decisions vary even when based on the same scientific data will rightly vary between societies	Group 2 (industry)
The clarity of legal text and/or ways to implement it is affected by interpretation of the actors, affecting consistency	Group 2 (industry)
Improvements could be made to increase consistency between different actors involved in the framework	Group 2 (industry)
Generation of guidance using expert groups involving all actors is a good, practical way forward	Group 2 (industry)
Article 95 mandates usefully highlight differences in process, functioning and transparency, triggering consistency but are burdensome	Group 2 (industry)
Improvements could still be made in preparing e.g. response to comments documents, better justifications for specific legal acts	Group 2 (industry)
Taking relevant and evidence-based decisions requires the possibility to assess the evidence (time and resources), to debate the relevance with involved actors & experts	Group 2 (industry)
Other themes	
Suggestion in new General Product Safety Directive that applies even to environmental risks	Group 3 (public authority)
Efforts are clearly made to increase transparency, which is now rather satisfactory	Group 2 (industry)
Notes: [1] BPR = Biocidal Products Regulation. [2] Substances of Very High Concern = SVHC.	

3.3.11.4 Comparison of themes

The comparison of themes associated with the relevant considerations are summarised in Table 3-32 below. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-32: Comparison of responses on relevant considerations taken into account in regulatory decision-making			
Non-questionnaire responses		OPC responses	
Sufficiently considered	Not sufficiently considered	Sufficiently considered	Not sufficiently considered
Jobs and/or competitiveness			
	Group 2 (1)		Group 2 (11)
Societal benefits			
	Group 2 (1)	Group 3 (1)	
Vulnerable groups			
	Group 2 (1)	Group 2 (1)	Group 3 (1) Group 4 (1)
Cost-benefit analysis/socio-economic analysis			
	Group 2 (2)		Group 3 (1) Group 2 (10)
Combination effects			
	Group 3 (1) Group 2 (1) Group 4 (1)	Group 2 (1)	Group 1 (3) Group 3 (2) Group 2 (3) Group 4 (6)
New science and data			
	Group 3 (1) Group 4 (1)		Group 1 (1) Group 2 (3) Group 4 (2)
Gaps			
	Group 3 (1): nanomaterials Group 4 (1): information requirements for below 100tpa to allow for classification for all endpoints		Group 2 (1): unintended consequences Group 2 (2): technical feasibility Group 4 (1): uncertainties Group 4 (2): exposure information Group 4 (1): nanomaterials Group 4 (1): endocrine disruptors
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from Question 5 of the OPC			

The table shows that most comments highlight issues that are currently considered to be insufficiently covered in regulatory decision-making. There are a large number of comments on the lack of consideration of jobs and competitiveness, and cost-benefit analysis/socio-economic analysis from Group 2. Combination effects are also thought to be insufficiently considered by Group 1 (3 comments), Group 2 (3), Group 3 (2) and Group 4 (6). Some of the key comments illustrating these points include:

- Comments on consideration of jobs and/or competitiveness:
    - Regarding beryllium, there is an ongoing decision for a European Occupational Exposure Limit (OEL). If this European limit is too low compared to the current national limits…there can be an impact on economic activities, employments, competitiveness and innovation (Group 2);

- Inception impact assessment should be systematic and better address employment and competitiveness issues across the industry chain (Group 2);
- Impacts on competitiveness of EU industry are generally not considered in the context of regulatory decision making on risk management. At best, these impacts are estimated before the main legislative act is proposed by the Commission to Parliament and Council – but not necessarily considered when the rules are finally adopted and become law or when they are implemented (Group 2).

- Comments on cost-benefit analysis/socio-economic analysis:
  - For example in the Biocidal Products Regulation SEA [socio-economic assessment] could be useful when Member States, ECHA and the Commission decide to not approve an active substance. By SEA it is possible to estimate the impact related to the prohibition of using an active substance (Group 3).

- Comments on combination effects:
  - The combined effects and vulnerable groups are mentioned in occupational safety and health legislation but it is not very clear how to enforce them (Group 3);
  - The evidence to date indicates that even when combined chemical exposures are found to potentially pose a risk, these are more often than not found to be driven by only one or just a few of the chemicals within the combination. In most of these cases, existing risk assessment processes and regulations are considered to be sufficient to identify and address the risk posed (Group 2);
  - There is no scientific justification to assume that the use of two or more PPPs produce anything more than additive effects (Group 2).

- Comments on vulnerable groups:
  - In general, risk assessments do not take into account the specific risk that chemical substances, including EDCs, pose to women and children. For instance, under the Pregnant Workers (Directive 92/85/EEC) EDC substances are not even identified as a risk and therefore there is no obligation on employers to reduce exposure (Group 4);
  - Ecotox-criteria seem not to be taken into account well enough due to lack of relevant criteria on population levels when there is no acute risk or even a chronic individual risk (Group 4);
  - 'Laundry detergent labelling of only some ingredients and only in percentage range quantities makes it difficult for me to see which ingredients may be triggering my child's allergy. It means if I find a product that is OK I have to keep buying it and can't explore other options (Group 1).

- Comments on new science and data:
  - The EU's current system of evaluating and managing chemicals hazards is outdated and not in line with the latest scientific findings in particular with regard to mixture toxicity, hormone-disrupting chemicals and nanomaterials (Group 4).

3.3.12 Question 16: To what extent are the following elements of the overall EU legislative framework for chemicals satisfactory?

3.3.12.1 Analysis of closed questions

Respondents were asked to assign a score of 1 (not satisfactory) to 5 (very satisfactory) across 12 different elements. There were between 279 and 285 responses to this question, depending on the

specific element. The results are presented in Table 3-33 by element and by group. Table 3-34 presents weighted scores by group and by element.

Table 3-33: Number and percentage of respondents by level of satisfaction with elements of the overall EU legislative framework (n=279 to 285)									
Group	Satisfaction score	Element a: transparency of procedures (n=285)		Element b: speed with which hazards/risks are identified (n=281)		Element c: speed with which identified risks are addressed (n=278)		Element d: time to allow duty holders to adapt (n=283)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=24 to 26)	1	7	27%	4	16%	3	12%	4	15%
	2	6	23%	5	20%	6	23%	0	0%
	3	3	12%	6	24%	4	15%	4	15%
	4	3	12%	1	4%	2	8%	4	15%
	5	0	0%	0	0%	0	0%	2	8%
	Don't know	7	27%	9	36%	11	42%	12	46%
2 (industry) (n=175 to 180)	1	17	9%	3	2%	5	3%	36	20%
	2	31	17%	18	10%	28	16%	63	35%
	3	52	29%	66	38%	45	26%	54	30%
	4	54	30%	48	27%	57	33%	17	9%
	5	16	9%	19	11%	20	11%	1	1%
	Don't know	10	6%	22	13%	20	11%	8	4%
3 (public authority) (n=33 to 34)	1	0	0%	2	6%	6	18%	0	0%
	2	4	12%	10	29%	6	18%	1	3%
	3	8	24%	11	32%	15	44%	13	38%
	4	16	47%	11	32%	7	21%	11	32%
	5	4	12%	0	0%	0	0%	5	15%
	Don't know	2	6%	0	0%	0	0%	4	12%
4 (NGO/ others) (n=43 to 46)	1	10	22%	15	33%	20	47%	1	2%
	2	12	27%	9	20%	4	9%	6	14%
	3	11	24%	11	24%	9	21%	6	14%
	4	9	20%	6	13%	6	14%	8	18%
	5	1	2%	1	2%	0	0%	13	30%
	Don't know	2	4%	4	9%	4	9%	10	23%
Group	Importance score	Element e: predictability of the outcomes (n=279)		Element f: stability of the legal framework (n=279)		Element g: clarity of the legal texts (n=281)		Element h: guidance documents and implementation support (n=281)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=24 to 26)	1	4	16%	2	8%	6	25%	5	20%
	2	3	12%	3	12%	1	4%	5	20%
	3	3	12%	2	8%	7	29%	3	12%
	4	1	4%	6	24%	3	13%	4	16%
	5	1	4%	2	8%	0	0%	0	0%
	Don't know	13	52%	10	40%	7	29%	8	32%
2 (industry) (n=175 to 180)	1	57	32%	19	11%	15	8%	28	16%
	2	66	37%	49	28%	50	28%	35	20%
	3	28	16%	55	31%	74	41%	44	25%
	4	8	5%	38	21%	29	16%	55	31%
	5	1	1%	6	3%	5	3%	13	7%

Table 3-33: Number and percentage of respondents by level of satisfaction with elements of the overall EU legislative framework (n=279 to 285)									
	Don't know	17	10%	10	6%	6	3%	4	2%
3 (public authority) (n=33 to 34)	1	1	3%	0	0%	1	3%	1	3%
	2	5	15%	0	0%	7	21%	7	21%
	3	11	33%	11	32%	17	50%	11	32%
	4	9	27%	17	50%	7	21%	8	24%
	5	0	0%	4	12%	2	6%	6	18%
	I don't know	7	21%	2	6%	0	0%	1	3%
4 (NGO/ others) (n=43 to 46)	1	3	7%	0	0%	2	5%	0	0%
	2	8	18%	3	7%	9	20%	6	14%
	3	12	27%	11	26%	22	50%	25	58%
	4	4	9%	9	21%	7	16%	10	23%
	5	7	16%	14	33%	1	2%	0	0%
	Don't know	10	23%	6	14%	3	7%	2	5%
Group	**Importance score**	**Element i: effective implementation and enforcement across Member States (n=281)**		**Element j: consistent implementation and enforcement across Member States (n=281)**		**Element k: public awareness and outreach (n=281)**		**Element l: international collaboration and harmonisation (n=279)**	
		No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
1 (citizens) (n=24 to 26)	1	6	24%	7	27%	8	31%	8	31%
	2	5	20%	5	19%	6	23%	7	27%
	3	6	24%	3	12%	1	4%	1	4%
	4	1	4%	2	8%	1	4%	2	8%
	5	0	0%	0	0%	4	15%	0	0%
	Don't know	7	28%	9	35%	6	23%	8	31%
2 (industry) (n=175 to 180)	1	32	18%	47	27%	14	8%	30	17%
	2	53	30%	62	35%	53	30%	54	31%
	3	62	35%	33	19%	60	34%	46	26%
	4	7	4%	7	4%	31	18%	18	10%
	5	8	4%	7	4%	7	4%	6	3%
	Don't know	16	9%	21	12%	12	7%	22	13%
3 (public authority) (n=33 to 34)	1	1	3%	1	3%	2	6%	0	0%
	2	6	18%	10	29%	8	24%	4	12%
	3	10	29%	8	24%	17	50%	13	38%
	4	6	18%	6	18%	6	18%	12	35%
	5	3	9%	2	6%	0	0%	0	0%
	Don't know	8	24%	7	21%	1	3%	5	15%
4 (NGO/ others) (n=43 to 46)	1	4	9%	3	7%	12	27%	0	0%
	2	12	27%	15	34%	19	43%	12	28%
	3	19	43%	17	39%	7	16%	9	21%
	4	1	2%	1	2%	3	7%	13	30%
	5	0	0%	0	0%	0	0%	1	2%
	Don't know	8	18%	8	18%	3	7%	8	19%

Table 3-34: Weighted scores based on number and percentage of respondents identifying level of satisfaction with elements related to chemical legislation (n=279 to 285)				
Element	Group			
	Group 1 (citizens) (n=24 to 26)	Group 2 (industry) (n=175 to 180)	Group 3 (public authority) (n=33 to 34)	Group 4 (NGO/others) (n=43 to 46)
16a) Transparency of procedures	2.1	3.1	3.6	2.5
16b) Speed with which hazards/risks are identified	2.3	3.4	2.9	2.3
16c) Speed with which identified risks are addressed	2.3	3.4	2.7	2.0
16d) Time to allow duty holders to adapt	3.0	2.3	3.7	3.8
16e) Predictability of the outcomes	2.3	1.9	3.1	3.1
16f) Stability of the legal framework	3.2	2.8	3.8	3.9
16g) Clarity of the legal texts	2.4	2.8	3.1	2.9
16h) Guidance documents and implementation support	2.4	2.9	3.3	3.1
16i) Effective implementation and enforcement across Member States	2.1	2.4	3.2	2.5
16j) Consistent implementation and enforcement across Member States	2.0	2.1	2.9	2.4
16k) Public awareness and outreach	2.4	2.8	2.8	2.0
16l) International collaboration and harmonisation	1.8	2.5	3.3	3.1
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the level of satisfaction placed by each group as a whole on chemical legislation. The calculation excludes don't know responses				

Table 3-34 provides a summary of results that makes it easier to compare across elements and groups. Overall, the results are:

- Lowest levels of satisfaction:
  - International collaboration and harmonisation: Group 1 assigns a score of 1.8 (26 responses). Group 2 is the next lowest at 2.5 (279) for this element with Group 4 at 3.1 (43) and Group 3 at 3.3 (34);
  - Predictability of the outcomes: Group 2 assigns a score of 1.9 (177 responses). Group 1 assigns a score of 2.3 (26) with Group 3 and at 3.1 (33) and Group 4 also at 3.1 (44);
  - Speed with which identified risks are addressed: Group 4 assigns this a score of 2.0 (43 responses). This statement gets a score of 2.3 from Group 1 (26) and 2.7 from Group 3 (34) but a relatively high score of 3.4 from Group 2 (175). The score of 2.7 is the lowest score assigned by Group 3;
  - Public awareness and outreach: this is the equal lowest score from Group 4 (2.0 from 46 responses). Scores from the other groups range from 2.4 from Group 1 (26) to 2.8 from both Group 2 (177) and Group 3 (34).

- Highest levels of satisfaction:
  - Stability of the legal framework: this gets the highest score from Group 1 of 3.2 (25). This element also has the highest satisfaction score from Group 3 of 3.8 (34) and Group 4 (3.9 from 43 responses). Group 2 assigns a score of 2.8 from 177 responses;
  - Transparency of procedures: this gets the second highest score from Group 3 of 3.6 (34). The range of scores across the other groups is from 2.1 from Group 1 (26) to 3.1 from Group 2 (180);
  - Speed with which hazard/risks are identified: this scores 3.4 from Group 2 (176). The score from Group 2 is the highest of all four groups with Group 4 assigning the equal lowest score of 2.3 (46) with Group 1 (25). Group 3 assigns a score of 2.9 (34);
  - Speed with which identified risks are addressed: this scores 3.4 from Group 2 (175) and is one of two elements that received the highest score from Group 2. The scores of 2.0 assigned by Group 4 (43) and 2.3 from Group 4 (26) are the lowest for this statement.

3.3.12.2 Analysis of open text responses

Respondents were also asked to explain their answers and list any other aspect they consider relevant. In total 48 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-35. The table also shows which groups the comments were from.

Table 3-35: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)

Theme	By
Themes that are positive about the legislative framework	
Move from Directives to Regulations has led to reduction in differences between Member States	Group 2 (1)
Themes that are generally negative about the legislative framework	
Different sections of legislation are contradictory or inconsistent	Group 3 (1)
Regulatory framework for BPR[1] does not appear sufficiently thought through	Group 1 (1)
Interlinkages between CLP and other EU sectoral legislation can trigger automatic risk management measures with unintended consequences	Group 2 (1)
Interpretation of Article 15 of Cosmetic Products Regulation means substances classified as CMR[2] are automatically banned	Group 2 (1)
Solutions supporting bulk notifications are not very efficient	Group 2 (4)
There needs to be a focus on making chemical legislation more specific	Group 2 (1)
Evaluation procedures are very long leaving people and the environment exposed to substances	Group 2 (1) Group 4 (1)
Compliance with the Regulations is impossible without professional legal advice at high cost	Group 2 (1)
Definitions and requirements are not used consistently across legislation	Group 4 (2)
Need for automatic linkages between regulation so when a substance is regulated in one framework there is an alert all relevant bodies and trigger action	Group 4 (1)
Different pieces of legislation do not use each other's evaluations leading to unnecessary work and inconsistency	Group 4 (1)
Themes related to issues with gaps and omissions	
There is no method to assess imported products so objectives of POP[3]	Group 2 (1)

Table 3-35: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
regulation are not met	
There are no incentives in WFD[4] to influence upstream regulation	Group 4 (1)
Companies should be able to self-classify where there are no harmonised classifications	Group 4 (1)
Themes related to issues with time	
Arbitrary nature of classification by hazard is difficult to manage and causes delays and conflicts	Group 1 (1)
There is adequate time to adapt as the legislative updates are slow	Group 1 (1) Group 4 (1)
Companies can have short times to implement new decisions and it is often not easy to understand legal texts	Group 3 (1) Group 2 (4)
Speed of hazard/risk identification should be linked to complexity and availability of information	Group 2 (1)
Deadlines imposed on businesses are often shorter than the output of the texts or that implementation of accompanying texts	Group 2 (1)
Transition periods for ATPs[5] should be longer than 18 months	Group 2 (1)
Complexity of supply chains is not taken into consideration in determining times within which companies have to adapt	Group 2 (1)
Timelines for hazard identification and management are unacceptably slow	Group 4 (4)
Overhaul of the General Product Safety Directive and Market Surveillance system is unacceptably slow	Group 4 (2)
Themes related to issues with consistency, certainty and predictability	
The lack of consistency throughout EU impacts on legal certainty and predictability	Group 2 (1)
Third countries develop EU-like initiatives without harmonisation leading to important inconsistencies	Group 2 (1)
Rules/interpretations are constantly changing leading to legal uncertainty	Group 2 (6)
There is a lack of outcome predictability, especially at stages which precede decision-making	Group 2 (1)
Many suppliers of treated articles are unaware the BPR affects them	Group 2 (1)
ECHA should be in charge of all evaluations to avoid overlaps	Group 4 (1)
Themes related to issues on transparency and clarity	
SCOEL[6] does not operate in a transparent manner	Group 3 (1)
Carcinogen and mutagen directive lack clarity in the text	Group 3 (1)
There should be global common principles for information sharing	Group 2 (1)
Biocide active substance review is not transparent nor predictable	Group 2 (2)
BPR is not very transparent due to lack of clarity in the legislation and guidance and due to changing regimes	Group 2 (3)
The rationale behind charging regimes for the BPR is not set out	Group 2 (1)
There is no possibility for obsoleting notifications and no clarity on obligations for substances no longer in a company portfolio	Group 2 (4)
TTIP[7] and chemicals negotiations are not transparent	Group 4 (2)
Lack of transparency due to refusal of EFSA to publish industry studies on which opinions are based	Group 4 (1)
Lack of transparency on animal welfare, procedures and decisions	Group 4 (1)

Table 3-35: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Raw data and data underlying assessments should be made available to the public	Group 4 (NGO/others)
Themes related to issues of wording and drafting	
All chemical legislation must use 'regulation' as legislative instrument	Group 3 (public authority)
Generic terms lead to different interpretations of materials that should be considered	Group 2 (industry)
Themes related to issues on guidance	
Quality and relevance of guidance is variable	Group 1 (citizens) Group 3 (public authority)
Guidance needs to be in native languages	Group 1 (citizens) Group 4 (NGO/others)
All chemical legislation must have guidance documents and implementation support	Group 3 (public authority)
Need more examples of good practice on implementation of regulatory risk management measures	Group 3 (public authority)
FAQ documents are essential for helping to understand the legal requirements	Group 2 (industry)
Infocards can be misleading	Group 2 (industry)
Lack of guidance for users/producers of some chemicals	Group 2 (industry)
Guidance should be provided on a more scientifically robust weight-of-evidence approach	Group 2 (industry)
There is too much guidance	Group 2 (industry)
Guidance documents are sometimes contradictory with the legal test or go further than the legal requirements	Group 2 (industry)
Themes related to implementation and enforcement	
Implementation of chemical agents directive is not clear	Group 3 (public authority)
Transposition and implementation of directives is not consistent among Member States	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Effectiveness of implementation and enforcement is inconsistent between Member States	Group 2 (industry) Group 4 (NGO/others)
Implementation of regulations is mostly consistent across Member States but interpretation and enforcement are not streamlined	Group 2 (industry)
Wide variation in compliance and surveillance amongst Member States	Group 4 (NGO/others)
Themes related to harmonisation	
There should be a harmonised classification of substances under the UN-GHS	Group 1 (citizens) Group 4 (NGO/others)
There is a barrier in national specifications that affects harmonisation	Group 2 (industry)
Regional differences in GHS implementation add complexity to supply chain communication	Group 2 (industry)
Lack of harmonised test methods and pass/fail criteria affect biocide efficacy	Group 2 (industry)
Some endpoints of concern are not covered by CLP, result in CLP not being “harmonised” with other chemicals legislation	Group 4 (NGO/others)
Themes related to issues on innovation and substitution	
Assessment should be performed for groups of chemicals with similar properties to speed up the process	Group 4 (NGO/others)

Table 3-35: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=48; Group 1 (citizens) = 5, Group 2 (industry) = 28, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Other themes	
ECHA needs to engage more directly with individual stakeholders	Group 2 (industry)
Contamination through diffuse presence of PFOS[8] in waterways may contaminate products that require water for processing	Group 2 (industry)
Too much or too detailed information could mean insufficient information is conveyed and assimilated and could mean critical requirements are not considered	Group 2 (industry)
International collaboration is needed in sharing of data and testing techniques	Group 4 (NGO/others)
Notes: [1] BPR = Biocidal Products Regulation. [2] CMR = Carcinogen, Mutagens and Reprotoxins. [3] POP = Persistent Organic Pollutant. [4] WFD = Water Framework Directive. [5] ATP = Adaptation to Technical Progress. [6] SCOEL = The Scientific Committee on Occupational Exposure Limits. [7] TTIP – Transatlantic Trade and Investment Partnership. [8] PFOS = Perfluorooctane Sulfonate	

3.3.12.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-36 provides a summary of the themes from these non-questionnaire responses.

Table 3-36: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes that are positive about the legislative framework	
Transparency is better than before	Group 3 (public authority)
It is very important that there is EU legislation on chemicals	Group 3 (public authority)
Implementation of GHS would not have reached the level of harmonisation it has achieved or been cost effective for the EU member states in any other way	Group 3 (public authority)
EU legislation also enables work-sharing and avoiding of the double work that occurred before EU legislation was enacted	Group 3 (public authority)
Chemical-related legislation has been quite effective in achieving a well-functioning internal market	Group 3 (public authority)
The legislation has also been effective to a certain extent in protecting human health and the environment	Group 3 (public authority)
EU chemicals legislation is based on good principles and is well developed in many ways, especially for human health	Group 3 (public authority)
There are significant benefits generated for EU society by the EU chemical and chemical related legislation that offset some of the costs involved	Group 3 (public authority)
Certain that without the legislation there would be other costs (maybe greater) e.g. increased burden on health services and environmental clean-up	Group 3 (public authority)
The consensus was that overall the legislative framework had made an effective contribution to meeting its objectives and that this was reflected in improvements over time in human wellbeing and in environmental health when compared to other major industrialised counties outside the EU which do not have comparable regulatory frameworks	Group 4 (NGO/others)

Table 3-36: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
Current framework includes appropriate tools to meet the primary objective	Group 2 (industry)
The Regulation allows decisions to be made by the Commission that give legal certainty	Group 3 (public authority)
Little innovation happens in chemical sectors without legal restrictions being imposed	Group 3 (public authority)
The legislation should in theory be able to stimulate competitiveness and innovation	Group 3 (public authority)
The BPD[1], BPR[2] and REACH have and will go much further in reducing risks in the home through heightened awareness of risks from chemical products and chemicals in articles than would have occurred without EU level regulation	Group 3 (public authority)
Shift of 'burden of proof' to industry and the generation of data and emphasise industry's responsibilities, exerting a positive impact on the set up and functioning of a correct chemicals framework	Group 2 (industry)
We did not note a major shift in the trade of chemicals due to REACH, although authorisation requirements have led to the import of articles containing the substances over local manufacturing	Group 2 (industry)
Themes that are generally negative about the legislative framework	
Technical complexity means public are not aware of implications of chemicals legislation	Group 3 (public authority)
There are certain aspects which are not dealt with sufficiently in the legislation	Group 3 (public authority)
Urgent need for consolidated EU chemicals framework	Group 2 (industry)
Registration and evaluation processes are going too slowly so chemicals continue to be used even though they will have their use restricted	Group 4 (NGO/others)
Not aware of any specific examples where the EU legislative framework for chemicals has contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	Group 2 (industry)
Risk management on restrictions does not seem very effective due to a lack of prioritisation	Group 2 (industry)
'One fits all' approach may compromise innovative or sustainable sectors' strengths and characteristics	Group 2 (industry)
The overall complexity of the framework affects its correct understanding and interpretation, discouraging also some key actors in continuing to invest in pro-active, anticipative chemicals management	Group 2 (industry)
Overlapping regulatory processes, inconsistencies push the people to a 'wait and see' position, limiting resources, rather than investing in data and assessments	Group 2 (industry)
The "registration" part of the Framework seems now to have completed its function (with the exception of updates, maintenance and dissemination) and resources could be better used for evaluation and risk management	Group 2 (industry)
Themes related to issues with gaps and omissions	
The European Commission has not fulfilled their legal obligation to deliver scientific criteria for identifying endocrine disruptors for decision making.	Group 3 (public authority)
Specific provisions for the protection of vulnerable groups such as born and unborn children and youths should be incorporated into all chemical legislation and not only that for toys.	Group 3 (public authority)
In order to obtain a toxic-free and resource-efficient recycling and to create a market for secondary material of high quality, the content of	Group 3 (public authority)

Table 3-36: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
hazardous substances in materials/articles must be addressed in the waste legislation	
A substance can be forbidden in making an article in the EU but permitted in imported articles. This can lead to confusion	Group 4 (NGO/others)
In many cases the analytical procedures have yet to be developed for the extraction and quantification of many substances of high concern in products	Group 2 (industry)
The means to achieve the same level of protection of human health and environment may differ and/or be adapted to specificities to ensure more efficiency	Group 2 (industry)
The more generalised a regulatory measure, the more difficulties it will have to cover and properly address all "relevant considerations"	Group 2 (industry)
Themes related to issues with time	
Companies have to react within very tight deadlines	Group 2 (industry)
Can take years to work through process to identify hazards and risks	Group 3 (public authority)
Risk identification can be quick if a risk has been identified through reporting of adverse symptoms	Group 3 (public authority)
Risk identification usually takes an extremely long time	Group 3 (public authority)
Themes related to issues with consistency, certainty and predictability	
Rules in the form of technical/regulatory guidelines or agreements on interpretation are constantly changing	Group 2 (industry)
Legal certainty and predictability is very low for biocides	Group 2 (industry)
Legal interpretations are rarely in writing and vaguely motivated	Group 3 (public authority)
When in writing, legal interpretations are not easy to find	Group 3 (public authority)
Outcomes may be less predictable when based on weight of evidence (expert judgements) and as science is evolving	Group 3 (public authority)
Widening the definition of 'negligible exposure' has resulted in unpredictability of approvals procedure	Group 3 (public authority)
There are particular problems with predictability in the biocide area	Group 3 (public authority)
Evaluators sometimes find unexpected problems when undertaking in-depth risk assessments	Group 3 (public authority)
There are issues with consistency and coherence, differences in 'level playing fields' and overload of parallel regulatory agendas	Group 2 (industry)
Themes related to issues on transparency and clarity	
Transparency varies depending on the procedure	Group 3 (public authority)
Transparency of comitology and delegated acts is poor	Group 3 (public authority)
Complicated legislation such as BPR needs better transparency through whole process	Group 3 (public authority)
Process of identification of PBT[3]/vPvB[4] substances is not transparent for general public	Group 3 (public authority)
Scope of the Biocidal Products Regulation is clearer but involves changes from scope of Biocidal Products Directive	Group 3 (public authority)
It can be difficult to identify the borderline between legislation	Group 3 (public authority)
It should be avoided that a scope is defined as everything that is not within the scope of other legislation	Group 3 (public authority)
The legislation is so complicated that a lot of room for diverging interpretation exists	Group 3 (public authority)

Table 3-36: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
Support transparency of procedures, expect all legislation to be sustainable, proportionate and workable as well as being consistently monitored and enforced equally across all Member States once implemented	Group 2 (industry)
Themes related to issues of wording and drafting	
Wording of certain provisions in PPPR[5] are in conflict with intended functioning of the legislation	Group 3 (public authority)
Some provisions of PPPR are too vague	Group 3 (public authority)
Simple language should be used	Group 3 (public authority)
There is a need for improvements in the field of legal drafting	Group 3 (public authority)
Linguistic/legal check on translations in insufficient	Group 3 (public authority)
There was insufficient attention to writing clear legal provisions	Group 3 (public authority)
Need for legal scrutiny	Group 3 (public authority)
There should be one simplified EU regulatory framework covering both environmental and occupational health exposures to chemical and hazardous substance	Group 2 (industry)
Themes related to issues on guidance	
Lack of clarity leads to attempts to find solutions in guidance documents, and can lead to incorrect interpretations	Group 3 (public authority)
Guidance and implementation support is difficult to find	Group 3 (public authority)
Best to gather guidance documents	Group 3 (public authority)
Need to review guidance so content is more accessible	Group 3 (public authority)
Themes related to implementation and enforcement	
The quality and the frequency of enforcement differs in different Member States	Group 3 (public authority)
To achieve an even higher level of protection for the human health and the environment there is a need for a better implementation and enforcement	Group 3 (public authority)
Lack of coherence in implementation and enforcement of some Directives and Regulations, results in differences between the Member States	Group 2 (industry)
Differences in levels and practices of enforcement render compliance with REACH country-specific, creating a barrier to a single market	Group 2 (industry)
Restrictions need to be implemented in the same way on both manufacture/uses of substances/mixtures/articles and their import	Group 2 (industry)
Themes related to harmonisation	
The level of international collaboration and harmonisation is highly variable	Group 3 (public authority)
Increased efforts are needed to increase harmonisation	Group 3 (public authority)
A fully harmonised system for regulating the use of chemicals in food contact materials is required [examples of key elements given]	Group 4 (NGO/others)
A harmonised EU chemicals legislation is necessary to uphold a high level of protection for human health and the environment	Group 3 (public authority)
Harmonised EU legislation also stimulates innovation when legal restrictions are being imposed to move the markets away from chemicals posing risk	Group 3 (public authority)
It is essential that there is joint policy coordination between the Commission's Directorates-General	Group 2 (industry)

Table 3-36: Q16: satisfaction with overall EU legislative framework for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
(DGs) to create a unified EU chemicals framework.	
To become a facilitating agent in international trade of chemicals, the EU chemicals framework should contribute to the respect of level playing field between different jurisdictions	Group 2 (industry)
Themes related to issues on innovation and substitution	
Although substitution may have led to a reduction in levels of some hazardous chemicals, this does not necessarily equate to greater safety	Group 2 (industry)
Resources are mainly invested in ensuring compliance or defensive actions, not on development of innovation	Group 2 (industry)
Other themes	
Commission needs to take action where Member Stes have been too generous in granting emergency authorisations (PPPR Article 53)	Group 3 (public authority)
We should not let the balance weigh heavier for competitiveness than for protection	Group 3 (public authority)
It is important to look at the consequences, including economic consequences, of not having EU chemical legislation, both where we have it and where we lack it	Group 3 (public authority)
It is difficult to develop a view on the overall effectiveness of EU legislative framework because the framework covers a wide range of complex legislation	Group 4 (NGO/others)
To become a facilitating agent in international trade of chemicals, the EU chemicals framework should present an added value	Group 2 (industry)
We are always dealing with currently estimated toxicity which may not be the same as the real toxicity	Group 4 (NGO/others)
The EU should not promote recycling of products containing persistent organic pollutants	Group 4 (NGO/others)
Correct functioning requires to address and involve efficiently all actors	Group 2 (industry)
Designing other modes of cooperation between all actors involved in the functioning may prove to be more beneficial	Group 2 (industry)
Further integration of Evaluation and Risk Management, a clear role for the RMOs[6], alternative options for Risk Management Measures such as voluntary agreements and Risk Management by use are new avenues to explore, so as to create a better momentum for Risk Management.	Group 2 (industry)
The inclusion of Chemicals management compliance should ideally become part of the management system of the company and a standard included in certification systems like for safety objectives and management.	Group 2 (industry)
It may be more efficient to promote the efficient collaboration with other EHS[7] or OSH[8] fields to create synergies	Group 2 (industry)
Stakeholders seem to be regularly consulted but the 'consultation tool' starts to be over-used, requiring in itself non-negligible resources	Group 2 (industry)
Notes: [1] BPD = Biocidal Products Directive. [2] BPR = Biocidal Products Regulation. [3] PBT = Persistant, Bioaccumulative, Toxic. [4] vPvB = very Persistent very Bioaccumulative. [5] PPPR = Plant Protection Products Regulation. [6] RMO = Risk Management Option. [7] EHS = Environmental Health and Safety. [8] OSH = Occupational Safety and Health	

3.3.12.4 Comparison of themes

The comparison of positive and negative themes in relation to the overall EU Legislative framework is summarised in the table below. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-37: Comparison of responses on satisfaction with overall EU legislative framework

Non-questionnaire responses		OPC responses	
Positive	**Negative**	**Positive**	**Negative**
Themes on the framework overall			
Group 3 (13) Group 2 (2) Group 4 (1)	Group 3 (2) Group 2 (8) Group 4 (1)	Group 2 (1)	Group 1 (1) Group 3 (1) Group 2 (9) Group 4 (5)
Key: others captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from question 5 of the OPC			

Table 3-37 shows that there is a significantly greater proportion of negative themes about the EU legislative framework under the OPC than from the non-questionnaire responses. In both cases, though, Group 2 responses tend to be more negative than positive. Some of the comments associated with positive and negative themes are:

- Comments that are generally negative about the EU legislative framework:
  - For example, the EU Biocidal Products Regulation 2012-528, the impression is that the regulatory framework is not sufficiently thought through (Group 1);
  - The interlinkages between the CLP Regulation (e.g. harmonized classification) and other EU sectoral legislation (or downstream legislation) can in some cases trigger automatic risk management measure(s) under sectoral / downstream legislation. This can have unintended consequences and create further uncertainty and unpredictability (Group 2);
  - Whilst the overall framework is satisfactory, there is one aspect which is of high concern to the cosmetics industry, namely the process regarding CMR substances (Group 2);
  - We believe the public awareness could be more satisfactory if there were an increased focus on making the chemicals legislation more specific. With a specific based legislation the arguments for why something is banned or restricted is easier for everyone in the chain to understand, accept and not least communicate (Group 2).

- Comments that are generally positive about the EU legislative framework:
  - The move from Directives to Regulations has certainly led to improvements but there are still differences between the interpretation of regulations as well as enforcement (Group 2).

Examples and further explanation of issues were also provided by respondents in terms of the factors that they were dissatisfied with. Illustrative comments include:

- Comments on gaps and omissions:
  - For example if the WFD is breached by a certain substance and its source is identified, WFR has no mandate to influence the regulation covering the actual source (Group 4);
  - When no harmonised classification exists, companies should do their own classification of their substance. As a start, these self-classifications should be used as triggers for harmonised classification (Group 4);
  - As a member of the public I don't know which ingredients are not explicitly listed and why. Apart from being unhelpful this serves to fuel suspicion and fear about 'nasty chemicals'. I understand that more ingredients are displayed in other EU countries and I don't know why (Group 1).

- Comments on issues related with time:
  - Under the EU biocides legislation, rules in the form of technical/regulatory guidelines or agreements on interpretation between competent authorities are constantly changing and their applicability can be immediate – with companies having to react within very tight deadlines (Group 2);
  - Constant changes still appear in the agreements between competent authorities to which companies have to adapt within very tight deadlines…Complexity of supply chains of products and long-lasting business contracts between suppliers with their customers is not well understood or taken into account when new provisions and restrictions are put in place with too short transitional periods (Group 2);
  - Timelines for hormone disrupters and nanomaterials are unacceptably slow. The Commission let various legal deadlines pass without taking satisfactory action on hormone disrupters for biocides, pesticides, cosmetics, waste water and is not taking sufficient action to address hormone disrupters in other consumer products (Group 4);
  - With regard to transparency, [we are] concerned about late notification/publication of specific obligations. Just recently the revised Annex II of the ELV Directive has been published in May 2016 with a phase out date on 1 January 2016 for lead in particular applications (exemption 8h). A publication date after a phase out date makes it extremely difficult for OEMs [Original Equipment Manufacturers] and impossible for suppliers (in particular if they are deeper in the supply chain) to adjust processes accordingly (Group 4).

- Comments related to consistency, certainty and predictability:
  - The interlinkages between the CLP Regulation (e.g. harmonized classification) and other EU sectoral legislation (or downstream legislation) can in some cases trigger automatic risk management measure(s) under sectoral / downstream legislation. This can have unintended consequences and create further uncertainty and unpredictability (Group 2);
  - Legal uncertainty remains in the EU, particularly surrounding which chemical substances will be targeted, when, and under which regime (Group 4).

- Comments associated with transparency and clarity:
  - The lack of clarity of legal texts has raised the need to produce massive amounts of guidance documents. There are plenty of guidance documents available.

Sometimes so much, that especially for SME's they are too massive and lack the practical approach (Group 2);
    - Every Member State has different implementing legislation, sometimes impossible to read as written only in local language (Group 1).

- Comments on wording and drafting:
    - The mention of the generic term "other coated materials" next to textiles for assessing PFOS on the surface rather than on the mass, lends to different interpretations on the materials that should be considered. This is also a problem for the effective and consistent implementation and enforcement of the rules applying to certain materials, coated or not (Group 2).

- Comments related to guidance:
    - The quality and relevance of guidance documents varies, as does the time taken to produce them (Group 3);
    - Guidance should be provided on a more scientifically robust weight-of-evidence approach, including an objective scoring methodology that allows selecting the most reliable, relevant and highest quality data at different levels including environmental measurements. Existing guidance explicitly refers to the need to "use all available data for assessing bio-accumulation" but it unfortunately is always followed by "the weight-of-evidence and all the available data need to be compared back to the criteria defined in the legal text" which for bio-accumulation is only the Bioconcentration Factor (Group 2).

- Comments associated with implementation and enforcement:
    - The transposition and implementation of the Signs at Work Directive is not consistent among the Member States (Group 3);
    - Interpretation and enforcement in Member States are very often not streamlined: e.g. placing on the market (CLP), multilingual fold-out labels (CLP), "bleach" versus disinfection (BPR) (Group 2).

- Comments on harmonisation:
    - The regional differences in GHS implementation add complexity to supply chain communication. In this context what is often mentioned is a lack of harmonization in the applied hazard classes and categories (Group 2);
    - The process of harmonised classification is slow and risk processes are very slow (Group 4);
    - Harmonised EU legislation, "mutual recognition" between Member States for substances (chemicals, metals, etc.) used as food contact materials and articles does not function always well (Group 2).

3.3.13 Question 17: To what extent are the following elements of risk management satisfactory?

3.3.13.1 Analysis of closed question responses

Respondents were asked to indicate their satisfaction with six elements. In total there were between 280 and 285 responses to this question, depending on the specific element. The results are provided in Table 3-38. Table 3-39 then provides the weighted scores calculated from the responses to give an easier indication of the implications of the differences in responses from the groups.

Table 3-38: Number and percentage of respondents by level of satisfaction with risk management (n=280 to 285)							
Group	Satisfaction score	Element a: hazard identification criteria (n=285)		Element b: risk assessment and characterisation (n=283)		Element c: risk assessment and characterisation (n=284)	
		No.	%	No.	%	No.	%
1 (citizens) (n=28)	1	4	14%	4	14%	4	14%
	2	5	18%	7	25%	4	14%
	3	4	14%	3	11%	7	25%
	4	4	14%	5	18%	5	18%
	5	1	4%	0	0%	1	4%
	I don't know	10	36%	9	32%	7	25%
2 (industry) (n=175 to 178)	1	5	3%	8	5%	11	6%
	2	23	13%	26	15%	25	14%
	3	47	27%	60	34%	53	30%
	4	77	44%	66	37%	48	27%
	5	10	6%	5	3%	25	14%
	I don't know	15	8%	12	7%	16	9%
3 (public authority) (n=33 to 34)	1	0	0%	0	0%	0	0%
	2	3	9%	3	9%	3	9%
	3	4	12%	6	18%	9	27%
	4	19	56%	19	58%	16	48%
	5	6	18%	2	6%	3	9%
	I don't know	2	6%	3	9%	2	6%
4 (NGO/ others) (n=43 to 46)	1	6	13%	5	11%	2	4%
	2	13	28%	16	36%	16	36%
	3	12	26%	11	24%	15	33%
	4	9	20%	9	20%	5	11%
	5	2	4%	1	2%	3	7%
	I don't know	4	9%	3	7%	4	9%

Group	Importance score	Element d: hazard and risk communication measures to workers (n=284)		Element e: risk management measures restricting or banning the use of chemicals (n=282)		Element f: risk management measures regulating the safe use of chemicals (n=280)	
		No.	%	No.	%	No.	%
1 (citizens) (n=28)	1	2	7%	6	21%	3	11%
	2	5	18%	4	14%	4	14%
	3	4	14%	3	11%	4	14%
	4	7	25%	6	21%	8	29%
	5	2	7%	1	4%	1	4%
	I don't know	8	29%	8	29%	8	29%
2 (industry) (n=175 to 178)	1	0	0%	19	11%	2	1%
	2	6	3%	33	19%	5	3%
	3	38	21%	45	26%	27	15%
	4	75	42%	50	28%	73	42%
	5	45	25%	15	9%	48	27%
	I don't know	13	7%	14	8%	20	11%
3 (public authority) (n=33 to 34)	1	1	3%	1	3%	0	0%
	2	1	3%	4	12%	2	6%
	3	5	15%	6	18%	8	24%
	4	21	62%	17	52%	20	59%

Table 3-38: Number and percentage of respondents by level of satisfaction with risk management (n=280 to 285)							
	5	4	12%	4	12%	3	9%
	I don't know	2	6%	1	3%	1	3%
4 (NGO/ others) (n=43 to 46)	1	2	4%	9	20%	9	21%
	2	6	13%	15	33%	11	26%
	3	15	33%	9	20%	6	14%
	4	8	18%	5	11%	6	14%
	5	5	11%	5	11%	5	12%
	I don't know	9	20%	2	4%	6	14%
Notes: a score of 1 = not satisfactory and a score of 5 = very satisfactory							

Table 3-39: Weighted scores based on number and percentage of respondents identifying level of satisfaction with risk management (n=280 to 285)				
Element	Group			
	Group 1 (citizens) (n=28)	Group 2 (industry) (n=175 to 178)	Group 3 (public authority) (n=33 to 34)	Group 4 (NGO/others) (n=43 to 46)
17a) Hazard identification criteria	2.6	3.4	3.9	2.7
17b) Risk assessment and characterisation	2.5	3.2	3.7	2.6
17c) Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	2.8	3.3	3.6	2.8
17d) Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	3.1	4.0	3.8	3.2
17e) Risk management measures restricting or banning the use of chemicals	2.6	3.1	3.6	2.6
17f) Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	3.0	4.0	3.7	2.6
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the level of satisfaction placed by each group as a whole on chemical legislation. The calculation excludes don't know responses				

As with other questions requesting level of satisfaction, responses from Group 1 suggest that they are less satisfied than Group 2 and 3 and have a similar level of satisfaction to Group 4. The lowest and highest scores are as follows:

- Lowest scores:
  - The lowest score assigned by Group 1 is 2.5 (28) for risk assessment and characterisation. This compares with scores of 2.6 from Group 4 (45), 3.2 from Group 2 (177) and 3.7 from Group 3 (33);
  - The lowest scores assigned by Group 2 (3.1 from 176 responses) and equal lowest for Group 3 (3.6 from 33 responses) are for risk management measures restricting or

banning the use of chemicals. Group 4 assigns a score of 2.6 overall (45) as does Group 1 (28);
    - Three elements achieve the lowest score from Group 4 at 2.6. These are risk assessment and characterisation (45), risk management measures restricting or banning the use of chemicals (45) and risk management measure regulating the safe use of chemicals (43).

- Highest scores:
    - The highest score overall is 4.0, assigned by Group 2 to hazard and risk communication measures to workers (177), and to risk management measures regulating the safe use of chemicals (175);
    - The highest score from Group 1 is 3.1 for hazard and risk communication measures to workers (28);
    - The highest score from Group 3 is 3.9 hazard identification criteria (34);
    - Group 4 assigns the highest score (3.2) to hazard and risk communication measures to workers (45).

3.3.13.2 Analysis of open text responses

Respondents were also asked to provide more information to explain their score if they assigned a 1, 2 or 3 as their level of satisfaction. In total 45 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-40. The table also shows which groups the comments were from.

Table 3-40: Q17: satisfaction with elements of risk management themes from non-questionnaire responses (n=45; Group 1 (citizens) = 5, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)

Theme	By
Themes on hazard identification criteria	
Classification for carcinogenicity and reproductive toxicity does not take account of potency, with problems for communication and downstream consequences for use of chemicals	Group 1 (citizens)
Methodology in EC guidelines for potency should be used more widely	Group 1 (citizens)
Changes introduced by 2nd ATP[1] to CLP are too conservative and lead to variety of more stringent labelling	Group 1 (citizens)
Other classification criteria are missing	Group 2 (industry)
Criteria are not always clear	Group 3 (public authorities) Group 2 (industry) Group 4 (NGOs/others)
Criteria for identifying PBT[2] substances are scientifically obsolete and should be updated frequently in response to scientific progress	Group 2 (industry)
Hazard identification criteria are subject to overly precautious interpretation	Group 2 (industry)
Distinctions with regard to particular application of products are not fully consistent	Group 2 (industry)
Hazard identification criteria for PBTs and vPvBs[3] do not work	Group 2 (industry)
Hazard identification criteria must consider the weight-of-evidence approach	Group 2 (industry)
Hazard identification and methodologies should be aligned as much as possible across different legislations	Group 2 (industry)
Impact Assessment needed before criteria for hazard identification are developed in the future to inform decisions and lead to pragmatic	Group 2 (industry)

Table 3-40: Q17: satisfaction with elements of risk management themes from non-questionnaire responses (n=45; Group 1 (citizens) = 5, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
outcomes	
Some of the criteria used to define hazards miss specific aspects of metals, metal compounds and their mixtures	Group 2 (industry)
Hazard identification needs to be a living science, but this also means that there needs to be sufficient time to develop the required regulatory capacity-building	Group 2 (industry)
Hazard identification criteria are clear but are subject to different interpretations	Group 2 (industry)
Issues such as low dose exposures, sensitive exposure windows, nanomaterials, neurotoxicity or immunotoxicity are not being addressed	Group 4 (NGOs/others)
Hazard should not be considered on its own without consideration of exposure for proper risk management	Group 2 (industry) Group 4 (NGOs/others)
Exposure scenarios are a challenge to check and communicate	Group 2 (industry)
Exposure scenarios are not clear for downstream users	Group 2 (industry)
Exposure characterisation is based on models which are irrelevant to real life exposures	Group 4 (NGOs/others)
Themes on risk management in general	
Potential for innovation and research in terms of substitution to avoid significant loss of functionality	Group 1 (citizens)
Lack of clear regulation and instructions for personal protection at use for consumers	Group 3 (public authorities) Group 2 (industry)
Consumers having the right to request information if an article contains SVHC[4] on candidate list is a very weak measure	Group 3 (public authorities)
Integrated approach of PPPR[5] and BPR[6] work much better than legislation where risk management procedures are kept separate	Group 3 (public authorities)
Currently many substances are targeted for bans multiple times from different EU legislation	Group 2 (industry)
Cost calculation should be mandatory part of decisions	Group 2 (industry)
Creation of an RMOA[7] step is important innovation is seeking the best regulatory outcome for managing risks of hazardous substances	Group 2 (industry)
Risk management measures should only be triggered on the basis of hazard classification, not by automatic linkages between CLP and downstream legislation	Group 2 (industry)
The risk management process is so slow that it does not adequately protect people and the environment	Group 4 (NGOs/others)
Themes on risk communication	
If all mixtures are classified as hazardous no-one pays attention to the pictograms	Group 1 (citizens) Group 2 (industry)
Communication is lacking for use and precautions with substances used domestically	Group 1 (citizens) Group 2 (industry)
Additional information on the label for industrial goods is not needed under Article 69 of BPR	Group 1 (citizens)
Consumer associations should be involved to improve methods of communications about safe use of chemical products by consumers	Group 3 (public authorities)
Risk communication is insufficient for articles for professionals and/or consumers	Group 3 (public authorities) Group 2 (industry)Group 4 (3)
Communication on risks to consumers is not consistent	Group 2 (industry)

Table 3-40: Q17: satisfaction with elements of risk management themes from non-questionnaire responses (n=45; Group 1 (citizens) = 5, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
Communication on risks to consumers for cosmetic products is risk-based and works very well	Group 2 (industry)
Labels are overloaded, confusing and may not provide the consumers with relevant and meaningful information about the safe use of a product	Group 2 (industry)
New labels need to be developed in a resource efficient way, proportionate to a product's actual risks	Group 2 (industry)
Safety data sheets are not sufficient for employer's risk assessment	Group 3 (public authorities)
Safety data sheets and labelling are often of poor quality	Group 2 (industry) Group 4 (NGOs/others)
REACH and CLP obligations are improving significantly the quality of safety data but more enforcement is needed	Group 2 (industry)
Implementation and dissemination of safety data sheets is not always applied	Group 4 (NGOs/others)
Some hazards are incomprehensible or non-instinctive	Group 2 (industry)
Infocards should be translated into all EU languages	Group 4 (NGOs/others)
Themes on authorisation	
No comments made	
Themes on gaps and uncertainties	
Scientific criteria for endocrine disruptors are missing	Group 3 (public authorities) Group 4 (NGOs/others)
Unclear how combined effects of chemicals are taken into account in risk assessments	Group 3 (public authorities) Group 4 (NGOs/others)
Uncertainties and data gaps should be resolved before decisions are taken	Group 3 (public authorities)
Solution for making ES for mixtures is missing	Group 2 (industry)
Other themes	
EU legislation is very complex	Group 1 (citizens)
Descriptor tools are very broad and not clear	Group 2 (industry)
Risk that imported products fail legislative requirements is extremely high and risk that non-compliant products are caught is very small	Group 2 (industry)
Enforcement is not consistent across Member States	Group 2 (industry)
Too little attention is paid to imported articles	Group 4 (NGOs/others)
Expert judgements favour large companies who have the resources over small companies who do not	Group 2 (industry)
Notes: [1] ATP = Adaptation to Technical Progress. [2] PBT = Persistant, Bioaccumulative, Toxic. [3] vPvB = very Persistent very Bioaccumulative. [4] SVHC = Substances of Very High Concern. [5] PPPR = Plant Protection Products Regulation. [6] BPR = Biocidal Products Regulation. [7] RMOA = Risk Management Option Analysis	

3.3.13.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-41 provides a summary of the themes from these non-questionnaire responses.

Table 3-41: Q17: satisfaction with elements of risk management themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes hazard identification criteria	
Hazard identification criteria must use the weight of evidence approach	Group 2 (industry)
Hazard identification and methodologies for risk assessment should be aligned as much as possible	Group 2 (industry)
Hazard identification criteria are missing for some endpoints	Group 3 (public authority)
Limited toxicity data make hazard identification and characterisation very challenging	Group 4 (NGO/others)
Reference data sets on hazard can be used for other chemical legislative purposes	Group 2 (industry)
Themes on risk management in general	
Cooperation between regulatory bodies should be improved	Group 2 (industry)
Risk Management divergences between worker protection H&S directives and REACH/CLP regulations cause compliance difficulties for employers	Group 2 (industry)
Risk management divergences should be rationalised, simplifying compliance requirement	Group 2 (industry)
Risk management measures and reduction of exposures already lead to benefits to consumers and general public in improving human health and the environment.	Group 4 (NGO/others)
The overall Risk Management system is not very effective or efficient.	Group 2 (industry)
There is a lack of consultation at the RMOA development level, which may result in not selecting the most appropriate Risk Management Measure.	Group 2 (industry)
Once the substance is on the Candidate List, the procedure and adoption to proceed to prioritisation is very slow, cumbersome and not consistently reflecting the potential benefits for society.	Group 2 (industry)
Building more on the pivotal role of the RMOA[1] is probably the best way to improve the efficiency of the risk management.	Group 2 (industry)
Voluntary agreements by the manufacturing industry or users could be a third pillar of Risk Management	Group 2 (industry)
Integrated approach of PPPR[2] and BPR[3] work better than where risk management procedures are kept separate	Group 3 (public authority)
Themes on risk communication	
Risk communication is insufficient for articles for professionals and consumers	Group 3 (public authority)
Giving consumers right to request information on SVHC[4] in articles is a very weak measure	Group 3 (public authority)
Themes on authorisation	
Authorisation applies to all uses in an equal way. This leads to different degrees of compliance depending on the relevance for a use sector.	Group 2 (industry)
Restrictions or Authorisations can also generate "collateral damage effects" like regrettable substitution, negative impact on resources and on energy policies or simply transfer the problem to another compartment	Group 2 (industry)
Themes on gaps and uncertainties	
By using the Bioconcentration Factor in the REACH guidance, a highly liphophilic substance could be deemed bioaccumulative even if it is broken down and never increases in concentration in the food chain	Group 2 (industry)

Table 3-41: Q17: satisfaction with elements of risk management themes from non-questionnaire responses (n=9)	
Theme	**By**
Criteria for terrestrial bioaccumulation and substances not bioaccumulating via lipid partitioning are missing	Group 3 (public authority)
Criteria for endocrine disruptors are awaited	Group 3 (public authority)
Uncertainty issues should be addressed before decision-taking	Group 3 (public authority)
No labels/pictograms for PBT[5]/vPvB[6] substances	Group 3 (public authority)
Other themes	
Political considerations can interfere with the scientific analysis underpinning hazard identification	Group 2 (industry)
Trade associations are expressing concerns about use of test methods for food contact plastics	Group 4 (NGO/others)
Restrictions on use of chemicals may not be comprehensive enough, creating loopholes	Group 4 (NGO/others)
There should not be special arrangements to allow the continued presence of hazardous substances in products made from recycled material	Group 4 (NGO/others)
Advocates widening the range of uses that are covered by generic risk assessments (or hazard based cut-offs), focussing on situations where there is exposure of the general public and the environment	Group 4 (NGO/others)
The large number of notifications through the EU Rapid Alert System for dangerous products (RAPEX) regarding harmful chemicals in consumer products which pose a serious risk show that there are still many gaps that need to be closed	Group 4 (NGO/others)
Greater emphasis should be put on adequate implementation and enforcement.	Group 4 (NGO/others)
The question of compliance, enforceability, plausibility should be debated at the early stage, with all involved actors, before the decision to move to a specific RMM[7] is taken	Group 2 (industry)
Self-assessment and certification systems or voluntary reduction programmes can be much more effective and will focus the role of the authorities	Group 2 (industry)
Notes: [1] RMOA = Risk Management Option Analysis. [2] PPPR = Plant Protection Products Regulation. [3] BPR = Biocidal Products Regulation. [4] SVHC = Substances of Very High Concern. [5] PBT = Persistant, Bioaccumulative, Toxic. [6] vPvB = very Persistent very Bioaccumulative. [7] RMM = Risk Management Measures	

3.3.13.4 Comparison of themes

The comparison of themes associated with satisfaction with elements of risk management are summarised in the table below. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes. The 'type' of response from Table 3-40 and 3-41 are used as the basis for the analysis in Table 3-42 with comments attributed to the positive responses and issues identified as negative issues.

Table 3-42: Comparison of responses on satisfaction with overall EU legislative framework			
Non-questionnaire responses		OPC responses	
Positive	Negative	Positive	Negative
Themes on the hazard classification criteria			
Group 2 (1)	Group 3 (1) Group 4 (1)		Group 1 (2) Group 3 (1) Group 2 (16) Group 4 (6)
Themes on risk management in general			
Group 4 (1) Group 3 (1)	Group 2 (6)	Group 1 (1) Group 3 (1)	Group 3 (2) Group 2 (4) Group 4 (2)
Themes on hazard/risk communication			
	Group 3 (2)	Group 2 (2)	Group 1 (3) Group 3 (3) Group 2 (23) Group 4 (5)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from question 5 of the OPC			

Examples of the types of issues raised in response to question 17 are provided below:

- Comments on the hazard classification criteria:
  - Classification should give guidance on the potential hazards of chemicals. Once the nature of the hazard is known, potency is the most important indicator of the degree of the hazard (Group 1);
  - For metals, some of the criteria used to define…sometimes miss specific aspects of metals, metal compounds and their mixtures…Examples include: Water solubility test and WAF test….Environmental classifications…Skin/eye irritation/corrosion testing…Classifications for STOT-RE…Physical form…Bioavailability…This could be improved by developing and recognising metal-specific hazard assessment approaches and rules for inorganic substances, and by ensuring that EU hazard assessment experts do apply such approaches whenever applicable (Group 2);
  - The criteria for identifying PBT and EDC substances are scientifically obsolete and should be updated frequently in line with the progress of science (Group 2, translated).

- Comments on risk management:
  - We see many substances being targeted for bans multiple times via different EU legislation: REACH and RoHS, REACH and OSH, REACH and POPs (Group 2);
  - Distinctions with regard to the particular application of products are often not fully consistent. E.g. very energy efficient lamps containing mercury (Hg) are restricted under ELV legislation but welcomed/tolerated in buildings and public illumination as energy saver even though Hg amounts are higher (Group 2);
  - Risk management…process is so slow that known substances of very high concern can still be widely used even in consumer articles and goods, and with little regard to the public's right to know. That is an unacceptable risk to human health and the environment (Group 4);
  - We would like to emphasize that REACH and CLP obligations are improving significantly the quality of the safety data for chemicals from a downstream user

perspective although the quality of SDS is still lacking to some extent and increased enforcement is required (Group 2);
    - Children and pregnant women are not protected sufficiently across legislation (Group 4).

- Comments on hazard/risk communication:
    - Efficient tools to communicate safety data is of paramount importance for downstream user companies…Errors and inconsistencies…can lead to risk to human health and to the environment which could lead to legal penalties and loss of company reputation. To reduce this, companies must undertake burdensome checks and engagement with suppliers (Group 2);
    - Some hazards are incomprehensible, for example, "environmentally hazardous" for completely biodegradable surfactants that meet the criteria of the Detergents Regulation (Group 2, translated);
    - Hazard communication (under CLP) has become more complete, but also more confusing, leading to information overload and hence lesser understanding for workers. Excessive labelling…and difficult to read extended safety data sheets lead to dilution of valuable information (Group 2);
    - There are two pictograms which appear to be particularly non-instinctive: the one of “gas under pressure” and the one on “serious health hazard”. These could be replaced by more instinctive ones (Group 2);
    - Risk characterisations are inadequate as appropriate information on hazardous properties of chemicals in the market is still widely lacking, in particular for endpoints such as endocrine disruption or neurotoxicity (Group 4);
    - Labels etc. is satisfactory in some, not satisfactory in others, e.g. no requirements for labelling of non-perfume allergens in toys (Group 3).

- Other comments:
    - Unclear how combined effects of chemicals are taken into account in risk assessments. In the classification of hazardous waste, the combined/interactive effects of chemicals are not taken into account (Group 3);
    - The transition from DSD [Dangerous Substances Directive] to CLP brought along complexity, which resulted in general tightening of classification and significant difference in notified classifications (Group 2).

3.3.14 Question 18: Do you consider the quality requirements aimed at ensuring the reliability and reproducibility of safety data for chemical to be appropriate?

3.3.14.1 Analysis of closed question responses

Respondents were also asked to indicate whether they considered the quality requirements for safety data for chemicals to be appropriate. There were 287 responses in total to this question. The results are provided by group in Table 3-43, which shows a mixed response across the groups. The majority of Group 2 (63% or 111) replied ‘yes’ that they did think the quality requirements were appropriate. ‘Yes’ was still the most common response for Group 3 but the proportion providing this response was 51% (18) with 37% (13) saying that they did not know. The most common response from Group 1 was ‘don’t know’ at 48% (13), followed by ‘yes’ at 41% (11). For Group 4, though, the most common response was ‘no’ at 44% (21) with 31% (15) saying ‘yes’ and 25% saying ‘don’t know’.

Table 3-43: Extent to which respondents considered that the quality requirements for safety data for chemicals were appropriate (n=287)								
Response	Group 1 (citizens) (n=27)		Group 2 (industry) (n=177)		Group 3 (public authority) (n=35)		Group 4 (NGO/others) (n=48)	
	No.	%	No.	%	No.	%	No.	%
Yes	11	41%	111	63%	18	51%	15	31%
No	3	11%	22	12%	4	11%	21	44%
I don't know	13	48%	44	25%	13	37%	12	25%

3.3.14.2 Analysis of open text responses

Respondents were also asked to explain their answer if they had replied no to the closed question. In total 28 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-44. The table also shows which groups the comments were from.

Table 3-44: Q18: appropriateness of quality requirements of safety data for chemicals themes from non-questionnaire responses (n=28; Group 1 (citizens) = 1, Group 2 (industry) = 16, Group 3 (public authority) = 4, Group 4 (NGO/others) = 7)	
Theme	By
Themes on access to hazard information	
Weight-of-evidence approach needs to be used	Group 3 (public authority) Group 4 (NGO/others)
Data from public literature and highly respected labs can be very reliable and should not be discarded even if tests were not conducted under GLP[1] conditions	Group 2 (industry) Group 4 (NGO/others)
Bioassays on GLP certified studies should not be ignored	Group 3 (public authorities)
Physico-chemical data requirements need improvement	Group 2 (industry)
Physico-chemical data are unnecessary	Group 2 (industry)
Themes on quality systems and criteria	
Scientific validity including relevance and applicability of the methods need to be considered	Group 2 (industry)
Appropriate quality systems are in place for physico-chemical data	Group 2 (industry)
Decline in study and report quality since implementation of REACH	Group 4 (NGO/others)
Market forces are being used to cut corners in test laboratories such that GLP is not being effectively implemented or reported	Group 4 (NGO/others)
Themes on GLP	
GLP is important to ensure reliability of information used for risk and hazard assessment	Group 3 (public authority) Group 2 (industry)
GLP is too formalistic	Group 1 (citizen)
GLP does not guarantee the reliability and relevance of the results to the risk assessment	Group 3 (public authority) Group 2 (industry)
GLP studies may have limitations when looking for specific effects related to a specific chemical	Group 3 (public authority)
GLP should be limited to cases where high precision is needed	Group 2 (industry)
Not all data points are equally critical so GLP should not be an automatic requirement	Group 2 (industry)
The analytical method validation study should be run under GLP as it is used to determine the level of active ingredient in other studies	Group 2 (industry)

Table 3-44: Q18: appropriateness of quality requirements of safety data for chemicals themes from non-questionnaire responses (n=28; Group 1 (citizens) = 1, Group 2 (industry) = 16, Group 3 (public authority) = 4, Group 4 (NGO/others) = 7)	
Theme	**By**
There is a need for harmonisation of measurement methods and units for OEL[2]	Group 2 (industry)
GLP underpins mutual acceptance of test data, reducing duplicative testing and costs	Group 2 (industry)
GLP does not reflect the quality of study design or interpretation on execution	Group 4 (NGO/others)
GLP ensures a high standard of practice within laboratories	Group 4 (NGO/others)
Other themes	
Additional market specific analysis methods should be transposed into global standards	Group 2 (industry)
The use of natural materials as a source of biocides is made unnecessarily difficult	Group 2 (industry)
Notes: [1] GLP = Good Laboratory Practice. [2] OEL = Occupational Exposure Limit	

3.3.14.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-45 provides a summary of the themes from these non-questionnaire responses.

Table 3-45: Q18: appropriateness of quality requirements of safety data for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on access to hazard information	
Supply chain should be given easy access to information on the identity of hazardous substances in products, beyond current requirements for SVHC[1]	Group 4 (NGO/others)
Information on chemicals (hazard aspects) is now accessible via several tools. This information is mainly focusing on hazard aspects without raising in parallel the socio-economic information that may explain why a 'toxic' substance is still used.	Group 2 (industry)
Websites, providing they are kept updated and user-friendly may be very useful sources of information for both workers and Group 1	Group 2 (industry)
The use of remote auditors and coaching by internet could be most relevant and helpful for smaller companies but for larger companies when it comes to larger issues	Group 2 (industry)
Themes on quality systems and criteria	
Appropriate quality systems are in place for physico-chemical data	Group 2 (industry)
Quality control is a fundamental requirement for the production of scientific data in general, including that related to safety for chemicals	Group 2 (industry)
Themes on GLP	
GLP[2] is not always sufficient to decide on most relevant safety/study data	Group 2 (industry)
GLP is useful in contributing to good scientific practice	Group 3 (public authority)
Other themes	
When assessing the safety of a chemical used in a product, it should be	Group 4 (NGO/others)

Table 3-45: Q18: appropriateness of quality requirements of safety data for chemicals themes from non-questionnaire responses (n=9)	
Theme	**By**
assumed that 100% will be recycled at end of life	
The potential reduction in chemical substances primarily because of the high costs of testing rather than on the basis of their hazardous properties	Group 2 (industry)
The way the information should be used (for which purposes, limitations, scope…) should appear very clearly to avoid dissemination of 'facebook-like information' or misuse	Group 2 (industry)
The integration of REACH checks with the environmental or workplace company permits could also improve the consistency and integration.	Group 2 (industry)
Notes: [1] SVHC = Substances of Very High Concern. [2] GLP = Good Laboratory Practice.	

3.3.14.4 Comparison of themes

The comparison of themes associated with the appropriateness of quality requirements of safety data are summarised in the table below. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes. The 'type' of response from Table 3-44 and 3-45 are used as the basis for the analysis in Table 3-46 with comments attributed to the positive responses and issues identified as negative issues.

Table 3-46: Comparison of responses on appropriateness of quality requirements of safety data for chemicals			
Non-questionnaire responses		**OPC responses**	
Positive comments	**Negative comments**	**Positive comments**	**Negative comments**
Themes on access to hazard information			
Group 2 (1)	Group 2 (1)		Group 3 (1) Group 2 (3) Group 4 (1)
Themes on quality systems and criteria			
Group 2 (2)		Group 2 (1)	Group 2 (2) Group 4 (2)
Themes on GLP			
Group 3 (1)	Group 2 (1)	Group 3 (1) Group 2 (3) Group 4 (1)	Group 1 (1) Group 3 (3) Group 2 (4) Group 4 (4)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from question 5 of the OPC			

A number of the comments received to Question 18 are somewhat contradictory. These include comments associated with:

- The extent to which GLP is considered to be important for ensuring reliability of information:
  - GLP ensures a sufficiently detailed description of experimental studies. However, it does not guarantee the reliability and relevance of the study results for the risk assessment (Group 3);

- Reliability and reproducibility does not depend on GLP-testing. This is a common misunderstanding. Reliability should be assessed case by case, for GLP-studies as well for studies from public literature (Group 3);
- GLP is critical to ensure reliability and reproducibility of data and further to ensure that any protocol deviations are captured for assessment (Group 2);
- GLP is not always sufficient to decide on the most relevant study/safety data (data-rich substances): relevance, robustness are criteria that should be equally considered. GLP only ensures reproducibility of the study (Group 2); and
- GLP should not be used to judge the quality of research studies. GLP is a measure of good laboratory practice, not good study design, execution or interpretation (Group 4).

- Consideration of physico-chemical data:
  - With exception of physico-chemical information (in response to question Do you consider these requirements to be appropriate?) (Group 2);
  - Physico-chemical data requirements need improvement (Group 2);
  - For physico-chemical data we believe that appropriate quality systems are in place (Group 2);
  - Physico-chemical data is becoming more and more expensive due to the implication of GLP conditions. Industry understands the necessity for GLP in relation to toxicity and ecotoxicity data but requiring physico-chemical data is unnecessary and adds excessive costs (Group 2).

- Positive comments about GLP:
  - GLP underpins the mutual acceptance of test data between countries, which avoids duplicative testing and reduces costs for industry and governments (Group 2);
  - Common principles for GLP also facilitate the exchange of information and prevents the emergence of non-tariff barriers to trade, while contributing to the protection of human health and the environment (Group 2);
  - GLP practices and certification should be considered as sine qua non when laboratories validate testing methods (Group 2);
  - Standardised quality requirements such as GLP are important instruments to ensure reliability of information used for risk and hazard assessment (Group 3); and
  - GLP ensures a high standard of practice within laboratories (Group 4).

- Negative comments about GLP:
  - GLP is too formalistic (Group 1);
  - Compared to academic studies, the OECD GLP studies may have limitations when looking for specific effects related to a specific chemical (Group 3);
  - GLP should be limited to cases where it is appropriate and high precision is needed (Group 2);
  - GLP can be important and sometimes necessary, but is not in itself sufficient to ensure good quality decision-making because it does not assess the robustness, weight of evidence and human and environmental relevance of data (Group 2);
  - We believe that market forces are leading to corners being cut in test laboratories, and that GLP is not effectively implemented or reported. In many cases, the raw study data are not provided / available, yet it is here that the real problems of a study become evident, and not from an executive summary (Group 4).

3.3.15 Question 19: What are the significant benefits generated for EU society by the EU chemical and chemical-related legislation?

Respondents were asked to select which of seven different benefits they thought had been generated by EU chemical legislation. There were a total of 284 respondents, with the results broken down by group in Table 3-47, with Figure 3-16 showing the proportion of each group that agreed with each benefit type.

Table 3-47: Number and percentage of benefits identified by group (n=284)

Benefit	Group							
	Group 1 (citizens) (n=26)		Group 2 (industry) (n=177)		Group 3 (public authority) (n=37)		Group 4 (NGO/others) (n=44)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
19a) Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	14	54%	140	79%	35	95%	35	80%
19b) Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	14	54%	151	85%	34	92%	40	91%
19c) Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollination, etc.	15	58%	148	84%	33	89%	31	70%
19d) Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy	7	27%	17	10%	15	41%	31	70%
19e) Stimulating competition and trade within the EU single market	1	4%	8	5%	8	22%	8	18%
19f) Stimulating international trade between the EU and other countries	2	8%	7	4%	7	19%	4	9%
19g) I don't know	6	23%	13	7%	0	0%	1	2%

Notes: [1] percentage is based on number of respondents by group that identified at least one benefit type or answered 'don't know'

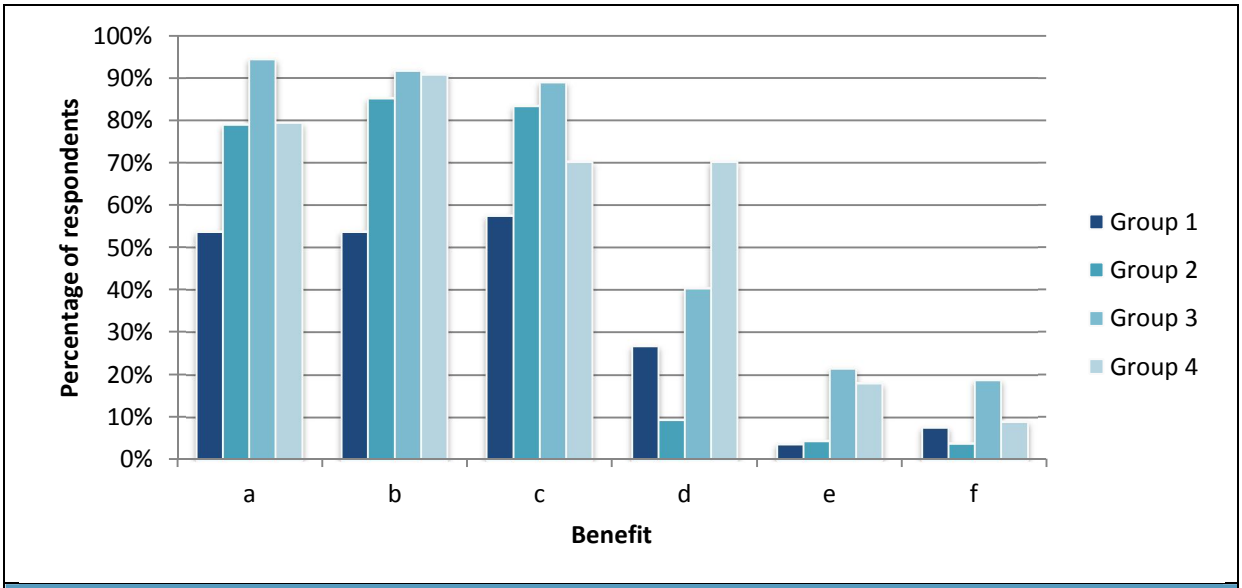

Figure 3-16: Chart showing percentage of respondents to Q19 by group that indicated that they thought the benefit was generated by EU chemical legislation, excludes don't know responses (Group 1 (citizens): n=26, Group 2 (industry): n=177, Group 3 (public authority): n=37, Group 4 (NGO/others): n=44)

Both Table 3-47 and Figure 3-16 show that respondents indicated that EU chemical legislation and chemical-related legislation generate benefits from:

a) Reducing the exposure of consumers and citizens to toxic chemicals: 95% (35) of Group 3 respondents agreed that this benefit was generated compared with 80% (35) of Group 4 and 79% (140) of Group 2. As has been seen with other questions, considerably fewer Group 1 respondents indicated that this benefit was generated (54% or 14).
b) Reducing the exposure of workers to toxic chemicals: Group 3 again had the highest level of agreement at 92% (34), although more of Group 2 (85% or 151) and Group 4 (91% or 40) agreed with this benefit than for the benefit to consumers and citizens. The number of respondents indicating that this benefit was generated from Group 1 was the same as for consumers and citizens, at 54% (14).
c) Reducing damage to the environment and ecosystems: again Group 3 has the highest level of response at 89% (33), followed by Group 2 at 84% (148). The level of agreement from Group 4 is lower than for exposure to consumers/citizens and workers at 70% (31), while that for Group 1 is higher than for all other benefit types at 58% (15).
d) Encouraging research and innovation, generating new jobs and improving competitiveness: Group 4 has the highest response to this benefit at 70% (31), while respondents from the other groups are much less likely to identify this as a significant benefit of EU chemicals legislation. Only 10% (17) of Group 2 respondents identified this as a benefit compared with 41% (15) from Group 3 and 27% (7) from Group 1.
e) Stimulating competition and trade within the EU single market: the percentage of respondents from all groups is much lower for this benefit with the highest proportion identifying this as a significant benefit coming from Group 3 at 22% (8). Just 5% (8) of Group 2 respondents identified this as a significant benefit, slightly higher than the 4% (1) from Group 1.
f) Stimulating international trade between the EU and other countries: again the level of agreement that this is a significant benefit was lower, and lower than for within the EU single market for all groups except Group 1 (here 8% highlighted this as a benefit but the

number of responses is very low, at 2). The highest level of agreement came from Group 3 at 19% (7) while just 4% (7) of Group 2 thought this was a significant benefit.

3.3.16 Question 20: what are the most significant costs incurred by EU society due to EU chemical and chemical-related legislation?

Respondents were given six different cost types (plus 'don't know') to select who they thought incurred costs. There were a total of 283 respondents, with the results broken down by group in Table 3-48, with Figure 3-17 providing a visual representation of the results.

Table 3-48: Number and percentage of costs identified by group (n=283)

Cost	Group							
	Group 1 (citizens) (n=26)		Group 2 (industry) (n=178)		Group 3 (public authority) (n=36)		Group 4 (NGO/others) (n=43)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
20a) Costs for authorities at EU level	4	15%	33	19%	9	25%	17	40%
20b) Costs for authorities at national level	6	23%	40	22%	12	33%	18	42%
20c) Costs for small and medium sized enterprises	8	31%	159	89%	23	64%	30	70%
20d) Costs for large enterprises	3	12%	129	72%	9	25%	10	23%
20e) Costs for consumers	4	15%	64	36%	7	19%	5	12%
20f) Costs for society in general	6	23%	45	25%	3	8%	16	37%
20g) I don't know	12	46%	4	2%	11	31%	1	2%

Notes: [1] percentage is based on number of respondents by group that identified at least one benefit type or answered 'don't know'

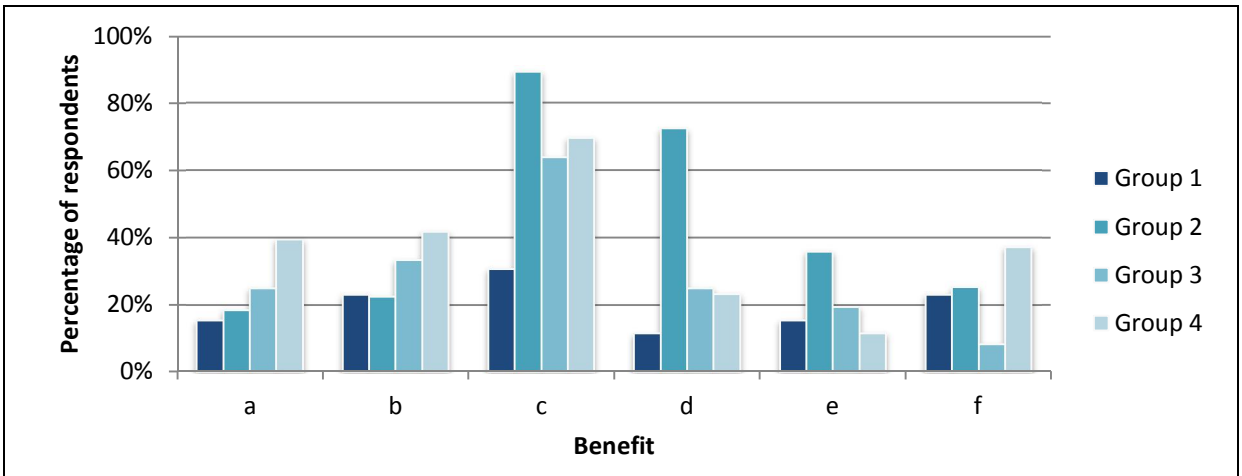

Figure 3-17: Chart showing percentage of respondents to Q20 by group that identified who they thought incurred costs, excludes don't know responses (Group 1 (citizens): n=26, Group 2 (industry): n=178, Group 3 (public authority): n=36, Group 4 (NGO/others): n=43)

Table 3-48 and Figure 3-17 show that (excluding 'don't know' responses) the most common responses across all four groups is costs for small and medium enterprises. In total 89% (159) of

Group 2 respondents thought costs for small and medium sized enterprises were the most significant, although 72% (129) of Group 2 respondents also identified costs for large enterprises as being significant. A further 70% (30) of Group 4 and 64% (23) of Group 3 also thought costs to small and medium sized enterprises were significant, but far fewer respondents from both of these groups also identified that large companies incurred significant costs: 25% (9) from Group 3 and 23% (10) from Group 4. Respondents from Group 1, again showing consistency with previous questions, provided much lower levels of agreement that costs to SMEs were significant (31% or 8) or that costs to large enterprises were significant (12% or 3). In addition, 46% of respondents from Group 1 answered 'don't know' to this question.

Around 40% of Group 4 respondents also identified significant costs for authorities at EU level (40% or 17) and costs for authorities at national level (42% or 18). Interestingly, the proportion of Group 3 (representing governments and public authorities) identifying significant costs at the EU level was just 25% (9) and at the national level was just 33% (12).

Group 4 also had the highest proportion of responses that identified costs for society (f) as significant at 37% (16). Here only 8% (3) of Group 3 identified costs to society as significant, although 23% (6) from Group 1 and 25% (40) from Group 2 also identified costs to society as significant.

3.3.17 Question 21: Do any of the following requirements in the legislative framework lead to significant costs for companies?

3.3.17.1 Analysis of closed question responses

Respondents were asked to identify which types of costs might result in significant costs for companies with seven possible responses (plus 'don't know'). In total there were 269 respondents who answered this question, with the results broken down by group in Table 3-49. Figure 3-18 provides a visual representation of the results.

Table 3-49: Percentage of respondents indicating different types of costs were likely to be significant for companies (n=269)

Cost	Group							
	Group 1 (citizens) (n=24)		Group 2 (industry) (n=174)		Group 3 (public authority) (n=33)		Group 4 (NGO/others) (n=38)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
21a) Classification requirements for substances and mixtures	6	25%	100	57%	12	36%	7	18%
21b) Chemical labelling and packaging requirements	6	25%	102	59%	8	24%	9	24%
21c) Risk management measures under the different legislation	1	4%	127	73%	14	42%	16	42%
21d) Understanding and keeping up-to-date with changes in legal requirements	5	21%	147	84%	9	27%	16	42%
21e) Training staff to ensure compliance with legal requirements	3	13%	106	61%	8	24%	9	24%
21f) Inspections and administrative requirements	1	4%	100	57%	6	18%	9	24%
21g) We do not view the business	2	8%	2	1%	2	6%	9	24%

Table 3-49: Percentage of respondents indicating different types of costs were likely to be significant for companies (n=269)								
Cost	Group							
	Group 1 (citizens) (n=24)		Group 2 (industry) (n=174)		Group 3 (public authority) (n=33)		Group 4 (NGO/others) (n=38)	
	No.	%[1]	No.	%[1]	No.	%[1]	No.	%[1]
costs of meeting EU chemicals legislation to be significant								
21h) I don't know	13	54%	5	3%	12	36%	8	21%
Notes: [1] percentage is based on number of respondents by group that identified at least one benefit type or answered 'don't know'								

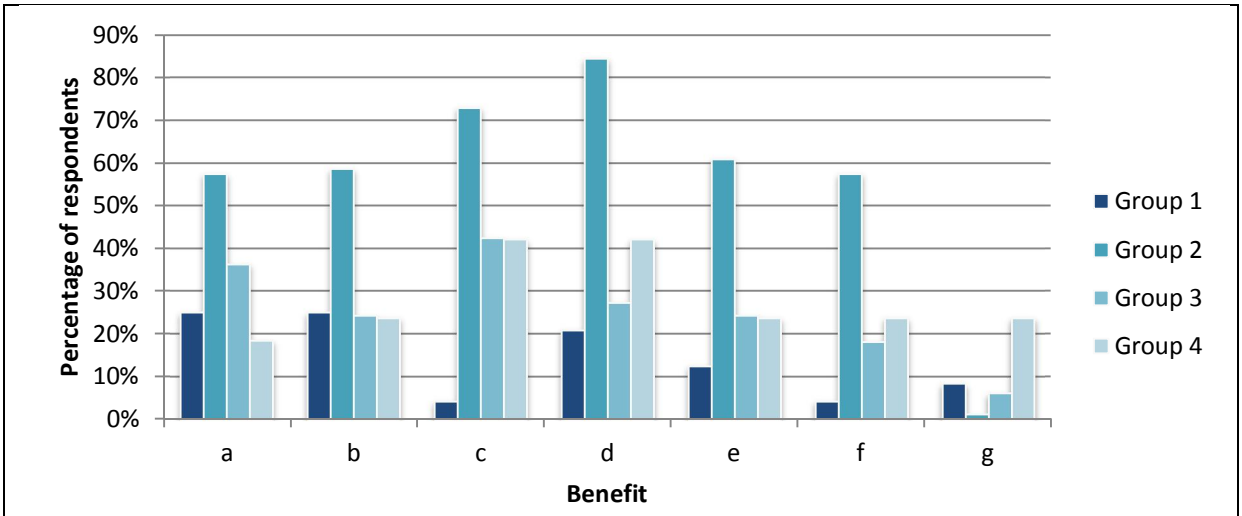

Figure 3-18: Chart showing percentage of respondents to Q21 by group that identified where the legislative requirements lead to significant costs (Group 1 (citizens): n=24, Group 2 (industry): n=174, Group 3 (public authority): n=33, Group 4 (NGO/others): n=38)

Both Table 3-49 and Figure 3-18 clearly show that it is respondents from Group 2 that identify that there are significant costs incurred as a result of the legislative framework. The highest level of agreement from Group 2 is with costs associated with understanding and keeping up-to-date with changes in legal requirements where 84% (147) of respondents identified this as a significant cost. There were also 73% (127) that identified risk management measures under the different legislation, and 61% (106) who highlighted training staff to ensure compliance with legal requirements. A total of 57% (100) respondents from Group 2 also suggested that classification requirements for substances and mixtures, and inspections and administrative requirements result in significant costs, while 59% (102) highlighted chemical labelling and packaging requirements.

The most common response from other groups (excluding 'don't know') is 42%, with this proportion of respondents from Group 3 (14) and Group 4 (16) identifying risk management measures under the different legislation as leading to significant costs. The same proportion of respondents (42%) from Group 4 (16) also identified the cost of understanding and keeping up-to-date with changes in legal requirements as being significant.

Group 1 has a high level of 'don't know' responses (54% or 13) which means the proportion identifying the different types of costs as significant is considerably less than for the other groups. The highest proportion is 25% (6) for both classification requirements for substances and mixtures and chemical labelling and packaging requirements.

The level of responses to the option of 'We do not view the business costs of meeting EU chemicals legislation to be significant' is low across all groups with a maximum of 24% from Group 4 (9) and a minimum of 1% (2) from Group 2. Group 1 (8% or 2) and Group 3 (6% or 2) are closer to the level of response from Group 2 than that of Group 4.

3.3.17.2 Analysis of open text responses

Respondents were given the opportunity to provide other sorts of costs in an open text box. In total 35 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-50. The table also shows which groups the comments were from.

Table 3-50: Q21: specific requirements of EU chemicals legislative framework that leads to particularly significant costs for companies themes from non-questionnaire responses (n=35; Group 1 (citizens) = 3, Group 2 (industry) = 20, Group 3 (public authority) = 5, Group 4 (NGO/others) = 7)

Theme	By
Themes on fees and costs for companies: types of costs	
Costs of safety data sheets	Group 3 (public authority) Group 2 (industry)
Implementation of CLP leads to increased costs	Group 3 (public authority)
Costs depend on the intensiveness of research to classify a substance	Group 3 (public authority)
Costs associated with training and maintenance of necessary specialist knowledge	Group 3 (public authority)
External consultant needs are costly	Group 2 (industry)
Expensive to prepare and collect compliance information	Group 2 (industry) Group 4 (NGO/others)
Costs associated with IT systems	Group 2 (industry)
Costs associated with transportation and storage of chemicals	Group 2 (industry)
Supply chain management costs	Group 2 (industry)
Costs of generation and maintenance of registration dossiers and associated testing costs	Group 2 (industry)
Cost burdens due to adjustments to labelling and packaging requirements	Group 2 (industry)
Cost of substituting traditional materials	Group 2 (industry) Group 4 (NGO/others)
Themes on fees and costs for companies: causes of costs	
Every Member State requires different legal requirements with a big cost for SMEs[1]	Group 1 (citizen)
Member States should not be allowed to create additional, specific provisions	Group 1 (citizen) Group 2 (industry)
Resources have to be redirected to regulatory processes and to ensure compliance, possibly to the detriment of other priorities such as investment in R&D[2]	Group 2 (industry)
The variety of definitions that a single provider has to comply with if they operate in more than one sector	Group 2 (industry)
New legislative draft proposal for addition of Annex VIII to CLP would introduce significant extra work and costs	Group 2 (industry)
High bureaucracy	Group 2 (industry)

Table 3-50: Q21: specific requirements of EU chemicals legislative framework that leads to particularly significant costs for companies themes from non-questionnaire responses (n=35; Group 1 (citizens) = 3, Group 2 (industry) = 20, Group 3 (public authority) = 5, Group 4 (NGO/others) = 7)	
Theme	**By**
Themes on fees and costs for companies: wider comments on costs	
Costs for chemical producers is a consequence of the polluter pays principle	Group 3 (public authority)
Costs focus on worst performing companies potentially penalising those companies that have already invested in new technology	Group 3 (public authority)
Significant costs are not incurred and requirements are necessary	Group 2 (industry)
There has been some relocation of chemical suppliers in extra-EU, reducing offer of chemicals in certain sectors and reduction in choice and increase in prices	Group 2 (industry)
Environmental legislation costs for companies are not significant compared with energy or labour costs, or compared to sales and profits	Group 4 (NGO/others)
Also need to consider which costs are created for companies because of an absence of adequate chemical management	Group 4 (NGO/others)
Absence of adequate chemicals provisions also contributes to diminished consumer trust with risk of reputational costs and business losses	Group 4 (NGO/others)
Absence of adequate chemicals provisions can contribute to competitive disadvantage for European industry	Group 4 (NGO/others)
Evaluation of primary references about toxicity and ecotoxicity are not sufficient	Group 4 (NGO/others)
Themes on benefits	
There are also benefits from a level playing field, clear requirements on duties and stimulators for innovation	Group 3 (public authority)
Benefits outweigh costs for environment	Group 3 (public authority)
There is no evidence that the cost for companies is higher than the burden that society has to suffer due to the negative consequences of chemicals	Group 4 (NGO/others)
Themes on enforcement	
No specific themes	
Themes on costs for authorities	
Burden for Member State authorities could be reduced by close cooperation, transparency and communication	Group 3 (public authority)
Other themes	
Not easy to divide costs across tasks	Group 3 (public authority)
Classification has a domino effect on a range of EU legislation, with no account being taken of the risk assessment	Group 2 (industry)
Without clear legal obligations, industry tends to elude obligations to provide safety data and continues to place chemicals on the market that may be found to have caused significant harm	Group 4 (NGO/others)
Notes: [1] SME = Small and Medium-sized Enterprises. [2] R&D = Research and Development	

3.3.17.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-51 provides a summary of the themes from these non-questionnaire responses.

Table 3-51: Q21: specific requirements of EU chemicals legislative framework that leads to particularly significant costs for companies themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on fees and costs for companies	
Some work is not covered by fees	Group 3 (public authority)
Some costs for authorities are covered by fees from companies but these will eventually be paid for by consumers through increases in the price of products	Group 3 (public authority)
Allowing industry to submit Annex XV proposals for restrictions could be an effective way to increase the efficiency as it will reduce the burden for authorities	Group 2 (industry)
Better use of resources could be ensured if competent authorities did not re-evaluate the first evaluation by Member States	Group 2 (industry)
Themes on enforcement	
SMEs[1] must also be subject to legislation and even to the same standard of protection for human health and the environment	Group 3 (public authority)
Enforcement is presently the exclusive task of authorities but insurance companies and certification centres could play an important role as well.	Group 2 (industry)
Enforcement might be much more efficient, for measures that are aiming at ensuring level playing fields and market restrictions to be organized at EU level	Group 2 (industry)
Other themes	
Restrictions need to be developed by authorities whilst the evidence and experience are often with manufacturers, users or article manufacturers.	Group 2 (industry)
Notes: [1] SME = Small and Medium-sized Enterprises	

3.3.17.4 Comparison of themes

The themes associated with the specific requirements of the EU chemicals legislative framework that lead to costs for companies are summarised in the table below. Here the themes focus on the types of costs that have been identified. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-52: Comparison of responses on specific requirements of EU chemicals legislative framework that leads to particularly significant costs for companies			
Non-questionnaire responses		**OPC responses**	
Type of cost	**Themes from**	**Type of cost**	**Themes from**
Themes on fees and costs for companies			
Fees payable by companies to cover work by authorities	Group 3 (2)	Implementation and compliance, including dossiers and testing and redirection of resources	Group 3 (1) Group 2 (5) Group 4 (1)
		Safety data sheet	Group 3 (1) Group 2 (1)
		Research	Group 3 (1)
		Training and maintenance of specialist knowledge	Group 3 (1)
		External consultants	Group 2 (4)
		IT systems	Group 2 (2)
		Transportation and storage	Group 2 (1)

Table 3-52: Comparison of responses on specific requirements of EU chemicals legislative framework that leads to particularly significant costs for companies			
Non-questionnaire responses		OPC responses	
Type of cost	Themes from	Type of cost	Themes from
		Supply chain management	Group 2 (1)
		Adjustments to labelling and packaging	Group 2 (3)
		Substitution of materials	Group 2 (1) Group 4 (1)
		Dealing with different requirements in Member States	Group 1 (2) Group 2 (1)
		Dealing with variety of definitions across sectors	Group 2 (1)
		Bureaucracy and dealing with updates and changes to legislation	Group 2 (2)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from question 5 of the OPC			

As well as the types of costs, there were significant comments on the causes of the costs as well as more detail on the costs themselves. These include:

- More details on types and causes of costs:
  - The implementation of EU chemical legislation has led… the relocation of chemical suppliers in extra-EU for servicing a market without restrictions. This has led to a reduction of the offer of chemicals in certain sectors and a consequent reduction of choice and increase in prices for EU companies…EU consumers do not benefit necessarily from the stricter legislative framework (Group 2);
  - The increasing complexity of the EU chemical legal framework, the many EU regulatory processes and the constant changes in legislation (e.g. amendments to the CLP Regulation) imply very often the need for external consultancy and legal advice for companies (to understand, implement the legislation and follow its changes)…This can bring additional significant costs for businesses (Group 2);
  - Furniture producers have to comply with several different flammability standards and test methods in order to place their products on the EU internal market. The different flammability standards and bans throughout Europe are complicated to comply with and place a costly burden on the producers…This complex system prevents the free circulation of goods and hinder competition, creating a barrier to trade in the internal market (Group 2);
  - New regulatory requirements introduced by Article 61(1) of CLP Regulation imposed a change of colours for labels: from 2 colours (orange and black) to 3 different colours (black, white and red). - The incorporation of additional colours induced unnecessary additional costs (Group 2);
  - Large cost burdens arising from the pursuit of the ongoing adjustments to the labelling and packaging requirements, the loss of starting materials and the resulting conversion products (Group 2);
  - Every Member State requires different legal requirements which are a big cost for SMEs to ensure compliance at EU level (Group 1);

- The scheme of RoHS Directive itself which restricts substances at "homogeneous material" leads to high costs for substitution, application for exemptions and management in the global supply-chain (Group 2); and
- When all business fulfil their parts the burden on each actor is not unreasonable, but it can lead to significant costs when other parts of the supply chain do not fulfil their obligations (Group 3).

- Comparison of costs and benefits:
  - With regard to the environment it is our understanding that benefits of current chemicals legislation - are outweighing costs (Group 3);
  - We would like to point out that the legislative framework leads to significant benefits for companies with respect to the effective protection of safety and health of workers and the prevention of claims of damages (Group 4);
  - There is no evidence that the cost for companies to implement EU environmental and chemicals legislation is higher than the burden that society has to suffer from the negative consequences of chemicals. Placing the burden on companies is the biggest incentive to prevent negative effects on the public (Group 4);
  - Should also look into which significant costs are created for companies because of an absence of adequate chemicals management…These costs include both direct and indirect costs for human health, the environment and society related to the exposure to and dispersion of chemicals, such as: costs related to human diseases resulting in e.g. productivity loss, increased sick leave, morbidity, health care costs etc.; costs related to the degradation of natural resources (e.g. water supplies); or costs arising as a result of a need for remediation, restoration and compensation as well as business loss due to unacceptable pollution or other financial risks in case of liability claims (Group 4).

3.3.18 Question 22: Are there specific requirements in the EU legislative framework which lead to particularly significant costs for authorities?

3.3.18.1 Analysis of closed question responses

Respondents could answer, 'yes', 'no' or 'don't know' to this question. There were 285 responses in total to the question. The results are shown in Table 3-53. The table shows that the majority of respondents from Group 1 (61% or 17) and Group 2 (70% or 123), plus 47% (21) of those from Group 4 replied 'don't know', perhaps reflecting that this question specifically asks about costs to authorities. The majority of Group 3 respondents (representing government or public authorities) (56% or 20) did answer 'yes', that there are specific requirements in the EU legislative framework that lead to particularly significant costs for authorities. There are also 19% (7) of Group 3 respondents that answered 'no' and a further 15% (9) who responded 'I don't know'.

Table 3-53: Extent to which respondents agreed that there are specific requirements in the EU legislative framework that lead to significant costs (n=285)

Response	Group 1 (citizens) (n=28)		Group 2 (industry) (n=176)		Group 3 (public authority) (n=36)		Group 4 (NGO/others) (n=45)	
	No.	%	No.	%	No.	%	No.	%
Yes	5	18%	46	26%	20	56%	17	38%
No	6	21%	7	4%	7	19%	7	16%
I don't know	17	61%	123	70%	9	25%	21	47%

3.3.18.2 Analysis of open text responses

Respondents who answered yes to the closed question were asked to explain what these costs are. In total 32 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-54. The table also shows which groups the comments were from.

Table 3-54: requirements in the legislative framework that lead to significant costs for authorities themes from non-questionnaire responses (n=32; Group 1 (citizens) = 2, Group 2 (industry) = 18, Group 3 (public authority) = 6, Group 4 (NGO/others) = 6)	
Theme	**By**
Themes on resource needs (burden)	
Consequences of classification and lack of scientific validity result in long disputes leading to major costs for authorities	Group 1 (citizen)
Missing harmonised regulations causes costs for authorities	Group 3 (public authority) Group 2 (industry)
Labour costs	Group 3 (public authority)
Training costs	Group 3 (public authority) Group 2 (industry)
Understanding and keeping up to date with changes in legal requirements	Group 3 (public authority)
Implementation and compliance (inspection) costs	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Reporting requirements	Group 3 (public authority)
Effective market surveillance	Group 2 (industry)
System for market surveillance is ineffective and inefficient	Group 4 (NGO/others)
Registration and authorisation under REACH	Group 2 (industry) Group 4 (NGO/others)
National nanomaterial registers	Group 2 (industry) Group 4 (NGO/others)
Seveso requirements	Group 2 (industry)
Burden placed on competent authorities to implement 1272/2009 for PPPs[1] caused numerous problems on resources	Group 2 (industry)
Huge administrative burdens for authorities	Group 4 (NGO/others)
Cost of cleaning up pollution	Group 4 (NGO/others)
Themes on potential for cost savings	
Identification of hazardous properties and legal classification by competent authorities would save costs	Group 3 (public authority)
Binding criteria should be established regarding implementation of new and complex methods	Group 3 (public authority)
Complete declaration of all ingredients on packaging would be desirable	Group 3 (public authority)
Duplication of testing costs	Group 3 (public authority)
Tendency to charge companies for compliance inspections	Group 2 (industry)
Better implementation of polluter pays principle is needed	Group 4 (NGO/others)
Extended producer responsibility should be included across chemical legislation to displace the economic burden of recycling, clean-up and regulation	Group 4 (NGO/others)
Themes on enforcement	
No specific themes	
Other themes	

Table 3-54: requirements in the legislative framework that lead to significant costs for authorities themes from non-questionnaire responses (n=32; Group 1 (citizens) = 2, Group 2 (industry) = 18, Group 3 (public authority) = 6, Group 4 (NGO/others) = 6)	
Theme	**By**
Product families are more attractive as an instrument to industry than authorities	Group 3 (public authority)
Drinking Water Directive sets quality standards that take no account of the variation in chemical properties of 484 substances approved as pesticides in EU	Group 2 (industry)
Notes: [1] PPPs = Plant Protection Products. [2] SME = Small and Medium-sized Enterprises	

3.3.18.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-55 provides a summary of the themes from these non-questionnaire responses.

Table 3-55: requirements in the legislative framework that lead to significant costs for authorities themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on resource needs (burden)	
Implementation of legislation is resource-intensive	Group 2 (industry)
BPR[1] requirements are over-burdensome	Group 2 (industry)
Authorisation costs can push businesses out of Europe	Group 2 (industry)
Compliance costs with Seveso III Directive put financial and administrative squeeze on business and affect EU competitiveness	Group 2 (industry)
There is a cost linked to the implementation of legislation	Group 2 (industry)
There is also a cost associated with the "perception" of the substance, mixture by users/buyers further down in the supply chain and some blacklisting, purely driven by hazard whilst there may be no risk and/or the risk is controlled	Group 2 (industry)
The testing for higher tiers is completely focussed on the reconfirmation of negative evidence by a higher testing requirement. Such a system is very inefficient and leads to large amounts of higher tier vertebrate tests with a low level of positive responses	Group 2 (industry)
Themes on enforcement	
SMEs[2] must also be subject to legislation and even to the same standard of protection for human health and the environment	Group 3 (public authority)
Enforcement might be much more efficient, for measures that are aiming at ensuring level playing fields and market restrictions to be organized at EU level	Group 2 (industry)
Other themes	
Polluter pays principle need to be applied more widely	Group 3 (public authority)
Notes: [1] BPR = Biocidal Products Regulation.	

3.3.18.4 Comparison of themes

The themes associated with the specific requirements of the EU chemicals legislative framework that lead to costs for authorities are summarised in the table below. Here the themes focus on the types

of costs that have been identified. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-56: Comparison of responses on specific requirements of EU chemicals legislative framework that leads to particularly significant costs for authorities			
Non-questionnaire responses		**OPC responses**	
Type of cost	**Themes from**	**Type of cost**	**Themes from**
Themes on fees and costs for authorities			
Implementation of legislation	Group 2 (3)	Implementation of legislation	Group 3 (1) Group 2 (7)
Compliance costs	Group 2 (1)	Compliance costs	Group 4 (1)
Authorisation costs	Group 2 (1)	Authorisation costs and reporting requirements	Group 3 (1) Group 2 (2) Group 4 (1)
Perception of hazard	Group 2 (1)	Missing harmonised regulations	Group 3 (1) Group 2 (2)
Testing costs	Group 2 (1)	Labour costs	Group 3 (2)
		Training costs	Group 3 (2) Group 2 (1)
		Market surveillance	Group 2 (2)
		National registers for nanomaterials	Group 2 (1) Group 4 (1)
		General administrative burden	Group 4 (1)
		Cost of cleaning up pollution	Group 4 (1)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from Question 5 of the OPC			

Table 3-56 shows the types of costs identified by respondents. Specific comments on causes of these costs and their likely significance include:

- Costs associated with implementation and compliance:
  - Plant Protection Products: The so-called "unless-clause" in the uniform principles for the decision-making in the framework of the authorisation of PPP opens the floodgates to an excessive use of more and more complex and extensive higher tier methods by the applicants in their dossiers. This has led to a considerable increase in the expenditure of the competent authorities in the risk assessment, partly exceeding the limits of their capacity (Group 3);
  - RoHS exemption renewals and applications consume a significant amount of resources and time for authorities because of the nature of open scope under current RoHS legislation (Group 2);
  - The implementation of chemicals control legislation is time- and resource-intensive, also for authorities. Many of the smaller or less economically robust Member States are lacking in the resources needed for review, evaluation, and implementation. The stronger Member States in the EU become disproportionately burdened (Group 2);
  - There are substantial costs to the enforcement agencies within the Member States, several of which are related to unnecessary bureaucratic and or administrative burdens, especially with regards to reporting duties (Group 3);

- Chemical data needs to be reported to numerous authorities due to numerous requirements. (ECHA, Commission (ozone depleting substances…), National Authorities for workers safety, Seveso, environment, VOC, fluorinated gases…) This leads to costs for both enterprises and authorities (Group 2);
- Risk assessments are very costly, especially when the burden of proof is on authorities and not on industry. A change in this would ease the burden for authorities and be in line with the polluter pays principle (Group 3).

- Costs associated with market surveillance:
  - Meaningful inspection regimes to ensure legislation is properly and reasonably applied requires staff who are scientifically and technically competent in the industry being regulated…Example - for Water Framework Directive, significant skills are required in sampling, sample management followed by analytical capability and capacity (Group 2);
  - Proper and exhaustive market surveillance and enforcement of existing requirements to be able to stop all (or a majority of) dangerous toys entering the EU market would certainly be costly for authorities (Group 2);
  - Inspections of undertakings require a good knowledge of the regulation and its interpretation and the time to analyse the procedures in place (Group 2, translated);
  - The current market surveillance system is ineffective and inefficient and the EU must urgently unblock the product safety and market surveillance package to create an EU-based and more harmonised system which equips market surveillance authorities with better financial and human resources (Group 4);
  - Very high sophisticated and too detailed regulation like e.g. RoHS are very difficult for being crosschecked. Enforcement of regulations for less than one microgram inside an electronic component is requiring enormous effort in analytics (Group 2).

- Potential for cost savings:
  - Avoidable duplication of testing as lack of crop protection agents and biocides European legal mechanisms for the regulation of substances (Group 3, translated);
  - A better implementation of the polluters pay principle is needed. A good example to follow is the Toxics Use Reduction Act from Massachusetts, which obliges users of SVHC to pay a fee which is used by authorities to help reducing the use of SVHC. This act has successfully reduced the emission of hazardous substances to the environment as well as the generation of hazardous waste while supporting local companies (Group 4);
  - The extended producer responsibility should be included across chemical legislation to displace the economic burden of recycling, clean-up costs and regulation on the chemical industry. The extended producer responsibility already exists in the Batteries (Directive 2006/66/EC), where producers are responsible for financing waste battery collection and recycling (Group 4).

3.3.19 Question 23: To what extent has the EU legislative framework for chemicals contributed to a reduction in use of hazardous chemicals and/or substitution with safer alternatives?

Respondents were asked to assign a score of between 1 (no contribution) to 5 (large contribution) to the role of the EU legislative framework in reducing the use of hazardous chemicals and/or substitution with safer alternatives. There were 280 responses to this question, with the results

provided by group in Table 3-57. Figure 3-19 shows visually how the scores assigned by each group vary. Table 3-57 also gives the weighted scores calculated across all responses for each group.

Table 3-57: Scores assigned to extent to which the EU legislative framework has contributed to a reduction in the number/use of hazardous chemicals and/or substitution with safer alternatives (n=280)

Score	Group 1 (citizens) (n=25)		Group 2 (industry) (n=177)		Group 3 (public authority) (n=36)		Group 4 (NGO/others) (n=42)	
	No.	%	No.	%	No.	%	No.	%
1	3	12%	8	5%	0	0%	1	2%
2	3	12%	13	7%	2	6%	8	19%
3	5	20%	64	36%	11	31%	21	50%
4	3	12%	63	36%	19	53%	8	19%
5	2	8%	15	8%	0	0%	1	2%
I don't know	9	36%	14	8%	4	11%	3	7%
Weighted score	2.9		3.4		3.5		3.0	

Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the more each group as a whole considers the legislative framework to have contributed to a reduction in use or substitution. The calculation excludes don't know responses

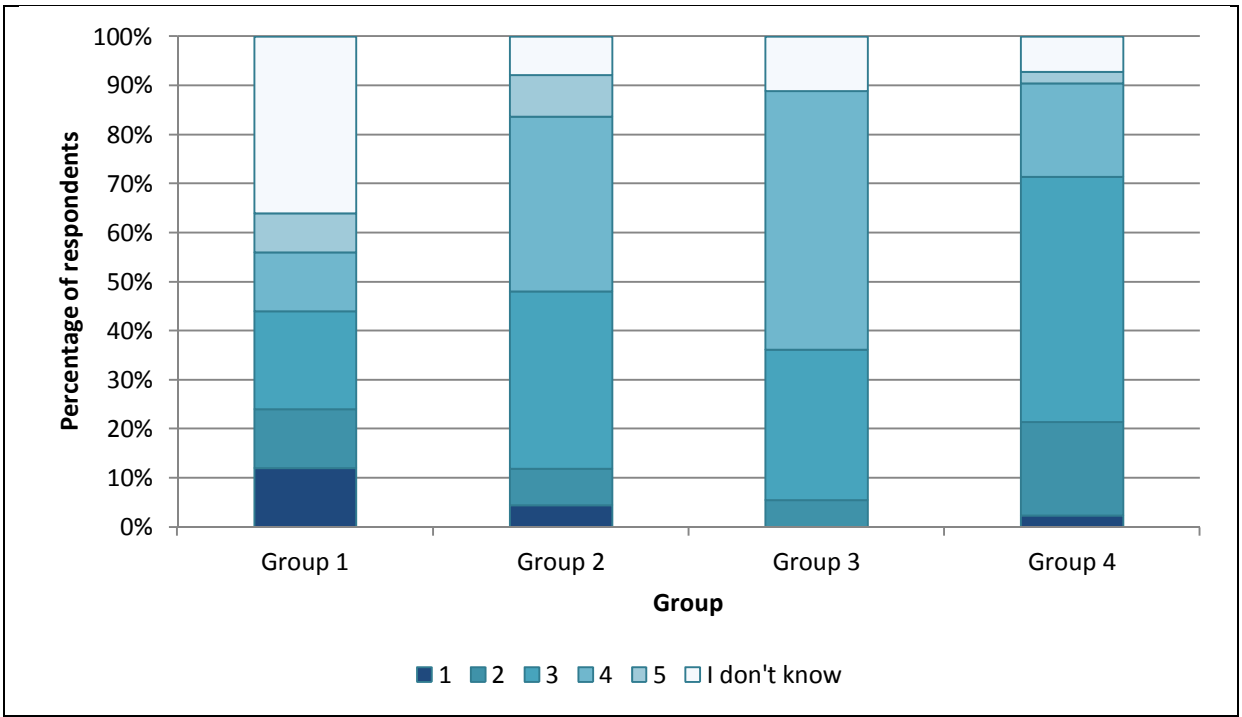

Figure 3-19: Chart showing scores assigned to extent to which the EU legislative framework has contributed to a reduction in the number/use of hazardous chemicals and/or substitution with safer alternatives (n=280)

Table 3-57 and Figure 3-19 show considerable variation across responses from the four groups. The weighted scores show that it is Group 2 and 3 (with weighted scores of 3.4 and 3.5, respectively) that consider the EU chemicals framework to have made the largest contribution to a reduction in number or use of hazardous chemicals and/or an increase in substitution to safer alternatives.

Responses from Group 2 show an equal proportion assigning scores of 3 or 4, both at 36% (although a score of 3 received 64 responses to 63 for a score of 4).

For Group 3, it is a score of 4 that received the most responses (53% or 19), with no scores of 1 or 5 assigned by any respondents from this group. Scores from Group 1 again result in the lowest weighted score (of 2.9), but this is similar to the weighted score from Group 4 (3.0). As with many other questions, the proportion of 'don't know' responses from Group 1 is considerably higher than for any other group at 36% (9) with the next highest being 11% (4) from Group 3. Ignoring 'don't know' responses from Group 4 leaves a symmetric pattern where a score of 3 receives 50% (21) of responses, while scores of 2 and 4 receive 19% (8) and scores of 1 and 5 receive 2% (1).

3.3.20 Question 24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern?

3.3.20.1 Analysis of closed question responses

Respondents were asked to assign a score from 1 (emerging areas of concern are not sufficiently addressed) to 5 (emerging areas of concern are sufficiently addressed). There were 281 responses to this question with the results broken down by group in Table 3-58 and in Figure 3-20.

The table and figure show that Group 2 is overall the most positive about the extent to which the EU legislative framework sufficiently addresses emerging areas of concern. The weighted score of 3.5 suggests that this is above moderately sufficient. The largest proportion of responses from Group 2 is just 28% (49) for a score of 4 and the overall results are well-distributed. The highest proportion across any of the groups for any one score is 39% (17) from Group 4 for a score of 2. Almost one-quarter of this group (23% or 10) assigns a score of 1.

Group 3 has the second highest weighted score at 2.8 with responses, like those for Group 2 being well-distributed across all five scores. The highest proportion for any one score is 28% (10) for a score of 3.

Group 4 has the lowest weighted score, at 2.3, with the weighted score for Group 1 at 2.7.

Table 3-58: Scores assigned to extent to which the EU legislative framework sufficiently addresses emerging areas of concern (n=281)

Score	Group 1 (citizens) (n=26)		Group 2 (industry) (n=175)		Group 3 (public authority) (n=36)		Group 4 (NGO/others) (n=44)	
	No.	%	No.	%	No.	%	No.	%
1	5	19%	12	7%	4	11%	10	23%
2	2	8%	12	7%	9	25%	17	39%
3	3	12%	41	23%	8	22%	6	14%
4	5	19%	49	28%	10	28%	6	14%
5	1	4%	32	18%	1	3%	2	5%
I don't know	10	38%	29	17%	4	11%	3	7%
Weighted score	2.7		3.5		2.8		2.3	

Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the more each group as a whole considers the legislative framework to be sufficient in addressing emerging areas of concern. The calculation excludes don't know responses

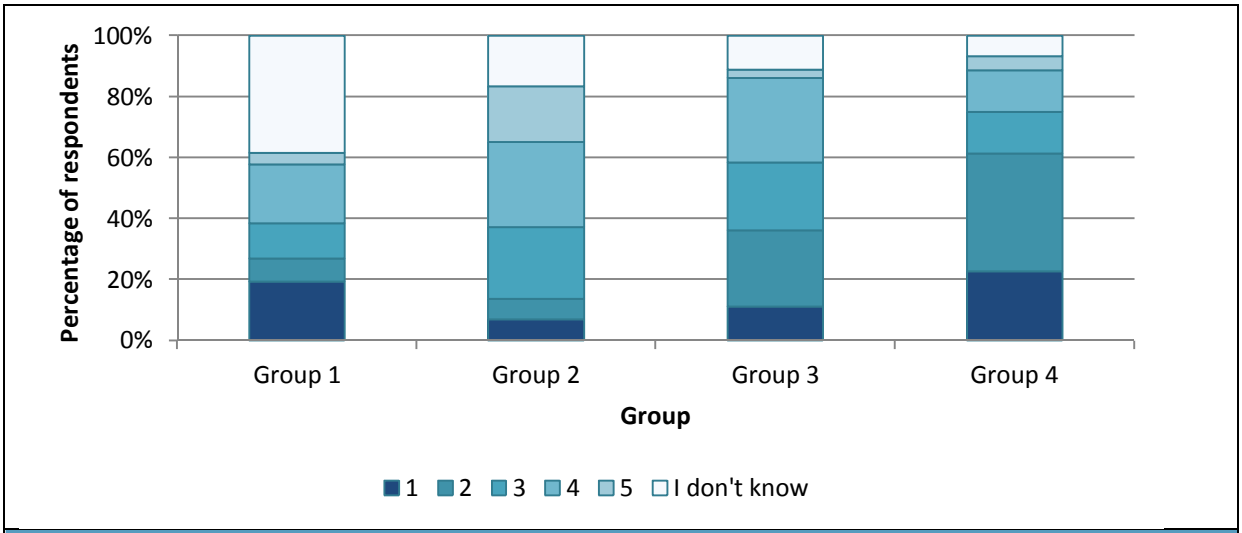

Figure 3-20: Chart showing scores assigned to extent to which the EU legislative framework sufficiently addresses emerging areas of concern (n=281)

3.3.20.2 Analysis of open text responses

Respondents were also asked to comment using an open text box. In total 39 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-59. The table also shows which groups the comments were from.

Table 3-59: Q24: extent to which existing EU legislative framework addresses emerging areas of concern themes from non-questionnaire responses (n=39; Group 1 (citizens) = 3, Group 2 (industry) = 22, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)

Theme	By
Positive themes on existing framework	
Emerging areas of concern can already be addressed in the current EU legislative framework	Group 3 (public authority)
Emerging areas of concern can be easily addressed through modification of existing legislative frameworks	Group 2 (industry) Group 4 (NGO/others)
Generally negative themes on existing framework	
The current legislative framework causes delays in the development of new chemical substances	Group 1 (citizen)
New areas of concern are slow to be taken into account and often delayed in relation to authorisation	Group 1 (citizen)
Emerging risks are discussed but not addressed at the level of specific legislation	Group 3 (public authority)
Process of developing legislation is too slow	Group 3 (public authority) Group 4 (NGO/others)
The scope of precautionary regulation needs to be discussed	Group 3 (public authority) Group 2 (industry)
New hazard identification takes too long meaning stability and predictability is insufficient to allow investment and R&D[1] effort	Group 2 (industry)
New use innovation is not quickly implemented with the regulatory approach	Group 2 (industry)
Promotion of proven safer alternatives needs to be optimised	Group 2 (industry)
Emerging areas should first be handled by non-legislative frames and tools	Group 2 (industry)

Table 3-59: Q24: extent to which existing EU legislative framework addresses emerging areas of concern themes from non-questionnaire responses (n=39; Group 1 (citizens) = 3, Group 2 (industry) = 22, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8)	
Theme	**By**
which are less rigid to implement and allow a more flexible learning curve	
Innovation is penalised due to high financial and time burdens	Group 2 (industry)
The risk is not considered	Group 2 (industry)
Themes related to issues with science	
New test methods take a long time to be accepted	Group 3 (public authority)
Scientific and/or regulatory controversies on impacts delay addressing of emerging areas of concern	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Science and regulatory developments do not operate in tandem	Group 2 (industry)
Research funds should be focused on outcomes that respond to regulatory questions and not just academic ones	Group 2 (industry)
Latest scientific advances need to be considered	Group 2 (industry) Group 4 (NGO/others)
Existing test methods need to be updated and new tests are needed	Group 4 (NGO/others)
Research into substitution of hazardous products needs to be strengthened	Group 4 (NGO/others)
Themes related to issues with gaps and uncertainties	
Account needs to be taken of social benefits	Group 1 (citizen)
The existing framework does not sufficiently address combination effects, nanomaterials, endocrine disrupting chemicals, goods without packaging, etc.	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Assessment and management of effects on biodiversity under PPP[2] Regulation is an important innovation, but has not yet become effective	Group 3 (public authority)
Failure to identify and manage risks of EDC[3] properties in the Waste Framework Directive is especially problematic as different categories of waste can be excluded from registration, etc.	Group 4 (NGO/others)
Other themes	
Difficulties recruiting independent experts	Group 1 (citizen)
Emerging issues provide opportunities to align regulations with other major international partners to prevent divergence	Group 2 (industry)
Partnership between EU policy institutions, academia and other interested parties could help build capacity to take decisions based on new information	Group 2 (industry)
EU does not understand the difficulties faced by industry	Group 2 (industry)
Comments on questionnaire	Group 2 (industry)
Notes: [1] R&D = Research and Development. [2] PPP = Plant Protection Product. [3] EDC = Endocrine Disrupting Chemicals	

3.3.20.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-60 provides a summary of the themes from these non-questionnaire responses.

Table 3-60: Q24: extent to which existing EU legislative framework addresses emerging areas of concern themes from non-questionnaire responses (n=9)	
Theme	**By**
Positive themes on existing framework	
Current EU legislative framework is appropriate	Group 2 (industry)
Generally negative themes on existing framework	
The existing EU legislative framework does not sufficiently address areas like combination effects, nanomaterials, and endocrine disrupting chemicals	Group 3 (public authority)
The process of developing legislation is too slow	Group 3 (public authority)
The methods of legislating in complex areas should be reassessed	Group 3 (public authority)
OECD initiative is a necessary step towards a further adaptation of the classification system	Group 3 (public authority)
Many more chemicals are used for which there is no EU-wide authorisation list	Group 4 (NGO/others)
Themes related to issues with science	
Emerging science should be considered more strongly in chemical safety management	Group 4 (NGO/others)
Latest scientific advances need to be considered	Group 2 (industry)
There will nearly always be a significant information deficit and it is almost inevitable that regulatory actions will lag behind scientific development	Group 2 (industry)
Policy should be informed by scientific evidence	Group 2 (industry)
Themes related to issues with gaps and uncertainties	
Current classification criteria can make read-across and in-vitro difficult to apply	Group 3 (public authority)
Endocrine disrupting chemicals are included in those authorised for chemicals in food	Group 4 (NGO/others)
Exposure to mixtures is still largely ignored	Group 4 (NGO/others)
There are important differences between risks from chemicals and risks from other sources	Group 2 (industry)
A further complication arises from the fact that toxicity usually depends on the species and exposure route as well as the amount involved	Group 2 (industry)
Other themes	
It is essential that overly precautious regulatory action should not be used to inhibit the early stages of research, discovery and innovation	Group 2 (industry)
Policy should consider control and licensing options, as opposed to prohibition, so that the potential benefits of new products are not lost	Group 2 (industry)
The decision that the existence of endocrine disrupting properties should be sufficient to deny any agrochemical an authorisation seems to be misguided	Group 2 (industry)

3.3.20.4 Comparison of themes

The themes associated with the extent to which the existing EU legislative framework addresses emerging areas of concern are summarised in the table below. Here the themes focus on the types of costs that have been identified. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-61: Comparison of responses on specific requirements of EU chemicals legislative framework that leads to particularly significant costs for authorities			
Non-questionnaire responses		OPC responses	
Positive themes	Negative themes	Positive themes	Negative themes
Themes on existing framework			
Group 2 (1)	Group 3 (4) Group 4 (1)	Group 3 (1) Group 2 (6) Group 4 (1)	Group 1 (2) Group 3 (4) Group 2 (7) Group 4 (1)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from Question 5 of the OPC			

Table 3-61 shows that there is variation across the different types of respondent in the extent of positive or negative themes. The detailed comments help to further highlight this variation:

- Positive comments about the existing legislative framework include:
  - The current EU legislative framework is appropriate to address emerging areas of concern (Group 2);
  - Emerging areas of concern could easily be addressed through modification of existing legislative frameworks. One example is where the CMD & CAD Directives for worker protection could be modified and updated to cover nano-materials (Group 2);
  - This is ensured by the ATP's (Group 2).

- Negative comments about the existing legislative framework include:
  - Emerging areas are addressed in legislations but due to the need for predictability of regulatory decisions this usually takes a (too) long time and is often hampered by scientific and/or regulatory controversies including political discussions about impacts (Group 3);
  - The EU legislative framework addresses emerging areas of concern properly, but solutions are often dependent on scientific progress and additional research (Group 2);
  - The framework should however consider the latest scientific advances with regards to new test methods, new methodologies, and ensure required testing is linked to clear human health or environment emerging concerns (Group 2);
  - Legislation struggles to keep pace with the advancement in technology and is often lagging 4 to 5 years behind (Group 2); and
  - The process take too long time, it is politicized and scientific studies are excluded from the decision-making (Group 4).

A lot of comments focused on areas that were not considered to be adequately covered. These areas and the number of comments mentioning them are:

- Nanomaterials (Group 3, 5; Group 2, 7; Group 4, 5);
- Endocrine disrupting chemicals (Group 3, 3; Group 4, 3);
- Combination effects/combined exposure/mixtures (Group 3, 2; Group 4, 3);
- Environmental risks of pharmaceuticals/veterinary pharmaceuticals (Group 4, 2)
- Goods without packaging (Group 3, 1);
- Pesticides (Group 3, 1);
- Developmental neurotoxicity and immunotoxicity (Group 4, 1);

- Low dose and non-monotonic adverse effects (Group 4, 1);
- Pest resistances (Group 4, 1);
- Antimicrobial/antibiotic resistances (Group 4, 1);
- Persistent, bioaccumulative and toxic substances (Group 4, 1);
- Life-cycle management (Group 4, 1); and
- Waste (Group 2, 1; Group 4, 1).

Some specific issues in relation to the above areas include:

- Nanomaterials:
    - Nanomaterials feature a good example to demonstrate the shortcoming of the EU legislative framework… In principle, nanomaterials are covered by the current legislations…However, there are still no specific regulatory obligations for an adequate risk assessment of nanomaterials… Even though discussion at the EU level regarding the adaptation of REACH to nanomaterials are going on for years, nearly no adaptation took place yet. In addition, CLP, the Plant Protection Products Regulation, or the pharmaceutical directives do not feature specific provisions for nanomaterials. Only the Biocidal Products Regulation includes a definition of nanomaterials and states that a separate risk assessment has to be performed. However, no guidance is developed yet how to perform this and which elements need to be considered (Group 3);
    - Nanomaterials…some are dangerous and some are not, and yet the Commission is developing a definition out of a specific context which creates controversy, increased information requirements under Cosmetics and other legislation, and has asked ECHA to host a EU Nanomaterials Observatory that gives the impression that nanomaterials must be supervised because they are suspicious (Group 2);
    - Nanotechnology still has too many variations in legislative definitions to be managed effectively (Group 2);
    - Nanotechnologies…could be the competitive industry of the future…If the regulation framing this new technology and the materials and products it produces is too rigid, it could stifle its development and impact the competitiveness of European industry (Group 2);
    - Nanomaterials give rise to concern as a result of their new physico-chemical properties compared to the same chemical in its conventional form. However…there is no definitive legal definition of nanomaterials and only a few pieces of legislation specifically address or regulate the manufacture and use of nanomaterials. Therefore, whereas REACH, CLP and the Cosmetic Products Regulation (Regulation (EC) 1223/2009) do apply to nanomaterials, the Plant Protection Products Regulation and environmental legislation does not (Group 4).

- Endocrine disruptors:
    - There are significant gaps and inconsistencies in the regulation and prohibition of EDCs in chemical control legislation, and similar deficiencies are also found in environmental protection legislation. For instance, in the Waste Framework (Directive 2008/98/EC) EDC and PBT properties are not taken into account when classifying “hazardous waste” and the Directive does not address the life-cycle risk management of these substances (Group 4);
    - The failure to identify and manage the risks of EDC properties under the Waste Framework Directive is especially problematic as the different categories of “waste” in the Directive can be excluded from registration, downstream users’ obligations and evaluation under REACH (Group 4).

3.3.21 Question 25: Indicate the extent to which you agree with the following statements relating to the EU legislative framework

Respondents were asked to consider three statements and to identify the extent to which they agreed with each, from strongly disagree to strongly agree. Table 3-62 provides a breakdown of the results by group, with Figures 3-21 to 3-23 providing charts comparing the responses from each group for each statement. A weighted score has also been calculated for each group and each statement using scores of -2 for strongly disagree, -1 for disagree, 0 for neither agree nor disagree, +1 for agree and +2 for strongly disagree. The results are presented in Table 3.63.

Table 3-62: Number and percentage of respondents agreeing/disagreeing with each statement (n=271 to 276)

Group	Importance score	a) The EU chemicals legislation framework contains gaps and missing links (n=276)		b) The EU chemicals legislation framework has overlaps (n=274)		c) The EU chemicals legislation framework is internally inconsistent (n=271)	
		No.	%	No.	%	No.	%
1 (citizens) (n=23 to 24)	Strongly disagree	2	8%	1	4%	3	13%
	Disagree	3	13%	1	4%	2	9%
	Neither agree nor disagree	8	33%	9	39%	12	52%
	Agree	2	8%	7	30%	4	17%
	Strongly agree	9	38%	5	22%	2	9%
2 (industry) (n=170 to 173)	Strongly disagree	5	3%	0	0%	2	1%
	Disagree	44	26%	8	5%	18	11%
	Neither agree nor disagree	46	27%	35	20%	48	28%
	Agree	68	40%	99	57%	76	45%
	Strongly agree	8	5%	31	18%	26	15%
3 (public authority) (n=34 to 37)	Strongly disagree	0	0%	0	0%	1	3%
	Disagree	5	14%	2	6%	6	18%
	Neither agree nor disagree	11	30%	15	44%	16	47%
	Agree	18	49%	15	44%	10	29%
	Strongly agree	3	8%	2	6%	1	3%
4 (NGO/ others) (n=44)	Strongly disagree	0	0%	0	0%	0	0%
	Disagree	4	9%	20	45%	6	14%
	Neither agree nor disagree	5	11%	9	20%	12	27%
	Agree	26	59%	13	30%	23	52%
	Strongly agree	9	20%	2	5%	3	7%

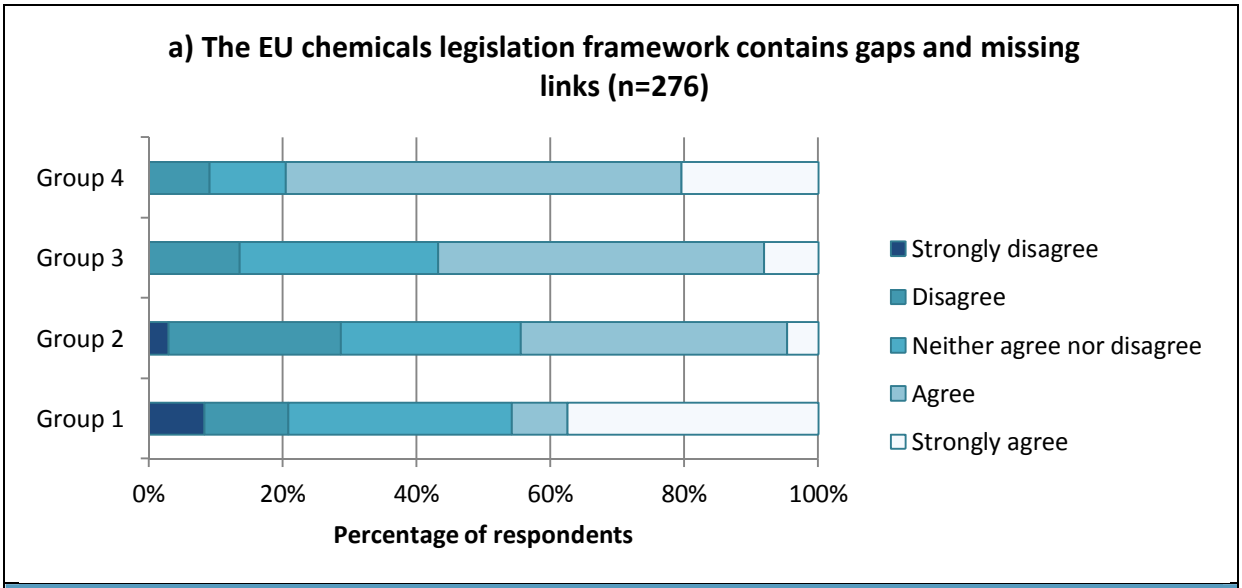

Figure 3-21: Chart showing percentage of respondents agreeing/disagreeing with statement a (n= 276) (n=281)

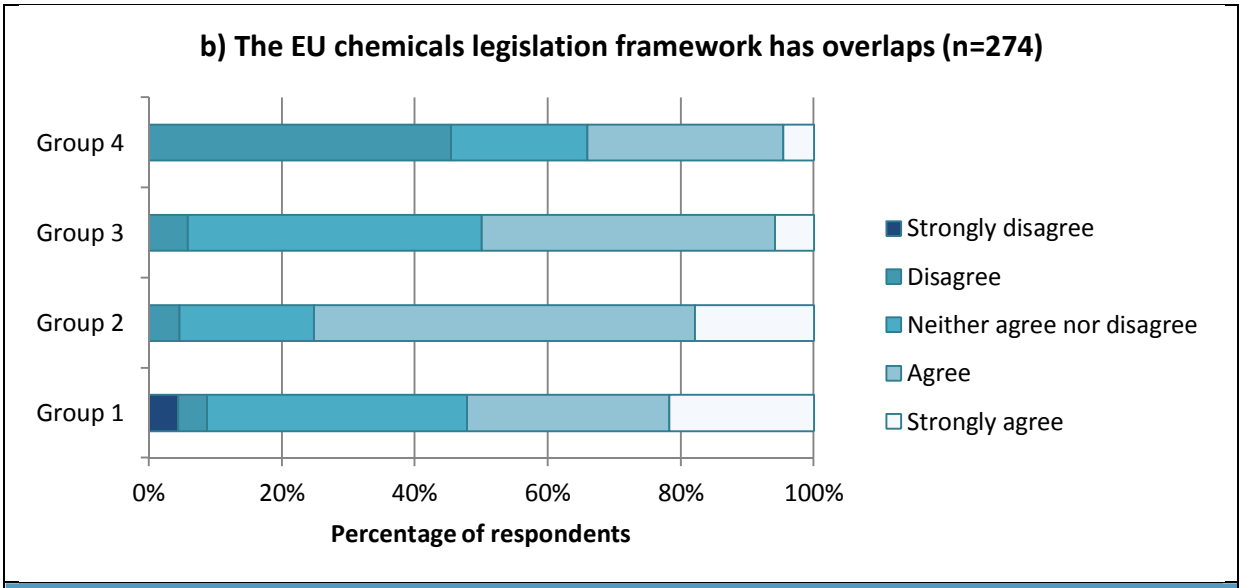

Figure 3-22: Chart showing percentage of respondents agreeing/disagreeing with statement b (n= 274) (n=281)

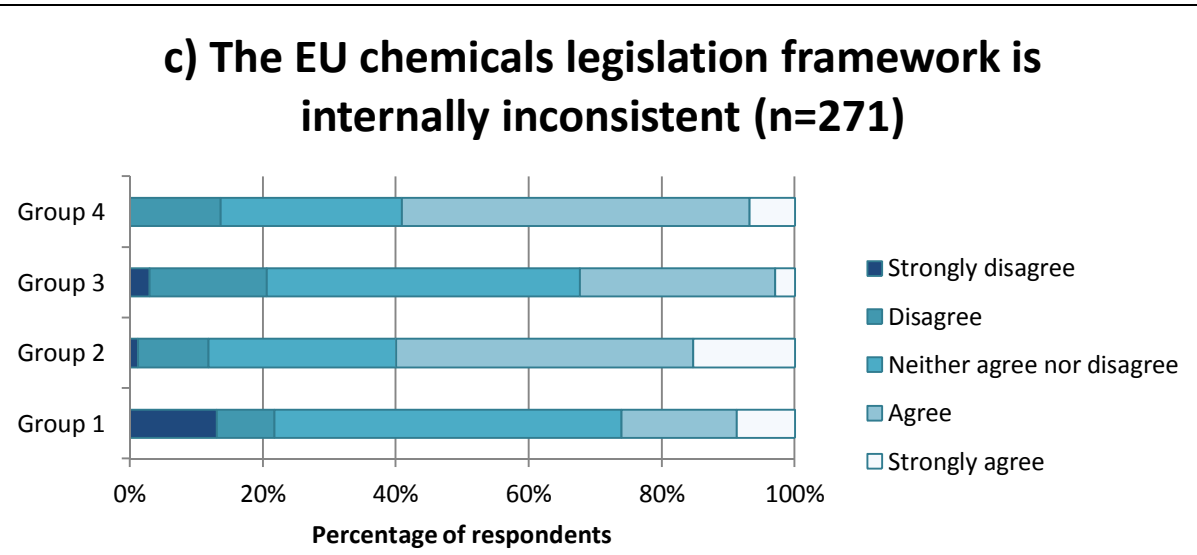

Figure 3-23: Chart showing percentage of respondents agreeing/disagreeing with statement c (n= 271) (n=281)

Table 3-63: Weighted score by group and by statement (n=271 to 276)

Group	a) The EU chemicals legislation framework contains gaps and missing links (n=276)	b) The EU chemicals legislation framework has overlaps (n=274)	c) The EU chemicals legislation framework is internally inconsistent (n=271)
Group 1 (citizens) (n=23 to 24)	0.5	0.6	0.0
Group 2 (industry) (n=170 to 173)	0.2	0.9	0.6
Group 3 (public authority) (n=34 to 37)	0.5	0.5	0.1
Group 4 (NGO/others) (n=44)	0.9	-0.1	0.5

Figures 3-21 to 3-23 do not show a clear pattern across the groups for any of the statements and the results are quite variable. With the exception of Group 4 to statement b (the EU chemicals legislation framework has overlaps) where there is a high proportion of respondents that disagree (36% or 16), there is generally quite a low level of disagreement. There are high proportions of respondents that gave an answer of 'neither agree nor disagree' across all groups and statements with the highest level being 52% (12) from Group 1 for statement c (the EU chemicals legislation framework is internally inconsistent) and the lowest level being 11% again from Group 1 (5) for statement a (the EU chemicals legislation framework contains gaps and missing links).

The weighted scores from Table 3-63 show that:

- Highest level of agreement: this is from Group 2 with the statement that the EU chemicals legislation framework has overlaps (score of 0.9 from 34 responses) and Group 4 with the statement that the EU chemicals legislation framework contains gaps and missing links (score of 0.9 from 44 responses);
- Lowest level of agreement: this is from Group 4 with the statement that the EU chemicals legislation framework has overlaps. The score of -0.1 (from 44 responses) suggests a slight

disagreement with this statement. This conflicts with views of industry (Group 2) for whom this was the statement with the highest level of agreement;

- Statement c that the EU chemicals legislation framework is internally inconsistent receives scores from 0 (i.e. overall neither agree nor disagree from Group 1, 23 responses) to a score of 0.6 from Group 3 (34 responses).

3.3.22 Question 26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between different pieces of legislation which are under the scope of this fitness check

3.3.22.1 Analysis of open text responses

There was no closed element to this question. Respondents were also asked to focus on aspects related to hazard identification, risk assessment and risk management of chemicals. In total, 39 comments in relation to gaps and missing links, 39 comments related to overlaps and 41 comments on inconsistencies were reviewed.

The samples for Question 26 were taken for each of the text boxes on gaps, overlaps, and inconsistencies, thus there are around three times as many comments that have been reviewed as for the other questions. This ensures that equal weight is given to responses on each of the possible types of incoherence. Some comments covered overlaps or inconsistencies in the box for gaps, overlaps in the box for inconsistencies, etc. Therefore, the results for Question 26 have been presented together rather than providing a separate analysis on gaps, overlaps and inconsistencies for each text box. This ensures a more comprehensive assessment across all sampled responses.

The key themes from these comments have been extracted and are summarised in Table 3-64. The table also shows which groups the comments were from.

Table 3-64: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (Gaps: n=39; Group 1 (citizens) = 5, Group 2 (industry) = 20, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8; Overlaps: n=39; Group 1 = 5, Group 2 = 22, Group 3 = 6, Group 4 = 6; Inconsistencies: n=41; Group 1 = 4, Group 2 = 24, Group 3 = 6, Group 4 = 7)

Theme	By
Themes on gaps and omissions	
Too little account of new risks	Group 1 (citizen)
Maximum residue limits between pesticides and biocides	Group 3 (public authority)
Better transfer of information on hazardous substances to the waste section	Group 3 (public authority)
Clear definition of criteria for endocrine disruptors	Group 3 (public authority) Group 4 (NGO/others)
Gaps in and between specific legislation (no details given)	Group 2 (industry)
Food contact materials	Group 2 (industry) Group 4 (NGO/others)
Cosmetics Products Regulation outlines specific safety assessment procedures that cannot always be found in other legislation	Group 2 (industry)
CLP packaging requirements	Group 2 (industry)
Classification of mixtures	Group 2 (industry) Group 4 (NGO/others)
Additional steps needed in risk management of active substances for biocides to allow for cost-benefit analysis	Group 2 (industry)
Carcinogens and Mutagens Directive does not cover substances toxic for	Group 2 (industry)

Table 3-64: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (Gaps: n=39; Group 1 (citizens) = 5, Group 2 (industry) = 20, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8; Overlaps: n=39; Group 1 = 5, Group 2 = 22, Group 3 = 6, Group 4 = 6; Inconsistencies: n=41; Group 1 = 4, Group 2 = 24, Group 3 = 6, Group 4 = 7)	
Theme	**By**
reproduction	Group 4 (NGO/others)
Gaps in communication along the supply chain	Group 2 (industry)
Missing connections relating to hazard characteristics and those relating to risk assessment	Group 2 (industry)
Gaps for specific substances	Group 4 (NGO/others)
Gap concerning evaluation and reporting on chemicals in low volumes	Group 4 (NGO/others)
Gap in chemical regulations and content information to consumers for the majority of consumer goods	Group 4 (NGO/others)
Exposure of consumers to hazardous chemicals in imported articles and goods is not adequately addressed	Group 4 (NGO/others)
No clear limit value on content of chemicals in medical devices	Group 4 (NGO/others)
Setting standards for emission of pollutants in indoor air	Group 4 (NGO/others)
Drinking Water Directive needs to be enhanced to improve chemical safety of water supply materials	Group 4 (NGO/others)
Themes on overlaps and duplications	
Unclear boundaries between IED[1] and Urban Waste Water Directive and Water Framework Directive need to be addressed	Group 3 (public authority)
Same substances could be notified and/or evaluated under different legislative frameworks	Group 2 (industry)
PPP[2] requires full risk assessment but this can be overridden by classification if the risk assessment indicates safe use	Group 1 (citizen)
Overlaps between directives/regulations (but no details given)	Group 1 (citizen) Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
PG2 and 5 overlap with well-functioning and implemented national regulation and laws	Group 1 (citizen)
Same chemicals can be covered by CLP, biocides and plant protection products regulations and different outcomes can be reached even with the same dataset	Group 3 (public authority)
RoHS[3] and toys directive have same substances regulated	Group 3 (public authority)
Double regulation of dioxins/furans in POP[4] regulation and national ChemVerbotsV	Group 3 (public authority)
Classification and labelling requirement has unduly become reference for waste classification	Group 2 (industry)
Substances on the candidate list and POP regulation	Group 2 (industry)
RoHS and REACH have substance related overlaps	Group 2 (industry)
Some instances of double regulation due to legislative changes or guidance	Group 4 (NGO/others)
Themes on inconsistencies and conflicts	
Preventing hazardous substances getting into materials and products	Group 3 (public authority)
Use of SVHC[5] is hindering recycling	Group 3 (public authority)
Different approaches at national level to nanomaterials	Group 2 (industry) Group 3 (public authority)

Table 3-64: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (Gaps: n=39; Group 1 (citizens) = 5, Group 2 (industry) = 20, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8; Overlaps: n=39; Group 1 = 5, Group 2 = 22, Group 3 = 6, Group 4 = 6; Inconsistencies: n=41; Group 1 = 4, Group 2 = 24, Group 3 = 6, Group 4 = 7)	
Theme	**By**
Tighter hazard categories in Seveso Directive from CLP will result in more substances falling under Seveso requirements	Group 2 (industry)
Classification can be very different for one product for human use	Group 2 (industry)
CLP values are not suitable to set safe rules for chemical use in toys	Group 4 (NGO/others)
Substance restrictions with different rules	Group 2 (industry)
Changes in CLP environmental classification automatically triggers requirements under Seveso III and there is no assessment as to whether these requirements are appropriate in risk management terms	Group 2 (industry)
Incorrect application of Article 15 of Cosmetics Products Regulation creates an overlap with CLP which leads to inconsistency	Group 2 (industry)
Risk assessment used in some cases risk management by hazard identification in Group 4	Group 1 (citizen) Group 2 (industry)
Directives should be united in regulations and directly implemented at national level	Group 1 (citizen)
Inconsistencies between regulations/directives (no further details given)	Group 1 (citizen) Group 3 (public authority) Group 2 (industry)
Controls on biocides and plant protection products are more restrictive than on general chemicals due to classification based exclusion criteria	Group 3 (public authority)
Harmonised definition of nanomaterials is needed	Group 3 (public authority) Group 4 (NGO/others)
Ban on animal testing for cosmetics but biocides regulation specifically asks for animal testing	Group 3 (public authority)
Issue of animal testing in cosmetics regulation versus other regulations	Group 2 (industry)
PBT[6] assessment is not consistent within different parts of the legislation	Group 3 (public authority)
Difference in classification of substances between transport and supply and use	Group 3 (public authority)
Divergence between commitment to weight-of-evidence considerations and how substances are identified as PBT/vPvB[7]	Group 2 (industry)
Different migration limits for same chemicals for different FCM[8]	Group 2 (industry)
The influence of individual views of Member States	Group 2 (industry)
CLP has led to unpredicted burden for waste management	Group 2 (industry)
Waste legislation might be inconsistent with REACH for recycling purposes	Group 2 (industry)
OELs[9] vary from country to country	Group 2 (industry)
Glass is a substance and should not be subject to RoHS	Group 2 (industry)
Risk assessment principles differ in Toy Safety Directive and Cosmetics Product Regulation with regard to treatment of children	Group 2 (industry)
There are inconsistencies between labelling of substances under CLP and some sectoral legislation (biocides, detergents)	Group 2 (industry)
Inconsistency of restrictions in POP regulation	Group 2 (industry)
Regulation on marketing and use of explosives is inconsistent with statistical and physical measurement bases	Group 2 (industry)
Not all inconsistencies between different legislation are negative	Group 4 (NGO/others)

Table 3-64: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (Gaps: n=39; Group 1 (citizens) = 5, Group 2 (industry) = 20, Group 3 (public authority) = 6, Group 4 (NGO/others) = 8; Overlaps: n=39; Group 1 = 5, Group 2 = 22, Group 3 = 6, Group 4 = 6; Inconsistencies: n=41; Group 1 = 4, Group 2 = 24, Group 3 = 6, Group 4 = 7)	
Theme	**By**
Lists of substances in different pieces of legislation should be harmonised	Group 4 (NGO/others)
CLP has no *de minimis* exemption unlike Dangerous Goods directive	Group 4 (NGO/others)
Themes on labelling	
Labelling requirements under different pieces of legislation need to be better integrated to facilitate compliance	Group 2 (industry)
Inconsistent labelling requirements	Group 2 (industry)
Detergents Regulation has its own labelling requirements beyond what is required according to CLP	Group 3 (public authority) Group 2 (industry)
CLP and plant protection regulation/biocidal products have different requirements for advertising and labelling	Group 3 (public authority)
Labelling requirements in transport of dangerous goods, in CLP and in national authorities requirements	Group 2 (industry)
Labelling under BPR[10] and CLP for treated articles	Group 2 (industry)
Classification and labelling differs between ADR[11] and CLP	Group 2 (industry)
Themes on coordination with other legislation	
Automatic legal consequences in downstream legislation should be avoided	Group 2 (industry)
Need for visual mapping and overview of broader architecture and vertical and horizontal linkages between different legislation	Group 2 (industry)
Derogation of glass under RoHS should not be reopened by REACH authorisation process	Group 2 (industry)
When a substance is restricted in regulation X, this should trigger a restriction in regulation Y, Z and evaluation in regulation A, B, C	Group 4 (NGO/others)
Themes on definitions	
Coherent definitions of hazardous substances	Group 3 (public authority) Group 2 (industry)
There is not always a common definition	Group 2 (industry)
Other themes	
Risk assessment should be studied by a laboratory independent of the manufacturer	Group 1 (citizen)
Set of shared references	Group 1 (citizen)
Product bans	Group 1 (citizen)
Risk assessment issues	Group 3 (public authority)
Ignorance of users	Group 2 (industry)
Not all substances in Seveso are capable of uncontrolled or spontaneous release of energy or matter*	Group 2 (industry)
Chemical producers should not undertake the evaluation of risks	Group 1 (citizen)
Notes: *This is not considered an inconsistency, as Seveso intentionally includes substances that can initiate or aggravate the effects of a major accident. [1] IED = Industrial Emissions Directive. [2] PPP = Plant Protection Product. [3] RoHS = Restriction of Hazardous Substances Directive. [4] POP = Persistent Organic Pollutant. [5] SVHC = Substances of Very High Concern. [6] PBT = Persistant, Bioaccumulative, Toxic. [7] vPvB = very Persistent very Bioaccumulative. [8] FCM = Food Contact Materials. [9] OEL = Occupational Exposure Limit. [10] BPR = Biocidal Products Regulation. [11] ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road	

3.3.22.2 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-65 provides a summary of the themes from these non-questionnaire responses.

Table 3-65: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on gaps and omissions	
There is a gap in the requirements for toys	Group 3 (public authority)
Additional steps in risk management of active substances are needed for biocides	Group 2 (industry)
There is no provision within Regulation EC 396/2005 to enable MRLs[1] to be set for BPR[2] product	Group 3 (public authority)
Gaps, overlaps, confusions and contradictions creep into the text during negotiations which are not intended	Group 3 (public authority)
Themes on overlaps and duplications	
The same substance must be assessed for both PPP[3] and BP Regulations	Group 3 (public authority)
Hazard assessment of the same substances under both Regulation (EC) no 1107/2009) and Regulation (EU) no 528/2012 should be avoided	Group 3 (public authority)
Article 69(1) BPR (Regulation EU no 528/2012) refers to the provisions of CLP, including requirements to have labels in the national languages (art. 17(2) CLP). The same issue is dealt with in art. 69(3) BPR	Group 3 (public authority)
The Detergents Regulation has its own additional labelling requirements beyond what is required according to CLP	Group 3 (public authority)
The demands are unnecessary since CLP entered into force and it could be removed	Group 3 (public authority)
Both CLP and the Plant Protection Products Regulation/Biocidal Products Regulation have rules regarding for example advertising and labelling	Group 3 (public authority)
The RoHS[4] Directive and the Toys directive have the same substances regulated	Group 3 (public authority)
Creosote between BPR and REACH	Group 3 (public authority)
The large number of separate directives for specific issues e.g. toys, adds to the complexity	Group 3 (public authority)
The parallel existence of hazard reviews under the CLP, BPR and PPP schemes can prove to be very ineffective and impacting resources	Group 2 (industry)
None of the three legal texts (CLP, Biocides, and REACH Regulations) foresee a timely sequence or practical code of work to maximise the use of generated data and the efficiency of the overall classification process	Group 2 (industry)
Neither do methodologies documented under one benefit the other.	Group 2 (industry)
This may result in classifications decided on the basis of incomplete or non-fit-for-purpose datasets	Group 2 (industry)
The hazard assessment for BPR, PPPR and REACH and CLP leads often to double or multiple work	Group 2 (industry)
We should move from an ad hoc system in which classification proposals are submitted under different umbrellas (e.g. Biocides, CLP, etc.), to a more systematic and integrated system.	Group 2 (industry)
Article safety legislation is far from harmonised and streamlined	Group 2 (industry)
Themes on inconsistencies and conflicts	
The derogation for medical devices which are invasive in CLP is not written in the same way as in REACH	Group 3 (public authority)

Table 3-65: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (n=9)	
Theme	**By**
The properties of PFAS[5] do not fit in the criteria laid down by REACH Annex XVIII	Group 3 (public authority)
There is a divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs[6]/vPvBs[7]	Group 2 (industry)
When it comes to PBT/vPvB criteria the consequences of fulfilling the criteria are very different. For REACH no immediate consequences; for PPP non-authorisation. The difference in consequences leads to differences in interpretation	Group 3 (public authority)
Regulatory efforts and costs varies significantly between different legislations	Group 3 (public authority)
The whole REACH system became utterly complex with all the different substances 'statuses'	Group 2 (industry)
This could be simplified to a great extent by focussing on the potential for and pathway of exposure	Group 2 (industry)
Themes on labelling	
Labelling requirements could be better integrated	Group 2 (industry)
Labelling requirements under BPR and CLP are sometimes contradictory	Group 2 (industry)
In the BPR the risks from products might be the same but the extent to which they are regulated depends upon the claims made on the label	Group 3 (public authority)
Themes on coordination with other legislation	
Monitoring data from other legislation would be useful (e.g. WFD[8])	Group 3 (public authority)
Need to highlight issues for other legislation where water bodies do not fulfil criteria of WFD	Group 3 (public authority)
Needs to be more coordination between WFD and other legislation	Group 3 (public authority)
REACH datasets are often disregarded in Member State and EU policies, such as the Water Framework Directive, IED and OSH[9] where they are not yet fully recognised as reliable references	Group 2 (industry)
Better integration is needed with EU rules on chemicals, articles and waste	Group 3 (public authority)
It is not possible for EU-authorities to get data on the use of ingredients in cosmetics	Group 3 (public authority)
Themes on definitions	
The term "ingredients" is not defined in CLP leading to unclear legal text	Group 3 (public authority)
Article 1(5) CLP is not clear with regard to the scope of the exemption from CLP	Group 3 (public authority)
Reg (EC) no 1107/2009 and Reg (EC) no 1272/2008 are vague as to the designating responsibility to produce classification dossiers	Group 3 (public authority)
Same definitions can mean different things in different legislations	Group 3 (public authority)
Better to have rules that impose the same restrictions on all items	Group 3 (public authority)
Other themes	
Automatic legal consequences to more substances falling under Seveso requirements should be avoided	Group 2 (industry)
Evaluation process for active substances in PPP and CLH[10] process need to be re-examined	Group 3 (public authority)
The approach indicated by the legislator for 'cut off criteria' is not followed in practise.	Group 3 (public authority)
It is not clear that the legislation leads to substances that stay on the market are safer than the ones that are removed	Group 3 (public authority)
Somewhat unclear or illogical structure of the chemicals legislation in EU particularly in relation to the legislation concerning substances and mixtures in	Group 3 (public authority)

Table 3-65: Q26: incoherence between different pieces of legislation under the scope of the fitness check themes from non-questionnaire responses (n=9)	
Theme	**By**
articles (products)	
Make better use of self-classifications and to discuss at expert panel level or a broader/more integrated and dynamic group, only self-classifications deviating from the classification rules	Group 2 (industry)
Mutual recognition of legislation on food contact materials is not working effectively	Group 2 (industry)
Limit values in different legislations are potentially overlapping and incoherent	Group 3 (public authority)
Notes: [1] MRL = Maximum Residue Limit. [2] BPR = Biocidal Products Regulation. [3] PPP = Plant Protection Product. [4] RoHS = Restriction of Hazardous Substances Directive. [5] PFAS = Perfluorinated alkylated substances. [6] PBT = Persistant, Bioaccumulative, Toxic. [7] vPvB = very Persistent very Bioaccumulative. [8] WFD = Water Framework Directive. [9] OSH = Occupational Safety and Health. [10] CLH = Harmonised Classification and Labelling	

3.3.22.3 Comparison of themes

The themes associated with the incoherence between different pieces of legislation are summarised in the table below. Here the themes focus on the regulations and directives where gaps, overlaps and inconsistencies have been identified. Not all comments provide further details as to what the gap is, where the overlaps are or why there are inconsistencies. Those regulations and directives listed in Table 3-66 that were not included as themes in Tables 3-64 and 3-65 are where no further detail has been provided. Therefore, the table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes. Further details on the gaps, overlaps and inconsistencies are set out below the table, where these were provided by respondents.

Table 3-66: Comparison of responses on incoherence between different pieces of legislation under the scope of the fitness check			
Non-questionnaire responses		**OPC responses**	
Regulation/directive(s)	**By**	**Regulation/directive(s)**	**By**
Regulations and directives where gaps were identified			
Toys	Group 3 (1)	Cosmetic Products Regulation and other legislation	Group 2 (1)
Biocides	Group 3 (1)	CLP packaging requirements	Group 2 (1)
		Carcinogen and Mutagens Directive	Group 2 (1) Group 4 (1)
Regulations and directives where overlaps were identified			
PPPR[1] and BPR[2]	Group 3 (2)	Biocides and pesticides	Group 4 (1)
BPR and CLP	Group 3 (1)	CLP and BPR	Group 1 (1) Group 4 (1)
		BPR and REACH (creosote)	Group 3 (1)
PPPR, BPR and CLP	Group 3 (1) Group 2 (1)	CLP, biocides, PPPR	Group 3 (1)
CLP, biocides and REACH	Group 2 (1)		
PPPR, BPR, CLP and	Group 2 (1)		

Table 3-66: Comparison of responses on incoherence between different pieces of legislation under the scope of the fitness check			
Non-questionnaire responses		**OPC responses**	
Regulation/directive(s)	**By**	**Regulation/directive(s)**	**By**
REACH			
		Biocides and medical devices, cosmetics and detergents	Group 1 (1)
		Drinking Water Directive, BPR	Group 3 (1)
		Drinking Water directive, BPR, REACH	Group 1 (1)
Detergents Regulation and CLP	Group 3 (1)	CLP and Detergents Regulation	Group 2 (1)
		CLP, BPR and detergents	Group 2 (1)
		Cosmetic Products Regulation and REACH	Group 2 (1)
RoHS and Toy Safety Directive	Group 3 (1)	RoHS[3] and Toy Safety Directive	Group 3 (1)
		RoHS and REACH	Group 2 (1)
		RoHS, ELV[4] and Battery Directives, REACH	Group 2 (1)
		IED[5], Urban Waste Water Directive, Water Framework Directive	Group 3 (1)
		Dioxins/furans in POP[6] Regulation and national ChemVerbotsV	Group 3 (1)
		CLP and waste classification	Group 2 (1)
		Substances on candidate list and POP Regulation	Group 2 (1)
		Occupational health legislation, REACH/CLP	Group 2 (3) Group 4 (1)
		Worker protection exposure values (DNEL[7], OEL[8], European and National)	Group 2 (1)
		CLP and transport regulations	Group 2 (1)
		CLP and F-Gas regulation, Ecodesign	Group 2 (1)
		PPP and pharmaceutical law	Group 2 (1)
Regulations and directives where inconsistencies and conflicts were identified			
Medical devices, CLP and REACH	Group 3 (1)		
PFAS and REACH	Group 3 (1)		
PBT/vPvB in PPPR and REACH	Group 3 (1)		
		CLP and BPR	Group 2 (1)
		Seveso and CLP	Group 2 (4)
		CLP and toys	Group 4 (1)
		Cosmetic Products Regulation and CLP	Group 2 (2)

Table 3-66: Comparison of responses on incoherence between different pieces of legislation under the scope of the fitness check			
Non-questionnaire responses		**OPC responses**	
Regulation/directive(s)	**By**	**Regulation/directive(s)**	**By**
		CLP and transport regulations	Group 2 (1)
		Drinking Water Directive, BPR	Group 1 (1)
		Contaminants in food, MSFD[9], IED	Group 3 (1)
		CAD[10] and CMD[11]	Group 2 (1)
		RoHS	Group 2 (1)
		National legislation versus EU legislation	Group 2 (1)
Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from Question 5 of the OPC. Notes: [1] BPR = Biocidal Products Regulation. [2] PPPR = Plant Protection Products Regulation. [3] RoHS = Restriction of Hazardous Substances Directive. [4] ELV = End of Life Vehicles Directive. [5] IED = Industrial Emissions Directive. [6] POP = Persistent Organic Pollutant. [7] DNEL = Derived No Effect Level. [8] OEL = Occupational Exposure Limit. [9] MSFD = Marine Strategy Framework Directive. [10] CAD = Chemical Agents Directive. [11] CMD = Carcinogens and Mutagens Directive.			

Some of the comments provided just a short summary of the issue without providing any further information. Others, though, provided a detailed discussion of the problem. Examples of key points are provided below:

- Comments on gaps and omissions:
  - While we agree it can be useful to look for current gaps and missing links in current legislation, we hold the view that not all inconsistencies are bad by definition. There can be good reasons to adapt rules to specific chemical uses or intrinsic hazardous properties. For example, the use of generic risk assessments to phase out chemicals with the most harmful properties from applications with clear exposure of people, including children (Group 3);
  - Need to speed up the process of including restrictions for use of certain chemicals in packaging materials, batteries and vehicles in line with the new information on hazards and risks that is generated e.g. under REACH. We propose that a review process should be included in these directives to regularly evaluate the existing limit values and assess the need for including additional substances in the directives (Group 3);
  - Glass is not harmonized with regard to food contact (Group 2);
  - Food contact materials and the plastics implementing measure is only covering plastics and not for example adhesives, metals and rubber (Group 2);
  - Currently there is no harmonised EU-level legislation on food contact chemicals permitted in paper, card, ink, glues or coatings (Group 4);
  - There is no linkage between REACH SVHC designation and any of the legislation on chemicals in food contact materials (Group 4);
  - There is no provision for a generic risk assessment approach in the food contact legislation (Group 4);
  - Current gaps in the legislation include lack of implemented protection against endocrine disruptors, nanomaterials, polymers, combined effects, mixture effects and low-dose exposure (Group 4);

- Significant gap in the current legislation concerning chemicals in low volumes with lack of evaluation and reporting (Group 4);
- Gap in chemical regulations and content information to customers when it comes to the majority of consumer goods, for example textiles and building materials (Group 4);
- In general the issue of chemicals in most consumer articles is not covered well by EU regulations, for example there is a lack of control on chemicals in home furnishings and carpets, in spite of the fact that these could easily be exposing children to as much chemical exposure as toys do (as can be seen from chemical contaminants in dust) (Group 4);
- Directive 2002/32 Contaminants In Feed: Toxins are described but no microbiological criteria evaluated as the source of the toxins (to deal with feed safety criteria and feed hygiene criteria) (Group 2);
- Mixture toxicity and cumulative effects of chemicals are not sufficiently taken into account between the different legislative frameworks. The relation between sectoral and horizontal legislation should be strengthened. E.g. substances that are banned in new products can still be placed on the market in recycled material (Group 3);
- Radiotoxic effects. Should be implemented in REACH (Group 4);
- The toy safety directive 2009/48 lacks appropriate level of protection as the CLP values are not suitable to set safe levels for chemical use in toys and as not all relevant chemicals have been regulated with specific limit values. As a consequence, market surveillance authorities have not enough clarity which toys should be taken off the market despite the fact that they are harmful to children (Group 4).

- Comments on overlaps and duplications:
  - The unclear boundary between the Industrial Emissions Directive (IED - 2010/75/EU) and the Urban Waste Water Directive (91/271(EEC) needs to be addressed. It is also unclear how the Water Framework Directive (WFD - 2000/60/EC should apply in relation to the IED. The IED includes limit values for some industrial substances and sources. However, if comparing the limit value for e.g. mercury in effluents from cleaning of waste gases is very high compared to the levels that should not be exceeded in the aquatic environment. Thus the limit (and BAT) values should be reviewed, from a WFD perspective (Group 3);
  - Hazard assessment of the same substances under both Regulation (EC) no 1107/2009) and Regulation (EU) no 528/2012 should be avoided. Article 69(1) BPR (Regulation EU no 528/2012) refers to the provisions of CLP, including requirements to have labels in the national languages (art. 17(2) CLP). The same issue is dealt with in Art. 69(3) BPR giving the Member State an option to adopt such provisions in their national legislation and thus creating a possible overlap (Group 3);
  - Both CLP and the Plant Protection Products Regulation/Biocidal Products Regulation have rules regarding for example advertising and labelling. The requirements are not the same and the period of grace for labelling is different between the legislations (Group 3);
  - Glass is a substance. The derogation under RoHS Directive should not be reopened by any REACH authorisation process. A use could be covered by a specific derogation but still under a more generic regulation. A mutual recognition of derogation should be implemented to avoid submission of the same document within different frameworks (Group 2);

- For aerosols, overlap between Inland transport of dangerous goods and Aerosol Dispensers Directive (Group 2);
- The EU Ecolabel for furniture products overlaps with the GPP criteria requirements. However, they should respond to a different logic and scope (Group 2); and
- We sometimes witness overlaps between food contact materials and biocides (Group 2).

- Comments on inconsistencies and conflicts:
  - Notification requirements for substances under the BPR, the Cosmetic Products Regulation and REACH differ and the same substance could be evaluated under different legislative frameworks without consideration of the evaluations carried out for other regulations (Group 2);
  - The regulation of nanomaterials is patchy. There are several definitions in different pieces of legislation, and the harmonized definition is not legally enforceable as it is only contained in a recommendation (though it has been used in the Biocidal Products (Regulation (EU) No 528/2012). Also, only certain pieces of legislation specifically seek to assess the risks from nanomaterials as distinct from the correspondent bulk substance. Therefore, for nanomaterials, the legislation is completely inconsistent (Group 4);
  - The incorrect application of Article 15 of the Cosmetic Products Regulation creates an overlap with CLP which leads to inconsistency (conflicting requirements for the same substance between CLP and the Cosmetic Products Regulation) (Group 2);
  - At present there is divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs/vPvBs within Europe and at international level too (Group 2);
  - The application of CLP has led to unpredicted burden for waste management. Inconsistent application of CLP-requirements to waste materials and waste products, which are not chemicals (Group 2);
  - Once glass is produced, its constituents do not exist anymore. Some legislation should clarify this so as to avoid inappropriate legislation to the glass sectors. For instance, glass sectors are not processing respirable crystalline silica dust, but handling respirable crystalline silica for an extremely limited part of the glass manufacturing process…Applications for glasses with constituents in the RoHS list were proven not dangerous to the environment – those constituents cannot be replaced and the repeated requests for derogations put excessive and usefulness burden on the optical and crystal glass industry (Group 2);
  - The risk assessment principles between the implementation of the Toy Safety Directive and the Cosmetic Products Regulation differ in approach with regard to the treatment of children. The SCCS Opinion that covers risk assessment for children indicates that in general no additional safety factors are employed during the risk assessment process. The Toy Safety Directive however requires that an additional safety factor of 10 times or more is used to account for other exposures (Group 2);
  - CLP classification can trigger different waste related requirements at the national level. This is an important issue in terms of alignment and market distortions (Group 2);
  - A useful tool would be to use e.g. PACT to list all on-going hazard assessment initiatives for a given substance, to avoid overlaps or inconsistent work across authorities and legislative contexts (Group 2);
  - Chemicals may be borderline or used for multiple purposes. When this happens (e.g. REACH and Plant Protection Products or Biocides legislations), chemicals may

be required to be tested under the requirements of each legislation resulting in duplicate testing and unnecessary animal use (Group 4);
    - Triclosan – restricted for use in soaps and shampoos used by medical professionals but allowed to be used in soaps for consumer use (Group 4);
    - We would like to highlight inconsistencies in the setting of M-Factors, Specific Concentration Limits (SCL) and Ecotoxicity References Values (ERV) among the following directives: Plant Protection Products (PPP, Regulation (EC) No 1107/2009), Biocidal Products (Regulation (EU) No 528/2012), Classification, Labeling and Packaging (Regulation No (EC) 1272/2008) (Group 2).

There were also some areas that raised particular themes. Specific comments on these issues include:

- Comments on labelling:
    - Labelling requirements under the different pieces of legislation (cf. F-gas Regulation, REACH Annex XVII, BPR, PPPR), could be better integrated to facilitate compliance (Group 2);
    - The Detergents Regulation has its own additional labelling requirements beyond what is required according to CLP. The demands are too detailed and unnecessary since CLP entered into force and it could be removed (Group 2);
    - labelling requirements in Transport of dangerous goods, in CLP and also in national authorities requirements for piping and container labelling under the Seveso Directive are contradictory (Group 2);
    - classification and labelling differs between ADR and CLP. For example, one additive is classified toxic (class 6) for ADR and warning (SGH 07) for CLP (Group 2);
    - CLP requires the presence of some substances to be labelled but this is also the case of some sectoral legislation such as biocides, detergents, and both are not always consistent with each other. For instance there are inconsistencies in terms of thresholds and position of the label on packaging (Group 2).

- Comments on coordination with other legislation:
    - IED and Seveso legislation. Not all substances now in Seveso are capable of uncontrolled or spontaneous releases of energy and/or matter with Major Accident potential. There is no need for such substances to be regulated by Seveso. The type of use and risks therein are as important as the intrinsic properties (Group 2);
    - CLP and Seveso III (for environment). Changes in CLP environmental classification automatically triggers requirements under Seveso III. CLP classification has therefore a direct impact on the downstream level (Group 2).

- Comments on definitions:
    - Definitions of hazardous substances and substances of very high concern should be used in a more consistent way throughout the chemicals and waste legislation. The use of terms such as dangerous (WEEE Directive) and harmful (Waste Framework Directive) creates uncertainty about which substances are covered by different regulations (Group 3);
    - A harmonised definition of nanomaterials within the various legislations of chemical safety is needed to be able to identify nanoscale forms of substances (Group 3).

3.3.23 Question 27: Please indicate incoherence between legislation covered by this fitness check and other legislation as regards the regulation and risk management of chemicals

3.3.23.1 Analysis of open text responses

There was no closed element to this question. Respondents were also asked to highlight any gaps, missing links, overlaps or inconsistencies between the legislation covered by this fitness check and other legislation related to the regulation and risk management of chemicals. In total 43 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-67. The table also shows which groups the comments were from.

Table 3-67: Q27: incoherence with other legislation themes from non-questionnaire responses (n=43; Group 1 (citizens) = 4, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 7)	
Theme	**By**
Themes on overlapping or diverging requirements	
Incoherence between Directives (no further details given)	Group 1 (citizens) Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Variety of specific legislation leads to high administrative costs and inhibit the innovation capacity and competitiveness of EU companies	Group 1 (citizens)
Evaluation process for active substances in PPP[1] and CLH[2] are not totally coherent	Group 3 (public authority)
Limit values in different legislations are potentially overlapping and incoherent	Group 3 (public authority)
Setting legal limits on disinfectant residues which are used in the food supply chain to ensure microbiological hygiene	Group 2 (industry)
Clarification is needed regarding legislation covering treated seeds	Group 3 (public authority)
New regulation on mercury includes virtually no investigation of how the proposals made should function in relation to existing legislation	Group 3 (public authority)
Tobacco Products Directive contains a provision that could be interpreted as double regulating the CLP Regulation (Article 5(2))	Group 3 (public authority)
DNEL[3] versus OEL[4]	Group 3 (public authority) Group 2 (industry)
Additional application of, e.g. "Candidate Listing and Authorisation" under REACH should be avoided where workplace legislation addresses identified risk	Group 2 (industry)
Overlaps between REACH and OSH[5] should be avoided and the best risk management measure should be selected	Group 2 (industry)
There is a need for harmonisation and consistency of OELs across Member States	Group 2 (industry)
Workers legislation could not qualify as equivalent to REACH and 58.2 of REACH could not be used in these cases	Group 4 (NGO/others)
REACH has overlaps and missing links and inconsistencies with many of the legislation covered by this fitness check	Group 2 (industry)
Austrian Environment Agency methodology for identification and assessment of substances for inclusion in the list of restricted substances under the RoHS[6] 2 Directive likely to create inconsistencies	Group 2 (industry)
REACH and RoHS for lead makes it difficult to know if compliance is being met	Group 2 (industry)
Approach to selecting substances to be restricted in EEE[7] or under REACH does not seem to be consistent	Group 2 (industry)
RoHS granted exemptions should be recognised as grounds for a possible exemption from REACH authorisation obligations	Group 2 (industry)

Table 3-67: Q27: incoherence with other legislation themes from non-questionnaire responses (n=43; Group 1 (citizens) = 4, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 7)	
Theme	**By**
Inconsistency for beryllium between CLP and carcinogens directive	Group 2 (industry)
Infocards and brief profiles display classification submitted via unjustified CLP notification on same level as information documented in REACH dossiers	Group 2 (industry)
REACH one-fits-all legislative solution will miss specifics and will not work	Group 2 (industry)
More attention should be paid to the potential impacts which risk management options can have across different policy areas	Group 2 (industry)
Difference in requirements for physical hazards	Group 2 (industry)
Self-classification under REACH is one of the reasons for different classifications being notified for the same substance	Group 2 (industry)
There is a trend to use the worst classification reported in the C&L inventory[8]	Group 2 (industry)
Treatment of mixtures is inconsistent	Group 2 (industry)
CLP Article 12(c) may require additional data not required under REACH	Group 2 (industry)
Inconsistency and overlap between CLP and REACH Regulations	Group 2 (industry)
Substances with multiple uses may have different MRLs[9] for the same type of products	Group 2 (industry)
Relevant opinions from Risk Analysis Committee and Socio-Economic Analysis Committee should be taken into account	Group 2 (industry)
Overlaps and inconsistencies between REACH and Water Framework Directive	Group 2 (industry)
Paper, card, ink, coatings & adhesives in food contact materials are unregulated	Group 4 (NGO/others)
Different definitions of nanomaterials in specific/sectoral pieces of legislation	Group 2 (industry)
Non-intentional contamination of industrial products is inconsistent with other regulations	Group 2 (industry)
Disconnect between alcohol denaturants and biocides and medical devices regulations	Group 2 (industry)
Exemptions appear inconsistent in some cases	Group 2 (industry)
Veterinary pharmaceuticals are not covered by this fitness check but they can cause environmental damage as do other chemicals	Group 4 (NGO/others)
Legislation on veterinary pharmaceuticals do not include hazard based exclusion criteria for the environment	Group 4 (NGO/others)
Construction Products Regulation should also be considered	Group 4 (NGO/others)
Themes on data and data needs	
There is a need for a system where data and information can be stored and shared	Group 1 (citizens) Group 3 (public authority)
Monitoring data on priority substances from Water Framework Directive would be useful for other legislation	Group 3 (public authority)
REACH datasets are disregarded in Member States and EU policies	Group 2 (industry)
REACH datasets could be used for reclassification but companies refrain from doing so due to high burden required	Group 2 (industry)
A process is needed to allow refinements of Annex VI classification based on REACH data	Group 2 (industry)
Legislation such as biocides or REACH offer good opportunities to validate methodologies and generate data	Group 2 (industry)
Themes on implementation and enforcement	
Efforts are needed to ensure sufficient implementation of already existing legislation	Group 3 (public authority)
Themes on recycling	

Table 3-67: Q27: incoherence with other legislation themes from non-questionnaire responses (n=43; Group 1 (citizens) = 4, Group 2 (industry) = 26, Group 3 (public authority) = 6, Group 4 (NGO/others) = 7)	
Theme	**By**
CLP will impact the classification of waste	Group 2 (industry)
Themes on food contact materials	
No specific comments	
Themes on imported articles	
No specific comments	
Other themes	
High standards of regulation of chemicals should not be jeopardised through trade agreements with countries outside of EU	Group 3 (public authority)
RMOAs[10] rightly identify the best regulatory option to manage the risk inside or outside of REACH	Group 2 (industry)
Test methods not entailing use of animals under certain legislations need to be immediately considered for inclusion and uptake	Group 4 (NGO/others)
Notes: [1] PPP = Plant Protection Products. [2] CLH = Harmonised Classification and Labelling. [3] DNEL = Derived No Effect Level. [4] OEL = Occupational Exposure Limit. [5] OSH = Occupational Safety and Health. [6] RoHS = Restriction of Hazardous Substances Directive. [7] EEE = Electronic and Electrical Equipment. [8] C&L Inventory = Classification and Labelling Inventory. [9] MRL = Maximum Residue Level. [10] RMOA = Risk Management Option Analysis	

3.3.23.2 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-68 provides a summary of the themes from these non-questionnaire responses.

Table 3-68: Q27: incoherence with other legislation themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on overlapping or diverging requirements	
Overlapping requirements between REACH and occupational health legislation as well as between REACH and RoHS[1]	Group 2 (industry)
Tobacco Products Directive (2014/40/EU) which contains a provision that could be interpreted as double regulating the CLP Regulation (Art. 5(2)).	Group 3 (public authority)
Risk Management divergences exist between worker protection H&S[2] directives and REACH/CLP regulations	Group 2 (industry)
The scope of substitution is broader than under H&S directives, adding further complexity for employers.	Group 2 (industry)
A universal, simplified and consolidated approach to chemicals and its interaction with H&S in the workplace from EU policy makers is needed to reduce administrative burdens	Group 2 (industry)
The Seveso II Directive and H&S and environmental legislation overlap and cause further problems for downstream users and employers	Group 2 (industry)
The objective must be to avoid dual legislation (double jeopardy)	Group 2 (industry)
There is also a lack of understanding at the user level between the requirements of water legislation, e.g. Water Framework Directive (WFD) and legislation that relates to food production (e.g. Common Agriculture Policy impacts) and legislation relating to energy use and production.	Group 2 (industry)
The positive aspect is that REACH, can as a major data source, deliver to other EU policies (WFD, air quality, …).	Group 2 (industry)

Table 3-68: Q27: incoherence with other legislation themes from non-questionnaire responses (n=9)	
Theme	**By**
The less positive aspect is that REACH does not strive for cooperation with other legislations (OSH[3], EQS[4] Directive). It rather promotes a conflict model on risk management, which can never be effective.	Group 2 (industry)
Themes on data and data needs	
A coordinated EU-database of environmental monitoring data would be very useful	Group 3 (public authority)
It would be useful to have data on accidents/incidents caused by chemical substances	Group 3 (public authority)
Themes on implementation and enforcement	
More efforts are needed to ensure a sufficient implementation of already existing legislation	Group 3 (public authority)
Themes on recycling	
Recycling processes may be contaminated without adequate regulation of chemicals going into food	Group 4 (NGO/others)
Lack of proper controls on chemical use in packaging is contradictory to binding recycling targets	Group 4 (NGO/others)
Recycling may not have been considered during safety assessment of chemicals	Group 4 (NGO/others)
It may not be clear if products for recycling contain restricted products or not	Group 4 (NGO/others)
Themes on food contact materials	
Member States are putting their own regulations for food contact materials in place	Group 4 (NGO/others)
How would mutual recognition work when there are few national regulations?	Group 4 (NGO/others)
Themes on imported articles	
Products for recycling may contain hazardous chemicals that were legal when the product was manufactured but are now restricted or banned	Group 4 (NGO/others)
Imported articles may contain chemicals that were not restricted outside the EU	Group 4 (NGO/others)
Other themes	
The high standards of regulation of chemicals within the EU should not be jeopardized through trade agreements with countries outside of the EU	Group 3 (public authority)
Clarification is needed regarding legislation covering treated seeds	Group 3 (public authority)
Virtually no investigation of how the proposals made should function in relation to existing legislation (new EU regulation on mercury)	Group 3 (public authority)
An alternative would be the mutual recognition of goals and tools allowing the RMOs[5] to assess and identify the most relevant, most effective Risk Management Measure/legislation	Group 2 (industry)
Notes: [1] RoHS = Restriction of Hazardous Substances Directive. [2] H&S = Health and Safety. [3] OSH = Occupational Safety and Health. [4] EQS = Environmental Quality Standard. [5] RMO = Risk Management Option	

3.3.23.3 Comparison of themes

The themes associated with the incoherence with other legislation are summarised in the table below. Here the themes focus on the regulations and directives where gaps, overlaps and inconsistencies have been identified. Not all comments provide further details as to what the gap is, where the overlaps are or why there are inconsistencies. Those regulations and directives listed in Table 3-69 that were not included as themes in Tables 3-67 and 3-68 are where no further detail has been provided. Therefore, the table provides a summary of the types of issues identified and the

number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes. Further details on the gaps, overlaps and inconsistencies are set out below the table, where these were provided by respondents.

Table 3-69: Comparison of responses on incoherence with other legislation

Non-questionnaire responses		OPC responses	
Regulation/directive(s)	**By**	**Regulation/directive(s)**	**By**
Regulations and directives where overlapping or diverging requirements were identified			
REACH and RoHS[1]	Group 2 (1)	REACH and RoHS	Group 2 (4) Group 4 (1)
Tobacco Products Directive and CLP Regulation	Group 3 (1)		
Worker protection, H&S[2] directives and REACH/CLP regulations	Group 2 (3)		
REACH, OSH[3], EQS[4]	Group 2 (1)	REACH and OSH	Group 1 (1) Group 2 (8) Group 4 (1)
Seveso II and H&S and environmental legislation	Group 2 (1)	CLP, Detergents Regulation and Seveso	Group 2 (1)
		Biocidal Products Regulation, Drinking Water Directive, Drinking Water Regulations	Group 1 (1)
		Biocides and REACH	Group 2 (1)
		Drinking Water Directive, Construction Products Regulation	Group 3 (1)
		Common Agricultural Policy	Group 3 (1)
		Decopaint and VOC[5] Directive	Group 3 (1)

Key: Group 4 captures non-governmental organisation (NGO), consumer association, trade association, trade union, academia or a research or educational institute, other from Question 5 of the OPC.
Notes: [1] RoHS = Restriction of Hazardous Substances Directive. [2] H&S = Health and Safety. [3] OSH = Occupational Safety and Health. [4] EQS = Environmental Quality Standard. [5] VOC = Volatile Organic Compound

Some of the comments provided just a short summary of the issue without providing any further information. Others, though, provided a detailed discussion of the problem. Examples of key points are provided below:

- Comments on inconsistencies associated with REACH:
  - The European Commission mandated the Austrian Environmental Agency to develop a Methodology for identification and assessment of substances for inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive. Although this methodology has not been yet included in the European legislative framework, it is foreseen it will be. Moreover, Member States and the European Commission will follow such methodology, which differs in many aspects from the substance

assessment methodology used for REACH or POPs. This methodology then has a potential to create inconsistencies of RoHS with other legislation (Group 2);
    - Example of lead: inconsistency between REACH (0.3% lead for massive form) and RoHS (0.1% - Exemption up to 4% for copper alloys). This is therefore not always clear to know if we are in compliance or not with the European regulations (Group 2).

- Comments on inconsistencies with occupational safety and health:
    - The reference DNELs derived by RAC under REACH causes confusion in the OSH context, where OELs prevail, because of differences in interpretation (e.g. Point of Departure, Assessment Factors) and methodologies (threshold vs. non-threshold) (Group 2);
    - We encourage the Commission to continue its work to better align OSH legislation and REACH to create synergies and avoid possible overlaps and inconsistencies (e.g. OELs vs. DNELs, identification of OSH as risk management option (RMO) in RMO Analyses) (Group 2);
    - When substances are being assessed under REACH but have already been addressed under RoHS, the scope of uses/applications under REACH should clearly exclude EEE products already regulated by RoHS (Group 2).

- Comments on CLP and REACH:
    - The CLP text is sometimes vaguer than REACH on the conditions to be met for information to be considered reliable (e.g. debate on the quality requirements for labs performing physico-chemical tests, which lasted for > 1 year in CARACAL). This also applies to the water solubility test, which has an equivalent specifically designed for metals, namely the Transformation Dissolution test (OECD 29) (Group 2);
    - There is some level of inconsistency and overlap between the CLP and the REACH Regulations, especially for substances which are already listed on Annex VI of the CLP Regulation. The inconsistency is two-fold: a) several substances do not exist on the EU market (e.g. some nickel compounds), b) for some of the substances, the information generated for REACH indicates that the harmonised classification is either correct, but needs to be completed for some endpoints, or is incorrect on the basis of the most recent dataset. This situation is challenging for companies to implement with inconsistencies present in the information provided to end-users (Group 2).

- Comments on CLP and other legislation:
    - The new CLP Regulation will noticeably impact the classification of waste according to Waste framework Directive (Directive 2008/98/EC) and List of Waste, and the Waste shipments Regulation (Regulation (EC) No 1013/2006). Our concern is that a large part of the packaging waste deriving from the separate collection from households – which were classified as non-hazardous, and are thus recycled into high-quality products – are now classified as “hazardous waste” (Group 2).

- Comments on REACH and Water Framework Directive:
    - REACH/Water Framework Directive: potential overlap and inconsistencies Substances proposed for inclusion as priority substances, or priority hazardous substances, under the Environmental Quality Standard (EQS) Directive have already been subject to other pieces of EU legislation that introduced specific risk management measures (Group 2).

- Other comments on incoherence:
    - Veterinary pharmaceuticals are not covered by this fitness check. But once released in the environment veterinary pharmaceuticals interact with the ecosystem and can cause environmental damage due to their substance properties as other chemicals do (Group 4);
    - When considering the above gaps regarding water supply materials and products leading to indoor emissions, the Construction Products Regulation should also be considered. This does not set performance requirements - so (construction) products producing indoor emissions or these are - in theory - subject of the General Product Safety Directive (GPSD) (Group 4);
    - Some substances are allowed by one regulation but restricted by another but both have similar uses, e.g. Trichloroacetic acid is banned in cosmetics but allowed in injectable medical devices (Group 3).

There were also comments related to data, including that generated by REACH. These include:

- It would be very useful with a coordinated EU-database with regards to environmental monitoring data (Group 3);
- It would be useful with access to data on accidents/incidents caused by chemical substances (Group 3);
- The USETox database used in Life-Cycle Assessments also disregards REACH datasets (although we are working to improve this). Group 2 has the impression that due to this focus on regulating chemicals through ECHA (where resources are) and REACH and CLP-related implementing acts, the trend is to use REACH as a patch cover to address weaknesses of other chemicals legislation (Group 2);
- Despite being exhaustive and expensive hazard assessments, without real precedent, REACH datasets (sometimes even validated at OECD under the Mutual Acceptance of Data scheme) are often disregarded in Member State and EU policies, such as the Water Framework Directive (for the derivation of Environmental Quality Standards) or IED (for the identification of priority pollutants that require emission control). In these policies and various others, REACH datasets are not yet fully recognised as reliable references (Group 2);
- REACH also developed additional data sets and read-across evidence for substances with existing classifications in Annex VI. Depending on the endpoint, these data can be used for re-classification. However, many companies refrain from doing so due to the high burden required to change a harmonised hazard identification even for a “simple endpoint” like acute toxicity. This triggers inconsistency between REACH and CLP classifications (Group 2);
- information generated under REACH on substances, their classification, uses, exposure and best risk management options should be fully taken into consideration in the context of RoHS. To maximise the necessary synergies with REACH, we recommend that all relevant opinions from the Risk Analysis Committee (RAC) and Socio-Economic Analysis Committee (SEAC), as well as the regulatory decision of the Commission, are taken into account (Group 2).

3.3.24 Question 28: Indicate the extent to which communication of hazards to workers and consumers is effective

Respondents were asked to assign a score from 1 (not effective) to 5 (very effective) to two statements:

a) To what extent are CLP labels effective in communicating hazards to workers? There were 263 responses on the effectiveness of CLP labels for workers; and
b) To what extent are CLP labels effective in communicating hazards to consumers? There were 262 responses on the effectiveness of CLP labels for consumers

A breakdown of the results is provided in Table 3-70, with Figures 3-24 and 3-25 showing the variation in responses across the groups for each statement.

Table 3-70: Scores assigned to extent to which CLP communicates hazards to workers and consumers (n=281)

Score	Group 1 (citizens) (n=21 to 22)		Group 2 (industry) (n=166)		Group 3 (public authority) (n=31 to 32)		Group 4 (NGO/others) (n=43 to 44)	
	No.	%	No.	%	No.	%	No.	%
a) To what extent are CLP labels effective in communicating hazards to workers?								
1	2	9%	1	1%	0	0%	0	0%
2	3	14%	6	4%	0	0%	2	5%
3	2	9%	26	16%	1	3%	6	14%
4	7	32%	82	49%	14	45%	19	43%
5	0	0%	44	27%	9	29%	4	9%
I don't know	8	36%	7	4%	7	23%	13	30%
Weighted score	3.0		4.0		4.3		3.8	
b) To what extent are CLP labels effective in communicating hazards to consumers?								
1	3	14%	11	7%	0	0%	0	0%
2	3	14%	40	24%	3	9%	13	30%
3	5	24%	52	31%	10	31%	11	26%
4	4	19%	38	23%	7	22%	10	23%
5	0	0%	9	5%	5	16%	2	5%
I don't know	6	29%	16	10%	7	22%	7	16%
Weighted score	2.7		3.0		3.6		3.0	

Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the more each group as a whole considers the CLP labels to be effective. The calculation excludes don't know responses

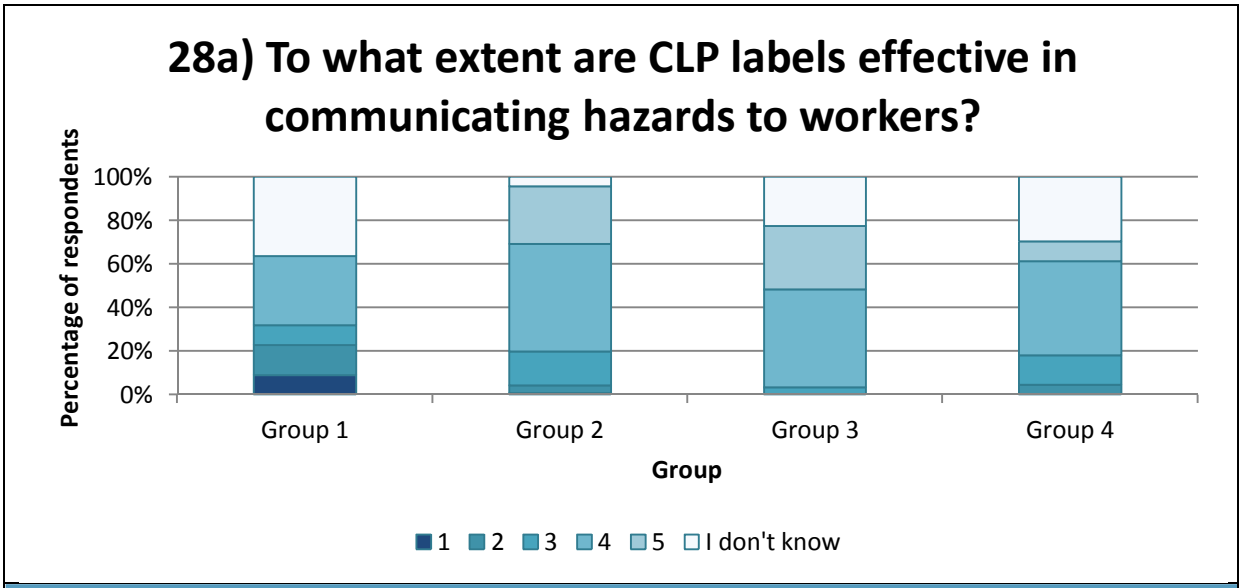

Figure 3-24: Chart showing percentage of respondents agreeing/disagreeing with statement a (n=263)

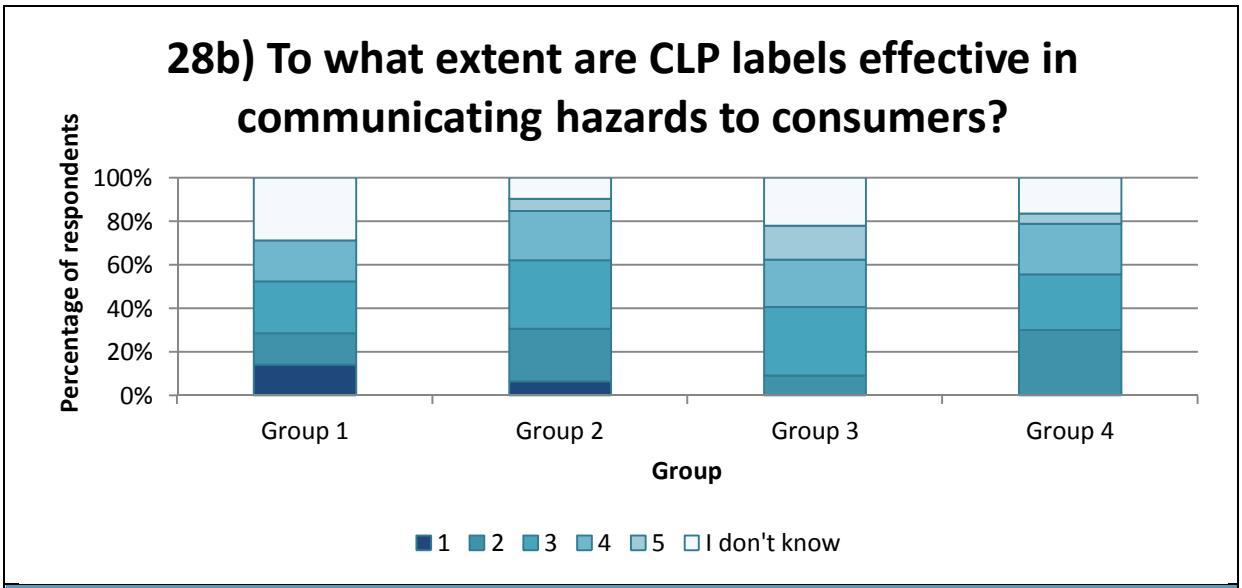

Figure 3-25: Chart showing percentage of respondents agreeing/disagreeing with statement b (n=262)

Table 3-70 and Figure 3-24 show that Group 3 believes CLP to be the most effective at communicating hazards to workers. Here, 45% (14) assigned a score of 4 and 29% (9) assigned a score of 5 (very effective). The overall weighted score for Group 3 is 4.3. Group 2 also assigns relatively high effectiveness scores, resulting in an overall weighted score of 4.0. A total of 49% (82) of this group assigned a score of 4 while a further 27% (44) assigned a score of 5. The scores for Groups 1 and 4 are lower, although both are still at or above moderate effectiveness. Responses from Group 1 result in a weighted score of 3.0 with the most common response (32% or 7) being a score of 4. Responses from Group 4 result in a weighted score of 3.8, with the most common response being 43% (19) again for a score of 4.

Table 3-70 and Figure 3-25 present the results related to the effectiveness of CLP labels in communicating risks to consumers. The weighted scores for all four groups are lower than those

assigned for workers. The maximum score is again from Group 3 at 3.6, although the most common response from this group is 31% (10) for a score of 3. The most common response from Group 2 is also for a score of 3 (31% or 52), giving a weighted score of 3.0; this is one full point lower than the results from Group 2 for effectiveness for workers. The most common response from Group 1 is also a score of 3 (24% or 5) but the weighted score is 2.7, reflecting a larger proportion of scores of 1 and 2 (both 14% or 3). For Group 4, the most common response is a score of 2 (30% or 13) but there are also a reasonably high level of responses for scores of 3 (26% or 11) and 4 (23% or 10) such that the weighted score is 3.0.

Scores for 'don't know' are excluded from the calculation of the weighted score but there was a high proportion of 'don't know' responses from Group 1 (29% or 6) and Group 3 (22% or 7).

3.3.25 Question 29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

3.3.25.1 Analysis of closed question responses

Respondents were asked to consider whether hazard classes for environmental risks, physical risks and human health risks cover all relevant hazards. In total there were 263 responses to this question (262 for physical risks). The results are presented in Table 3-71.

Table 3-71: Extent to which respondents agreed that all relevant hazards are covered (n=262 to 263)

Response	Group 1 (citizens) (n=22)		Group 2 (industry) (n=166)		Group 3 (public authority) (n=31 to 32)		Group 4 (NGO/others) (n=43)	
	No.	%	No.	%	No.	%	No.	%
a) Environmental risks								
Yes	7	32%	136	82%	14	44%	9	21%
No	5	23%	8	5%	11	34%	24	56%
I don't know	10	45%	22	13%	7	22%	10	23%
b) Physical risks								
Yes	10	45%	141	85%	22	71%	30	70%
No	2	9%	4	2%	0	0%	0	0%
I don't know	10	45%	21	13%	9	29%	13	30%
c) Human health risks								
Yes	8	36%	142	86%	20	63%	15	35%
No	4	18%	5	3%	7	22%	23	53%
I don't know	10	45%	19	11%	5	16%	5	12%

Table 3-71 shows that the highest level of agreement is from Group 2. Here, 82% (136) agreed that the hazard classes in the CLP cover all relevant environmental hazards, 85% (141) agreed that all relevant physical risks are covered and 86% (142) agreed that all relevant human health risks are covered. Groups 3 and 4 also have high proportions that agree that all relevant physical risks are covered, with 71% (22) from Group 3 and 70% (30) from Group 4 saying 'yes'. For human health risks, 63% of Group 3 respondents (20) also agree that these are covered.

The pattern is much more mixed for other groups. For Group 1, there are at least as many 'don't know' responses as either 'yes' or 'no' responses and 'don't know' is the most common response across all three types of risk. Excluding 'don't know', it is 'yes' responses that are most common,

especially for physical risks where 45% (10) of Group 1 respondents said 'yes' compared with just 9% (2) that said 'no'.

Responses from Group 4 are clearly 'yes' for physical risks (70% or 30) but the most common responses for environmental and human health risks are 'no' (56% or 24 for environmental and 53% for 23 for human health risks).

3.3.25.2 Analysis of open text responses

Respondents were asked to list any hazard classes that are not covered. There were 58 comments reviewed. These have been grouped into those that suggested additional hazard classes and more general comments in Table 3-72. There are no themes from the non-questionnaire responses for Question 29, therefore, all the comments shown in Table 3-72 are from the OPC.

Table 3-72: Q29: comments including hazard classes that are not covered (n=58)

Theme	Type	By
Comments on additional hazard categories		
Animals	Environment	Group 2 (3)
Atmospheric	Environment	Group 2 (1)
Climate	Environment	Group 3 (1)
Ecotoxicology	Environment	Group 4 (1)
Endocrine disruptors	Environment	Group 2 (1) Group 3 (1) Group 4 (7)
Former risk phrases R54-58	Environment	Group 4 (1)
GHS classification aquatic acute 2 and 3	Environment	Group 4 (1)
Insects	Environment	Group 2 (2)
Nanomaterials	Environment	Group 4 (1)
PBT[1] substances	Environment	Group 3 (1) Group 4 (8)
Plants	Environment	Group 2 (2)
POPs[2]	Environment	Group 4 (1)
Sediment/soil	Environment	Group 1 (1) Group 2 (3) Group 3 (1) Group 4 (1)
Terrestrial	Environment	Group 2 (4) Group 3 (5) Group 4 (3)
vPvBs[3]	Environment	Group 4 (1)
Environmental endpoints	Environment	Group 4 (1)
Bee toxicity	Environment	Group 2 (1) Group 3 (1) Group 4 (1)
Intrinsic hazards such as dust explosion	Physical	Group 1 (1)
Respiratory sensitizers	Physical	Group 2 (1)
Comments on additional hazard categories: human health		
Additional category for lack of knowledge	Human health	Group 4 (1)

Table 3-72: Q29: comments including hazard classes that are not covered (n=58)		
Theme	**Type**	**By**
Allergenic properties and nanomaterials/nanoforms	Human health	Group 4 (2)
Corrosive to respiratory system	Human health	Group 2 (1)
Endocrine disruptors	Human health	Group 2 (1) Group 3 (1) Group 4 (9)
Immunotoxicity	Human health	Group 4 (6)
Neurotoxocity	Human health	Group 4 (6)
PBT substances	Human health	Group 4 (1)
Comments on additional hazard categories: risk type not specified		
Asphyxiants	Not specified	Group 3 (1)
Bioaccumulation	Not specified	Group 4 (1)
Biodegradation (persistence)	Not specified	Group 4 (3)
Ecotoxic	Not specified	Group 3 (1)
Endocrine disrupting chemicals	Not specified	Group 1 (1) Group 3 (6) Group 4 (11)
Immunotoxicity	Not specified	Group 3 (1) Group 4 (4)
Mutagenicity	Not specified	Group 4 (1)
Nanos	Not specified	Group 1 (2) Group 4 (4)
Neurotoxicity	Not specified	Group 4 (3)
PBT	Not specified	Group 1 (1) Group 3 (3) Group 4 (8)
POPs	Not specified	Group 3 (1) Group 4 (1)
Potential for antimicrobial/antibiotic resistance	Not specified	Group 4 (1)
vPvB	Not specified	Group 3 (1) Group 4 (7)
More general comments		
Absence of clear scientific criteria for EDC[4] and PBT substances creates gaps in implementation of risk management measures		Group 4 (1)
Need for a definition of endocrine disruptors		Group 2 (1)
Better if all hazard classes were based on potency		Group 2 (1)
Classification is often not consistent with use of the product		Group 2 (1)
Combined effects of chemicals in mixtures are not adequately addressed		Group 2 (1) Group 3 (1)
Correct material form of nanomaterials should be considered when assessing validity of data		Group 3 (1)
Exclusion of cosmetic products		Group 4 (1)
Exclusion of medicinal products for human and veterinary use		Group 4 (1)
Expanding hazard classes would make it unmanageable		Group 4 (1)
Explosives need to be reported by environmental/toxic hazards as physical hazards are known		Group 2 (1)
Information on label on hazardous substances formed during intended use		Group 3 (1)

Table 3-72: Q29: comments including hazard classes that are not covered (n=58)		
Theme	**Type**	**By**
Lack of understanding of pictograms and their associated risks		Group 2 (1)
No pictograms for H412, H413, H362		Group 3 (1)
Several environmental hazard classes were lost when adapting to GHS		Group 4 (6)
Some hormonal effects have not been considered at all, e.g. anti-thyroid effect		Group 4 (1)
Stability issues are not fully addressed		Group 2 (1)
STOT classification should be divided into more classes		Group 4 (1)
Untested chemicals are treated as harmless		Group 4 (1)
Notes: [1] PBT = Persistant, Bioaccumulative, Toxic. [2] POPs = Persistent Organic Pollutants. [3] vPvB = very Persistent very Bioaccumulative. [4] EDC = Endocrine Disrupting Chemical		

In addition to the themes above, there are some key points made in some of the comments. These include, mainly in relation to gaps:

- The absence of clear scientific criteria for identifying EDC and PBT substances creates gaps in regards to the implementation of risk management measures across chemical legislation. This is seen, for example, in the Pregnant Workers Directive, the BPR and REACH (Group 4);
- In addition, the CLP excludes a number of products from the scope of the Regulation, including medicinal products for human and veterinary use and cosmetic products (Article 1(5)(a)(b)(c)). This leads to gaps in the information available to consumers as regards to the presence of hazardous chemicals in products (Group 4);
- the expansion of the CLP classification criteria to also address…Environmental endpoints, including those lost in the transition to GHS (e.g. soil) (Group 4);
- Information on the labels on hazardous substances formed during intended use would help to bring attention to the risk to the users (Group 3);
- Ecotox: massive, massive data gaps, especially from semi-chronic and chronic exposures (Group 4);
- One simple way of including other compartments could be to add e.g. tests on terrestrial organisms and to broaden the class from "Hazardous to the aquatic environment" to simply "Hazardous to the environment". Especially since there is no longer any indication of danger as we had in the older classification and labelling system as "Dangerous to the environment". However, we appreciate that this would require changing GHS before we could change CLP (Group 3);
- Many well-known hormonal effects have not been considered at all, e.g. the anti-thyroid effect of thiocyanate (Group 4);
- The classification of a product in terms of danger is often not consistent with the use of the product. And it is difficult to classify a product differently according to its risks as part of workers and consumers (Group 2).

3.3.26 Question 30: How effective is the support to companies through formal guidance documents and national helpdesks?

3.3.26.1 Analysis of closed questions

Respondents were asked to assign a score of 1 (not effective) to 5 (very effective) across four types of assistance (guidance documents, helpdesks, industry association guidance and materials, and

other). There were between 249 and 258 responses to this question, depending on the specific type of support. The results are presented in Table 3-73. Table 3-74 presents weighted scores.

Table 3-73: Number and percentage of respondents by perceived effectiveness of support (n=249 to 258)

Group	Effectiveness score	a: guidance documents (n=256)		b: helpdesks (n=258)		c: industry association guidance and materials (n=251)		d: other (training, conferences, etc.) (n=249)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=21 to 22)	1	2	10%	2	10%	3	14%	2	9%
	2	1	5%	3	14%	0	0%	2	9%
	3	2	10%	2	10%	0	0%	3	14%
	4	4	19%	0	0%	5	24%	2	9%
	5	1	5%	0	0%	1	5%	0	0%
	No experience	11	52%	14	67%	12	57%	13	59%
2 (industry) (n=160 to 167)	1	5	3%	8	5%	4	2%	2	1%
	2	27	16%	20	12%	1	1%	2	1%
	3	32	19%	36	22%	21	13%	52	33%
	4	78	47%	57	34%	85	52%	64	40%
	5	15	9%	19	11%	42	26%	12	8%
	No experience	10	6%	26	16%	10	6%	28	18%
3 (public authority) (n=31 to 32)	1	0	0%	0	0%	1	3%	0	0%
	2	1	3%	1	3%	2	6%	1	3%
	3	4	13%	1	3%	2	6%	3	9%
	4	8	26%	8	25%	6	19%	9	28%
	5	6	19%	8	25%	3	9%	3	9%
	No experience	12	39%	14	44%	18	56%	16	50%
4 (NGO/ others) (n=35 to 39)	1	0	0%	0	0%	4	11%	0	0%
	2	5	14%	2	5%	0	0%	0	0%
	3	5	14%	11	28%	7	20%	5	14%
	4	10	27%	5	13%	6	17%	6	17%
	5	1	3%	2	5%	2	6%	1	3%
	No experience	16	43%	19	49%	16	46%	23	66%

Table 3-74: Weighted scores based on number and percentage of respondents by perceived effectiveness of support (n=249 to 258)

Support type	Group			
	Group 1 (citizens) (n=21 to 22)	Group 2 (industry) (n=160 to 167)	Group 3 (public authority) (n=31 to 32)	Group 4 (NGO/others) (n=35 to 39)
30a) Guidance documents	3.1	3.5	4.0	3.3
30b) Helpdesks	2.0	3.4	4.3	3.4
30c) Industry association guidance and materials	3.1	4.0	3.6	3.1
30d) Other (training, conferences, etc.)	2.6	3.6	3.9	3.7
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the level of effectiveness placed by each group as a whole. The calculation excludes don't know responses				

Table 3-74 provides a summary of results that makes it easier to compare results across the groups. Overall, the results are:

- Lowest levels of effectiveness:
  - The lowest score overall is 2.0 from Group 1 for helpdesks[16] (this is perhaps to be expected as the helpdesk is intended for use by businesses rather than by citizens (21). This type of support also has the lowest score from Group 2 (166), although at 3.4 the score is considerably higher than that assigned by respondents from Group 1;
  - The lowest score from Group 3 is 3.6 for industry association guidance and materials (32). This type of support also gets the lowest score from Group 4 at 3.1 (3.5). However, industry association guidance and materials gets the highest score from Group 2 (4.0), perhaps reflecting that it is targeted to a business audience.

- Highest levels of effectiveness:
  - The highest overall score is 4.0, from Group 2 for industry association guidance and materials (163), and from Group 3 for guidance documents (31);
  - The highest score from Group 4 is 3.3 for guidance documents (37);
  - The highest score from Group 1 is 3.1, for both guidance documents (21) and industry association guidance and materials (21).

3.3.26.2 Analysis of open text responses

Respondents were also asked to add further details to their response to the closed question. In total 29 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-75. The table also shows which groups the comments were from.

Table 3-75: Q30: effectiveness of support to companies through formal guidance and national helpdesks themes from non-questionnaire responses (n=29; Group 1 (citizens) = 3, Group 2 (industry)= 18, Group 3 (public authority) = 2, Group 4 (NGO/others) = 6)

Theme	By
Themes on guidance documents	
Translate all documents into native languages	Group 1 (citizens) Group 3 (public authority) Group 2 (industry)
There are several guidance documents for the same regulation	Group 1 (citizens)
Guidelines should be shorter/simpler	Group 1 (citizens) Group 3 (public authority) Group 2 (industry)
There are areas where more guidance is needed	Group 3 (public authority)
Guidance should be made available centrally	Group 3 (public authority)
Specific comments on CLP guidance	Group 2 (industry)
Guidance is not consistently implemented by authorities	Group 2 (industry)
Some associations provide additional guidance which is sometimes integrated into authorities guidance and sometimes remains internal	Group 2 (industry) Group 4 (NGO/others)

[16] This is perhaps to be expected as the helpdesk is intended for use by businesses rather than by citizens.

Table 3-75: Q30: effectiveness of support to companies through formal guidance and national helpdesks themes from non-questionnaire responses (n=29; Group 1 (citizens) = 3, Group 2 (industry)= 18, Group 3 (public authority) = 2, Group 4 (NGO/others) = 6)	
Theme	**By**
Guidance sometimes go further than the legislation	Group 2 (industry)
Guidelines make an important contribution to enable implementation of regulations by companies	Group 2 (industry)
Guidance and training are perceived better in more homogenous industries	Group 2 (industry)
There is no specific guidance that relates to the classification of nanomaterials	Group 4 (NGO/others)
Guidance to clarify manufacturer's labelling obligations do not exist leading to uncertainty	Group 4 (NGO/others)
Themes on helpdesks	
All queries to be made anonymously	Group 1 (citizens)
Allow helpdesks to be more pragmatic	Group 1 (citizens) Group 2 (industry)
Important to sustain good cooperation between helpdesks	Group 3 (public authority)
Advice from helpdesks is not always accepted by Member State authorities	Group 2 (industry)
CLP helpdesk should give aid on classification problems/discussions	Group 2 (industry)
Guidance documents and national helpdesks are not always SME oriented	Group 2 (industry)
Accuracy and efficiency of helpdesks at member state level varies widely	Group 2 (industry)
Waiting time for helpdesks is often very long	Group 2 (industry)
Information from helpdesks can be misleading/incorrect	Group 2 (industry)
Helpdesk answers do not always relate to the original question and refer to general phrases	Group 2 (industry)
Many Member States do not have sufficient resources for helpdesks	Group 4 (NGO/others)
Guidance documents interpret legislation in the most unambitious manner	Group 4 (NGO/others)
Themes on training	
Hold information sessions	Group 1 (citizens)
Training and conferences are appreciated but the need is endless	Group 3 (public authority)
Training needs to go into more detail	Group 2 (industry)
Training costs are too high for SMEs	Group 2 (industry)
Other themes	
Usability of the ECHA website should be improved	Group 3 (public authority)
The search function and related database must be improved	Group 2 (industry)
Authorities are not explaining the pictograms to consumers	Group 2 (industry)

3.3.26.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-76 provides a summary of the themes from these non-questionnaire responses.

Table 3-76: Q30: effectiveness of support to companies through formal guidance and national helpdesks themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on guidance documents	
Guidance documents are not consistently implemented by authorities	Group 2 (industry)
Guidance documents could be simplified	Group 3 (public authority)
Guidance documents are helpful as are helpdesks	Group 3 (public authority)
There are areas where more guidance is needed	Group 3 (public authority)
Guidance should be made available centrally	Group 3 (public authority)
Other themes	
Helpdesks are highly appreciated and effective	Group 3 (public authority)
Training and conferences are appreciated but the need is endless	Group 3 (public authority)

3.3.26.4 Comparison of themes

The themes associated with comments on the effectiveness of support to companies through formal guidance and national helpdesks are summarised in Table 3-77. The themes are organised into those that are generally positive and those that are generally negative. The table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-77: Comparison of responses on effectiveness of support through formal guidance and national helpdesks			
Non-questionnaire responses		**OPC responses**	
Generally positive	**Generally negative**	**Generally positive**	**Generally negative**
Themes on guidance			
Group 3 (1)	Group 2 (1) Group 3 (3)	Group 3 (1) Group 2 (1)	Group 1 (4) Group 3 (4) Group 2 (8) Group 4 (3)
Themes on helpdesks and training			
Group 3 (2)	Group 3 (1)	Group 3 (1)	Group 1 (2) Group 2 (10) Group 4 (3)

Some specific comments on guidance include:

- These are quite heavy and could preferably be simplified where possible. Nevertheless, they are helpful not only directly for companies, but also indirect through use within helpdesks and they include a number of good examples (Group 3);
- There are…areas where more guidance is needed, e.g. health classification of solid metals, strategy for classifying alloys (health and environment), bridging principles, weight of evidence, a more clear definition of bioavailability (Group 3);
- It is particularly beneficial when guidance is made available centrally (via the Commission or ECHA) because it strengthens harmonisation and reduces double work across Member States (Group 3);

- Guidance documents are not consistently implemented by authorities. For example, the revised interpretation from ECHA guidance on the application of classification as H318 for substances classified as H314 has not been reflected in the ATPs to the CLP for a prolonged period of time – creating uncertainty for operators (Group 2);
- The issue is not about finding guidance material, but rather the rapid change of interpretations and guidances which puts significant burden on companies to try to follow all the changes all the time (Group 2);
- In the case of the metals Group 2, Eurometaux provides additional guidance to that of the authorities. This is mainly in linking the guidance to the specificities of carrying out hazard assessments for metals and metal compounds (Group 2);
- Guidelines are unduly used as if they were laws. They sometimes add binding requirements while their role should be explanatory. They therefore also create legal uncertainty which lead companies to adopt an over-precautionary legal approach in their decisions, thereby adding excessive costs for their operations (Group 2);
- The great majority of various guides are in English and are translated only late…it seems to me that the documents should be translated into 3 official languages SIMULTANEOUSLY of EUROPE (Group 2, translated);
- Due to the number of guides, particularly for SMEs, the impression is of a chaotic flood of information and it is difficult to find the relevant answers to specific questions in the amount of information (Group 2, translated);
- On some important issues there are no guidance documents: The definition for nanomaterials in cosmetics contains unclear terms such as "insoluble" and "bio-accumulative". A guidance to clarify manufacturers labelling obligations don't exist leading to uncertainty (Group 4).

Specific comments on helpdesks include:

- Helpdesks are highly appreciated and effective (Group 3)
- The advices from the help desks are not consistently accepted from Member State authorities. The interpretation from local authorities differs sometimes substantially. More consistency and coherence is required to provide a reliable and useful source of information – maintaining a neutral position that is not influenced by any particular Member State opinion (Group 2);
- Training and conferences are always appreciated. But the need for more seems endless and often at a deeper level than our resources allow (Group 3);
- Helpdesks rarely give useful information. Most of the answers we receive are quotations of the legislation (which we know how to find). They do not help interpreting the legislation or give advice in case of borderline cases which are not covered in guidance (Group 2);
- National helpdesks are a key tool to provide support for companies. However, many Member States do not have sufficient resources for them. Indeed, for nanomaterials there is limited guidance coming from the EU Commission on how to deal with them in each regulatory context (Group 4).

3.3.27 Question 31: to what extent is CLP enforced in a harmonised manner across Member States?

Respondents were asked to identify if CLP is harmonised across Member States. In total, there were 255 responses to this question. The results are presented in Table 3-78. The table shows that the majority of responses from Group 1 (59% or 13), Group 3 (58% or 18) and Group 4 (63% or 24) answered 'don't know'. The most common response from Group 2 was enforcement is *not*

harmonised across most Member States by 40% (66). This is also the most common response excluding 'don't know' for Group 1 (18% or 4) and Group 4 (29% or 11). For Group 3, the most common response (excluding 'don't know') was that enforcement is harmonised across most Member States with 19% (6) respondents giving this response. There were also 13% (4) respondents from Group 3 who said that enforcement is *not* harmonised across most Member States.

Table 3-78: Extent to which respondents think that CLP is harmonised across Member States (n=255)

Response	Group 1 (citizens) (n=22)		Group 2 (industry) (n=164)		Group 3 (public authority) (n=31)		Group 4 (NGO/others) (n=38)	
	No.	%	No.	%	No.	%	No.	%
Enforcement is harmonised across all Member States	2	9%	16	10%	3	10%	1	3%
Enforcement is harmonised across most Member States	3	14%	40	24%	6	19%	2	5%
Enforcement is not harmonised across most Member States	4	18%	66	40%	4	13%	11	29%
I don't know	13	59%	42	26%	18	58%	24	63%

3.3.27.1 Analysis of open text responses

Respondents were also asked to add further details to explain their answer to the closed question. In total 29 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-79. The table also shows which groups the comments were from.

Table 3-79: Q31: extent to which CLP is enforced in a harmonised manner across Member States themes from non-questionnaire responses (n=29; Group 1 (citizens) = 3, Group 2 (industry) = 16, Group 3 (public authority) = 5, Group 4 (NGO/others)= 6)

Theme	By
Themes on implementation and enforcement	
Article 45 needs to be implemented separately et each Member State level - very expensive for SMEs	Group 1 (citizen) Group 2 (industry) Group 4 (NGO/others)
Differences in implementation in terms of requirements for self-classification prior to formal implementation dates	Group 3 (public authority)
Enforcement differs between different Member States	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
The flow of information and cooperation between Member States should be urgently improved	Group 3 (public authority)
Should be better training on use of ICSMS[1]	Group 3 (public authority)
ICSMS should be improved in terms of usability	Group 3 (public authority)
Article 41 of CLP is not enforced	Group 2 (industry) Group 4 (NGO/others)
Enforcement of CLP across the EU seems mediocre	Group 2 (industry)
Enforcement issues are often linked to a lack of inspectors in many countries	Group 4 (NGO/others)
Themes on harmonisation	
There are many questions in the legislation that are open to interpretation; these interpretations need to be harmonised as far as possible	Group 3 (public authority) Group 2 (industry)
Harmonisation is supported by Forum	Group 3 (public authority)

Table 3-79: Q31: extent to which CLP is enforced in a harmonised manner across Member States themes from non-questionnaire responses (n=29; Group 1 (citizens) = 3, Group 2 (industry) = 16, Group 3 (public authority) = 5, Group 4 (NGO/others)= 6)	
Theme	**By**
	Group 2 (industry)
Acceptance of bioavailability varies from one Member State to another	Group 2 (industry) Group 4 (NGO/others)
There are still diverging opinions/views across Member States that need discussions in Forum or HelpNet	Group 2 (industry)
There are a lot of different classifications for one product across the EU	Group 2 (industry)
EU national authorities add specific requirements during implementation of EU legislation giving a non-harmonised background	Group 2 (industry)
There are especially significant discrepancies in areas of skin and eye irritancy/corrosivity	Group 2 (industry)
Some countries have different interpretation of CLP classification which does not facilitate expert to those countries	Group 2 (industry)
Too many national initiatives in the form of special registers	Group 2 (industry)
ECLIPS project shows high deficiencies in quality of MSDS[2] throughout the EU	Group 4 (NGO/others)
Themes on automatic link between CLP, REACH and Seveso	
No specific themes	
Other themes	
UK has less information on detergent packaging than other EU states	Group 1 (citizen)
Notes: [1] ICSMS = Information and Communication System on Market Surveillance. [2] Material Safety Data Sheets	

3.3.27.2 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-80 provides a summary of the themes from these non-questionnaire responses.

Table 3-80: Q31: extent to which CLP is enforced in a harmonised manner across Member States themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on implementation and enforcement	
Enforcement differs in resources and organisation between different Member States	Group 3 (public authority)
There needs to be better implementation and enforcement	Group 3 (public authority)
Implementation of tools more specifically linked to risk management and communication can still be variable from Member State to Member State	Group 2 (industry)
Themes on harmonisation	
It is highly desirable that interpretations are coordinated and harmonized as far as possible	Group 3 (public authority)
Harmonised EU chemicals legislation is necessary to uphold a high level of protection	Group 3 (public authority)
Thanks to CLP (and partly REACH) the implementation of GHS[1] have reached a high level of harmonisation and been cost effective for the EU member states	Group 3 (public authority)
Differences in adopted classification modules/categories limit overall harmonisation	Group 2 (industry)

Table 3-80: Q31: extent to which CLP is enforced in a harmonised manner across Member States themes from non-questionnaire responses (n=9)	
Theme	**By**
The REF programmes promote a given level of harmonisation	Group 2 (industry)
Harmonisation between Member States will ensure an EU consistent framework, which is key to be considered as credible partner at global level	Group 2 (industry)
Same chemical can be requested to have different sets of C&L[2] information between Member States	Group 2 (industry)
Themes on automatic link between CLP, REACH and Seveso	
Concern over the automatic link between CLP Regulations, REACH and the Seveso Directive.	Group 2 (industry)
The automatic link between CLP/REACH and Seveso needs to be discussed and the Commission must come up with proposals to deal with substances which are reclassified but are not considered to have major accident potential	Group 2 (industry)
Other themes	
CLP legislation is complicated for biocidal products and requires experts in classification	Group 2 (industry)
Risk Management divergences exist between worker protection H&S directives and REACH/CLP regulations	Group 2 (industry)
There is an urgent need for a consolidated EU chemicals framework	Group 2 (industry)
Certain countries, companies or sectors do not apply for Authorisation while they should normally do	Group 2 (industry)
There may be issues with companies/ sectors that do not comply (deliberately or not).	Group 2 (industry)
Either society chooses for an open unified EU market or for a closed national based system but a mix a present the case is not efficient	Group 2 (industry)
Notes: [1] GHS = Globally Harmonised System. [2] C&L = Classification and Labelling	

3.3.27.3 Comparison of themes

The themes associated with the extent to which CLP is enforced in a harmonised manner across Member States is summarised in Table 3-81. The themes are organised into those that are generally positive and those that are generally negative. The table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-81: Comparison of responses on incoherence with other legislation			
Non-questionnaire responses		**OPC responses**	
Generally positive	**Generally negative**	**Generally positive**	**Generally negative**
Themes on implementation and enforcement			
	Group 3 (2) Group 2 (1)		Group 1 (1) Group 3 (6) Group 2 (10) Group 4 (4)
Themes on harmonisation			
Group 3 (1) Group 2 (1)	Group 2 (2)	Group 3 (1) Group 2 (1)	Group 3 (1) Group 2 (10) Group 4 (3)

Specific comments on issues with implementation and enforcement include:

- Enforcement is a national matter and it differs in resources and organisation between different Member States. However, there are many questions in the legislation which are open to interpretation (Group 3);
- Differences in the levels of enforcement, e.g. control over labelling, classification of mixtures, etc. (Group 2);
- The acceptance of bioavailability also varies from one Member State to another. This is explicitly discussed in the context of using bioelution information to derive the classification of complex inorganic materials and alloys. (Group 2);
- Article 41 of CLP is not enforced (and there is not yet an agreed interpretation of what an "agreed entry" could mean in the context of and considering the limitations…of the C&L Inventory, which is a second reason why the C&L Inventory is populated by multiple classifications for the same substance (in addition to the fact the classifications notified outside a REACH dossier do not need to substantiated/justified) (Group 2);
- Enforcement of CLP across the EU seems mediocre, particularly concerning the provision of CLP compliance SDS. Even after numerous requests, some suppliers are still not supplying compliant SDS (Group 2);
- The legislation requires a lot of explanatory guidance/FAQs, which have no legal status and thus can be (and often are) differently interpreted by enforcement agencies (even on national level) (Group 2);
- Not uncommon are cases where the same chemical is requested to have different sets of C&L information between different Member States. This is particularly the case for plant protection products and biocidal products. Active substances for use in biocidal products are subject to harmonised classification and labelling under CLP…For biocidal products however, the CLP legislation is quite complicated and requires 'experts' in classification...Moreover, the biocidal product's classification is determined by the evaluating Competent Authority which in certain cases leads to non-harmonised classification for the same product (Group 2);
- Slovakia has high demands, Italy has low requirements (Group 2).

Specific comments on harmonisation include:

- Overall it is harmonised but there are still diverging opinions/views across Member States that need discussions in FORUM or HelpNet. The discussion on the classification of preparations including other preparations is an example of diverging views among Member States (Group 2); and
- The ECLIPS project report shows very high deficiencies in quality of MSDS sheets throughout the EU, including wrong classification of substances and mixtures (Group 4).

3.3.28 Question 32: To what extent are the current elements relating to the CLP classification criteria satisfactory?

3.3.28.1 Analysis of closed questions

Respondents were asked to identify how satisfied they were with four elements of CLP. There were 251 to 257 responses to this question depending on the element of CLP classification criteria. The results are summarised in Table 3-82. Table 3-83 presents weighted scores.

Table 3-82: Number and percentage by satisfaction with CLP classification elements (n=251 to 257)									
Group	Satisfaction score	a: ease of implementation for duty holders (n=253)		b: appropriateness of classification criteria and methods for substances (n=256)		c: appropriateness of classification criteria and methods for mixtures (n=257)		d: international harmonisation through the Globally Harmonised System (GHS) (n=251)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=20 to 21)	1	4	19%	3	15%	3	15%	4	20%
	2	0	0%	0	0%	2	10%	0	0%
	3	0	0%	2	10%	1	5%	4	20%
	4	5	24%	6	30%	4	20%	3	15%
	5	0	0%	0	0%	0	0%	1	5%
	I don't know	12	57%	9	45%	10	50%	8	40%
2 (industry) (n=161 to 164)	1	9	6%	3	2%	14	9%	7	4%
	2	28	17%	6	4%	28	17%	32	20%
	3	66	41%	26	16%	50	30%	50	31%
	4	39	24%	90	55%	47	29%	46	29%
	5	7	4%	11	7%	7	4%	8	5%
	I don't know	13	8%	27	17%	18	11%	18	11%
3 (public authority) (n=32)	1	1	3%	0	0%	0	0%	0	0%
	2	5	16%	1	3%	3	9%	1	3%
	3	3	9%	9	28%	12	38%	3	9%
	4	8	25%	16	50%	9	28%	13	41%
	5	1	3%	1	3%	1	3%	5	16%
	I don't know	14	44%	5	16%	7	22%	10	31%
4 (NGO/ others) (n=38 to 41)	1	2	5%	2	5%	3	7%	2	5%
	2	3	8%	8	20%	10	24%	3	8%
	3	7	18%	13	32%	13	32%	7	18%
	4	5	13%	8	20%	3	7%	6	16%
	5	1	3%	1	2%	1	2%	2	5%
	I don't know	20	53%	9	22%	11	27%	18	47%
Notes: a score of 1 = not satisfactory and a score of 5 = very satisfactory									

Table 3-83: Weighted scores based on number and percentage identifying level of satisfaction with elements related to chemical legislation (n=251 to 257)				
Element	Group			
	Group 1 (citizens) (n=20 to 21)	Group 2 (industry) (n=161 to 164)	Group 3 (public authority) (n=32)	Group 4 (NGO/others) (n=38 to 41)
32a) Ease of implementation for duty holders	2.7	3.0	3.2	3.0
32b) Appropriateness of classification criteria and methods for substances	3.0	3.7	3.6	2.9
32c) Appropriateness of classification criteria and methods for mixtures	2.6	3.0	3.3	2.6
32d) International harmonisation through the Globally Harmonised System (GHS)	2.8	3.1	4.0	3.2
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the level of satisfaction placed by each group as				

Table 3-83: Weighted scores based on number and percentage identifying level of satisfaction with elements related to chemical legislation (n=251 to 257)				
Element	Group			
	Group 1 (citizens) (n=20 to 21)	Group 2 (industry) (n=161 to 164)	Group 3 (public authority) (n=32)	Group 4 (NGO/others) (n=38 to 41)
a whole. The calculation excludes don't know responses				

Table 3-83 provides a summary of results that makes it easier to compare results across the groups. Overall, the results are:

- Lowest levels of effectiveness:
  - The lowest score from Group 1 is for appropriateness of classification criteria and methods for mixtures at 2.6 (20). This element also has the lowest score from Group 4, also at 2.6 (41) and the equal lowest score from Group 2 at 3.0 (164);
  - The lowest score from Group 3 is for ease of implementation for duty holders at 3.2 (32). This also gets the equal lowest score from Group 2 at 3.0 (162).

- Highest levels of effectiveness:
  - The highest score overall is 4.0 from Group 3 for international harmonisation through the Globally Harmonised System (GHS) (32). This element also attracts the highest score from Group 4 at 3.2 (38);
  - The highest score from Group 2 is 3.7 for appropriateness of classification criteria and methods for substances at 3.7 (163). The highest score from Group 1 (3.0) is also for this element (20).

3.3.28.2 Analysis of open text responses

Respondents were also asked to provide further information to explain their answer to the closed question. In total 38 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-84. The table also shows which groups the comments were from.

Table 3-84: Q32: extent to which current elements relating to CLP classification criteria are satisfactory themes from non-questionnaire responses (n=38; Group 1 (citizens) = 4, Group 2 (industry) = 22, Group 3 (public authority) = 5, Group 4 (NGO/others) = 7)	
Theme	By
Themes on building block approach of GHS	
No harmonisation through building blocks	Group 1 (citizen) Group 2 (industry)
GHS is not harmonised and major issues are seen due to implementation of different version of GHS around the world	Group 2 (industry) Group 4 (NGO/others)
Communication issues due to use of different building blocks in non-EU countries leads to significant costs	Group 2 (industry)
Themes on international harmonisation	
CLP is not always accepted internationally	Group 1 (citizen)
EU-wide ideas should first be introduced at UN GHS before gaining legal validity in EU	Group 1 (citizen)

Table 3-84: Q32: extent to which current elements relating to CLP classification criteria are satisfactory themes from non-questionnaire responses (n=38; Group 1 (citizens) = 4, Group 2 (industry) = 22, Group 3 (public authority) = 5, Group 4 (NGO/others) = 7)	
Theme	**By**
EU does not implement some of the lower categories of hazard in the GHS system	Group 3 (public authority)
Still differences between CLP and GHS	Group 2 (industry)
International harmonisation is the main benefit from GHS implementation and should be further improved	Group 2 (industry)
Mandatory classifications in EU and other regions pose difficulties	Group 2 (industry)
Harmonised classification for industrial and professional use of chemicals is basically good	Group 2 (industry)
Harmonisation of classification criteria of GHS is not yet achieved, especially for environmental endpoints	Group 4 (NGO/others)
Themes on difficulties applying classification	
Classification does not distinguish between different orders of potency	Group 1 (citizen)
Classification is highly complex and requires specialist knowledge, especially difficult for SMEs	Group 1 (citizen) Group 3 (public authority) Group 2 (industry)
Problem of different interpretation of data and resulting divergent classifications	Group 3 (public authority)
Direct application of CLP in downstream legislation has caused more confusion than added safety	Group 2 (industry)
It is difficult to evaluate which classification is correct when there is classification based on REACH registration and more severe classifications	Group 2 (industry)
Confusion where the old classification is still present for a time	Group 2 (industry)
Classification criteria are not always appropriate	Group 2 (industry)
Data requirements and applicability of classification methods are challenging	Group 2 (industry)
Criteria not necessarily relevant to classification of detergents (irritation, corrosion)	Group 2 (industry)
Relevance and readability of labelling is not immediately clear for detergents and cleaners for private consumers	Group 2 (industry)
Tightening of NOEC has led to stricter classification which blurs the distinction between truly problematic substances and mixtures and those that are degradable	Group 2 (industry)
Hazard based identification and classification establishes a clear, predictable and systematic approach for identification	Group 4 (NGO/others)
Use of CLP classification criteria for waste is difficult due to heterogeneous nature of waste	Group 4 (NGO/others)
A more precautionary approach is needed when applying the criteria	Group 4 (NGO/others)
New hazard categories should be added	Group 4 (NGO/others)
Themes on tests and test methods	
In vitro criteria are still lacking for certain hazard classes and categories	Group 3 (public authority)
Better use should be made of available epidemiological data	Group 4 (NGO/others)
Available tests should be introduced for additional endpoints	Group 4 (NGO/others)
Non-standard studies from academia should be included in assessments, where relevant and available	Group 4 (NGO/others)
Synergistic effects are not adequately covered when no data is available from tests	Group 3 (public authority)
Themes on mixtures	

Table 3-84: Q32: extent to which current elements relating to CLP classification criteria are satisfactory themes from non-questionnaire responses (n=38; Group 1 (citizens) = 4, Group 2 (industry) = 22, Group 3 (public authority) = 5, Group 4 (NGO/others) = 7)	
Theme	**By**
Classification criteria for mixtures have become more complex and difficult to apply	Group 3 (public authority) Group 2 (industry) Group 4 (NGO/others)
Gap in the current regulations on specific issue of mixtures classification	Group 2 (industry) Group 4 (NGO/others)
Mixtures of varying level of danger for the consumer are labelled with the same CLP labelling	Group 2 (industry)
Risk-proportionate labelling for mixtures requires companies to do testing or bridging making implementation more difficult	Group 2 (industry)
Other comments	
Guidelines are not clear and sufficiently understandable	Group 1 (citizen)
Some elements of the classification seem to have little grounding in the real world	Group 3 (public authority)
A number of the EU phrases are soundly based	Group 3 (public authority)
CLP has added new requirements on duty holders	Group 2 (industry)
Without derogations from CLP classification, a lot of the formaldehyde industries in Europe would have closed	Group 2 (industry)
None of the elements have provided satisfactory for nanomaterials	Group 4 (NGO/others)
STOT RE criteria are incorrect/confusing	Group 4 (NGO/others)

3.3.28.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-85 provides a summary of the themes from these non-questionnaire responses.

Table 3-85: Q32: extent to which current elements relating to CLP classification criteria are satisfactory themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on building block approach of GHS	
Non-EU countries selected to implement different building blocks of GHS	Group 2 (industry)
GHS gives harmonised criteria but due to the building block approach it is not implemented in a fully harmonised way.	Group 3 (public authority)
Some aspects specific to the EU classification system can create barriers of trade	Group 2 (industry)
Themes on difficulties applying classification	
CLP is a very technical legislation which requires high level of knowledge and experience for companies as well as for authorisations.	Group 3 (public authority)
Expansion of the CLP classification criteria to also address additional properties, which are currently not covered in CLP	Group 4 (NGO/others)
Themes on tests and test methods	
Wider use of non-animal tests will have to be accompanied by changes in classification criteria to enable these tests to be used for classification	Group 4 (NGO/others)
There is a need to update existing test methods to include additional endpoints for endocrine disruptors, and a need for new tests to cover 'new' endocrine disrupting mechanisms.	Group 4 (NGO/others)

Table 3-85: Q32: extent to which current elements relating to CLP classification criteria are satisfactory themes from non-questionnaire responses (n=9)	
Theme	**By**
It is important that classification is not just based on studies done to 'Good Laboratory Practice' (GLP), as other studies may examine endpoints that are not covered by established GLP methods, and can be of equal or higher scientific quality.	Group 4 (NGO/others)
One simple way of including other compartments could be to add tests and to broaden the class	Group 3 (public authority)
Other themes	
The pictogram and hazard statements process is useful, but more targeted awareness raising activities are needed	Group 4 (NGO/others)
Most importantly, more information is needed on which chemicals are contained in consumer products to allow for an informed choice.	Group 4 (NGO/others)
EU MSs and the Commission need to allocate proper resources at the UN level for development of CLP and for rules related to safety data sheets (REACH)	Group 3 (public authority)
Sediment and terrestrial ecosystems should be covered as well	Group 3 (public authority)
Concerned with the automatic link between CLP Regulations, REACH and the Seveso Directive.	Group 2 (industry)
More efforts and further studies are needed in addition to ECHA's very useful classification and labelling inventory	Group 4 (NGO/others)
New databases and technologies and apps that assist the public in finding out about SVHCs in articles are an important start in this area.	Group 4 (NGO/others)

3.3.28.4 Comparison of themes

The themes associated with the extent to which current elements relating to CLP classification criteria are satisfactory are summarised in Table 3-86. The themes are organised into those that are generally positive and those that are generally negative. The table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-86: Comparison of responses on extent to which current elements relating to CLP classification criteria are satisfactory			
Non-questionnaire responses		**OPC responses**	
Generally positive	**Generally negative**	**Generally positive**	**Generally negative**
Themes on harmonisation and building block approach			
	Group 2 (1) Group 3 (1)	Group 2 (1)	Group 1 (2) Group 3 (1) Group 2 (10) Group 4 (2)
Themes on classification			
	Group 3 (1) Group 4 (1)	Group 4 (3)	Group 1 (2) Group 3 (2) Group 2 (10) Group 4 (5)
Themes on tests and test methods			
	Group 4 (3)		Group 3 (2) Group 4 (4)

Positive comments were reviewed in relation to the current level of satisfaction with the CLP classification criteria. For example:

- Hazard based identification and classification provides a scientific base for identifying hazardous properties of substances, thus establishing a clear, predictable and systematic approach for identification. This system is very important for workers and occupational health and safety legislation, ranging from communication about hazards and risks to providing comparable data sets for alternatives assessment and replacement with safer alternatives. It is also the appropriate base for taking measures for consumers and environmental protection (Group 4).

The majority of comments, though, were more negative. Specific comments on issues with a lower level of satisfaction with current elements relating to CLP classification include:

- Comments on harmonisation:
  - Stronger harmonisation would reduce the risk of misinterpretation due to subtle variations. Legal stability framework is key (Group 2);
  - Harmonization of mandatory national classification lists (e.g. CLP Annex VI) (Group 2);
  - Harmonization of implemented building blocks and UN GHS revision number (e.g. harmonization of national update frequencies (Group 2);
  - Harmonization of the use of GHS for consumer products (not implemented in e.g. USA) (Group 2);
  - There is a need to align the language versions of CLP – as the differences in the different official language versions leads to additional works and problems (Group 2).

- Coverage of classification criteria:
  - Classification criteria are not appropriate. Classification should give guidance on the potential hazards of chemicals. Classification for carcinogenicity and reproductive toxicity does not distinguish between chemicals with up to 7 orders of magnitude difference in potency. This can cause problems in communication and has downstream consequences for the use of chemicals which may be inappropriate (Group 1);
  - Substances and mixtures of low volatility and with no uses that can generate fine particles can still be classified for acute inhalation toxicity based on the results of an atmosphere of artificially generated fine particles (Group 3);
  - The classification criteria…should systematically take into account the physical and chemical forms of the substance. Example of beryllium: common classification (Carcinogen 1B) for beryllium metal and beryllium soluble salts while the bio availability and therefore the toxicity of the 2 forms are obviously different (Group 2);
  - A metallic alloy containing a metal as an additive should not be classified like the pure metal…There is a lack in the current regulations on this specific issue of mixtures classification (Group 2);
  - Alloys may not act as simple mixtures of their constituent elements. Rather, they may have unique physical, mechanical and chemical properties that affect the bioavailability of these constituents. Since current classification rules do not reflect this effect, we promote the concept of bioelution to overcome this (Group 2);

- We believe that…hazard categories for endocrine disruption, neurotoxicity, allergenic properties, nanoforms/nanomaterials, biodegradation and PBTs/vPvBs should be added (Group 4);
- Tests should be introduced for additional endpoints such as immunotoxicity, neurotoxicity, endocrine disruption, persistence, etc. (Group 4);
- Scientific criteria and categories should be established for: EDCs, PBTs, POPs, vPvBs and nanoforms/nanomaterials and allergenic properties (Group 4);
- We noted that criteria for hazard identification or for classification are sometimes based on outdated high dose animal testing that are often performed by a route of exposure not relevant to actual human exposure. Environmental classification is based on test methods that 'force' the presence of a chemical even when naturally it cannot stay in water (volatility, strong binding to sediment or organic matter etc.) (Group 2).

- Issue of interpretation of data and divergent classifications:
  - Hazards could be underestimated with the summation method when the sum of components with a relevant aquatic toxicity is just below the threshold for classification (Group 3);
  - C&L notifications existing without the visibility for the basis, difficult to evaluate which classification is correct when there is e.g. classification based on the REACH registration and more severe classifications. C&L notification database should be completely removed and something more reliable set up in return e.g. based on existing REACH registration data (Group 2).

- Specific comments in relation to mixtures:
  - Synergistic effects should be addressed under CLP, but are not adequately covered when no data is available from tests with whole mixtures and assessment has to rely on a component-based approach (Group 3);
  - The additivity method for classification of mixtures does not seem to be appropriate in some cases, particularly for corrosivity. Judgement is required (Group 2);
  - Data requirements and applicability of classification methods are challenging especially for importers of chemical mixtures and private label owners. More flexibility is needed to enable better utilization of all relevant data on mixture properties (Group 2);
  - The classification criteria and methods for mixtures seem to be challenging…Some Member States recommend using the classification submitted under REACH, while Group 4 recommend using the worst case available. This could be corrected by harmonising the rules (follow GHS?) and improving the accuracy of the C&L Inventory (Group 4).

- Comments relating to communication of hazards to consumers:
  - Having the 'corrosive' label on too many products will make the consumer respect the label a lot less, with potential adverse effects if exposed to the products on the 'bad' end of the scale. There should be a more nuanced labelling system (Group 2);
  - Despite the fact that cyanoacrylates cause many allergies they are not classified as allergens. The method or the implementation of the criteria can be the cause of this (Group 3).

- Other comments:
  - Without derogations from the CLP-classification of formaldehyde, the closure of a lot of industries in Europe would have been the consequence. Formaldehyde is not

considered to be water-hazardous. Nevertheless, it is planned to raise it to a higher class, which has huge consequences (Group 2);

- The use of CLP classification criteria for the classification of waste (following the mixtures rules) is not at all straightforward because the heterogeneous nature of waste makes it difficult to check its composition, and because the impact of having a hazardous classification of waste has more far-reaching consequences for e.g. transport (Basel Convention) (Group 4);

3.3.29 Question 33: Do transitional periods allow sufficient time to implement new or revised classification criteria?

Respondents were asked to consider whether the transition times following revisions to CLP were sufficient to allow new or revised classification criteria to be implemented. In total, there were 252 responses to this question. The results are presented in Table 3-87. The table shows that only Group 3 appears to have a strong overall opinion with 63% (20) stating that the transition period is appropriate. A further 34% (11) from Group 3 did not know or had no opinion. The most common response from Group 2 is that the transition period is sufficient at 43% (70). This is closely followed by those who think the transition period is too short (41% or 66). Respondents from Group 4 were most likely to answer that the transition period is sufficient (38% or 15) or state that they did not know or had no opinion (also 38% or 15). For Group 1, the most common response was 'don't know/no opinion' at 50% (9), with the next most common response being 'transition period is sufficient' at 22% (4).

Table 3-87: Extent to which respondents think that CLP is harmonised across member States (n=252)

Response	Group 1 (citizens) (n=18)		Group 2 (industry) (n=162)		Group 3 (public authority) (n=32)		Group 4 (NGO/others) (n=40)	
	No.	%	No.	%	No.	%	No.	%
Transition period is sufficient	4	22%	70	43%	20	63%	15	38%
Transition period is too short	2	11%	66	41%	0	0%	4	10%
Transition period is too long	3	17%	3	2%	1	3%	6	15%
I don't know or have no opinion	9	50%	23	14%	11	34%	15	38%

3.3.29.1 Analysis of open text responses

Respondents were also asked to elaborate if they had replied that the transition period was too short or too long to the closed question. In total 31 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-88. The table also shows which groups the comments were from.

Table 3-88: Q33: sufficiency of transitional periods following revision of CLP themes from non-questionnaire responses (n=31; Group 1 (citizens) = 2, Group 2 (industry) = 20, Group 3 (public authority) = 3, Group 4 (NGO/others) = 6)

Theme	By
Themes on transition time	
CLP implementation periods are a reasonable match for timescales in the related legislation	Group 3 (1)
Transition period is appropriate	Group 3 (1) Group 2 (2) Group 4 (3)
Legal procedure to adopt the adaptations is too slow	Group 3 (1)

Table 3-88: Q33: sufficiency of transitional periods following revision of CLP themes from non-questionnaire responses (n=31; Group 1 (citizens) = 2, Group 2 (industry) = 20, Group 3 (public authority) = 3, Group 4 (NGO/others) = 6)	
Theme	**By**
Date could be fixed every second year to make it more efficient and give greater stability	Group 3 (1)
Transition period is often too short in case of mixtures	Group 2 (2)
Specificity of certain supply chains may also mean more time is needed	Group 2 (1)
There are issues with times when there are changes that trigger automatic requirements under other legislation	Group 2 (1) Group 4 (2)
More time is needed for capacity building to build consensus on key scientific challenges	Group 2 (3) Group 4 (1)
Longer transitional periods are needed for changes to the text of H and P statements	Group 2 (4) Group 4 (1)
Not always sufficient time for biocidal products	Group 2 (1)
Short transition periods increase risk that labels, bottle and finished product cannot be sold	Group 2 (4)
Transition periods are too short for home care products	Group 2 (1)
Transition period is too short for cosmetic products	Group 2 (1)
Time is too short for regulators and affected stakeholders to grasp the scientific challenge	Group 2 (1)
It depends on the new obligations it entails	Group 2 (1)
A minimum of 18 months should be mandatory	Group 2 (2) Group 4 (1)
Transition period is too short for highly complex product portfolios	Group 2 (1)
Companies may need better information at an early stage rather than longer transitional periods	Group 4 (2)
Themes on impacts of changes in classification	
The legal consequences of classification change are very significant	Group 1 (1) Group 2 (1)
There are costly administrative burdens	Group 1 (1)
Expensive technical changes are incurred	Group 1 (1)
There is insufficient checking on the consequences of classification change	Group 1 (1)
The secondary and tertiary impacts of changes to CLP need to be mapped before adopting the decision to change CLP	Group 2 (2) Group 4 (1)
There is the question on use of RAC opinions as best scientific knowledge and use when classifications are changes rather than waiting for legal application of the classification	Group 2 (1)
There needs to be acceptance from surveillance authorities of editorial adjustments	Group 2 (2) Group 4 (1)
Other themes	
Raw material suppliers do not provide SDS	Group 2 (1)
SDS update hardly follows the evolution of product classifications with problems for downstream users	Group 2 (1)

3.3.29.2 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Only one relevant theme was identified from this, with this being the need for longer transition times (industry).

3.3.29.3 Comparison of themes

The themes associated with the extent to which current elements relating to CLP classification criteria are satisfactory are summarised in Table 3-89. The themes are organised into those that are generally positive and those that are generally negative. The table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-89: Comparison of responses on sufficiency of transitional periods following revision of CLP

Non-questionnaire responses		OPC responses	
Generally positive	**Generally negative**	**Generally positive**	**Generally negative**
Themes on transition time			
	Group 2 (1)	Group 3 (2) Group 2 (2) Group 4 (3)	Group 3 (1) Group 2 (20) Group 4 (4)
Themes on impacts of changes in classification			
			Group 1 (4) Group 2 (5) Group 4 (2)

Some positive comments were reviewed in terms of the sufficiency of transition times. These include:

- As a regulator dealing mainly with pesticides and biocides, I believe the CLP implementation periods are a reasonable match for timescales in the related legislation (Group 3);
- Sufficient time is generally given to implement the new classification of substances (Group 2);
- We believe that the time for companies to adapt to technical progress is sufficient taking into account that it takes several years since a substance is proposed for a harmonised classification and transition periods are considered (Group 4).

There were many negative comments as well from those who did not feel that the transition periods were sufficient. These include:

- The transition period may be sufficient in the case of some substances, but it is often too short in the case of mixtures (Group 2);
- This [sufficient time for transition] is not always the case for biocidal products as the revised classification of a mixture requires prior approval by a Member State authority (Group 2);
- The timing for mixtures is very often too short. By implementing a stepwise approach with 3 timings would avoid extra costs of relabeling, outdated stocks, etc. - Dateline for SUBSTANCES - DATELINE for PRE-MIXTURES (Raw materials) - DATELINE for END MIXTURES (Group 2);

- The transition period for labelling changes should be longer to decrease costs impact (Group 2);
- For Home Care Products too short transition periods are often linked to the fact that mixtures used as ingredients have the same deadlines as the final mixtures that contain these ingredients mixtures, putting pressure on the last actor in the chain to do very fast transitions (Group 2);
- For editorial changes to the text of H and P statements stemming from revisions of the UN GHS Model Regulation longer transitional periods would be beneficial for the industry (Group 2, Group 4);
- The update frequency and transitional periods should differentiate between "major changes" and "minor changes" (Group 2);
- Unless you are constantly monitoring the ECHA website it is very easy to miss changes in legislation or substance classification (Group 2).

Comments were also provided on the impacts of changes in classification. These include:

- A change in a classification of a substance can, from one day to the next, change the status of a site into Seveso. If Article 4 of Seveso wanted to be invoked, e.g. to obtain an exemption on the basis of the unlikelihood of exposure, the time for the site to comply with the change in CLP and its impact on Seveso is shorter than the time the full Article 4 notification takes (5-7 years) (Group 2);
- If the secondary and tertiary impacts of the changes to CLP would be mapped before adopting the decision to change CLP, it would identify the number and extent of impacts, consider the relevance of the change, as well as the implementation timeframe (Group 2);
- There is a great risk of labels, bottles and finished products having to be disposed of as the turnover of a product and the process of updating labels do not always have a timeline that is sufficient when the transition period is so short (Group 2).

3.3.30 Question 34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory?

3.3.30.1 Analysis of closed question responses

Respondents were asked to identify how satisfied they were with four elements of the procedures for harmonised classification and labelling. There were 251 to 253 responses to this question depending on the element. The results are summarised in Table 3-90. Table 3-90 presents weighted scores.

Table 3-90 shows a high proportion of responses from Group 1 are 'don't know', with other scores being reasonably evenly spread. The number of responses from Group 1 that assigned a score of 1 to 5 is low, up to a maximum of 4. Responses from Group 2 tend towards higher scores (4) for transparency of the procedures and quality of scientific information and towards moderate scores (3) for involvement of stakeholders and speed of the procedure. Group 3 also has reasonably high proportions of 'don't know' responses (31% to 44%), with those assigning scores tending towards higher scores of 4 and even 5, especially for transparency of procedures and involvement of stakeholders. Scores from Group 4 vary considerably across the elements, with the maximum proportion (excluding 'don't know') of 49% (18) assigning a score of 4 for transparency of the procedures, 47% (17) assigning a score of 3 for involvement of stakeholders, 31% (11) assigning a score of 2 for quality of scientific data and related information and 28% (10) assigning a score of 1 for speed of the procedures.

Table 3-90: Number and percentage of respondents by satisfaction with harmonised classification and labelling (n=251 to 253)									
Group	Satisfaction score	a: transparency of the procedures (n=253)		b: involvement of stakeholders (n=252)		c: quality of scientific data and related information (n=252)		d: speed of the procedure (n=251)	
		No.	%	No.	%	No.	%	No.	%
1 (citizens) (n=19)	1	3	16%	3	16%	2	11%	3	16%
	2	1	5%	3	16%	3	16%	3	16%
	3	3	16%	2	11%	0	0%	1	5%
	4	2	11%	3	16%	4	21%	1	5%
	5	0	0%	0	0%	0	0%	0	0%
	I don't know	10	53%	8	42%	10	53%	11	58%
2 (industry) (n=164 to 165)	1	9	5%	6	4%	3	2%	3	2%
	2	17	10%	33	20%	26	16%	22	13%
	3	33	20%	65	39%	37	22%	70	43%
	4	71	43%	32	19%	53	32%	28	17%
	5	11	7%	3	2%	6	4%	5	3%
	I don't know	24	15%	26	16%	40	24%	36	22%
3 (public authority) (n=32)	1	0	0%	0	0%	0	0%	0	0%
	2	0	0%	0	0%	1	3%	2	6%
	3	3	9%	6	19%	4	13%	7	22%
	4	11	34%	6	19%	11	34%	11	34%
	5	7	22%	7	22%	2	6%	2	6%
	I don't know	11	34%	13	41%	14	44%	10	31%
4 (NGO/ others) (n=36 to 37)	1	1	3%	1	3%	2	6%	10	28%
	2	3	8%	2	6%	11	31%	3	8%
	3	4	11%	17	47%	4	11%	6	17%
	4	18	49%	6	17%	2	6%	5	14%
	5	1	3%	1	3%	0	0%	0	0%
	I don't know	10	27%	9	25%	17	47%	12	33%
Notes: a score of 1 = not satisfactory and a score of 5 = very satisfactory									

Table 3-91: Weighted scores based on number and percentage of respondents identifying level of satisfaction with elements related to harmonised classification and labelling (n=251 to 253)				
Element	Group			
	Group 1 (citizens) (n=19)	Group 2 (industry) (n=164 to 165)	Group 3 (public authority) (n=32)	Group 4 (NGO/others) (n=36 to 37)
a) Transparency of the procedures	2.4	3.4	4.2	3.6
b) Involvement of stakeholders	2.5	2.9	4.1	3.1
c) Quality of scientific data and related information	2.7	3.3	3.8	2.3
d) Speed of the procedure	2.0	3.1	3.6	2.3
Notes: weighted score calculated by multiplying score (1 to 5) by percentage of respondents that assigned each score. Therefore, the closer a score is to five, the higher the level of satisfaction placed by each group as a whole. The calculation excludes don't know responses				

Table 3-91 provides a summary of results that makes it easier to compare results across the groups. Overall, the results are:

- Lowest levels of effectiveness:
  - The lowest weighted score across all groups is 2.0 from Group 1 for speed of the procedure. Group 4 also assigns this the lowest weighted score of 2.3 (equal with quality of scientific data and related information). Group 3 also assigns its lowest weighted score to speed of the procedure but here the weighted score is 3.6;
  - The lowest weighted score from Group 2 is for involvement of stakeholders at 2.9.

- Highest levels of effectiveness:
  - The highest weighted score overall is from Group 3 for transparency of the procedures at 4.2. This element also gets the highest weighted score from Group 2 of 3.4 and from Group 4 of 3.6;
  - The highest weighted score from Group 1 is for quality of data and related information at 2.7. This weighted score is lower than any of the weighted scores from Group 2 and 3.

3.3.30.2 Analysis of open text responses

Respondents were also asked to explain their answer if they had assigned a score of 1, 2 or 3 to the closed question. In total 34 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-92. The table also shows which groups the comments were from.

Table 3-92: Q34: extent to which current procedures for harmonised classification and labelling are satisfactory themes from non-questionnaire responses (n=34; Group 1 (citizens) = 4, Group 2 (industry) = 20, Group 3 (public authority) = 4, Group 4 (NGO/others) = 6)

Theme	By
Themes on labelling	
Labelling standards for detergents do not seem to serve consumers	Group 1 (1)
Themes on CLP	
Procedure is very slow	Group 3 (1) Group 2 (1) Group 4 (4)
Final inclusion into Annex VI takes too long	Group 3 (1)
Uncertainty about when classifications may be reviewed by Member States	Group 2 (1)
Industry should be allowed to submit CLH proposals or changes to existing CLH	Group 2 (5) Group 4 (1)
Data used in CLH can often be interpreted in different ways	Group 2 (2) Group 4 (1)
Templates should be used to help assess quality, completeness and reliability of data	Group 2 (2) Group 4 (1)
There should be a common set of minimum guidelines to prepare and justify a CLH proposal	Group 2 (2) Group 4 (1)
CLH timeline of 45 days is too short to provide comments	Group 2 (1)
Epidemiological data should be better considered	Group 2 (1)
There are inefficiencies in the CLH process with respect to change that affect the exiting elements of harmonised C&L from Annex VI	Group 2 (1)
It can be difficult to identify data that were the basis of "older" Annex VI entries	Group 2 (1)

Table 3-92: Q34: extent to which current procedures for harmonised classification and labelling are satisfactory themes from non-questionnaire responses (n=34; Group 1 (citizens) = 4, Group 2 (industry) = 20, Group 3 (public authority) = 4, Group 4 (NGO/others) = 6)	
Theme	**By**
Problems of coordination between CLP classification procedures and procedures for adjustment of the Ecolabel criteria	Group 2 (industry)
Outcome and quality of CLP procedures are largely case specific and dependent on availability of data	Group 2 (industry)
No experience in classification and labelling related to nanomaterials	Group 4 (NGO/others)
Test methods need to be updated to better address endocrine disrupting substances	Group 4 (NGO/others)
Far too few chemicals undergo testing for effects on developmental neurotoxicity and immunotoxicity	Group 4 (NGO/others)
Independent academic data is given a lower value than industry data	Group 4 (NGO/others)
Themes on decision-making	
No/too little stakeholder involvement	Group 1 (citizen) Group 3 (public authority) Group 2 (industry)
Arguments of industry are not listened to at decision stages	Group 1 (citizen)
Pseudo-scientific considerations are given more weight than results from studies	Group 1 (citizen)
Influence of industry is not transparent enough	Group 1 (citizen)
Deadlines for comments and information should be handled more strictly	Group 3 (public authority)
German states are not involved in the procedure for harmonised classification, only the Federal Bureau of chemicals	Group 3 (public authority)
Decision-making process is not transparent	Group 2 (industry) Group 4 (NGO/others)
There should be an independent process/body to monitor/check the quality of data being used to support the opinions of RAC	Group 2 (industry) Group 4 (NGO/others)
Decisions around methodologies and assessment factors do not always recognise metal specificities	Group 2 (industry) Group 4 (NGO/others)
Involvement of stakeholders at RAC is applauded	Group 2 (industry)
Raw data should be made available to the public	Group 4 (NGO/others)
Other themes	
More time is needed for capacity building by regulators	Group 2 (industry) Group 4 (NGO/others)
Scientific assessments face methodological hurdles	Group 2 (industry)

3.3.30.3 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-93 provides a summary of the themes from these non-questionnaire responses.

Table 3-93: Q34: extent to which current procedures for harmonised classification and labelling are satisfactory themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on labelling	
A practical issue is the size of small labels. Providing all the necessary information required by legislation on bottles below 25ml is virtually	Group 2 (industry)

Table 3-93: Q34: extent to which current procedures for harmonised classification and labelling are satisfactory themes from non-questionnaire responses (n=9)	
Theme	**By**
impossible.	
The Classification, Labelling and Packaging (CLP) Regulation sets out minimum package labelling requirements. These requirements do not allow the consumer or manufacturer or retailer of garments, in this case nappies, to make informed decisions	Group 2 (industry)
Themes on CLP	
There are inefficiencies in the CLH process	Group 2 (industry)
CLP system is too complicated and detailed, and lacks clarity	Group 2 (industry)
Other themes	
For older Annex VI entries, there are difficulties in identifying the data that were the basis of original classification decisions	Group 2 (industry)
Historical records should be made available	Group 2 (industry)
There is no process for fast-track derogations due to coordination problems between CLP and Ecolabel criteria	Group 2 (industry)
The area that could be significantly improved is the time gap between the moment comments are provided by industry on the draft decision and the referral data, in particular for Substance Evaluations.	Group 2 (industry)
Procedures are still too anonymous for actors not directly involved.	Group 3 (public authority)
It would be advantageous to introduce a step in the 'classification process' where the dossier submitter is allowed to review and comment upon the draft opinion and classification proposal of the RAC rapporteur ahead of the RAC meeting to avoid misunderstandings	Group 3 (public authority)
There is a need for a better accordance check	Group 3 (public authority)
There is a need to develop exposure limit values which are consistent across all EU Member States and which are consistent across EU legislation which legislate both areas of workplace and environmental chemical exposure	Group 2 (industry)
There is an urgent need for a consolidated EU chemicals framework, setting out one harmonised system encompassing all elements of CAD[1], CMD[2], CLP, Seveso and REACH	Group 2 (industry)
ECHA is delivering opinions and decisions quite timely.	Group 2 (industry)
Notes: [1] CAD = Chemical Agents Directive. [2] Carcinogens and Mutagens Directive	

3.3.30.4 Comparison of themes

The themes associated with the extent to which current procedures for harmonised classification and labelling are satisfactory are summarised in Table 3-94. The themes are organised into those that are generally positive and those that are generally negative. The table provides a summary of the types of issues identified and the number of times each was reported. Note the count is the number of comments that were attributed to each theme, not the number of respondents. This means one respondent could be counted more than once in the sample if, for example, they made comments that were used in two or more themes.

Table 3-94: Comparison of responses on extent to which current procedures for harmonised classification and labelling are satisfactory			
Non-questionnaire responses		OPC responses	
Generally positive	Generally negative	Generally positive	Generally negative
Themes on CLP			
	Group 2 (2)		Group 3 (2) Group 2 (18) Group 4 (9)
Themes on decision-making			
		Group 2 (1)	Group 1 (4) Group 3 (3) Group 2 (17) Group 4 (2)

The majority of comments were negative in terms of satisfaction with current procedures for harmonised classification and labelling. One positive comment was received from Group 2. This was:

- The involvement of stakeholders at RAC is applauded (Group 2)

Remaining comments highlighted a range of different issues and, in some cases, proposed solutions to these issues. These comments include:

- Issues with CLP procedures:
  - Data used are often of good quality but can be considered/interpreted in different ways because of the context surrounding their "generation": e.g. source (industry data vs. peer-reviewed data), purpose for data generation, positive vs. negative result, and type of data (animal, epi, in vitro, in silico) (Group 2, Group 4);
  - CLH timeline of 45 days is too short to appropriately provide comments because evaluation of the published data as well as generation and alignment of information needs longer. We consider a 6 month commenting time frame as appropriate (Group 2);
  - The procedures are seen as generally transparent, although written procedures followed by RAC and decision-making in the Commission are generally less transparent than other segments of the overall procedure for CLH (Group 2);
  - PPP and BP sector not being allowed to submit a CLH similar to the general chemical industry and must work though a MSCA who are not always cooperative. This seems a gross unfairness to the PPP and BP sectors and should be rectified (Group 2);
  - A good indicator of the problems with CLH procedures is the fact that industry is self-classifying more substances as carcinogens than the authorities (ECHA's Classification and Labelling inventory shows that 1017 substances have a CLH classification as Category 1 carcinogens, however, industry has notified this classification for over 2400 substances (Group 4);
  - The continuous amount of information requests by the different pieces of EU legislation, make it virtually impossible for stakeholders to engage effectively in the consultations. The whole stakeholder engagement system should be reconsidered (e.g. envisaging less consultations on more substances at specific months in the year, instead of continuous publications of enquiries/consultations) (Group 2).

- Possible solutions include:

- Industry should also be allowed to submit CLH proposals or changes to existing CLH, as the absence of a correct CLH (meanwhile a Member State frees up resources to take ownership for the applicable CLH (amendment) proposal) may cause market distortions which penalise EU actors (Group 2, Group 4);
- Having a checklist allowing CLH experts to assess more easily epidemiological studies for completeness and reliability may help to make better use of the existing human data and observations. Having a quality checklist or streamlined format for reporting/assessing would also be a valid support (Group 2, Group 4);
- For the « older » Annex VI entries there are sometimes difficulties in identifying the data which were the basis of the original classification decisions leading to the current harmonised classification in Annex VI. If it would be possible to make these historical records available this would be of great assistance for companies when determining their classification globally but also when identifying if they hold actual new data that challenges existing Annex VI elements (Group 2);
- Current test methods need to be updated to better address endocrine disrupting endpoints. This also means that the test requirements in various EU laws have to be adapted accordingly to ensure that these data are generated (Group 4).

- Issues with decision-making:
  - More involvement of stakeholders in order to have a real vision of the consequences related to the implementation of the new classification and labelling of dangerous substances (Group 3);
  - There is uncertainty about when classifications may be reviewed by Member States. This is un-transparent. The fact that RAC members are hard to approach, is also an obstacle to the transparency of the process (Group 2);
  - There is too little discussion with the RAC and too little stakeholder engagement. Many discussions take place in closed sessions. It is not always clear on which scientific study basis a classification relies, nor the quality of this study (Group 2);
  - Access to data and preparatory documents is not direct nor quick enough. Access to meetings is denied and reports are late and sometimes not detailed enough (Group 2);
  - The lack of capacity and resources within CSO and SMEs hinder their capacity to participate in the CLH process (Group 4).

- Possible solutions include:
  - There should be an independent process to monitor/check the quality of scientific data/information that is being used to support the opinions of RAC. Industry stakeholders should be allowed more opportunity/time to present and explain their data/arguments. RAC should consider all available evidence, including REACH data and epidemiology studies (Group 2);
  - Appointing an independent advisory body to accompany RAC's work (similar to SCHER) could be helpful to address/resolve, in full transparency, specific scientific questions where expertise is scarcer or has a divided opinion (Group 2, Group 4);
  - Stakeholders should be more involved on the procedures of CLH definition and on the evaluation of the classification's impact (Group 2).

3.3.31 Question 35: additional comments

3.3.31.1 Analysis of open text responses

There was no closed element to this question. Respondents were also asked to provide any additional comments that they may have that were relevant to the public consultation. In total 33 comments were reviewed. The key themes from these comments have been extracted and are summarised in Table 3-95. The table also shows which groups the comments were from.

Table 3-95: Q35: Other comments / themes from non-questionnaire responses (n=33; Group 1 (citizens) = 4, Group 2 (industry) = 18, Group 3 (public authority) = 4, Group 4 (NGO/others) = 7)	
Theme	**By**
Themes on regulation versus legislation	
Substitute directives with regulations	Group 1 (citizen)
Inconsistencies in legislation can harm industry in the long-term when action is not taken in a timely fashion to resolve the inconsistencies	Group 2 (industry)
Value in having chemical management policy at EU level rather than at 28 national levels	Group 2 (industry)
There are gaps in EU legislation that are bridged by Member State national legislation hampering functioning of the single market	Group 2 (industry)
Themes on improvements to legislative process	
Fitness check should include REACH as well	Group 2 (industry)
Limited and uneven enforcement creates distortions in single market	Group 2 (industry)
Chemical regulatory framework does not properly address innovation	Group 2 (industry)
REACH should be baseline legislation for chemical management in EU	Group 2 (industry)
Chemicals legislation should allow repair as produced for products	Group 2 (industry)
Quality standards are needed for waste material flows to promote market-driven development of secondary materials	Group 2 (industry)
Overlaps and discrepancies between chemical legislation and specific product safety legislation create a lack of clarity	Group 2 (industry)
Two year cycle of changing transport legislation does not seem reasonable	Group 2 (industry)
Processes need to be simplified, streamlined and speeded up	Group 2 (industry)
Need good international teams that will interpret the methodology for assessing the risks of individual substances	Group 4 (NGO/others)
It would be good to perform the same REFIT exercise for the pharmaceutical products legislation in order to take into account water resources protection consideration	Group 2 (industry)
Themes on tools and data	
Environmental monitoring data should be considered in the risk assessment	Group 3 (public authority)
Current testing system is disconnected from issue at stake	Group 2 (industry)
There is insufficient data to support argument that EU chemicals legislation protected human health and the environment	Group 2 (industry)
A European database is needed with validated (eco) toxicity data	Group 2 (industry)
More effort should be made to properly implement measures to avoid animal testing	Group 4 (NGO/others)
Themes on hazard versus risk-based approaches	
Hazard-based approach and focus on laboratory testing does not reflect actual conditions of use or actual environmental conditions	Group 2 (industry)
Risk assessment coupled with hazard assessment provides better protection	Group 2 (industry)

Table 3-95: Q35: Other comments / themes from non-questionnaire responses (n=33; Group 1 (citizens) = 4, Group 2 (industry) = 18, Group 3 (public authority) = 4, Group 4 (NGO/others) = 7)	
Theme	**By**
and more targeted identification of best risk management options	
If a substance can be used safely then it should not be automatically substituted on hazard alone	Group 2 (industry)
Hazards can be understood as risks by people who have no/little training in chemical legislation	Group 2 (industry)
Themes on labelling	
Every label should contain information on the most common allergens using their generic name	Group 1 (citizen)
The vague labelling of ingredients is misleading	Group 1 (citizen)
GHS/CLP pictograms are poorly understood by the general public	Group 2 (industry)
Sectoral labelling for detergent and maintenance products should be considered	Group 2 (industry)
Many disconnects between PPPR[1] and CLP and responsibilities for classification and labelling	Group 2 (industry)
Themes on circular economy	
Consideration needs to be given to how circular economy policy may affect chemicals regulation in future	Group 2 (industry) Group 4 (NGO/others)
Themes on links with workers legislation	
Occupational exposure limits and environmental permit systems are not sufficiently covered by EU legislation	Group 2 (industry)
Better synergies are needed between worker safety legislation and chemical legislation	Group 2 (industry)
Need for quicker and more effective indicative limit values and binding values within workers legislation	Group 4 (NGO/others)
Themes on sources of administrative burden and other costs	
Implementing changes in Directives creates a lot of work for Member States	Group 3 (public authority)
Challenge of regrettable substitution is one of the major cost drivers in industry	Group 2 (industry)
Requirement for product (mixtures) files under biocides legislation are devastating for SMEs	Group 2 (industry)
Complexity, high costs and constant changes in legislation are challenging and burdensome especially for SMEs	Group 2 (industry)
Practical implementation and very strict interpretation of provisions of PIC Regulation[2] cause huge administrative burden	Group 2 (industry)
Other themes	
No experience in classification and labelling related to nanomaterials	Group 4 (NGO/others)
Comments on questionnaire	Group 1 (citizen) Group 2 (industry) Group 3 (public authority) Group 4 (NGO/others)
Notes: [1] PPPR = Plant Protection Products Regulation. [2] PIC Regulation = Prior Informed Consent Regulation	

3.3.31.2 Themes from analysis of sample of non-questionnaire responses

As well as the responses from the OPC, an analysis was made of the themes from nine other responses that were received. Table 3-96 provides a summary of the themes from these non-questionnaire responses.

Table 3-96: Q35: Other comments / themes from non-questionnaire responses (n=9)	
Theme	**By**
Themes on regulation versus legislation	
The Commission should consider the difference and the choice to be made between regulations and directives in accordance with the statements made in the interinstitutional agreement on better regulation (Art. 25)	Group 3 (public authority)
Themes on improvements to legislative process	
Many improvements to chemical regulation within the EU could be made through better implementation throughout the legislative process	Group 3 (public authority)
The lack of easily accessible and understandable tools summarising the lessons (to be) drawn from the ECHA Committees discussions and outcomes makes it close to impossible for companies to understand / plan data and motivation needs and/or to learn from other cases	Group 2 (industry)

3.3.31.3 Comparison of themes

Themes from Q35 are much wider given that they catch all the other comments that respondents wished to make. As such an analysis in terms of positive or negative comments is not possible. Instead, some key comments made by respondents under the overarching themes are provided below:

- Comments on regulation versus legislation:
  - A variety of differing Member State interpretations of EU level legislation hampers the functioning of the internal market. In order to correct this unfortunate situation, and to boost the functioning of the internal market, the existing gaps should be filled with EU level common rules. A harmonization of laws would reduce the burden and cost of compliance for companies (Group 2);
  - Most of the chemical related legislation is highly technical and some of it is subject to continuous amendments. It creates a lot of work in the Member States to implement changes in directives in their national legislation. The Commission should, therefore, consider the difference and the choice to be made between regulations and directives in accordance with the statements made in the interinstitutional agreement on better regulation (Group 3).

- Comments on improvements to the legislative process:
  - Revisions of EU legislation take a significant amount of time. However, redeveloping equipment to meet new requirements takes years and can take almost a decade. Consequently, when inconsistencies are noted, it harms the industry on a long term when action is not taken in a timely fashion to resolve those inconsistencies (Group 2);
  - All too often the discussion on innovation and chemicals legislation gets truncated to regulation-mandated substitution, which is overly simplistic…impacts on innovation should be systematically considered ex-ante and ex-post (Group 2);
  - If a substance can be used safely then it should not be substituted automatically based on hazard alone. The substitution of substances in the market place is a complex process depending upon performance, availability, technical and economic feasibility as well as regulatory drivers. Replacing major commodity chemicals, where justified, can take decades and billions of euros of investment – therefore this is not something which can be undertaken lightly (Group 2);

- REACH regulation has good processes to both foresee and verify substances of very high concern. These processes should developed more visible in public and taken in use in higher level in other more industry sector focused directives like RoHS, ELV, battery directive (Group 2);
- When legislation changes and new provisions are set, functioning of supply chains should be understood and should be taken into account in order to set reasonable transitional periods and other measures (Group 2).

- Comments on tools and data:
  - Current testing system tends to be disconnected from the issues at stake, for instance in terms of public health. In-lab tests are relevant as a starting point but the consideration of exposure should also be part of the hazard and risk assessment (Group 2);
  - A European substance database with validated acute (eco) toxicity data, for calculation of acute toxicity estimates for mixtures. To have a database with acute (eco) toxicity data would be welcomed by all actors in the supply chain (Group 2);
  - Chemical legislations which take up animal welfare, animal use only as a last resort and promotion of alternatives include REACH, biocidal products, cosmetics, plant protection products and the Directive 2010/63/EU on the protection of animals for scientific use, while all the rest which fall into this discussion have very little focus or totally lack any recognition of the need to decrease the use of testing on vertebrates, they have to take this up in any amendments proposed to the legislations (Group 4).

- Comments on hazard versus risk-based approaches:
  - The EU chemicals legislation is strongly hazard-based and focused on laboratory testing that does not reflect actual conditions of use or actual environmental conditions, therefore is disconnected from issues at stake (Group 2).

- Comments on labelling:
  - How can I choose between pound shop oxi bleach stain remover and the branded version when both say they have 15-30% active ingredient and one could have twice as much as the other? How do I know which biological detergent is offering me the full modern battery of enzymes and which has only one? (Group 1);
  - The misunderstanding between hazard and risk communication often leads to many questions. Hazards indicated by CLP labelling are understood as risks…communication of risks as required by medical device legislation (e.g. by instructions for use) is better understood (Group 2);
  - Under CLP, many products carry a corrosive classification – even ones such as non-biological laundry detergents. If a consumer swallowed a hydrochloric acid toilet cleaner, compared with a non-biological laundry detergent, the effects would be far more severe. However, the CLP classification of both does not distinguish this from a consumer's perspective. There is a danger, as more and more products become corrosive that customers will fail to identify those which genuinely need the most care (Group 1).

- Comments on the circular economy:
  - Legislations both for chemical and for circular economy should be carefully considered on balancing with the other existing schemes of laws and regulations. Especially, an individual law scheme should not be planned but legislators should think about the balance of many other fields of various existing laws (Group 2);

- A well-functioning circular economy can only work efficiently by using a risk-based approach instead of completely categorised regulation where only non-toxic substances are allowed. There is a need to define possible non-risky reusing or recovery for materials containing small quantities of risky substances, for example circulated metals including Pb or Cd (Group 2);
- In order to achieve a truly sustainable and safe circular economy, we must accept that not all materials can be reused or recycled, since they may contain unwanted substances that should not re-enter the market. Producers and downstream users need to be able to trust that the material they use is clean enough to keep customers safe and their brand reputations unharmed. This calls for traceability and making sure that hazardous substances are not diluted into materials of higher quality (Group 4).

- Comments on links with workers legislation:
  - For the sake of efficiency better synergies between chemical legislation and worker safety legislation should be sought for risk management, theoretical should be better combined with real life practice, starting from legal level (Group 2).

- Comments on sources of administrative burden and other costs:
  - The challenge of regrettable substitution is one of the major cost drivers in industry. We would like to reemphasize the importance of guidance to industry regarding the selection and use of safer alternatives to substances under legal scrutiny (Group 2);
  - With respect to the Biocides legislation, we believe that the requirements for the PRODUCT (mixtures) files are devastating for SMEs…We would like to recommend to revisit the PRODUCT requirements of the Biocides legislation. We can undertake the costs for proving the efficacy of our products but not that of toxicological and ecotoxicological assessment. The last two, could be covered by CLP. The active substance requirements and risks (which is the only differentiating element between biocides mixtures and other chemical mixtures) are "covered" by the active substance file (Group 2);
  - The practical implementation and very strict interpretations of the provisions of the PIC Regulation cause huge administrative burden to industry and authorities in those cases where due to restriction of a specific use also other, bulk, uses are affected by the restriction (Group 2).

Annex 1 SME Panel comments

Table A: Full comments to Q12 on how to simplify/improve the tools and mechanisms	
Issues and problems	**Suggested solutions**
• **Pictogram are not clear or informative enough** GHS 8 pictogram does not show the hazardous profile of the substance or mixture. Especially to the general public: it may seem a safe product and really is very harmful. Yes, they could be improved if the pictogram of various threats contrast strikingly with each other. The pictograms are often not very clear in reference to the danger in comparison with the old version GHS08 is not understood • **There is too much text** Too much text - especially when it must appear in multiple languages. No one reads the text when it is so long. Consumers and builders look max. pictograms. MAL-code idea was good • **CLP has made attaining warning more complicated than before** The CLP made the attainability of warnings more complicated than the previous regulations • **There are too many H and P sentences and they are not clear** The pictographs are effective, the sentences H and P are not so clear because are too many and often they are not clearly shown in the label. The "sentences" does not provide useful information to an average customer. • **Long chemical names are not meaningful to non-professional users** Long chemical names – no big value for unprofessional user	• **Hazard and precautionary statement should be made clearer and simpler** Make the sentences more clear and more simple. Labels with too much text (sentences H, P, additional instructions) distract the attention of the consumer More readable and easier Hazard and Precautionary Statements. • **Pictograms should be made instinctively comprehensible** simpler, more readable/clearer symbology, easily understandable The labels should be more immediate in the communication of the dangers: the pictograms are not "instinctively" comprehensible. use more immediate understanding of pictograms une personne qui n'est pas commun de ces pictogrammes ne peut pas en un coup d'œil comprendre leur sens Especially for the final consumer, explaining the risks and the appropriate protection similar pictogramms for dangerous goods and hazardous substances certains picto sont peu parlants "danger" et "attention" ne parlent pas au grand public • **Pictograms should be extended and more accurately show the risks** réserver et diviser le pictogramme dangereux pour la sureté à long terme Pictograms should show more accurately the risks connected with the use of chemicals and should be simplified. Worker or customer is not able to understand icons eg.H140 or similar. It would be extremely welcome to extend the range of danger pictograms. These ones should be more specific but easy to "read" at the same time. This extension could be very useful since pictograms and safe use suggestions are not read with the required attention due to their too long texts and complicated words. • **Add product composition** Adding the product composition with inputs to hundred kilos with dosage • **Use QR codes** Use of QR codes that drive to web pages where info about danger and safe use is provided

Table A: Full comments to Q12 on how to simplify/improve the tools and mechanisms	
Issues and problems	**Suggested solutions**
	Using QR codes QR Coding could enable marking • **Number of risk indications should be reduced** risk indications are often similar; they could be reduced • **Amount of text should be reduced** • A traffic light system should be used Les consommateurs ont besoin d'info claires et simplifiées (ex: un feu tricolore pour indiquer le niveau de danger). • **Type of hazard and to whom it is toxic should be indicated** By indicating the type of hazard - to whom especially it is toxic - target organ, reproductive abilities or acute toxic, and whether by inhalation or ingestion or dermally it will be useful, especially for cleaning products, to have detailed indications regarding the importance not to mix them with other products and eventual consequences • **An explanatory leaflet explaining pictograms should be included** inserting a small folding for proper use The products should have also an explanatory leaflet that describes the meaning of the pictographs, that gives indications and danger warning. • **Information should be better disseminated disseminate information** General information should be exposed in chemical stores Information boards in Shops, more skilled personnel in Shops, more skilled personnel in intermediary trade • **More attention should be given to hazards of mixtures** There should be paid more attention to more precise definition of mixture hazard taking into account the already assessed hazards in the mixture and not to assess them for the second time. The changes of bulk adhesive properties in the mixture that have been assessed as those for bulk substance also changes if the substance in the mixture is together with liquids.
General comments	**Other**
• **Safety data sheets should be provided for every delivery of chemicals** For every delivery of chemicals, safety data sheets should be provided. It is not the case anymore.	• **Advertising in media** • **Predictability** The permanent change of the rules is not necessary. The most important is predictability. Or if a change is

Table A: Full comments to Q12 on how to simplify/improve the tools and mechanisms	
Issues and problems	**Suggested solutions**
• **Technical characteristics of PPE must be better specific in safety data sheets** In chemicals Safety Data Sheets must be better specified technical characteristics of PPE (personal protective equipment) to be used and risky environmental characteristics • **Instruments and mechanisms are appropriate but classification should be simplified** The instruments and mechanisms are appropriate, simplification is not recommended, but the classification should be more clear and simple. • **Should be more simplification** Should be more simplification You can always improve but it should be simplified more. The question relies more on the user capacity	needed the cost should be borned by the legislature. The harmonization of the ADR and KRESZ(rule of the road) • **The harmonization of the ADR and** KRESZ **(rule of the road)**

Table C: Key comments on how to simplify/improve the tools and mechanisms	
Safety data sheets	**CLP and biocides/plant protection products**
The obligation to enroll in the safety data sheet composition and still in 2016 there are preparations and mixtures which do not declared all components. Arbejdstilsynets regler er ikke harmoniseret, bla. mal-koder som kun forefindes i Danmark,YL koder i sverige, I Norge fortolker de pt reglerne om SDS ret mærkeligt. Yderligere er kravene til hvad unge under 18 må arbejde med blevet skrævt vredet. Idet kravet her går på piktogrammet. (ætsende), hvilket f.eks har medført at unge under 18 ikke må arbejde med visse håndopvaskemidler. [WEA rules are not harmonized - codes only available in Denmark , YL codes in Sweden , in Norway interpret the present rules on SDS quite strange. Further , the requirements for what young people under 18 may work with skrævt been twisted . Since the requirement here goes to the polarity . (Corrosive) , which for example has led to young people under 18 may not work with certain hand dishwashing detergents .]	CLP og Biocidforordning - f.eks. inkonsekvens ift. stofnavne der skal angives på etiket (Forkortelser/IUPAC navne - CMIT/MIT contra 5-chloro-2-methyl-2H-isothiazol-3-on blanding med 2-methyl-2Hisothiazol-3-on (3:1) CLP and Biocides - eg. inconsistency relation. drug names to be included on the label (Abbreviations / IUPAC names - CMIT / MIT versus 5-chloro-2-methyl-2H-isothiazol-3-one mixture with 2-methyl-2Hisothiazol-3-one (3: 1) Plant protection products allowed only in some EU member states, and not in other states, with consequences on competitors Overlaps between different regulations are partially difficult and can only be understood by experts, when one and the same substance is used for different purposes e.g. biocidals and plant production products or natural formulation enhancers for PSM products or biocidal products. It is really difficult for citizens and it is not appropriately explained to them - different requirements for biocidals registration in the single countries

Table C: Key comments on how to simplify/improve the tools and mechanisms	
Waste	**REACH**
e.g. End of Waste unit is not yet standardized, there is a practice at national level , incoherence with REACH hazardous waste to the environment, arising from non-hazardous substances / mixtures to the environment. Other cases exist, and sometimes there is a general confusion because the regulations are too complicated or uncommon applicable It is not yet a proper alignment with the legislation on waste classification	overlap between reach and notifies ISS
Transport	**Cosmetics**
Partially inconsistent with ADR Yes. ADR material, non-hazardous, neither use nor as waste. Eg alkaline, Ni-MH. 1- There are products that do not match the pictograms of the label CLP with those of transport. 2- Flammable substance, according to APQ is a substance whose flash point is less than 55 ° C, in the ADR and CLP are considered flammable up to 60 ° C maximum.	In the Cosmetic Regulations there isn't any indication whether cosmetics need to have available the Material Safety Data Sheet, although there are customers from the EU who request it for their the Competent Authorities Cosmetics legislation prohibits the use of raw materials, which have been tested on animals, but the CLP and REACH requires to indicate the carried DDL tests on animals.
Food	**Other**
Food is not falling into the scope of the CLP field of application, but aroms are dangerous mix that must be labelled	Do not know The deviancy of the special authority's opinion within the country VOC NO See Point 18. There is no easy access to legislation of different countries in relation to thresholds of professional expositions, contact information of Poisoning centres and Rescue services - WGK (engl. WHC, Water Hazard Class) is a German product

Table C: Key themes from final comments on the implementation of chemicals legislation excluding REACH	
Issues with costs	**Issues with knowledge and understanding**
• Biocides legislation involves expensive costs for companies if you wish to sell in several countries you have to pay fees "Biocides legislation involves an expensive cost for companies. This is increased especially if you wish to sell in several countries where you would have again to pay fees, (in some cases extremely high), time and money. If a substance has many adverse effects on human health, it should be banned. • Changes require large amount of time and human resources In total it is large increase of time and human resources for the company that is bound by these changes. The requirements are not fully clear, the practice differs from theory, there is no security and confidence that the company has foreseen implementation of all changes. Information about problematic substances in mixtures in each country may differ - the requirements.	• Users do not always have the knowledge need to prevent emergency situations Awareness of users in other ways, because not all of them have the necessary knowledge to prevent emergency situations they may be involved in due to lack of knowledge • Pictograms do not show serious risks 8 GHS pictogram does not show the serious risks: carcinogenic, germ cell mutagenic or toxic to reproduction" • It can be difficult to get information on human health and environmental safety because information is not translated Difficulty of access to the national environment and labour safety links because basically they are not translated even in English and Russian languages.
Wider issues for SMEs	**Issues with sources of information**
• Move to more single entrepreneurs without employees "Hairdresser work primarily with cosmetic products. Should we get additional regulations like these one for companies, the single entrepreneurs will be increased, because they are not subject to health and safety at work audits. The companies with employees and apprentices will be less and less and also moving in the single entrepreneurs. There remain then only the chain Enterprises and the single entrepreneurs with out employees." • SMEs are at the mercy of big companies who hold the decisions behind labelling SMEs are at the mercy of the big companies that have registered. They can never grow, because if they want to be untied by the major European giants, have to import from abroad. This means monstrous costs increased by European giants who hold the recording and decided labeling. • Inspectors are not sufficiently aware of the problems of the industrial world veiller à ce que les inspecteurs qui font les contrôles soient moins dans la répression et plus au fait des problématiques du monde industriel [ensure that inspectors who make the controls are less in repression and more aware of the problems of the industrial world]	• Information can be downloaded from lots of different places concerning. spg. 18 information download many places from the trade association newsletters, suppliers," • Having SDS in language of each country is difficult but understandable, but this is disproportionate for exposition scenes To have the SDS into the language of each country makes an important difficult but acceptable. But we consider out of proportion having to create also the Exposition Scenes .We understand these documents are addressed to prevention technicians with University degree and that English would be enough to create and communicate these documents. • More training and informative events are required More informative events required It will be useful to foresee training programmes organized for SMEs through trade associations and for consumers through media. the training should focus on the contents of the CLP regulation, the understanding of the pictographs and danger warnings, the correct use of the chemical products and eventual their disposal. Regular organisation of workshops by local sectorial organizations and Chambers of commerce to keep SMEs informed
Issues with classification	**Other issues**
• Classification is too complicated and unclear The classification of certain chemicals is too complicated and unclear	• Chaos pf past three years has made it almost impossible for SMEs to work In the past years there was a chaos. It made almost impossible for the SMEs to work

Table C: Key themes from final comments on the implementation of chemicals legislation excluding REACH	
Issues with costs	**Issues with knowledge and understanding**
• Classification has not resulted in harmonised labelling The CLP regulation must harmonized labelling of existing substances and not, starting from certain classifications. This did not happen because: although for substances classification record it is not certain; the standard is complicated in some respects extruded from reality; It is required to notify the labeling for substances, when in fact those in use are mostly mixtures. Should be extended worldwide, not only European, easier for companies on the global market	• Human and environmental protection is not complete as too many substances are not covered by REACH and CLP Too many substances: eg. metals, polymers, of a different nature, are not covered by REACH and CLP Regulations, and thus the purpose of human and environmental protection is still incomplete. Substances produced / used in the EU in small quantities have disappeared or are likely to disappear not because of their dangerousness but because of their cost.

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