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

Evaluation Report

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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

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Abstract

As part of its Regulatory Fitness and Performance Programme (REFIT), the European Commission launched a fitness check on chemicals legislation (excluding REACH). This study supports the fitness check in evaluating the CLP Regulation ((EC) No 1272/2008) and its interface with other related chemicals legislation in terms of effectiveness, efficiency, coherence, relevance and EU added value. Mapping was undertaken to establish the scope of relevant legislation followed by desk research and a suite of stakeholder consultation activities, which assisted in answering a range of evaluation questions. The evaluation considered the rules and processes for classifying substances and mixtures, the methods of communication of the associated hazard information and the properties of concern that require consideration. It also considered linkages between CLP and downstream legislation, assessing risk management based on generic risk considerations (triggered automatically by a CLP classification) as opposed to risk management based on specific risk assessments. The study finds that, generally, the objectives of the chemicals legislative framework continue to be relevant and provide added value at the EU level. However, there are gaps, overlaps and inconsistencies, as well as implementation issues, that affect the effectiveness, efficiency, relevance and coherence of the framework.

Key words: Fitness check, evaluation, chemicals, CLP Regulation

Résumé

Dans le cadre de son programme pour une réglementation affûtée et performante (REFIT), la Commission européenne a entrepris un bilan de qualité de la législation sur les produits chimiques (hors règlement REACH). Cette étude vise à étayer le bilan de qualité en proposant une évaluation du règlement CLP ((CE) No 1272/2008) et de son interface avec d'autres législations connexes sur les produits chimiques en termes d'efficacité, d'efficience, de cohérence, de pertinence et de valeur ajoutée européenne. Une démarche d'identification a été menée afin d'établir le champ d'application de la législation pertinente, suivie de recherches documentaires et d'une série de consultations auprès des parties prenantes, dans le but de répondre à une série de questions propres à l'évaluation. Celle-ci couvre les règles et procédures de classification des substances et des mélanges, les méthodes de communication des informations de danger qui y sont associées et les propriétés préoccupantes devant être prise en compte. Les liens entre les législations CLP et en aval, évaluant la gestion des risques en fonction des considérations générales des risques (enclenchée automatiquement par la classification CLP) contrairement à la gestion des risques fondée sur l'évaluation spécifique des risques, sont également pris en compte. L'étude conclut qu'en règle générale les objectifs du cadre législatif sur les produits chimiques demeurent pertinents et constituent une valeur ajoutée européenne. Il existe toutefois des lacunes, des chevauchements et des incohérences, ainsi que des problèmes de mise en œuvre qui nuisent à l'efficacité, à l'efficience, à la pertinence et à la cohérence du cadre.

Mots-clés: Bilan de qualité, évaluation, produits chimiques, règlement CLP

Abstract

Im Rahmen des Programms zur Gewährleistung der Effizienz und Leistungsfähigkeit der Rechtsetzung (engl. "Regulatory Fitness and Performance Programme" – REFIT) hat die Europäische Kommission einen Fitness Check seines Chemikalienrechts (ausgenommen REACH) lanciert. Diese Studie unterstützt den Fitness Check in seiner Bewertung der CLP-Verordnung ((EC) Nr. 1272/2008) und deren Schnittstellen mit anderen chemikalienrechtlichen Vorschriften in Bezug auf Effektivität, Effizienz, Kohärenz, Relevanz und EU-Mehrwert. Zunächst wurde eine orientierende Analyse durchgeführt, um die für die Studie relevante Gesetzgebung zu identifizieren. Anschließend folgten eine Literaturrecherche und mehrere Konsultationsrunden mit Interessensvertretern, die zur Beantwortung einer Reihe von Bewertungsfragen beitragen sollten. Die Bewertung umfasste Regelungen und Prozesse zur Einstufung von Stoffen und Gemischen sowie die Methoden zur Kommunikation relevanter Gefahreninformationen und besorgniserregender Eigenschaften, die weitere Maßnahmen erfordern. Es wurden zudem Schnittstellen zwischen CLP und nachgeschalteten Rechtsvorschriften betrachtet. Dabei wurde analysiert, inwieweit Risikomanagement basierend auf allgemeinen Risikoerwägungen (automatisch ausgelöst durch eine Einstufung unter CLP) oder Risikomanagement basierend auf einer spezifischen Risikobewertung zur Anwendung kommen. Die Studie stellt fest, dass im Allgemeinen die Ziele des Gesetzesrahmens für Chemikalien weiterhin von Relevanz sind und deren Anwendung auf EU-Ebene einen Zusatznutzen darstellt. Gleichwohl existieren Lücken, Überschneidungen und Inkonsistenzen sowie Umsetzungsprobleme, welche die Effektivität, Effizienz, Relevanz und Kohärenz der Rahmengesetzgebung beeinträchtigen.

Schlagworte: Fitness Check, Bewertung, Chemikalien, CLP-Verordnung

Executive Summary

As part of its Regulatory Fitness and Performance Programme (REFIT), the European Commission (hereafter "the Commission") has launched a fitness check on chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries.[1]

The purpose of this study is to support the fitness check with its objective being to evaluate the CLP Regulation[2] and its interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. It thereby covers a substantial part of the scope of the fitness check roadmap. The evaluation is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value in accordance with the Commission's Better Regulation guidelines. This report sets out the higher level conclusions of the evaluation (based on the evaluation criteria), and is supported by a range of more detailed annexes.

The study was organised into four tasks: **Task 1** evaluating the implementation of the CLP Regulation, **Task 2** evaluating the horizontal links between EU legislation on hazard identification and 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, and **Task 4** supporting the Commission in organising an open public consultation, SME panel and workshop. In line with the fitness check roadmap, when analysing risk management measures under Task 3, the study distinguishes risk management based on generic risk considerations (i.e. risk management measures automatically triggered by a hazard classification under CLP, without further assessment of the risk) and risk management based on specific risk assessment (i.e. risk management measures following an assessment of both the hazards and specific exposure).

The methodology adopted for the evaluation was developed around the needs of these four tasks. The work included a literature review to obtain key information from impact assessments, position papers, academic and scientific research etc.; legal mapping to identify relevant legislation and specific provisions within this; consultation activities including the Open Public Consultation, a Stakeholder Workshop, an SME Panel, consultation as part of case study work as well as targeted consultation of key stakeholder groups; and case study research involving a more in-depth examination of some of the more pertinent issues identified as part of initial research.

The outcomes of the study are summarised below in terms of the five evaluation criteria.

Effectiveness

On balance, the CLP Regulation is considered to contribute towards ensuring a high level of protection for human health and the environment with respect to the hazard classification, labelling

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Regulatory Fitness and Performance (REFIT): Results and Next Steps', COM(2013) 685 final, 2 October 2013

[2] 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, amending Regulation (EC) No 1907/2006; OJ L353/1, 31 December 2008

and packaging of substances and mixtures. It provides the basis for identifying properties of concern, with this information then used in hazard communication (through labels under CLP and safety data sheets under REACH) to workers, downstream users and consumers of chemicals to ensure their safe use, as well as for risk management purposes under downstream legislation. CLP is broadly considered by industry, Member State authorities and civil society stakeholders to be a more easily applied system than the previous Dangerous Substances Directive and Dangerous Preparations Directive for the self-classification of substances and mixtures, with this also contributing towards objectives in relation to the single market and competitiveness.

However, there are areas where the effectiveness of the legislation with respect to achieving single market objectives could be improved through greater harmonisation of implementation. For example, there is a lack of clarity with respect to how some CLP bridging principles for classifying mixtures are to be applied. There is also concern that the current rules have a tendency to over-classify mixtures for some endpoints (e.g. for skin corrosion/irritation and eye damage/irritation). Furthermore, there are weaknesses in the ability of the mixture classification rules to adequately reflect bioavailability, with particular concerns arising for the classification of metals and their alloys. The evaluation has also identified several factors hindering its effectiveness linked to implementation of the legislative framework at the national level: differences across Member States in the acceptance of the use of different methods for the classification of mixtures; variations in the willingness of Member States to support harmonised classification dossiers under the Biocidal Products Regulation and Plant Protection Products Regulation; and variations in approaches to and levels of enforcement, which work against the single market objective and the establishment of a level playing field for companies.

The 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. Although this is considered to be a negative, it is acknowledged that the technical capacity to assess combination effects and multiple routes of exposure to the full extent does not currently exist. It is also clear that there have been delays in determining appropriate criteria for endocrine disrupting chemicals under some legislation, which will have impacts on the effective functioning of the legislation and its ability to ensure a high level of protection for human health and the environment.

The conclusions of the evaluation are generally positive regarding the quality and reliability of the data that are used for classification purposes. The data requirements underlying the legislative framework are considered adequate to ensuring the protection of human health and the environment. Where new tests are carried out, these are to adhere to the requirements of Good Laboratory Practice or, for certain tests, relevant standards (e.g. ISO 17025); older data are accepted where these are considered reliable. This contributes to effectiveness, and efficiency and coherence.

Issues that impact negatively on the effectiveness of hazard communication measures include the lack of consumer understanding of some of the CLP pictograms and information overload due to the level of information that must be included on labels, and which may result in consumers and downstream users not taking account of the warnings related to certain products, thus potentially impacting on the effectiveness of the legislation in ensuring protection of human health and the environment. Also, the lack of differentiation between certain hazards (i.e. products may be labelled with the same pictogram despite the actual hazards being markedly different) is considered to be leading to consumer confusion. There may be the potential for the increased use of more innovative tools to supplement current labelling requirements to increase the quality of the information being communicated (e.g. the use of Q-R codes, websites, etc.) and increase effectiveness of communication.

Efficiency

An important element of determining the efficiency of the legislative framework is examination of the costs and benefits of its implementation and operation; other key factors include the functioning and speed of processes and procedures, and the resource requirements of the legislation. In terms of headline figures, the costs associated with the implementation of and transition to CLP include the following:

- **Ongoing costs of CLP Implementation:** ongoing (annual) costs to industry include direct costs arising from annual up-dates to IT systems in line with adaptations to CLP and new harmonised classifications (CLH), staff training costs, ongoing compliance activities, hassle costs and packaging related costs. All costs (and benefits) were calculated on the basis of a 'null counterfactual' reflecting a present where there is no regulation. The central estimate of total costs is around €1.3 billion (€0.97-1.7 billion) excluding poison centre reporting costs (around €1.7 billion). This compares with a maximum figure of €1.47 billion as calculated by the Cumulative Cost Assessment;

- **Costs of transition to CLP:** the total classification, labelling and SDS costs for substances and mixtures are estimated at around €1.2 billion (upper bound estimate for the number of mixtures with a range €820-1.6 billion). Direct transition costs relating to new/updated IT and staff training are estimated at around €310 million (€220-400 million). Transitional costs relating to packaging have not been estimated. Indirect costs associated with reformulation of mixtures are estimated at between €68 million (±€20 million) and €140 million (±€42 million) depending on what is assumed for numbers of hazardous substances.

The human health and environmental benefits of the legislative framework stem from the availability of classification information and the role this plays in hazard communication, providing incentives for the use of less hazardous substances, and reductions in accidents/incidents and exposures to hazardous substances. As found by other studies, methodological and data constraints do not enable consideration of the full range of human health and environmental parameters. There is, however, statistical evidence that there has been a significant change in the level of information available on environmental and human health classifications, which will have fed through to better risk management. The study's (necessarily partial) analysis of human health benefits suggests that the 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. However, this does not include any quantification of the environmental benefits or of benefits to consumers and society more generally from reduced chemical exposures.

With respect to the linkages between CLP and downstream legislation, the study identified various risk management measures based on generic risk considerations, for example, the Biocidal Products Regulation, the Plant Protection Products Regulation, the Toy Safety Directive and the Regulation on plastic materials intended to come into contact with food. All of these include automatic risk management linked to CMR classifications, with the first two also having automatic measures linked to PBT/vPvB and to endocrine disruption properties. These automatic linkages were put in place on a precautionary basis to ensure that people and the environment were protected against exposures to the most hazardous substances, and due to the potential for non-controllable or widespread exposures. In the case of the Toy Safety Directive, they also help ensure protection of a vulnerable population – children. In addition to providing a high level of protection, this approach is also considered to provide industry with a clear and consistent indication of the substances/mixtures that they can and cannot use in their final products.

The evidence for benefits or unnecessary burdens imposed on stakeholders from such generic risk considerations 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, with an example being the banning of lead under the Toy Safety Directive. Other case study examples highlight the potential for significant costs to arise as a result of the automatic triggers that exist under the generic risk considerations approach (e.g. in relation to plant protection products) and the potential for regrettable substitutions or unintended consequences (e.g. impacts on recycling activities).

The need for risk management based on these generic risk considerations is not clear where sectoral legislation also requires extensive and detailed risk assessments, such as those prepared to support active substance approval under the Biocidal Products and Plant Protection Products legislation, which must cover risks across different environmental compartments and populations. These specific risk assessments should in themselves provide an indication of the level of risk associated with the continued use of a substance, across exposure scenarios. Furthermore, they should reflect the properties which lead to the triggering of generic risk considerations (i.e. the potency of a carcinogen, the level of persistence or toxicity of a PBT, hazards related to only one route of exposure, etc.). 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 ensures that risk management decisions are based on the acceptability of residual risks. This reinforces that classification decisions remain fully science-based, avoiding the need to consider the downstream consequences at the classification stage or to introduce derogations.

In addition, arguments that technical feasibility and socio-economic considerations should be taken into account are currently being made with regard to plant protection products, with industry highlighting the importance of some of these chemicals for society, emphasising the need to strike the right balance in the legislation. 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 the extension to treated articles. On the other hand, a number of areas for cost saving were identified (although none of these are linked to the generic risk considerations within the legislation). A major question 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, which is not currently known. In the interim, the availability of derogations on the basis of risk, technical feasibility and economic grounds may be important to ensuring the overall efficiency of the legislative framework in the future.

Changes in classification can also lead to significant impacts under other legislation such as Seveso III where, combined with tonnage considerations, a change in hazard classification may trigger a change in a site's status under the Directive, with potentially significant economic consequences; this includes significant costs for SME formulators, operators of warehouses, etc.

With respect to Occupational Health and Safety legislation, such as the Carcinogens and Mutagens Directive, a specific risk assessment approach is applied, and the trade-offs involved in the Commission's proposals are clear. Case study examples demonstrate the flexibility that is present within the legislation (e.g. gallium arsenide) and the desirability from a cost and feasibility perspective of recognising case-specific factors when developing the legislation.

In terms of the legislative framework more generally, aspects that contribute the most to the efficient functioning of the framework include: the reliance on CLP as the basis for classification across almost all other legislation will have increased the efficiency of the legislative framework as

has the availability of guidance and IT systems to assist companies in meeting their classification and labelling obligations. Aspects that hinder the efficient functioning of the legislation include the existence of parallel hazard assessment processes, resource and expertise constraints in Member States which hinders their ability to bring forward dossiers for the harmonised classification and labelling of substances, the fact that implementation of CLP across the Member States is still not fully harmonised, and the lack of potential for derogations from automatic bans on the use of a substance for technical feasibility reasons as a minimum.

Relevance

The objectives of the legislative framework continue to be relevant given that the reduction of exposure to hazardous chemicals remains important, while at the same time recognising that chemicals will remain fundamental to economic activities within the single market and be present in day to day products.

Some needs remain, however. For example, there needs to be a better legislative means of ensuring that the use of hazardous substances in consumer products is minimised, due to the lack of any criteria or information for hazard identification and exposure assessment under the General Product Safety Directive, with REACH currently being the only means of addressing risks in consumer products. In addition, the combined effects of chemicals, as well as exposures from multiple sources, are not sufficiently taken into account, with the need for further assessment methods in this regard. More generally, the data used for the identification of properties and the criteria being applied are considered to be relevant and appropriate, although there are issues related to the classification of metals and alloys, as well as other mixtures in a matrix.

In general, the study found that labelling information is relevant and appropriate to enabling downstream users and consumers to make informed choices regarding the products they purchase and use (positive examples include obligatory ingredient lists for cosmetics and personal care products). However, some consumers indicated that the lack of detailed ingredient lists (e.g. in relation to detergents, biocidal products, toys) restricts their ability to make informed decisions and thus avoid products containing certain substances. In addition, there may be a need for considering more innovative communication approaches, to reduce information overload and to enable consumers to access additional information on the properties of products and on safe use.

Coherence

The legal acts of the chemicals legislative framework all have the same objective of ensuring a high level of protection to human health and the environment, ensuring the efficient functioning of the single market and enhancing innovation and competition. Each of the pieces of legislation covered by this study takes steps to meet these objectives and are, therefore, coherent. An important finding of the study is that stakeholders from all groups (industry, Member State authorities, etc.) believe that harmonisation of data requirements for risk assessment would ensure better coherence of the work and hence conclusions of different agencies/committees (e.g. with an example being EFSA and ECHA's Committee for Risk Assessment (RAC) regarding the harmonised classification of Plant Protection Product active substances) and could be beneficial in increasing the coherence of the EU chemicals legislative framework.

There are certain gaps in the classification criteria within CLP, for example, with respect to terrestrial toxicity and immunotoxicity. Other chemicals legislation also requires identification of properties of concern, including those substances which are allergens, endocrine disruptors and PBTs and vPvBs (persistent, bioaccumulative and toxic or very persistent and very bioaccumulative). Classification for all of these properties will draw on information developed under CLP, as well as additional data,

and including them into CLP would result in it no longer conforming to GHS. Looking across the legislation, there is good coherence in the identification of PBT properties, but some lack of coherence with regard to the identification of allergens under different legislation. It remains too early to determine whether or not requirements in relation to endocrine disruptors will be harmonised across the relevant legislation.

It is also important to note though that there is, in general, considered to be a high level of coherence in data requirements and the use of data within the legislative framework. The prohibition on animal testing under the Cosmetic Products Regulation also represents an area where there is a lack of coherence. The Cosmetic Products Regulation requires all new data for cosmetics-only ingredients to be developed using alternative methods. However, ingredients that are used in cosmetics, as well as in other applications, may still require data from animal testing under the REACH Regulation, the Plant Protection Products Regulation, Biocidal Products Regulation or other legislation.

For the main pieces of legislation based on generic risk considerations, derogations are quite heavily weighted towards scientific proof (a specific risk assessment) that a substance is safe for use. Only the Biocidal Products Regulation has a broader scope for derogation, which may include both technical feasibility and social interest (or socio-economic) arguments. These differences in the arguments that can be made to gain a derogation reflect an incoherence in the legislative framework (and in particular the differences between biocides and plant protection products) that may also impact on the degree to which the framework contributes to economic growth, innovation, competitiveness and other policy objectives for the single market. Examples (e.g. ethanol) highlight the potentially significant socio-economic implications of the automatic triggers linked to CLP that exist in downstream legislation, especially where there may be no suitable alternatives with similar characteristics (e.g. in terms of performance). Thus, while the use of a generic risk consideration approach may have advantages in terms of simplicity in the regulation of the most hazardous substances under relevant sectoral legislation, it does have potential implications for EU society and the economy in the future if valuable substances are restricted from use in important applications. At the minimum, there need to be derogation possibilities based on a specific risk assessment approach and which includes consideration of more than just scientific criteria.

EU added value

The chemicals legislative framework is considered to provide added value at the EU level. In general, stakeholders from all groups 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. The framework is considered to be broadly consistent with wider EU policies in achieving the same general objectives (i.e. the single market, increased trade, protection of health and the environment) and EU-level intervention is necessary to achieving these objectives in an effective and efficient manner. This is particularly true with respect to risk management measures, to ensure the avoidance of barriers to trade which may occur if there are national differences in approaches to risk management, properties of concern for regulatory purposes or differences in criteria for triggering risk management. Hence, in general, the legislative framework is considered to provide added value (and ensures a more consistent and coherent approach) compared to a regulatory system that operated at the national level.

Synthèse

Dans le cadre de son programme pour une réglementation affûtée et performante (REFIT), la Commission européenne (ci-après dénommée « la Commission ») a entrepris un bilan de qualité de la législation sur les produits chimiques (hors règlement REACH), ainsi que de certains aspects connexes de la législation appliquées aux industries en aval[3].

Cette étude a pour but d'étayer le bilan de qualité en évaluant le règlement CLP[4] et son interface avec d'autres législations connexes sur les produits chimiques, y compris celles régissant l'identification et la communication des dangers et établissant des mesures de gestion des risques liées au règlement CLP. Elle couvre donc une partie importante du champ d'application de la feuille de route du bilan de qualité. L'évaluation se fonde sur les critères d'efficacité, d'efficience, de cohérence, de pertinence et de valeur ajoutée européenne conformément aux lignes directrices de la Commission pour l'amélioration de la règlementation. Le présent rapport présente les conclusions générales de l'évaluation (en fonction des critères d'évaluation) et est accompagné d'annexes plus détaillées.

Cette étude est divisée en quatre tâches : la **Tâche 1,** évaluant la mise en œuvre du règlement CLP, la **Tâche 2,** évaluant les liens horizontaux au sein de la législation européenne sur l'identification et la communication des dangers, la **Tâche 3,** évaluant les liens verticaux entre le règlement CLP et les législations nationales et européennes en aval pertinentes, en identifiant les mesures de gestion des risques basées sur la classification des dangers et la **Tâche 4,** assistant la Commission dans l'organisation d'une consultation publique ouverte, d'un panel de PME et d'un atelier. Conformément à la feuille de route du bilan de qualité, au cours de l'analyse des mesures de gestion des risques dans le cadre de la Tâche 3, cette étude distingue la gestion des risques basée sur la prise en considération générale des risques (c'est-à-dire des mesures de gestion des risques déclenchées automatiquement par la classification d'un danger en vertu du règlement CLP, sans évaluation supplémentaire des risques) de la gestion des risques basée sur une évaluation spécifique des risques (c'est-à-dire des mesures de gestion des risques prises suite à une évaluation des dangers et de l'exposition spécifique).

La méthodologie adoptée pour l'évaluation a été élaborée en fonction des exigences de ces quatre tâches. Ont été entreprises dans le cadre de la réalisation de l'étude : une analyse documentaire visant à réunir des informations de base à partir d'analyses d'impact, de documents élaborés par des parties prenantes concernées, de recherches universitaires et scientifiques, etc. ; l'identification de la législation pertinente et des dispositions spécifiques y figurant ; des activités de consultation, y compris la consultation publique ouverte, un atelier ouvert aux parties concernées, un panel de PME, une consultation dans le cadre de l'analyse des études de cas, ainsi qu'une consultation ciblée des groupes de parties prenantes concernées ; des recherches basées sur des études de cas comprenant un examen plus approfondi de certains des problèmes plus pertinents identifiés dans le cadre des recherches initiales.

[3] Communication de la Commission européenne au Parlement européen, au Conseil, au Comité économique et social européen et au Comité des régions, 'Programme pour une réglementation affûtée et performante (REFIT) : résultats et prochaines étapes', COM(2013) 685 final, 2 Octobre 2013

[4] Règlement (CE) No 1272/2008 du Parlement européen et du Conseil du 16 décembre 2008 relatif à la classification, à l'étiquetage et à l'emballage des substances et des mélanges, modifiant et abrogeant les directives 67/548/CEE et 1999/45/CE et modifiant le règlement (CE) no 1907/2006 ; JO L353/1, 31 Décembre 2008

Les résultats de l'étude sont résumés ci-dessous selon les cinq critères d'évaluation.

Efficacité

Dans l'ensemble, le règlement CLP est considéré comme contribuant à assurer un niveau de protection élevé en matière de santé humaine et d'environnement de par la classification des dangers, l'étiquetage et l'emballage des substances et des mélanges. Il fournit une base pour l'identification de propriétés préoccupantes. Ces informations sont ensuite utilisées dans la communication de dangers aux travailleurs, aux utilisateurs en aval et aux consommateurs de produits chimiques pour assurer la sécurité d'utilisation (au moyen d'étiquettes en vertu du règlement CLP et de fiches de données de sécurité en vertu du règlement REACH), ainsi qu'à des fins de gestion de risques en vertu de la législation en aval. Le règlement CLP est largement considéré par l'industrie, les autorités des États membres et les acteurs de la société civile comme étant un système plus facile à mettre en œuvre que la directive relative aux substances dangereuses et la directive sur les préparations dangereuses qui existaient auparavant pour l'auto-classification de substances et de mélanges. Le règlement contribue également aux objectifs relatifs au marché unique et à la compétitivité.

Il y a toutefois des domaines où l'efficacité de la législation en vue de la réalisation des objectifs relatifs au marché unique pourrait être améliorée au moyen d'une meilleure harmonisation de la mise en œuvre. On note par exemple un manque de clarté quant à la manière d'appliquer certains des principes d'extrapolation pour le classement des mélanges du règlement CLP. Il existe également des craintes quant à la tendance des règles actuelles à surclasser les mélanges concernant certains impacts (par exemple la corrosion/irritation cutanée et les lésions /l'irritation oculaires). En outre, on remarque des faiblesses concernant la capacité des règles de classification des mélanges à refléter adéquatement la biodisponibilité ; la classification des métaux et de leurs alliages est notamment l'objet de préoccupations particulières. L'évaluation a permis d'identifier plusieurs facteurs qui nuisent à l'efficacité de la mise en œuvre du cadre législatif au niveau national: des différences d'acceptation de l'utilisation de différentes méthodes pour la classification des mélanges entre les États membres ; des différences en ce qui concerne la volonté des États membres de soutenir l'élaboration de dossiers de classification harmonisés en vertu du règlement relatif aux produits biocides et du règlement relatif aux produits phytopharmaceutiques ; des différences en termes d'approche et de niveau d'application, allant à l'encontre de l'objectif du marché unique et de conditions égales pour les entreprises.

Plusieurs parties prenantes de l'ensemble du secteur concerné (industrie, ONG, États membres, universités) considèrent que l'absence d'évaluation des effets combinés et des multiples voies d'exposition constitue un obstacle à la protection de la santé humaine et de l'environnement. Bien que cette absence soit considérée comme un point négatif, le fait qu'il n'existe pas pour le moment de possibilités techniques d'évaluer pleinement les effets combinés et les multiples voies d'exposition est reconnu. Il est également clair que des retards sont survenus dans la détermination des critères appropriés pour les perturbateurs endocriniens dans certains textes législatifs, ce qui aura un impact sur le fonctionnement efficace de la législation et sur sa capacité à assurer un niveau élevé de protection de la santé humaine et de l'environnement.

Les conclusions de l'évaluation sont globalement positives en ce qui concerne la qualité et la fiabilité des données utilisées à des fins de classification. Les exigences en matière de données qui sous-tendent le cadre législatif sont jugées adéquates pour assurer la protection de la santé humaine et de l'environnement. Lorsque de nouveaux essais sont effectués, ceux-ci doivent respecter les exigences des bonnes pratiques de laboratoire ou, pour certains essais, les normes pertinentes (comme par exemple ISO 17025). Des données plus anciennes sont acceptées lorsqu'elles sont

considérées comme fiables, ce qui contribue à l'efficacité, à l'efficience et à la cohérence du système réglementaire en place.

Le manque de compréhension, parmi les consommateurs, de certains des pictogrammes CLP, ainsi que la surcharge d'informations présentées sur les étiquettes font partie des problèmes ayant un impact négatif sur l'efficacité des mesures de communication de danger. En effet, ces problèmes peuvent mener les consommateurs et les usagers en aval à ne pas tenir compte des avertissements sur certains produits et donc potentiellement avoir un impact sur l'efficacité de la législation sur la protection de la santé humaine et de l'environment. En outre, le manque de différenciation entre certains dangers (certains produits peuvent être étiquetés avec le même pictogramme malgré des dangers réels nettement différents) est considéré comme une source de confusion pour les consommateurs. Il pourrait y avoir la possibilité d'utiliser des outils plus innovants pour répondre aux exigences actuelles en matière d'étiquetage afin d'améliorer la qualité des informations communiquées (par exemple par l'utilisation de codes QR, de sites web, etc.) et l'efficacité de la communication.

Efficience

Un élément important dans la détermination de l'efficacité du cadre législatif est l'analyse des coûts et des bénéfices de sa mise en œuvre et de son fonctionnement. Le fonctionnement et la rapidité des processus et des procédures, ainsi que les ressources requises par la législation sont d'autres facteurs clés. En ce qui concerne les chiffres phares, les coûts liés à la transition vers et la mise en œuvre du règlement CLP comprennent notamment :

- Les **coûts récurrents de la mise en œuvre du règlement CLP :** les coûts récurrents (annuels) pour l'industrie comprennent les coûts directs résultant de la mise à jour annuelle des systèmes informatiques conformément aux modifications du règlement CLP et aux nouvelles classifications harmonisées (CLH), les coûts de formation des travailleurs, les activités de conformité récurrentes, les coûts associés à la charge disproportionnée de certaines activités et les coûts d'emballage. Tous les coûts (et les bénéfices) ont été calculés sur la base d'un « contrefactuel nul » correspondant à un temps présent où il n'existe pas de réglementation. L'estimation centrale du coût total s'élève à environ 1,3 milliard d'euros (0,97 à 1,7 milliard d'euros) à l'exclusion des coûts associés à l'élaboration de rapports pour les centres antipoison (environ 1,7 milliards d'euros). Ces coûts se rapportent au montant maximum de 1,47 milliard d'euros calculé par l'évaluation des coûts cumulés;

- **Les coûts de la transition vers le règlement CLP :** les coûts totaux de classification, d'étiquetage et de fiches SDS pour les substances et les mélanges sont estimés à environ 1,2 milliard d'euros (estimation de la limite supérieure pour le nombre de mélanges, de 820 à 1,6 milliard d'euros). Les coûts de transition directs relatifs à l'acquisition de nouveau matériel informatique et à la formation du personnel sont estimés à environ 310 millions d'euros (de 220 à 400 millions d'euros). Les coûts de transition relatifs à l'emballage n'ont pas été estimés. Les coûts indirects liés à la reformulation des mélanges sont estimés entre 68 millions d'euros (±20 millions d'euros) et 140 millions d'euros (±42 millions d'euros), selon les éléments présupposés quant au nombre de substances dangereuses.

Les bénéfices du cadre législatif pour la santé humaine et pour l'environnement découlent de la disponibilité d'informations de classification et du rôle que cela joue dans la communication des dangers (en encourageant l'utilisation de substances moins dangereuses) ainsi que de la réduction du nombre d'accidents/d'incidents et d'expositions à des substances dangereuses.

Comme l'ont montré d'autres études, les contraintes liées aux méthodes et aux données ne permettent pas de prendre en compte l'ensemble des paramètres de la santé humaine et de l'environnement. Il existe toutefois des preuves statistiques indiquant un changement significatif du niveau d'information disponible sur les classifications relatives à l'environnement et à la santé humaine, ce qui aura contribué à une meilleure gestion des risques. L'analyse (nécessairement partielle) des bénéfices pour la santé humaine réalisée dans le cadre de cette étude indique que la valeur annuelle des réductions des cas d'empoisonnement, des maladies professionnelles de la peau et des voies respiratoires et des cancers professionnels : depuis 2000, ces valeurs oscillent entre 391 et 512 millions d'euros par an ; depuis 2008, entre 217 et 338 millions d'euros par an. Toutefois, ces chiffres ne comprennent aucune quantification des bénéfices environnementaux, ni des bénéfices pour les consommateurs ou pour la société de manière plus globale, résultant d'un nombre réduit d'expositions aux produits chimiques.

En ce qui concerne les liens entre le règlement CLP et la législation en aval, l'étude a permis d'identifier diverses mesures de gestion des risques fondées sur des considérations générales des risques, comme par exemple le règlement relatif aux produits biocides, le règlement relatif aux produits phytopharmaceutiques, la directive relative à la sécurité des jouets et le règlement relatif aux matières plastiques destinées à entrer en contact avec les denrées alimentaires. Tous ces textes législatifs incluent la gestion automatique des risques liée aux classifications CMR, les deux premiers comportant également des mesures automatiques liées aux propriétés PBT et vPvB et aux perturbateurs endocriniens. Ces liens automatiques ont été d'une part mis en place à titre préventif afin de garantir la protection des personnes et de l'environnement contre les expositions aux substances les plus dangereuses, et d'autre part en raison du risque d'exposition non contrôlable ou généralisée. Dans le cas de la directive relative à la sécurité des jouets, ils contribuent également à assurer la protection d'un groupe vulnérable de la population – les enfants. En complément d'un niveau de protection élevé, cette approche est également considérée comme fournissant à l'industrie une indication claire et cohérente des substances/mélanges qu'il convient ou non d'utiliser dans les produits finaux.

Les preuves évidentes concernant les bénéfices ou les charges non-nécessaires imposées aux parties prenantes par de telles considérations générales des risques sont mitigées. Elles indiquent l'existence de cas où l'impact associé à une exposition continue à une substance peut être important et l'emporter nettement sur les effets sur l'industrie de l'interdiction de l'utilisation de cette substance. C'est par exemple le cas de l'interdiction du plomb en vertu de la directive relative à la sécurité des jouets. D'autres exemples tirés d'études de cas soulignent la possibilité que des coûts importants soient générés par les éléments déclencheurs automatiques qui existent dans le cadre de l'approche fondée sur les considérations générales des risques (par exemple, en ce qui concerne les produits phytopharmaceutiques) et par la possibilité de substitutions fâcheuses ou de conséquences imprévues (par exemple, l'impact sur les activités de recyclage).

La nécessité d'une gestion du risque basée sur ces considérations générales des risques n'est pas clairement établie dans les cas où la législation sectorielle prescrit également des évaluations approfondies et détaillées des risques, comme celles qui ont été développées pour soutenir l'approbation des principes actifs dans le cadre de la législation relative aux produits biocides et aux produits phytopharmaceutiques, censées porter sur les risques dans les différents populations et compartiments environnementaux. Ces évaluations spécifiques des risques devraient intrinsèquement fournir une indication du niveau de risque associé à l'utilisation continue d'une substance dans tous les scénarios d'exposition. En outre, elles doivent refléter les propriétés qui conduisent au déclenchement de considération générale des risques (c'est-à-dire la puissance d'un cancérogène, le niveau de persistance ou de toxicité d'un PBT, les dangers liés à une seule voie d'exposition, etc.). Par conséquent, les données nécessaires pour veiller à ce que les décisions

soient fondées sur une évaluation spécifique des risques effectuée pour une substance donnée et les caractéristiques spécifiques de son utilisation dans un contexte particulier devraient être disponibles. Le fait de s'appuyer sur une évaluation spécifique des risques dans de tels cas assure que les décisions prises relatives à la gestion des risques sont entièrement basées sur l'acceptabilité des risques résiduels, et contribue à s'assurer que les décisions prises relatives à la classification et au choix des critères de seuil restent entièrement fondées sur la science, évitant ainsi la nécessité de prendre en compte les conséquences en aval lors de la classification ou d'introduire des dérogations.

En outre, on remarque l'émergence d'observations en faveur de la prise en compte la faisabilité technique ainsi que des considérations socio-économiques en ce qui concerne les produits phytopharmaceutiques. L'industrie notamment souligne l'importance de certains de ces produits chimiques pour la société, mettant l'accent sur la nécessité de veiller à ce que la législation soit équilibrée. Le règlement relatif aux produits biocides prévoit des moyens d'en atténuer l'impact. D'une part, on note l'existence de coûts supplémentaires induits par le règlement liés à l'extension du champ d'application aux articles traités. D'autre part, des moyens de réduire les coûts ont été identifiés (bien qu'aucun d'entre eux ne soit lié aux considérations générales des risques figurant dans la législation). Une question majeure demeure à propos de la mesure dans laquelle les perturbateurs endocriniens seraient liés à des effets sur la santé et à propos de l'ampleur des effets d'exposition aux produits biocides (ou phytopharmaceutiques), ce qui n'est actuellement pas connu. A ce stade, la disponibilité de dérogations fondées sur les risques, la faisabilité technique et les raisons économiques pourrait être importante pour assurer l'efficacité globale du cadre législatif à l'avenir.

Certains changements dans la classification peuvent par ailleurs avoir un impact significatif sur d'autres législations telle que Seveso III où des changements dans la classification des dangers, combinés aux considérations quant au tonnage, peut avoir pour conséquence le changement de statut d'un site suivant la directive, avec des conséquences économiques potentiellement importantes, y compris des coûts significatifs pour les PME, les opérateurs d'entrepôts, etc.

En ce qui concerne la législation relative à la santé et la sécurité au travail, notamment la directive sur les substances cancérogènes et mutagènes, une approche fondée sur les évaluations spécifiques des risques est appliquée et les compromis inhérents aux propositions de la Commission sont clairs. Plusieurs exemples d'études de cas démontrent la flexibilité de la législation (par exemple sur l'arséniate de gallium) et l'opportunité, du point de vue des coûts et de la faisabilité, de reconnaître les facteurs spécifiques à chaque cas lors de l'élaboration de la législation.

Pour ce qui est du cadre législatif de manière plus générale, les aspects qui contribuent le plus au fonctionnement efficace du cadre comprennent l'utilisation du règlement CLP comme base de classification pour pratiquement toutes les autres législations aura permis d'améliorer l'efficacité du cadre législatif tout comme la disponibilité de documents d'orientation et de systèmes informatiques pour aider les entreprises à respecter leurs obligations en matière de classification et d'étiquetage. Parmi les aspects qui entravent le bon fonctionnement de la législation figurent l'existence de processus d'évaluation parallèles, les contraintes en matière de ressources et d'expertise dans les États membres qui entravent leur capacité de présenter les dossiers pour la classification et l'étiquetage harmonisés des substances, le fait que la mise en œuvre du règlement CLP dans tous les États membres ne soit pas encore totalement harmonisée, ainsi que l'absence de possibilité de dérogations aux interdictions automatiques de l'utilisation d'une substance pour des raisons de faisabilité technique au minimum.

Pertinence

Les objectifs du cadre législatif sont toujours d'actualité étant donné que l'objectif de réduction de l'exposition aux produits chimiques dangereux reste important, en reconnaissant toutefois que les produits chimiques demeurent essentiels aux activités économiques au sein du marché unique et sont présents dans les produits de la vie quotidienne.

Il existe néanmoins toujours certains besoins. Il est par exemple nécessaire d'améliorer les moyens législatifs visant à réduire au minimum l'utilisation de substances dangereuses dans les produits de consommation. Cette nécessité résulte de l'absence de critères et d'informations pour l'identification des dangers et de l'évaluation d'exposition en vertu de la directive relative à la sécurité générale des produits, REACH étant actuellement le seul moyen de traiter les risques liés aux produits de consommation. En outre, les effets combinés des produits chimiques ainsi que les expositions de sources multiples ne sont pas suffisamment pris en compte, et il est de fait nécessaire d'adopter d'autres méthodes d'évaluation à cet égard. Plus généralement, les données utilisées pour identifier les propriétés et les critères appliqués sont jugés pertinents et adaptés, bien qu'il subsiste des problèmes relatifs à la classification des métaux et des alliages.

En général, l'étude a révélé que l'information sur l'étiquetage est pertinente et adaptée à l'objectif de permettre aux utilisateurs en aval et aux consommateurs de faire des choix éclairés en ce qui concerne les produits qu'ils achètent et utilisent (les listes obligatoires des ingrédients pour les cosmétiques et les produits de soins personnels constituent l'un des exemples positifs). Toutefois, quelques consommateurs ont indiqué que l'absence de listes détaillées d'ingrédients (par exemple en ce qui concerne les détergents, les produits biocides ou les jouets) restreint leur capacité de prendre des décisions éclairées et donc d'éviter les produits contenant certaines substances. De plus, il peut être nécessaire d'envisager des approches de communication plus innovantes pour réduire la surcharge d'informations et permettre aux consommateurs d'accéder à des informations supplémentaires sur les propriétés des produits et sur la sécurité de leur utilisation.

Cohérence

Les actes juridiques au sein du cadre législatif sur les produits chimiques ont tous pour objectif d'assurer un niveau élevé de protection de la santé humaine et de l'environnement, d'assurer le fonctionnement efficace du marché unique et de favoriser l'innovation et la concurrence. Chacun des textes législatifs couverts par cette étude prescrit des mesures en vue de répondre à ces objectifs et sont de fait cohérents. Une conclusion importante de l'étude est que des parties prenantes de tous les groupes (industrie, autorités des États membres, etc.) estiment que l'harmonisation des exigences en matière de données pour l'évaluation des risques garantirait une meilleure cohérence des travaux effectués et, par conséquent, des conclusions des différents organismes/comités (par exemple l'EFSA et le comité d'évaluation des risques de l'ECHA en ce qui concerne la classification harmonisée des substances actives des produits phytopharmaceutiques). Cette harmonisation pourrait enfin permettre d'améliorer la cohérence du cadre législatif européen en matière de produits chimiques.

Les critères de classification du règlement CLP comportent certaines lacunes, par exemple en ce qui concerne la toxicité terrestre et l'immunotoxicité. D'autres textes législatifs sur les produits chimiques exigent également l'identification de propriétés préoccupantes, y compris les substances allergènes, les perturbateurs endocriniens et les PBT et vPvB (persistantes, bioaccumulables et toxiques ou très persistantes et très bioaccumulables). La classification de toutes ces propriétés devra être fondée sur les informations élaborées en vertu du règlement CLP ainsi que sur des données supplémentaires et leur inclusion dans le règlement CLP aurait pour conséquence de ne plus être conforme au SGH. En examinant la législation, on remarque un bon niveau de cohérence en ce qui concerne l'identification des propriétés PBT, mais il existe en revanche un manque de cohérence dans les différents textes législatifs en ce qui concerne l'identification des allergènes. Il

est encore trop tôt pour déterminer si les exigences en matière de perturbateurs endocriniens seront harmonisées dans la législation pertinente.

Il est cependant également important de noter que l'on considère qu'il existe globalement un haut niveau de cohérence dans les exigences en matière de données et dans l'utilisation des données dans le cadre législatif. Un manque de cohérence est à noter dans le domaine de l'interdiction de l'expérimentation animale en vertu du règlement relatif aux produits cosmétiques. Le règlement relatif aux produits cosmétiques prescrit que toutes les nouvelles données relatives aux ingrédients qui ne sont utilisés que dans des produits cosmétiques soient recueillies selon d'autres méthodes. Les ingrédients utilisés dans les produits cosmétiques ainsi que dans d'autres applications peuvent toujours exiger des données provenant d'essais sur les animaux en vertu du règlement REACH, du règlement relatif aux produits phytopharmaceutiques, du règlement relatif aux produits biocides et en vertu d'autres textes législatifs.

Pour ce qui est des principaux textes législatifs fondés sur les considérations générales des risques, les dérogations sont basées principalement sur les preuves scientifiques (une évaluation spécifique des risques) attestant qu'une substance peut être utilisée sans risque. Seul le règlement relatif aux produits biocides dispose d'un champ d'application plus étendu en ce qui concerne les dérogations et peut inclure des arguments de faisabilité technique et d'intérêt social (ou socio-économique). Ces différences dans les arguments qui peuvent être avancés pour obtenir une dérogation indique qu'il existe une incohérence dans le cadre législatif (notamment quant aux différences entre les produits biocides et phytopharmaceutiques) qui peut également avoir un impact sur la mesure dans laquelle le cadre contribue à la croissance économique, à l'innovation, à la compétitivité et à d'autres objectifs relatifs au marché unique. Quelques exemples (comme l'éthanol) soulignent les implications socio-économiques potentiellement importantes des éléments déclencheurs automatiques liés au règlement CLP existant dans la législation en aval, en particulier lorsqu'il n'existe potentiellement aucune alternative appropriée présentant des caractéristiques similaires (par exemple en termes de performance). Par conséquent, bien que l'adoption d'une approche fondée sur les considérations générales des risques puisse être avantageuse en termes de simplicité dans la règlementation des substances les plus dangereuses en vertu de la législation sectorielle pertinente, elle peut à l'avenir avoir des conséquences sur la société européenne et l'économie si l'utilisation de substances de valeur dans des applications importantes est interdite. Il convient au minimum de prévoir des possibilités de dérogations fondées sur une approche d'évaluation spécifique des risques et qui ne tiennent pas seulement compte de critères scientifiques.

Valeur ajoutée européenne

Le cadre législatif en matière de produits chimiques est jugé comme porteur d'une valeur ajoutée au niveau européen. En général, des parties prenantes de tous les groupes estiment qu'une approche communautaire harmonisée est adaptée pour atteindre les objectifs du cadre législatif européen relatif aux produits chimiques. Ce cadre est considéré comme étant globalement conforme aux politiques européennes au sens large en termes d'atteinte des mêmes objectifs généraux (c'est-à-dire le marché unique, l'accroissement des échanges commerciaux, la protection de la santé et de l'environnement) et une intervention au niveau de l'UE est nécessaire pour atteindre ces objectifs d'une manière efficace et efficiente. Cela est particulièrement vrai pour ce qui est des mesures de gestion des risques, afin d'éviter la formation d'obstacles au commerce qui peut survenir en cas de différences nationales dans les approches de gestion des risques, de propriétés préoccupantes aux fins de la réglementation ou de divergences entre les critères pouvant déclencher la procédure de gestion des risques. Ainsi le cadre législatif est globalement considéré comme porteur d'une valeur ajoutée (et comme garantissant une approche plus cohérente et uniforme) par rapport à un système de réglementation établit au niveau national.

Zusammenfassung

Im Rahmen des Programms zur Gewährleistung der Effizienz und Leistungsfähigkeit der Rechtsetzung (REFIT) hat die Europäische Kommission (im Folgenden „Kommission“) einen Fitness Check des Chemikalienrechts (ausgenommen REACH), sowie zugehöriger Aspekte der Rechtsvorschriften, die die nachgeschaltete Industrie betreffen, lanciert.[5]

Diese Studie soll den Fitness Check, dessen Ziel eine Bewertung der CLP-Verordnung[6] und ihrer Schnittstellen zu anderen chemikalienbezogenen Regelungen (einschließlich anderer Regelungen zur Ermittlung der Gefahreneigenschaften und deren Kommunikation sowie CLP-bezogener Regelungen zum Risikomanagement) ist, unterstützen. Somit deckt diese Studie einen wesentlichen Teil des Fitness Checks ab. Gemäß der Leitlinien der Kommission für eine bessere Rechtsetzung (Better Regulation Guidelines) liegen der Bewertung die Kriterien Effektivität, Effizienz, Kohärenz, Relevanz, und EU-Mehrwert zugrunde. Dieser Bericht enthält die wesentlichen Schlussfolgerungen der Untersuchung (basiered auf den oben genannten Bewertungskriterien) und wird durch eine Reihe von ausführlicheren Anhängen ergänzt.

Die Studie besteht aus vier Arbeitspaketen: Arbeitspaket 1 bewertet die Umsetzung der CLP-Verordnung, Arbeitspaket 2 analysiert die horizontalen Verbindungen zwischen EU-Regelungen zur Ermittlung der Gefahreneigenschaften und deren Kommunikation, Arbeitspaket 3 befasst sich mit den vertikalen Verbindungen zwischen der CLP-Verordnung und den relevanten nachgeordneten EU- und nationalen Regelungen zur Ermittlung von Risikomanagementmaßnahmen basierend auf einer Gefahreneinstufung und Arbeitspaket 4 hat die Kommission bei der Durchführung einer öffentlichen Konsultation, eines KMU-Panels und eines Workshops unterstützt. Entsprechend dem Fahrplan des Fitness Checks (Fitness Check Roadmap) unterscheidet die Studie im Arbeitspaket 3 bei der Bewertung von Risikomanagementmaßnahmen zwischen Risikomanagement, das auf allgemeinen Risikobetrachtungen (d.h. Risikomanagementmaßnahmen werden automatisch durch eine CLP-Einstufung und ohne weitere Risikobewertung ausgelöst) und spezifischen Risikobewertungen (d.h. Risikomanagementmaßnahmen werden nach einer Bewertung der Gefahren und der spezifischen Exposition ermittelt) beruht.

Die Evaluierungsmethode wurde dem Bedarf der vier Arbeitspakete entsprechend entwickelt. Die Studie umfasste eine Literaturrecherche zur Erhebung wichtiger Informationen aus Folgenabschätzungen, Positionspapieren, akademischen und wissenschaftlichen Forschungsergebnissen etc.; eine rechtliche Analyse um einen Überblick über die relevanten Rechtsvorschriften und spezifischen Regelungen zu erhalten; Konsultationen, einschließlich der öffentlichen Konsultation, eines Stakeholder Workshops und eines KMU-Panels, Befragungen im Rahmen der Fallstudien und gezielte Konsultationen der wichtigsten Stakeholdergruppen sowie Fallstudien zur vertieften Untersuchung einiger zu Beginn der Studie ausgewählter besonders relevanter Themen.

[5] Mitteilung der Kommission an das Europäische Parlament, den Rat, den Europäischen Wirtschafts- und Sozialausschuss und den Ausschuss der Regionen „Effizienz und Leistungsfähigkeit der Rechtsetzung (REFIT): Ergebnisse und Ausblick“, COM(2013) 685 final, 2. Oktober 2013

[6] Verordnung (EG) Nr. 1272/2008 des Europäischen Parliaments und des Rates vom 16. Dezember 2008 über die Einstufung, Kennzeichnung und Verpackung von Stoffen und Gemischen, zur Änderung und Aufhebung der Richtlinien 67/548/EWG und 1999/45/EG und zur Änderung der Verordnung (EG) Nr. 1907/2006, 31. Dezember 2008

Die Ergebnisse dieser Studie in Bezug auf die fünf Bewertungskriterien werden im Folgenden zusammengefasst.

Effektivität

Insgesamt trägt die CLP-Verordnung zur Gewährleistung eines hohen Schutzniveaus für die menschliche Gesundheit und die Umwelt im Hinblick auf die Gefahreneinstufung, die Kennzeichnung und die Verpackung von Stoffen und Gemischen bei. Die Verordnung bildet die Grundlage zur Identifizierung besorgniserregender Stoffe. Diese Informationen werden zur Gefahrenkommunikation an Arbeitnehmer, nachgeschaltete Anwender und Verbraucher von Chemikalien (unter CLP anhand des Etiketts, unter REACH mit dem Sicherheitsdatenblatt) genutzt. Dies ist ein wichtiger Beitrag zur sicheren Verwendung von Chemikalien und dient als Grundlage für das Risikomanagement im Rahmen von nachgeordneten Rechtsvorschriften. Die Industrie, die Behörden der Mitgliedstaaten und die Zivilgesellschaft sind weitgehend der Auffassung, dass die CLP-Verordnung einfacher anzuwenden ist als die frühere Gefahrstoffrichtlinie und die Richtlinie über gefährliche Zubereitungen für die Selbsteinstufung von Stoffen und Gemischen. Dies trägt auch zu den Zielen der Förderung des Binnenmarktes und der Wettbewerbsfähigkeit bei.

Es gibt jedoch auch Bereiche, in denen es Möglichkeiten gibt, die Effektivität der Gesetzgebung in Bezug auf die Ziele des Binnenmarktes durch mehr Harmonisierung der Umsetzung zu erhöhen. Zum Beispiel ist unklar, wie einige der CLP-Übertragungsgrundsätze zur Einstufung von Gemischen anzuwenden sind. Zudem besteht die Sorge, dass die derzeitigen Regelungen für einige Endpunkte (z. B. Hautverätzung/-reizung und Augenschaden/-reizung) tendenziell zu einer zu strikten Einstufung von Gemischen führen. Weiterhin gibt es Schwächen in den Einstufungsregeln für Gemische, die Bioverfügbarkeit adäquat widerzuspiegeln, insbesondere bei der Einstufung von Metallen und deren Legierungen.

Die Evaluierung hat darüber hinaus auch einige Hemmnisse für die Umsetzung des europäischen Rechtsrahmens aufgezeigt, die auf nationaler Ebene bestehen: Unterschiede zwischen den Mitgliedstaaten bezüglich der Akzeptanz verschiedener Methoden für die Einstufung von Gemischen; eine unterschiedliche Bereitschaft der Mitgliedsstaaten, Dossiers zur harmonisierten Einstufung im Rahmen der Biozidprodukteverordnung und der Pflanzenschutzmittelverordnung zu unterstützen und Unterschiede in den Ansätzen und dem Ambitionsniveau des Vollzugs, die dem Ziel der Vollendung des Binnenmarktes und der Schaffung gleicher Wettbewerbsbedingungen für Firmen entgegenwirken.

Stakeholder aus allen Gruppen (Industrie, Zivilgesellschaft, Mitgliedstaaten, Wissenschaft) verstehen das Fehlen einer Bewertung von Kombinationseffekten und vielfältigen Expositionswegen als eine Lücke bei der Gewährleistung eines hohen Schutzniveaus für die menschliche Gesundheit und die Umwelt. Obwohl dies negativ bewertet wird, erkennen die Stakeholder auch an, dass derzeit keine technischen Möglichkeiten zur vollständigen Bewertung von Kombinationseffekten und Mehrfachexpositionen vorhanden sind. Weiterhin gab es bei einigen Verordnungen Verzögerungen bei der Festlegung von Kriterien für endokrin wirksame Chemikalien, die sich auf die Funktionsfähigkeit dieser Regelungen und ihre Erreichung eines hohen Schutzniveaus für die menschliche Gesundheit und die Umwelt auswirken.

Die Schlussfolgerungen der Bewertung sind im Allgemeinen positiv, was die Qualität und Zuverlässigkeit der im Einstufungsverfahren verwendeten Daten angeht. Die dem Rechtsrahmen zugrunde liegenden Datenanforderungen werden zur Gewährleistung des Schutzes der menschlichen Gesundheit und der Umwelt als ausreichend angesehen. Werden neue Tests durchgeführt, sind die Anforderungen der Guten Laborpraxis oder, bei bestimmten Tests, die jeweiligen Normen (z. B. ISO 17025) einzuhalten. Existierende Daten werden akzeptiert insofern sie

als zuverlässig angesehen werden. Diese Vorgehensweise trägt zur Effektivität, Effizienz und Kohärenz bei.

Verschiedene Faktoren wirken sich negativ auf die Effektivität von Maßnahmen zur Gefahrenkommunikation aus: Verbraucher verstehen einige CLP-Piktogramme nicht und die Menge an Pflichtinformationen auf den Etiketten von Gemischen verursacht eine Informationsüberflutung, die dazu führen kann, dass Verbraucher und Endanwender von Chemikalien die Warnungen auf bestimmten Produkten nicht beachten, was potenziell negative Konsequenzen für die Effektivität der Gesetzgebung in Bezug auf die Gewährleistung des Schutzes der menschlichen Gesundheit und der Umwelt haben könnte. Außerdem könnte die fehlende Differenzierung zwischen bestimmten Gefahrenmerkmalen (d.h. verschiedene Produkte werden trotz deutlich unterschiedlicher Gefahren mit dem gleichen Piktogramm gekennzeichnet) die Verbraucher verwirren. Ein Potenzial zur Verbesserung der Qualität der vermittelten Informationen und der Effektivität der Kommunikation könnte darin bestehen, innovative Ansätze (z. B. QR-Codes, Webseiten, usw.) komplementär zu den geltenden Kennzeichnungsanforderungen verstärkt einzusetzen.

Effizienz

Ein wichtiger Teil der Bewertung der Effizienz des Rechtsrahmens ist die Untersuchung der Kosten und des Nutzens der Umsetzung und Anwendung. Weitere Schlüsselfaktoren sind die Funktionsfähigkeit und die Geschwindigkeit von Prozessen und Verfahren, und der durch die Gesetzgebung verursachte Aufwand. Zu den Schlüsselzahlen für die Kosten der Implementierung und den Übergang zur CLP-Verordnung gehören:

- **Die laufenden Kosten der CLP Implementierung**: zu den laufenden (jährlichen) Kosten für die Industrie zählen die direkten Kosten der jährlichen Aktualisierungen der IT-Systeme zur Anpassungen an die CLP-Verordnung und neue harmonisierte Einstufungen (CLH), Kosten für die Personalschulung, laufende Maßnahmen zur Gesetzeskonformität, Kosten für zusätzlichen Klärungsbedarf und Kosten, die mit der Produktverpackung zusammenhängen. Alle Kosten (und Nutzen) wurden im Vergleich zu einem Ausgangsszenario basierend auf einer Situation ohne Verordnung berechnet. Die zentrale Schätzung der Gesamtkosten liegt bei ca. 1,3 Mrd. Euro (0,97-1,7 Mrd. Euro) ohne Berücksichtigung der Kosten für Meldungen an die Giftinformationszentren (ca. 1,7 Mrd. Euro). Im Vergleich hierzu wurde im Rahmen der kumulativen Kostenabschätzung ein Höchstwert von 1,47 Mrd. Euro berechnet.

- **CLP-Übergangskosten**: die geschätzten Gesamtkosten für Einstufung, Kennzeichnung, und SDB für Stoffe und Gemische belaufen sich auf ca. 1,2 Mrd. Euro (oberer Schätzwert für die Anzahl von Gemischen liegt zwischen 820 Mio. Euro bis 1,6 Mrd. Euro). Die direkten Übergangskosten für neue/aktualisierte IT-Systeme und Mitarbeiterschulungen wurden auf 310 Mio. Euro (220 – 440 Mio. Euro) geschätzt. Übergangskosten für die Verpackung wurden nicht geschätzt. Die indirekten Kosten der Reformulierung von Gemischen wurden, in Abhängigkeit von der geschätzten Anzahl gefährlicher Stoffe in den Gemischen, auf 68 Mio. Euro (±20 Mio. Euro) bis 140 Mio. Euro (±42 Mio. Euro) geschätzt.

Nutzen des Rechtsrahmens für die menschliche Gesundheit und die Umwelt ergeben sich aus der Verfügbarkeit von Einstufungsinformationen und deren Einsatz in der Gefahrenkommunikation, aus Anreizen zur Verwendung weniger gefährlicher Stoffe und aus der Reduzierung von Unfällen/Vorfällen sowie der Verringerung der Exposition gegenüber gefährlichen Stoffen. Ähnlich wie bei anderen Studien war aufgrund von methodischen und datentechnischen Beschränkungen eine vollständige Untersuchung aller Gesundheits- und Umweltparametern nicht möglich.

Statistischen Daten zufolge hat aber eine wesentliche Änderung der Verfügbarkeit von Informationen zu Umwelt- und Gesundheitseinstufungen stattgefunden und es ist davon auszugehen, dass diese für ein verbessertes Risikomanagement genutzt wurden. Die im Rahmen dieser Studie zusammengestellte Teilbewertung der Gesundheitsnutzen deutet auf einen Rückgang von Vergiftungsfällen sowie berufsbedingten Haut-, Atemwegs- und Krebserkrankungen hin, die einem Wert von 391 bis 512 Mio. Euro jährlich seit 2000 und 217 bis 338 Mio. Euro jährlich seit 2008 entsprechen. In diesen Zahlen sind allerdings weder die Umweltnutzen noch die allgemeineren Nutzen für Verbraucher und die Gesellschaft als Ganzes enthalten, die sich aus einer verringerten Exposition mit Chemikalien ergeben.

Bezüglich des Verhältnisses zwischen CLP-Verordnung und nachgeordneter Gesetzgebung wurden in der Evaluierung verschiedene Risikomanagementmaßnahmen identifiziert, die auf allgemeinen Risikobetrachtungen beruhen. Zu diesen gehören beispielsweise die Verordnung über Biozidprodukte und die Pflanzenschutzmittelverordnung, die Spielzeugrichtlinie und die Verordnung über Materialien aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen. Alle diese Rechtsvorschriften beinhalten Risikomanagementmaßnahmen, die automatisch durch eine Einstufung als CMR ausgelöst werden. Die ersten beiden Verordnungen haben auch Automatismen für Maßnahmen, die durch PBT-/vPvB oder endokrin wirksame Eigenschaften ausgelöst werden. Diese Automatismen sind eine Umsetzung des Vorsorgeprinzips, um Mensch und Umwelt vor den gefährlichsten Stoffe zu schützen, und berücksichtigen die Gefahr einer weit verbreiteten und unkontrollierbaren Exposition. Im Fall der Spielzeugrichtlinie tragen die Automatismen auch zum Schutz einer besonders gefährdeten Bevölkerungsgruppe – Kindern - bei. Zusätzlich zur Gewährleistung eines hohen Schutzniveaus schafft dieser Ansatz klare und konsistente Regeln für die Industrie, welche Stoffen und Gemischen in Endprodukten verwendet werden dürfen oder nicht.

Die Erkenntnisse in Bezug auf die Frage, ob allgemeine Risikobetrachtungen Nutzen bringen oder unnötige Kosten verursachen, sind gemischt. Daten zeigen, dass es Fälle geben kann, bei denen die Folgen einer kontinuierlichen Exposition gegenüber einem Stoff so gravierend sein können, dass sie die Kosten eines Verbotes für die Industrie deutlich übersteigen. Ein Beispiel hierfür ist das Verbot von Blei unter der Spielzeugrichtlinie. Andere in Fallstudien dokumentierte Beispiele heben hervor, dass automatische Auslöser von Risikomanagementmaßnahmen, die mit dem allgemeinen Ansatz verbunden sind, signifikante Kosten verursachen (z. B. im Fall von Pflanzenschutzmitteln), zu einer bedauerlichen Substitution (regrettable substitution) führen, oder unbeabsichtigte Folgen (z.B. Auswirkungen auf das Recycling) haben können.

Die Notwendigkeit eines auf allgemeinen Risikobetrachtungen basierendem Risikomanagements ist zudem dann unklar, wenn branchenspezifische Rechtsvorschriften eine umfangreiche und detaillierte Risikobewertung erfordern, wie zum Beispiel die Bewertungen zur Unterstützung der Wirkstoffgenehmigungsverfahren nach der Biozidverordnung und der Pflanzenschutzmittelverordnung, die eine umfangreiche Risikobewertung für verschiedene Umweltkompartimente und Bevölkerungsgruppen enthalten müssen. Diese spezifischen Risikobewertungen sollen für alle betrachteten Expositionsszenarien Hinweise auf mögliche Risiken einer weiteren Verwendung des Stoffes liefern. Darüber hinaus sollen sie auch die Stoffeigenschaften berücksichtigen, die allgemeine Risikobetrachtungen auslösen (d.h. karzinogene Potenz, Grad der Persistenz oder Toxizität von PBT-Stoffen, gefährliche Eigenschaften, die nur eine Expositionsroute betreffen usw.). Diese Informationen ermöglichen eine Entscheidungsfindung basierend auf spezifischen Risikobewertungen, für einen konkreten Stoff und seine spezifischen Anwendungsbereiche. In diesen Fällen erlaubt die spezifische Risikobewertung Risikomanagemententscheidungen auf der Basis der Akzeptierbarkeit des Restrisikos. Dieser stärker wissenschaftsbasierte Ansatz vermeidet auch, dass die Folgen einer Einstufung auf die

nachgeschaltete Gesetzgebung im Einstufungsprozess spezifisch berücksichtigt oder Ausnahmen formuliert werden müssen.

Es wird darüber hinaus im Zusammenhang mit Pflanzenschutzmitteln argumentiert, dass auch die technische Machbarkeit und sozioökonomische Erwägungen berücksichtigt werden sollten. Die Industrie hebt hierbei die hohe Bedeutung einiger dieser Chemikalien für die Gesellschaft sowie die Notwendigkeit einer ausgewogenen Gesetzgebung hervor. Die Biozidverordnung sieht Möglichkeiten zur Folgenminderung vor. Einerseits entstehen durch die Verordnung zusätzliche Kosten infolge der Ausdehnung des Geltungsbereichs auf behandelte Waren. Andererseits wurden in verschiedenen Bereichen Kosteneinsparmöglichkeiten identifiziert (allerdings stehen diese nicht im Zusammenhang mit den allgemeinen Risikobetrachtungen in der Verordnung). Eine zentrale Frage, zu der derzeit noch wenig bekannt ist, betrifft das Ausmaß der Auswirkungen endokrin wirksamer Stoffe auf die menschliche Gesundheit und die Größenordnung negativer Auswirkungen durch die Expositionen gegenüber Bioziden (oder Pflanzenschutzmitteln). In der Zwischenzeit tragen Ausnahmen basierend auf spezifischen Bewertungen der möglichen Risiken, der technischen Machbarkeit und/oder wirtschaftlicher Gründe entscheidend zur Effizienz des Rechtsrahmens bei.

Veränderungen der Einstufung von Stoffen und Gemischen können signifikante Auswirkungen im Rahmen weiterer Gesetze haben, z. B. unter der Seveso III Richtlinie: eine veränderte Einstufung in Kombination mit Tonnagefaktoren kann den Status einer Anlage beeinflussen, was signifikante ökonomische Folgen haben kann, einschließlich hoher Kosten für KMUs, die Gemische formulieren, oder Betreiber von Lagerhäusern.

In der Arbeitsschutzgesetzgebung, wie z. B. in der Richtlinie über krebserregende und mutagene Stoffe, wurde ein spezifischer Risikobewertungsansatz gewählt. Die damit zusammenhängenden im Kommissionsvorschlag enthaltenen Kompromisse sind offenkundig. Beispiele aus Fallstudien zeigen die Flexibilität dieser Rechtsvorschriften (z. B. Galliumarsenid) und den, mit Kosten und Machbarbarkeiten begründeten, Bedarf, fallspezifische Faktoren in der Entwicklung von Gesetzgebungen zu berücksichtigen.

Insgesamt und in Hinblick auf den gesamten Rechtsrahmen tragen die folgenden Aspekte am meisten zu seinem effektiven Funktionieren bei: die Bezugnahme fast aller anderen Gesetze auf die CLP-Verordnung als Basis für die Einstufung hat die Effektivität des Rechtsrahmens erhöht, ebenso wie das Vorhandensein von Leitlinien und IT-Systemen, die die Unternehmen dabei unterstützen, die Anforderungen zur Einstufung und Kennzeichnung zu erfüllen. Ineffizienz im Funktionieren der Gesetzgebung entsteht unter anderem durch parallel laufende Gefahrenbewertungsprozesse, limitierte Ressourcen und Expertise in den Mitgliedsstaaten, die die niedrige Zahl an Dossiers zur harmonisierten Einstufung und Kennzeichnung von Stoffen (mit)begründen, die Tatsache, dass die Umsetzung der CLP-Verordnung in den Mitgliedsstaaten noch nicht vollständig harmonisiert ist sowie das Fehlen von Ausnahmen von automatischen Stoffverboten, insbesondere im Zusammenhang mit der technischen Machbarkeit.

Relevanz

Die Ziele des Rechtsrahmens sind nach wie vor relevant. Einerseits bleibt die Verringerung der Exposition gegenüber gefährlichen Stoffen ein wichtiges Ziel, und andererseits bleibt die Verwendung von Chemikalien für die wirtschaftlichen Aktivitäten im Binnenmarkt und auch für Alltagsprodukte essentiell.

Allerdings gibt es auch Bedarf an weiteren Regelungen. Zum Beispiel werden bessere gesetzgeberische Instrumente gebraucht, um sicher zu stellen, dass die Verwendung gefährlicher

Stoffe in Verbraucherprodukten minimiert wird, da es keine Kriterien oder Informationen zur Ermittlung von Gefahreneigenschaften und Expositionsbewertungen in der Richtlinie zur allgemeinen Produktsicherheit gibt und REACH derzeit die einzige Möglichkeit ist, Risiken in Verbraucherprodukten spezifisch und verbindlich zu beschränken. Außerdem werden Kombinationseffekte von Chemikalien und Expositionen aus unterschiedlichen Quellen nicht ausreichend berücksichtigt und es gibt einen Bedarf, entsprechende Bewertungsmethoden zu entwickeln.[3] Im Allgemeinen werden jedoch die zur Gefahrenermittlung genutzten Daten und die hierfür verwendeten Kriterien als relevant und angemessen angesehen, obwohl hier einige Aspekte bei der Einstufung von Metallen und Legierungen sowie anderer Gemische in einer besonderen Matrix zu klären sind.

Insgesamt hat die Studie gezeigt, dass die Informationen zur Kennzeichnung relevant und ausreichend sind, um nachgeschalteten Anwendern und Verbrauchern eine informierte Entscheidung über ihre Produkteinkäufe und –verwendungen zu ermöglichen (positive Beispiele sind die obligatorische Inhaltsstoffliste für Kosmetika und Körperpflegeprodukte). Allerdings wiesen einige Verbraucher darauf hin, dass das Fehlen detaillierter Inhaltsstofflisten (z. B. für Reinigungsmittel, Biozidprodukte, Spielzeuge) ihre Möglichkeiten, eine informierte Entscheidung zu treffen und somit Produkte zu vermeiden, die bestimmte Stoffe enthalten, einschränkt. Zusätzlich könnte es einen Bedarf geben, innovative Kommunikationsansätze anzuwenden, um eine Informationsüberflutung zu vermeiden und Verbrauchern Zugang zu zusätzlichen Informationen über Produkteigenschaften und ihre sichere Verwendung zu geben.

Kohärenz

Alle Regelungen im Rechtsrahmen über Chemikalien haben die Zielsetzung, ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt und ein effizientes Funktionieren des Binnenmarktes zu gewährleisten sowie die Innovations- und Wettbewerbsfähigkeit der EU-Industrie zu erhöhen. Da jede der in dieser Studie berücksichtigten Regelungen darauf abzielt, zu diesen Zielen beizutragen, können sie als kohärent angesehen werden. Eine wichtige Erkenntnis der Studie ist jedoch auch, dass Stakeholder aller Gruppen (Industrie, Behörden der Mitgliedsstaaten etc.) glauben, dass eine Harmonisierung der Datenanforderungen für die Risikobewertung eine bessere Kohärenz der Arbeit verschiedener Agenturen und Ausschüsse und damit ihrer Schlussfolgerungen zur Folge hätte (z. B. EFSA und das RAC in Bezug auf die harmonisierte Einstufung von Wirkstoffen in Pflanzenschutzmitteln). Dies wäre wiederum vorteilhaft, um die Kohärenz des gesamten EU Rechtsrahmens für Chemikalien zu erhöhen.

Es wurden Lücken in den Einstufungskriterien der CLP-Verordnung beschrieben, zum Beispiel bezüglich der terrestrischen Toxizität und der Immunotoxizität. Im Rahmen anderer Chemikaliengesetze werden ebenfalls Stoffe mit besorgniserregenden Eigenschaften identifiziert, einschließlich solcher, die allergen, endokrin wirksam oder PBTs und vPvBs sind (persistente, bioakkumulierbare und toxische oder sehr persistente und sehr biokkumulierbare Stoffe). Für die Einstufung dieser Eigenschaften werden Informationen genutzt, die im Rahmen der CLP-Verordnung erzeugt wurden, sowie weitere Daten. Die Aufnahme dieser Eigenschaften in die CLP-Verordnung würde bedeuten, dass keine Konformität mit dem GHS mehr bestünde. Über alle Gesetze hinweg ist die Kohärenz bei der Identifizierung von PBT-Eigenschaften gut. Bei der Identifizierung von Allergenen unter unterschiedlicher Gesetzgebung fehlt es allerdings an Kohärenz. Es ist noch zu früh, um zu entscheiden, ob die Anforderungen an endokrin wirksame Stoffe in den maßgeblichen Rechtsvorschriften harmonisiert werden müssen.

Es ist wichtig anzuerkennen, dass im Allgemeinen die Kohärenz der Datenanforderungen und die Nutzung von Daten innerhalb des Rechtsrahmens als hoch angesehen wird. Das Verbot von Tierversuchen unter der Kosmetikverordnung repräsentiert allerdings einen Bereich, wo es an

Kohärenz mangelt. Die Kosmetikverordnung erfordert, dass alle neuen Daten für Inhaltsstoffe, die nur in kosmetischen Mitteln eingesetzt werden unter Verwendung alternativer Methoden erzeugt werden. Allerdings kann es sein, dass für Inhaltsstoffe, die in Kosmetika und auch in anderen Verwendungen genutzt werden, Daten mittels Tierversuchen erzeugt werden müssen, z. B. unter REACH, der Pflanzenschutzmittelverordnung, der Biozidverordnung oder anderen Gesetzen.

In den meisten Gesetzen, bei denen das Risikomanagement auf allgemeinen Betrachtungen basiert, stützen sich die Möglichkeiten einer Ausnahme stark auf den wissenschaftlichen Nachweis der sicheren Verwendung (eine spezifische Risikobewertung). Nur die Biozidverordnung beinhaltet weiter gefasste Möglichkeiten für Ausnahmen, die sowohl auf der technischen Machbarkeit und gesellschaftlichen (oder sozio-ökonomischen) Argumenten beruhen können. Diese Unterschiede in der Argumentation, die eine Ausnahme begründen können, zeigen eine weitere Inkohärenz des Rechtsrahmens (und insbesondere Unterschiede in der Biozid- und der Pflanzenschutzmittelverordnung), die auch Auswirkungen darauf haben können, wie sehr der Rechtsrahmen zum wirtschaftlichen Wachstum, Innovation, Wettbewerbsfähigkeit und anderen Zielen des Binnenmarktes beiträgt. Beispiele (z. B. Ethanol) zeigen die potenziell signifikanten sozio-ökonomischen Auswirkungen der automatischen Auslöser für Risikomanagementmaßnahmen in nachgeordneter Gesetzgebung, besonders wenn passende Alternativen mit ähnlichen Eigenschaften (z. B. bzgl. der technischen Leistungsfähigkeit) fehlen. Daher wird es in der Zukunft potenzielle Auswirkungen für die EU-Gesellschaft und Wirtschaft haben, wenn wertvolle Stoffe in zentralen Anwendungen beschränkt werden, wenngleich der Ansatz der allgemeinen Risikobetrachtung Vorteile durch seine Einfachheit in der Regulierung besonders gefährlicher Stoffe in bestimmten Branchen hat. Dann sollte es aber zumindest die Möglichkeit geben, Ausnahmen aufgrund einer spezifischen Risikobewertung und über die wissenschaftlichen Kriterien hinausgehenden Betrachtungen zu schaffen.

EU - Mehrwert

Der EU Rechtsrahmen für Chemikalien bringt einen Mehrwert auf EU-Ebene. Grundsätzlich sind Akteure aller Gruppen der Meinung, dass es angemessen ist, einen EU-weit harmonisierten Ansatz zu haben, um die Ziele der europäischen Chemikaliengesetzgebung zu erreichen. Der Rechtsrahmen wird bezüglich der allgemeinen Ziele als mit anderen EU-Politiken konsistent angesehen (d.h. Binnenmarkt, Förderung des Handels und Schutz von Gesundheit und Umwelt). Eine Intervention auf EU-Ebene ist notwendig, um diese Ziele in effektiver und effizienter Weise zu erreichen. Dies ist insbesondere für die Umsetzung von Risikomanagementmaßnahmen der Fall, da hier Handelshemmnisse aufgrund nationaler Unterschiede in Risikomanagementansätzen zu regulierenden Gefährlichkeitsmerkmalen sowie Maßnahmen auslösender Kriterien vermieden werden müssen. Daher kann der Schluss gezogen werden, dass der EU Rechtsrahmen im Vergleich zu einem regulatorischen System, das auf nationaler Ebene umgesetzt wird, einen deutlichen Mehrwert erzielt (und einen konsistenteren und kohärenteren Ansatz ermöglicht).

Glossary

ADI	Acceptable Daily Intake
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement on the international transport of Dangerous Goods by Road
AEL	Adverse Effect Level
AISE	International Association for Soaps, Detergents and Maintenance Products
ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation AISBL
AOEL	Acceptable Operator Exposure Level
AOP	Adverse Outcome Pathway
ARfD	Acute Reference Dose
ASO	Accredited Stakeholder Organisations
ASPE	Animal Skincare Products Europe
ATD	Access to Documents
ATE	Acute Toxic Estimates
ATP	Adaptation to Technical Progress
BAF	Bioaccumulation Factor
BAT	Best Available Technique
BAuA	Federal Institute for Occupational Safety and Health (Germany)
BCF	Bioconcentration Factor
BCOP	Bovine Corneal Opacity & Permeability Assay
BEUC	The European Consumer Association
BIS	UK's Department for Business, Innovation and Skills
BLM	Biotic Ligand Model
BMF	Biomagnification Factor
BOELVs	Binding Occupational Exposure Limit Values
BP	Biocidal Product
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
BREF	Best Available Techniques Reference Documents
BRIC	Brazil, Russia, India, China
C&L	Classification and Labelling
CA	Competent Authority
CAD	Chemical Agents Directive
CAR	Competent Authority Report
CARACAL	Competent Authorities for REACH and CLP
Carc.	Carcinogenic
Cat	Category
CBA	Cost-benefit analysis
CCA	Cumulative cost assessment study
CEEMET	European Employers Association representing Metals, Engineering and Technology based industry
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
Cefic	European Chemical Industry Council
CEPA	European Council of Paint, Printing Inks, Artist's Colours Industry
CIFs	Child impeding fastenings

CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CLEAPSS	Consortium of Local Education Authorities for the Provision of Science Services
CLH	Harmonised Classification and Labelling
CLI	Classification and Labelling inventory
CLP	Classification, Labelling and Packaging
CMD	Carcinogen and Mutagen Directive
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
COM	Commission
Concawe	Conservation of Clean Air and Water in Europe
CoRAP	Community Rolling Action Plan
Corr.	Corrosive
COSME	Competitiveness of Small and Medium-sized Enterprises
CP	Cosmetic Products Regulation
CRC	Child Resistant Closures
CRED	Criteria for Reporting and Evaluating Ecotoxicity Data
CRF	Child Resistant Fastenings
CSR	Chemical Safety Report
D4/D5	Siloxane compounds
Dam.	Damage
DAR	Draft Assessment Report
DB-ALM	DataBase Service on ALternative Methods
DecaBDE	Decabromodiphenyl Ether
DGUV	German Social Accident Insurance
DMF	Dimethylfumarate
DNEL	Derived No Effect Level
DOI	Declaration of interest
DOT	Department of Transportation
DPD	Dangerous Preparations Directive
DR	Detergents Regulation
DSD	Dangerous Substances Directive
$E(L)C_{50}$	Effect (Lethal) Concentration showing effects on 50% of the test individuals
EC	European Commission
eCA	evaluating Member State Competent Authority
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECOS	European Environmental Citizens' Organisations for Standardisation
ECPA	European Crop Protection Association
EDCs	Endocrine disrupting chemicals
EEA	European Environment Agency
EEB	European Environmental Bureau
EEE	Electrical and Electronic Equipment
EEN	Enterprise Europe Network
EFSA	European Food Safety Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELV	End of life vehicles
EMA	European Medicines Agency
EoW	End of Waste
EQS	Environmental Quality Standards

eSDS	Extended Safety Data Sheet
ESR	Existing Substances Regulation
ETUI	European Trade Union Institute
EU RAR	European Union Risk Assessment Report
EU	European Union
EUH	European Union Hazard
EURL-ECVAM	European Union Reference Laboratory for Alternatives to Animal Testing
Eurometaux	Association Européenne des Métaux
EU-TGD	EU Technical Guidance Document for Risk Assessment
FCM	Food Contact Materials
FECC	European Association of Chemical Distributors
FET	Fish Embryo Acute Toxicity Test
Flam.	Flammable
GaAs	Gallium arsenide
GCL	Generic Concentration Limit
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GLP	Good Laboratory Practice
GPSD	General Product Safety Directive
HBCDD	Hexabromocyclododecane
HCB	Hexachlorobenzene
HCH	Hexachlorocylohexane
H-criteria	Hazard Criteria
HEAL	Health and Environment Alliance
HELCOM	Helsinki Commission
HLG	High Level Group on the Competitiveness of the European Chemicals Industry
HMP	Human Medicinal Products
HP	Hazardous Properties
HPVCs	High Production Volume Chemicals
HSE	Health & Safety Executive
H-statements	Hazard statements
IA	Impact Assessment
IARC	International Agency for Research on Cancer
IATA	Integrated Approach to Testing and Assessment
ICE	Isolated Chicken Eye test
ICRT	International Consumer Research & Testing
IED	Industrial Emissions Directive
IFRA	International Fragrance Association
ILA	International Lead Association
INCI	International Nomenclature Cosmetic Ingredient
IOELVs	Indicative Occupational Exposure Limit Values
IPBC	Iodopropynyl Butyl Carbamate
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
LC50	Lethal Concentration, concentration at which 50% of the test organisms die
LD50	Lethal Dose; dose at which 50% of the test organisms die
LEV	Local Exhaust Ventilation
Liq.	Liquid
LoW	List of Waste

LQ	Limited quantities
MAPP	Major Accident Prevention Policy
MARS	Major Accident Reporting System
MBM	N,N-Methylenebismorpholine
Me	Metal ion
MIT	Methylisothiazolinone
MoS	Margin of Safety
MPa	Mega Pascal
MRL	Maximum Residue Level
MS CA	Member State Competent Authority
MS	Member State(s)
MSC	Member State Committee
Mut.	Mutagenic
NAMs	New Assessment Methods
NGO	Non-Governmental Organisation
NHL	non-Hodgkin's lymphoma
Ni	Nickel
NIAS	Non-intentionally added substances
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NTB	Non-Tariff Barrier
NTM	Non-Tariff Measures to Trade
NVWA	Netherlands Food and Consumer Product Safety Authority
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OJEU	Official Journal of the European Union
OME	Ordnance munitions and explosives
OPC	Open Public Consultation
OSH	Occupational Safety and Health
OSPAR	Oslo Paris Convention
Ox.	Oxidative
P and H	Precautionary and Hazard
PAH	Polyaromatic hydrocarbons
PAN	Pesticide Action Network
PAR	Product Assessment Report
PBDEs	Polybrominated diphenyl ethers
PBDs	Polybrominated diphenyls
PBT	Persistent, Bioaccumulative and Toxic
PBTs	Persistent, Bioaccumulative and Toxic substances
PCB	Polychlorinated biphenyl
PCCs	Poison control centres
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PHMB	Poly(hexamethylene) biguanide hydrochloride
PHS	Priority Hazardous Substance
PIC	Prior Informed Consent Regulation
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
PPAMS	Plant Protection Products Application Management System
PPE	Personal Protective Equipment
PPPR	Plant Protection Products Regulation

PPPs	Plant Protection Products
P-statements	Precautionary statements
PT	Product Type
QQs	Qualifying Quantities
QR code	Quick Response code
QSAR	Qualitative Structure Activity Relationship
R&D	Research & Development
RAAF	Read Across Assessment Framework
RAC	Risk Assessment Committee
RAPIX	European Commission Rapid Information System
REACH	Registration, Evaluation, Authorisation & Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme
Rep. Exp.	Repeated Exposure
Repro.	Reproductive
RID	Regulation on the carriage of dangerous goods by rail
RIVM	National Institute for Public Health and the Environment (Netherlands)
RMM	Risk management measure
RMOA	Risk Management Options Analysis
RMS	Rapporteur Member State
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
ROI	Registry of intentions
RPA	Risk & Policy Analysts
SACKI	Solvent Abuse Can Kill Instantly
SCCPs	Short chain chlorinated paraffins
SCCS	Scientific Committee for Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SCL	Specific Concentration Limit
SCOEL	Scientific Committee on Occupational Exposure Limits
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SECR	ECHA secretariat
SED	Systemic Exposure Dosage
SIEF	Substance Information Exchange Forum
SKUs	Stock Keeping Units
SMEs	Small and Medium Sized Enterprises
SPC	Summary of Product Characteristics
STOT RE	Specific Target Organ Toxicity – Repeated Exposure
STOT SE	Specific Target Organ Toxicity – Single Exposure
STOT	Specific Target Organ Toxicity
SVHC	Substance of Very High Concern
T/D	Transformation Dissolution protocol
t/y	Tonnes per year
TCEP	Tris(2-chloroethyl)phosphate
TCPP	Tris(2-chloro-1-methylethyl)phosphate
TDCP	Tris[2-chloro-1(chloromethyl)ethyl]phosphate
TDG	Transport of Dangerous Goods
TIE	Toy Industries of Europe
ToR	Terms of Reference
Tox.	Toxicity

TSD	Toy Safety Directive
TTIP	Transatlantic Trade and Investment Partnership
TWD	Tactile Warnings of Danger
UBA	German Environment Agency
UEAPME	European Association of Craft, Small and Medium-sized Enterprises
UK	United Kingdom
UN GHS	United Nations Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
UN	United Nations
UNCTAD	United Nations Conference on Trade & Development
US EPA	Environmental Protection Agency of the United States
US OSHA	United States Occupational Safety & Health Administration
US	United States
VCI	Verband der Chemischen Industrie e.V.
VMP	Veterinary Medicinal Products
VOCs	Volatile Organic Compounds
vPvBs	Very Persistent and Very Bioaccumulative substances
VSA	Volatile Substance Abuse
WEEE	Waste Electrical and Electronic Equipment
WEN	Women's Environment Network
WFD	Water Framework Directive/ Waste Framework Directive
WG	Working Group
WHO	World Health Organisation
WHO/IPCS	World Health Organisation / International Programme on Chemical Safety
WoE	Weight of Evidence
WTO	World Trade Organisation
ZnO	Zinc oxide
zRMS	zonal Rapporteur Member State

1 Introduction

1.1 Study scope and objectives

As part of its Regulatory Fitness and Performance Programme (REFIT), the European Commission (hereafter "the Commission") has launched a fitness check on chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries.[7]

This study is one of the key studies in support of the fitness check. Its objective is to evaluate the CLP Regulation[8] and the interface with other related chemicals legislation, including other legislation governing hazard identification and communication and legislation establishing risk management measures linked to CLP. It thereby covers a substantial part of the scope of the fitness check roadmap, but not all aspects. The list of legislation that acts as the focus of the fitness check is provided in Table 1-1 overleaf. **Whilst the fitness check covers any aspects of this legislation related directly to chemicals, it does not aim to evaluate, in its entirety, each individual piece of legislation**.

The evaluation carried out by the study is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value in accordance with the Commission's Better Regulation guidelines (further details regarding these criteria are provided in Annex I). The work has included:

- An analysis of the different pieces and provisions of legislation, which make up the framework of chemicals regulation;
- The identification of areas where the cost of implementation is high compared to the benefits for health and the environment, as well as positive examples where the implementation is particularly efficient;
- The identification of gaps in health and environmental protection as well as gaps, overlaps, inconsistencies and other issues affecting the performance of the legislation;
- The identification of areas where potential for improvement, modernisation and simplification have not yet been harnessed; and
- The identification of existing mechanisms and procedures that work well and that could be considered as best practice.

However, it has been important that the assessment undertaken by this study did not get lost in detail, as the aim of the exercise is to evaluate the legislative framework and to identify both areas for improvement and best practices. Such potential areas for improvement are highlighted for further consideration by the Commission.

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Regulatory Fitness and Performance (REFIT): Results and Next Steps', COM(2013) 685 final, 2 October 2013

[8] 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, amending Regulation (EC) No 1907/2006; OJ L353/1, 31 December 2008

Table 1-1: Chemicals legislation and related legislation under the scope of the fitness check
Legislation covering hazard identification and classification
Classification, labelling and packaging (Regulation No (EC) 1272/2008)
Plant protection products (Regulation (EC) No 1107/2009)
Biocidal products (Regulation (EU) No 528/2012)
REACH, Annex XIII (Regulation (EC) No 1907/2006)
Inland transport of dangerous goods (Directive 2008/68/EC)
Chemical Agents (Directive 98/24/EC), Asbestos (Directive 2009/148/EC), Carcinogens and mutagens at work (2004/37/EC)
Legislation covering risk management measures[1]
Worker safety and transport legislation
Inland transport of dangerous goods (Directive 2008/68/EC)
Carcinogens and mutagens at work (Directive 2004/37/EC)
Young people at work (Directive 1994/33/EC)
Pregnant workers (Directive 1992/85/EEC)
Signs at work (Directive 92/58/EEC)
Chemical Agents (Directive 98/24/EC)
Asbestos (Directive 2009/148/EC)
Environmental protection legislation
Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
Waste framework (Directive 2008/98/EC) and List of Waste
Waste shipments (Regulation (EC) No 1013/2006)
Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
Water Framework (Directive 2000/60/EC)
Urban Waste Water (Directive 91/271/EEC)
Marine Strategy Framework (Directive 2008/56/EC)
Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
End of life vehicles (Directive 2000/53/EC)
Batteries (Directive 2006/66/EC)
Packaging and Packaging Waste (Directive 94/62/EC)
Chemicals control legislation
Biocidal products (Regulation (EU) No 528/2012)
Plant protection products (Regulation (EC) No 1107/2009)
Export and import of hazardous chemicals (Regulation No 649/2012)
Persistent organic pollutants (Regulation (EC) 850/2004)
Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
Residues of pesticides (Regulation (EC) No 396/2005)
Product controls
EU Ecolabel (Regulation (EC) 66/2010)
Safety of toys (Directive 2009/48/EC)
Cosmetic products (Regulation (EC) No 1223/2009)
Detergents (Regulation (EC) No 648/2004)
Drinking Water (Directive 98/83/EC)
Fertilisers (Regulation (EC) No 2003/2003)[2]
Medical devices (Directive 93/42/EEC, Directive 90/385/EEC and Directive 98/79/EC)
Aerosol dispensers (Directive 75/324/EEC)
Explosives for civil uses (Directive 2014/28/EU)
Pyrotechnic articles (Directive 2013/29/EU)
Pressure equipment (Directive 2014/68/EU)
Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009
General Product Safety (Directive 2001/95/EC)
Manufacture, presentation and sale of tobacco (Directive 2014/40/EU)
Supporting legislation
Test methods (Regulation (EC) No 440/2008)
Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
Protection of animals used for scientific purposes (Directive 2010/63/EU)

Notes:

[1] Risk management measures are defined in a broad manner as any step towards reducing the risk of a chemical to health or environment to an acceptable level, e.g. not only bans or restrictions of use, but also communication measures, emission limits or residue limits.

[2] Some relevant legislation has recently been recast or is currently undergoing a revision (e.g. fertilisers, medical devices). The ex post analysis of such recent or future legislation (replacing existing instruments) will therefore be limited to relevant aspects only (notably mapping and analysing the links). The analysis will take due account of the impact assessments and political decisions underlying these revised pieces of legislation.

To establish the scope of the relevant legislation, a mapping exercise was carried out which identified: the legislation that has linkages in terms of hazard identification, classification and communication (horizontal linkages); and that links risk management measures and risk assessment procedures to classification under CLP (vertical linkages). This legislation is referred to in this report as "related chemicals legislation". In the context of the fitness check more generally, which is broader than this study, 'related chemicals legislation' can be taken as referring to all chemicals legislation, as outlined in the roadmap, including that not linked to CLP.

1.2 Overview of CLP requirements and linked legislation

1.2.1 Introduction

Prior to CLP, the classification and labelling (C&L) of chemicals and mixtures/preparations 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 physicochemical hazards (explosive, oxidising and flammable properties), 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. The EU system of classification and labelling was generally considered to be one of the most effective and robust systems globally. 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 in the different legal jurisdictions were similar, the differences were significant enough to result in multiple classification and labelling requirements for the varying health and safety information that had to be provided for the same product in different countries and/or markets.

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, it was recognised internationally that there was a need for a globally harmonised approach. The GHS was therefore formally adopted by the United Nations (UN) in July 2003 and became the main driver for changing the system of classification and labelling in the EU.

1.2.2 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. Each country is able to determine which building blocks of the GHS it will use in their different sectors (workplace, transportation, consumers). The intention though is that the currently allowed for variance in the take-up of building blocks 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.

There are three main hazard groups within the UN GHS – physical hazards, health hazards and environmental hazards – each of which comprises hazard classes and categories. The CLP adopts all hazard classes set out in the UN GHS building block approach, although some of the hazard

categories within the different hazard classes were not taken up, because they were not reflected in the preceding Dangerous Substances Directive and Dangerous Preparations Directive; and their adoption would not have been consistent with information requirements on substance properties under the REACH Regulation. CLP does not generally go beyond the "safety level" as provided in the Dangerous Substances Directive.

In implementing GHS in the EU, the CLP Regulation applies to substances, mixtures and certain articles placed on the EU market, with some exceptions[9]. It applies to the workplace and consumers, but does not cover classification for transport purposes (which is covered by Directive 2008/68/EC).

The Regulation entered into force on 20th January 2009. Annex II provides further details of the obligations that CLP provides on different actors.

1.2.3 Related legislation within scope of the study

This study considers not just CLP but also other related chemicals legislation that has horizontal or vertical linkages to CLP, excluding the REACH Regulation. This is legislation that:

- Horizontal: specifies properties of concern, outlines requirements for communicating properties of concern and/or sets packaging requirements for chemicals;
- Vertical: draws on CLP classification for risk management purposes.

A master list of relevant pieces of legislation was the starting point for identifying that which was relevant to this study. A thorough screening of this list was carried out, followed by a mapping of legislation. The relevant horizontal legislation is given in Table 2-2 of Annex III, organised into categories related to their primary objectives.[10] It should be noted that a number of acts (e.g. veterinary medicines, toys) also 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.

Mapping of the vertical links between CLP and other EU chemical-related acts was based on an analysis of 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). Further details of this approach are provided in Section 2 of Annex IV. Although the focus has been on the legislation outlined in Table 2-1 of Annex IV, 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.

[9] 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.

[10] 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.

1.3 Relevance of the fitness check study

The use of chemicals is important to many aspects of modern life (e.g. through improving hygiene and contributing to enhancing human health); however, some chemicals can have detrimental impacts on health and the environment. In response to the increased use of chemical products across the EU, the European Commission has developed a series of legislation and policies in order to protect human health and the environment. Several of these prohibit or limit the use of hazardous chemicals and encourage the phase-out of those chemicals that are considered to be the most harmful. The CLP Regulation in particular is aimed at ensuring that citizens are informed about and protected against hazardous chemicals (European Commission, 2012)[11].

A study undertaken by the World Health Organization (WHO) in 2016[12] indicates that an estimated 1.3 million lives and 43 million disability-adjusted life-years were lost in 2012 globally due to exposures to selected chemicals. The report also notes that data were only available for a small number of chemical exposures with people being exposed to many more chemicals each day. For example, it is estimated that unintentional poisonings cause 193,000 deaths worldwide on an annual basis with the majority of these coming from preventable chemical exposures. Also, exposure to occupational carcinogens is estimated to be the cause of between 2% and 8% of all cancers. For the general population, it is estimated that 14% of lung cancers are attributable to ambient air pollution, 17% to household air pollution, 2% to second-hand smoke and 7% to occupational carcinogens (WHO, 2016). These statistics, although reflecting the global situation rather than the EU, highlight the significant consequences that can arise for human health and the environment from chemical exposures.

It is also estimated that 1-3% of the EU population has a skin allergy to fragrances. Overall, 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[13]. Although a range of factors have been identified as possible causes (increased diagnosis, increased allergen exposure, excessive cleanliness, sedentary lifestyle, etc.), they include exposure to sensitising chemicals. Another issue of growing concern relate to chemicals known as endocrine disruptors, which are characterised by their impacts on the body's endocrine system. Given the importance of the endocrine system, interferences with this from exposure to chemicals is a growing concern, and is continuing to be addressed through developments in EU legislation. In addition, recent reports have suggested that when chemical substances are combined together they may cause adverse effects to human health and the environment, even if the individual chemical substances are harmless[14]. The impacts of such combination effects of chemicals are currently poorly understood, particularly in the case of vulnerable groups of the population.

[11] European Commission (2012): Chemicals in the Environment and their Health Implications. Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/publications/chemicals_health.pdf

[12] WHO (2016): The Public Health Impact of Chemicals – Knowns and Unknowns, The World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/206553/1/WHO_FWC_PHE_EPE_16.01_eng.pdf?ua=1

[13] 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

[14] SCHER, SCCS, SCENIHR (2012): Opinion on the Toxicity and Assessment of Chemical Mixtures. Available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf

The legislative framework also has the objectives of ensuring the efficient functioning of the single market, as well as enhancing innovation and competitiveness. In this respect, it is important to recognise that the EU chemicals manufacturing (substances and mixtures) sector is important to the EU economy as a whole, with EU chemical sales estimated by Cefic at €519 billion for 2015, equivalent to around 14.7% of global sales, and representing about 1.1% of total EU GDP.

Table 1-2 below provides an overview of the key characteristics of the chemicals manufacturing sectors considered to be directly affected by the CLP Regulation and linked to the other main legislation falling within the scope of this study. As can be seen from the table, the full set of actors that may be affected accounts for a significantly larger proportion of GDP and contributes roughly €145 billion in Gross Value Added, and accounts for around 1.6 million jobs. However, as indicated by the Cumulative Cost Assessment for the EU chemical industry[15] the legislative framework can have a significant impact on industry, underlining the importance of evaluating the framework further to identify its impacts (both positive and negative) on industry as well as downstream users and consumers.

Table 1-2: Sectors considered to be affected by the legislation covered by the chemicals legislative framework (and hence the fitness check)

NACE code	Sector	Turnover (million EUR)	Value added at factor cost (million EUR)	Number of persons employed	Type of manufacturer
19.2	Manufacture of refined petroleum products	602,865	19,821	112,400	Substance manufacturers and formulators
20.13	Manufacture of other inorganic basic chemicals	29,527	7,465	68,700	Substance manufacturers and formulators
20.14	Manufacture of other organic basic chemicals	163,823	27,939	207,100	
20.15	Manufacture of fertilisers and nitrogen compounds	25,619	5,006	59,900	
20.16	Manufacture of plastics in primary forms	99,086	13,718	136,100	
20.17	Manufacture of synthetic rubber in primary forms	4,766	1,210	7,100	
20.2	Manufacture of pesticides and other agrochemical products	10,020	2,337	25,200	Mixture manufacturers
20.3	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	40,920	10,939	151,800	Mixture manufacturers
20.41	Manufacture of soap and detergents, cleaning and polishing preparations	26,059	6,029	92,400	Mixture manufacturers
20.42	Manufacture of perfumes and toilet preparations	36,967	9,220	137,100	
20.51	Manufacture of explosives	n/a	n/a	17,300	Substance manufacturers and formulators; Mixture
20.52	Manufacture of glues	5,627	1,414	18,200	
20.53	Manufacture of essential oils	n/a	n/a	18,500	

[15] Technopolis et al (2016): Cumulative Cost Assessment for the EU Chemical Industry. Available at: http://ec.europa.eu/growth/sectors/chemicals/ec-support_en

Table 1-2: Sectors considered to be affected by the legislation covered by the chemicals legislative framework (and hence the fitness check)					
NACE code	Sector	Turnover (million EUR)	Value added at factor cost (million EUR)	Number of persons employed	Type of manufacturer
20.59	Manufacture of other chemical products n.e.c.	64,142	13,971	131,200	manufacturers
24.1	Manufacture of basic iron and steel and of ferro-alloys	137,967	19,591	332,500	Mixture manufacturers
24.41	Precious metals production	10,396	935	9,100	Substance manufacturers and formulators
24.43	Lead, zinc and tin production	7,911	1,271	16,700	
24.44	Copper production	38,187	3,068	37,400	
24.45	Other non-ferrous metal production	10,733	1,689	20,600	
Total		**1,314,615**	**145,623**	**1,599,300**	

Of course a range of downstream sectors rely on these chemical products, including those essential to the EU economy such as agriculture and which are key are enabling technologies, such as semiconductors. Other key sectors are dependent on the use of chemicals in their everyday activities, such as the automotive and aerospace sectors, the paper and pulp sector, as well as the manufacture of everyday goods such as textiles, cosmetics, toys, etc. In virtually all manufacturing sectors, the use of chemicals is fundamental to the production activities and the continued innovation of products.

It is therefore clear that the effective regulation of chemicals is important to protecting human health and the environment whilst enabling the free movement of products and encouraging innovation in the future. Hence, the Commission is undertaking the fitness check of the legislative framework relating to chemicals (excluding REACH) in order to assess progress towards meeting its objectives. This study is supporting this fitness check by identifying and evaluating aspects that are working well and those that are not working so well so that, where necessary and appropriate, changes to the framework can be made to ensure that its objectives are fulfilled into the future. These aspects are discussed in greater detail in this report and the adjoining annexes.

1.4 Organisation of reporting

The remainder of this document has been organised as follows:

- Section 2 provides an overview of the methodology, including the approach taken, a summary of the intervention logic and the limitations associated with the study (Annex I provides further details including the full set of evaluation questions;
- Sections 3 to 7 then pull together the conclusions drawn from the study for each of the main evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value.

The aim of this report is to set out the higher level conclusions of the evaluation, drawing on the findings to the more detailed evaluation questions that are addressed by the research that has been carried out.

Annexes II to V provide summary reports of the findings for each task, with Annex VI providing separate reports on individual case studies undertaken to support the tasks. References are made throughout this report to the more detailed analysis provided in the Annexes that supports the conclusions presented here.

2 Methodology

2.1 Overview of study approach

The work required for this study has been organised into a series of main tasks and sub-tasks, with the main tasks being as follows (a full overview of the main tasks, sub-tasks and case studies is provided in Annex I).

- **Task 1**: Evaluating the implementation of the CLP Regulation – reported in Annex II;
- **Task 2**: Evaluating the horizontal links between EU legislation on hazard identification and communication – reported in Annex III;
- **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 – reported in Annex IV;
- **Task 4**: Open public consultation, SME panel and workshop – reported in Annex V.
- **Case studies** on (1) GHS implementation, (2) classification of metals, (3) parallel hazard assessments, (4) new test methods and Good Laboratory Practice (GLP), (5) detergents, (6) PBT/vPvB, (7) SME awareness, (8) toy safety, (9) consumer communication, (10) linkages with occupational health and safety legislation, (11) risk management measures triggered by CLP, (12) use of CLP classifications in waste management, (13) linkages between CLP and Seveso – reported in Annex VI.

2.2 The Intervention Logic

In order to ensure that the assessment was properly focused, the starting point for the study was the development of the intervention logic underpinning the rationale for the legislation that governs chemicals (hereafter chemicals legislation) and the CLP Regulation more specifically. These are given in Figures 2-1 and 2-2 respectively, overleaf[16].

As the CLP Regulation is framework legislation, it inter-relates (and in some cases may overlap) with the wider set of EU chemicals legislation which acts as the basis for chemicals risk management. The overall chemicals legislative framework and the actions required by the combination of legislation, the associated outputs and results, and the intended end impacts are depicted in Figure 2-1. The corresponding information is provided in Figure 2-2 for the CLP Regulation, for the key classification, labelling and packaging aspects of the Regulation. Taken together, these figures set out the issues that are to be addressed by the study and the context within which the evaluation is to take place. Further detail on the rationale for these figures is given in Annex I.

[16] Note: See also the Better Regulation Guidelines, European Commission (2015) Better Regulation Guidelines, SWD (2015) 111, accessed at: http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf

2.3 Evaluation methodology

2.3.1 Research approach

The methodology adopted for the evaluation was developed around the needs of the four main tasks. The work included the following activities:

- A literature review to pull key 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;

- Legal mapping to identify relevant legislation and specific provisions within this. This was then supported by a legal analysis to identify the nature of the obligations that these placed on different operators, how the legislation was implemented in practice, and areas where there appeared to be inconsistencies, overlaps and incoherences;

- Consultation activities which included the Open Public Consultation, a Stakeholder Workshop (published separately), consultation as part of case study work, and targeted consultation of different stakeholder groups to gain some of the additional evidence needed for the evaluation (and which was not covered by a case study or was at too detailed a level for the Open Public Consultation).

- Case study research, which involved a more in-depth examination of some of the more pertinent issues identified as part of initial research, either directly linked to the interface between CLP and other legislation, the functioning of specific legislation, or examining the tools or measures needed to support the legislation.

Further details of the approach to the stakeholder consultation is provided in Annex V, and further details of the case studies are provided in Table A1-1 in Annex I. The case studies themselves are presented in Annex VI.

More generally, the study has applied the tools set out in the Better Regulation Toolbox in assessing costs and benefits. For example, the Standard Administrative Costs Model has acted as the basis for estimating administrative costs to industry, and complementary approaches have been adopted for the estimation of compliance costs. Where appropriate, separate consideration is given to SMEs compared to larger companies. In this respect, efforts were made to ensure SME views are represented, for example, through use of the Commission's SME Panel, discussions with national associations, and separate analysis of cost information provided by SMEs where relevant.

All assumptions in this respect are made clear in the more detailed task reports. In addition to developing own estimations, figures have been drawn from other sources, in particular in relation to costs and benefits of measures under downstream legislation with vertical linkages to CLP for risk management purposes.

Further details of the evaluation baseline, the sources of data and the approach used to verify the information obtained from different sources (i.e. triangulation of the data) is provided in Annex I.

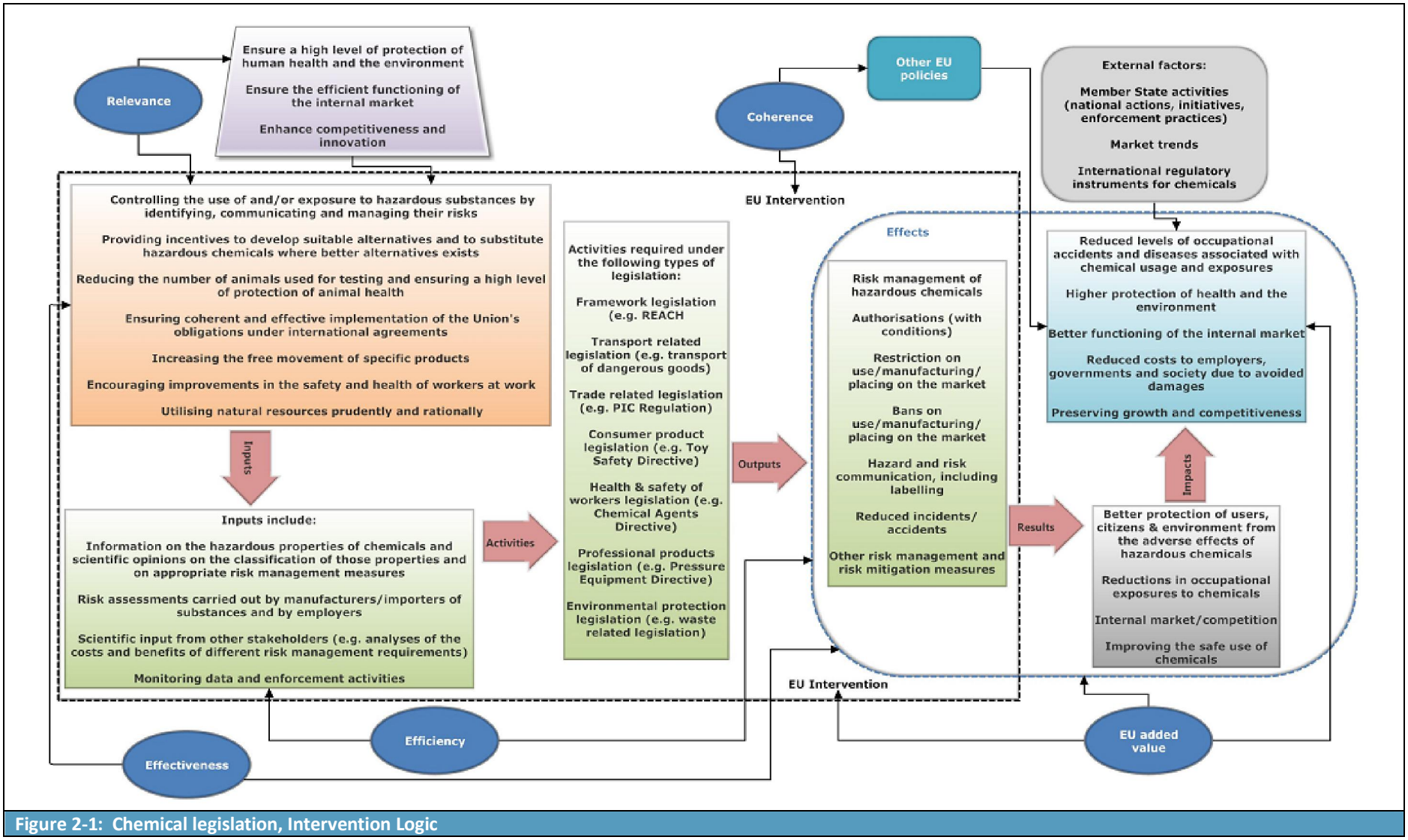

Figure 2-1: Chemical legislation, Intervention Logic

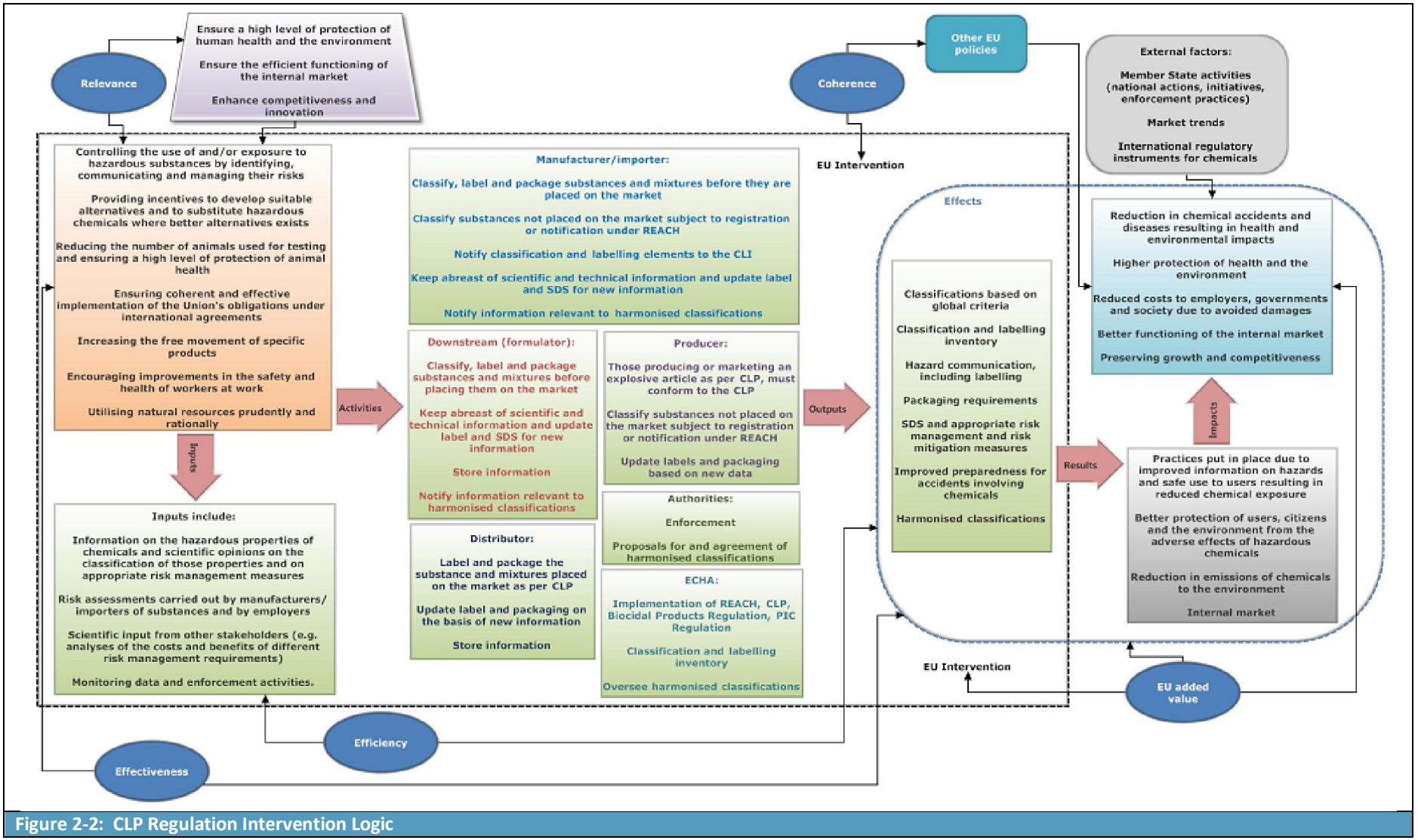

Figure 2-2: CLP Regulation Intervention Logic

2.4 Study 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. These include limitations stemming from the following (with further details provided in Annex I):

- The broad scope of the study and the number of pieces of legislation to be considered;
- The lack of available information on the scale of issues identified (both positive and negative) and the subsequent need to rely on information provided by stakeholders;
- The limited response received from civil society stakeholders. However, further desk-based research of published information from NGOs was undertaken to inform the study;
- The lack of available data to assist in determining the effectiveness and efficiency of the legislative framework (particularly in quantitative terms);
- The inability or unwillingness of companies to provide certain data creating difficulties in quantifying the impacts of CLP and other legislation; and
- The lack of up-to-date information regarding the effect of the CLP Regulation on consumer behaviour.

3 Effectiveness

3.1 Introduction

Assessing the effectiveness of the EU legislative framework in achieving or progressing towards its objectives has been carried out against four main questions, each of which is further defined with a series of more detailed questions. These main questions are as follows:

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)?

Each of these high level questions is examined below through consideration of the more detailed questions that were defined for each. The most detailed questions (4th level questions in Table 3-1) are not individually addressed here in detail, although they are considered as appropriate within the different tasks.

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

3.2.1 Overview

This key question regarding the extent to which the legislative framework is meeting its objectives is further defined in terms of those objectives.

- 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?
  - Ensuring the efficient functioning of the single market?
  - Enhancing competitiveness and innovation?

Given the scope of this study, there are no simple answers to the above questions. Instead, one must look across the different components of the legislation and consider how these fit together, as

well as how they are performing in practice. We have done this by drawing on key themes that form the basis for the Task 1 to 3 evaluations, as well as by referring to some of the more detailed sub-questions that underlie the main questions set out above. These key themes are as follows:

a) Hazard classification;
b) Identification of properties of concern;
c) Combination effects and multiple routes of exposure;
d) Data quality and reliability;
e) Communication measures;
f) Incentives to reduce exposures and access to substances with more favourable risk profiles;
g) Reductions in exposures and the incidence of accidents and diseases; and
h) Single market, competitiveness, innovation and international trade.

3.2.2 Hazard classification of substances and mixtures under CLP

3.2.2.1 General findings

On balance, the CLP is considered to contribute towards ensuring a high level of protection for human health and the environment with respect to the hazard classification of substances and mixtures. It provides the basis for identifying properties of concern, with this information then used in communications (through safety data sheets and labels) to workers, downstream users and consumers of chemicals to ensure their safe use. Responses to the Open Public Consultation (see Annex V), suggest that, overall, respondents from all stakeholder groups[17] are satisfied with this aspect of the legislative framework, and the consistency of the current requirements with those under previous legislation. Hazard classification also triggers the need for special packaging requirements in some cases, where it is important to protect vulnerable populations (e.g. child-resistant closures for corrosive liquids) and provides the basis in vertically linked legislation for triggering risk management measures. There is however evidence that there are also gaps in the framework and areas where its effectiveness could be improved.

Key positive findings in relation to the self-classification of hazards under CLP are as follows:

- Classification under CLP provides an appropriate basis for identifying the hazards to workers, consumers, the general public and the environment (Annex V, Section 2.5 and Section 3.3.13; Annex II, Section 4.2) for substances and mixtures;

- CLP is a more readily applied system than that which existed under the Dangerous Substances Directive and Dangerous Preparations Directive for the self-classification of substances and mixtures (Annex II, Section 4.2 and report on the Stakeholder Workshop) (although duty holders still face issues); and consistency across Member States has in general increased due to CLP being a regulation;

- It provides the basis for the harmonised classification of substances against the key criteria underpinning the EU chemicals legislative framework. The process is generally considered by the actors involved to be more efficient and effective than under the Dangerous Substances Directive although, measured in terms of the time taken to reach and enact decisions, the process appears no quicker (see Annex II, Section 5.2);

[17] Although "citizens" and NGOs show a lower level of satisfaction than industry and public authorities.

- Classification under CLP covers most of the main properties of concern or contributes to their identification. This includes the identification of carcinogens, mutagens, reproductive toxins and allergens (i.e. skin and respiratory sensitisers) (see Annex II, Section 4.2) in relation to human health, and aquatic toxicity with respect to the environment (see Annex III, Section 4.2). The key shortcomings would be the lack of classification for terrestrial hazards and the need for agreed criteria for identifying endocrine disruptors (see Annex III, Section 4.2);

- With respect to CLP and its take-up of GHS building blocks, the study finds that there are no significant dis-benefits from CLP not taking up all of the potential building blocks (Annex II, Section 9.2);

- Companies are required to comply with GLP when generating new data, with this helping to ensure that new data produced by studies are reproducible but also the mutual recognition of data generated within the EU globally; and

- CLP helps to ensure that information on chemical hazards from substances and mixtures placed on the market in the EU is more consistent with that for chemicals being placed on the market in other countries around the world that are also applying the UN GHS, further contributing towards the effectiveness of global classification systems in protecting human health and the environment.

It is of note that industry representatives view the guidance that has been developed by ECHA as being important to the more systematic application of the system across the EU. Not all industry stakeholders find the guidance easy to follow, however, and the Stakeholder Workshop (and consultation) identified some suggestions for improvement (e.g. more flowcharts).

On the negative side, there are areas where the effectiveness of the legislation may require further consideration. One such issue is the lack of criteria in CLP for classification for terrestrial toxicity and immunotoxicity. Another is the extent to which CLP may be over-classifying both substances and mixtures for skin corrosion/skin irritation, with over 68,000 substances self-classified as skin corrosion/irritation Cats 1A, B, C and 2 (see Annex II, Section 9.2); this may have implications for the effectiveness of hazard communication with respect to consumer products and especially mixtures produced by the detergents sector (Annex II, Section 4.3 and Case study 5).

Both industry and Member State authorities have expressed the view that CLP over-classifies both substances and mixtures for skin corrosion/skin irritation (see Annex II, Section 4.3). Although this was most strongly expressed by industry, and in particular the detergents sector, Member State authorities have also remarked that they believe this is the case. Where over-classification occurs in relation to substances, this will have a knock on effect for mixtures. If over-classification is taking place, it may not only send users of such substances an incorrect message concerning the safety of their use, it may also have knock-on effects for other human health and environmental protection objectives with respect to re-use, recycling and the circular economy.

Three key issues have been identified with respect to the classification of mixtures:

- There is a lack of clarity with respect to how some of the bridging principles within CLP as part of the classification of mixtures are to be applied, with this part of more general concern that the choice of classification method – testing, weight of evidence, bridging principles - may impact on the quality of an end self-classification (see Case Study 5 and Annex II, Section 4.3);

- There are weaknesses in the ability of the mixture classification rules to adequately reflect bioavailability, with particular concerns arising for the classification of metals and their alloys, with this having potential implications for the consistency of classifications (Annex II, Section 4.4 and Case Study 2); this issues is also raised with respect to other mixtures in a matrix; and

- There is a lack of appropriate methods for assessing the combination effects of substances and mixtures (and bearing in mind that testing of mixtures is only to be undertaken as a last resort, especially if it would involve animal studies, or is for CMR and certain aquatic hazards (Annex II, Section 4.3).

Member State authorities in particular have noted a lack of clarity from their perspective as to how some of the bridging principles are to be applied in practice; this has made it difficult for industry to implement the principles and for Member State authorities to enforce them. In this respect, it appears that the information requirements are not sufficiently clear to enable their harmonised application throughout the single market (see Case Study 5). This will not only impact effectiveness with respect to protecting human health and the environment, but also in relation to ensuring the functioning of the single market and to efficiency. In particular, it appears that some Member State authorities will accept classification based on bridging principles while others do not. This is an issue that could be addressed with further guidance.

Industry has also identified issues arising from the choice of classification method, noting that mixture classification may vary across the methods used (e.g. testing versus weight of evidence versus calculation approach - see Annex II, Section 4.3 and Case Study 5). Again, this has implications not only for the effectiveness of CLP in meeting its objectives in relation to a high level of protection of human health and the environment (as over-classification may have perverse effects), but also with respect to market distortions and uneven competition within the single market. Note that this issue and the restrictions on testing of mixtures under CLP link to EU policy regarding the avoidance of unnecessary vertebrate animal testing, for example under the Laboratory Animal Directive (Directive 2010/63/EU) and REACH.

3.2.2.2 Harmonised classifications

The creation of a list of substances with harmonised classifications for "hazard classes of highest concern" 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. These provisions act as one of the key cornerstones of the EU chemicals legislative framework, as the triggers for risk management in much of the downstream legislation are based on these harmonised classifications. Title V of the Regulation sets out the provisions for the establishment of a harmonised classification for 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; the latter in particular is relevant for plant protection products and biocidal products, as active substances within the meaning of these sectors' legislation shall normally be subject to harmonised classification and labelling.

From consultation, the harmonised classification process is considered by authorities and industry stakeholders to be more effective than it was under the Dangerous Substances Directive, although the evaluation finds there is room for improvement (Annex II, Section 5.2). In terms of numbers, immediately after the introduction of CLP there were 3,370 entries in Annex VI, with there now being 4,537 as of 4th January 2017 (with many of these added through the 1st ATP to CLP, bringing it in line with the final additions to the DSD); between 6,000 and 7,000 substances are now likely to

have a CLH. As of 4th January 2017, 323 CLH dossiers have been submitted to RAC (See Annex II, Section 5.2).

There has, therefore, been a significant increase in the number of substances that now hold harmonised classifications, but there are no figures for what was anticipated pre-implementation to establish effectiveness on this basis. Similarly, there are no observable health or environmental improvements at this point in time on which to base an assessment of effectiveness, although it is of note that a large percentage of the 300 plus CLH proposals relate to active substances under the Plant Protection Products Regulation and the Biocidal Products Regulation (with a lack of proposals related to industrial chemicals being a weakness).

However, the findings are not all positive:

- Most harmonised classification and labelling proposals to date relate to active substances under the Plant Protection Products Regulation and the Biocidal Products Regulation. The need for harmonised classifications under these Regulations is constraining the degree to which Member States are able to focus on industrial chemicals; even so, too few plant protection and biocidal active substances currently have a harmonised classification;

- The level of effort across Member States in bringing forward harmonised classification and labelling dossiers is uneven, suggesting that more could be done to require/encourage Member States in this regard (Annex II, Section 5.3);

- The Commission lacks the ability to ask ECHA to develop dossiers, which could ensure that substances of concern are being addressed; and

- Industry proposals for re-classification of substances on Annex VI of CLP find little support from Member State authorities, with this potentially resulting in the on-going over-classification of some substances or a lack of harmonised classification across currently non-harmonised endpoints (Annex II, Section 5.4).

In addition, the views of industry are mixed on the quality of some harmonised classification and labelling dossiers, with some arguing for greater checks by ECHA, more consultation between Member State rapporteurs and the dossier submitter (Annex II, Section 5.5) and more consultation with industry to ensure that the data on which classification decisions are being made are reliable and of high quality. In this respect, it is important that data generated for REACH registration purposes is not ignored.

Most commentators agree that the CLH process should remain hazard based up to the point of the RAC opinion, with impacts stemming from linkages between CLP and downstream legislation better addressed in the downstream legislation if they are not logical or proportionate (Annex II, Section 5.7; Annex IV, Section 6.1.3).

3.2.3 Identification of properties of concern

In almost all cases CLP provides the starting point for the identification of properties of concern, even where other legislation requires consideration of additional data, for example, with respect to bioaccumulation or persistence. The main exception to this is the OSH legislation which also draws on other international sources to identify properties of concern within the workplace (such as for process generated gases). CLP therefore provides a consistent starting point for the identification of properties of concern across the legislation framework. This is not only important for coherence,

but also for ensuring that there is a sound and effective database underlying the framework. This is important to helping to ensure a high level of protection, as well as helping to enhance the single market through the harmonisation of data requirements.

The main additional properties that are identified under the legislation with a horizontal linkage to CLP Regulation (see also Annex III, Section 4.1):

- Persistence, Bioaccumulation and Toxicity – PBT;
- very Persistent, very Bioaccumulative – vPvB;
- Endocrine Disruption – ED; and
- Allergenic properties (e.g. skin and respiratory sensitisation).

Although some stakeholders believe that the effectiveness of CLP in protecting human health and the environment would be increased if it included classification criteria (and labelling requirements) for these additional properties, that is not the overall conclusion of this study (Annex III, Section 4.2), as CLP already requires classification against criteria that inform assessment of all of the above properties.

In addition, the number of PBT substances identified to date is relatively small, with regulatory mechanisms in place to either remove their uses (the Biocidal Products Regulation and the Plant Protection Products Regulation) or to ensure that they are limited (e.g. REACH Authorisation or Restriction). Similarly, criteria will be set for endocrine disruption (more a mode of action than a property) under the Plant Protection Products, Biocidal Products, REACH and Cosmetics Regulation that may or may not be fully aligned depending on the final decision regarding their respective needs (Annex III, Section 4.3). With respect to allergens, substances and mixtures are already classified for skin and respiratory sensitising effects (Annex II, Section 4.2), with this data acting as the starting point for the identification of such substances under other legislation.

Furthermore, inclusion of such classification criteria into CLP would lead to the EU introducing new technical and labelling non-tariff barriers to trade, if they are not also adopted globally within the UN GHS system. As the EU has been a key partner in developing and moving the GHS forward this would be counter-productive (Annex III, Section 4.3).

3.2.4 Combination effects, multiple routes of exposure and vulnerable populations

3.2.4.1 Classification and combination effects

The effectiveness of the legislative framework in terms of its ability to address combination effects and multiple routes of exposure is assessed in terms of the requirements of individual pieces of legislation, as well as how the different pieces of legislation fit together. Key findings are:

- The mixture classification criteria, and in particular the calculation methods, are considered to take into account the additive effects of substances in mixtures, and mixtures of mixtures for the relevant hazard classes. Only test data, however, can capture 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. However, testing of mixtures is only to be undertaken as a last resort, especially if it would involve animal studies or is for CMR and certain aquatic hazards (Annex II, Section 4.3);

- As CLP sets the rules for the classification of mixtures in general, then the above statement also holds for mixtures falling under sectoral legislation such as fertilisers, plant protection products, regulated by sector.

ECHA notes that although it may only be possible to identify synergistic and antagonistic effects for most substances via testing, expert risk assessment and modes of action knowledge may enable an assessment of the likelihood of such effects. It is unclear therefore to what extent this represents a significant problem. It is clear that it is an issue of concern to all stakeholders, however, there is no good data for establishing what the potential magnitude of the impacts on human health or the environment are, especially associated with the lack of testing for mixtures. In this respect, it is important to recall that the restrictions on testing of mixtures under CLP link to EU policy regarding the avoidance of unnecessary vertebrate animal testing, for example under the Laboratory Animal Directive (Directive 2010/63/EU) and REACH.

3.2.4.2 Combination effects and multiple routes of exposure in risk assessment

With respect to risk management under the legislative framework, both positive and negative factors can be identified in terms of effectiveness. On the positive side:

- Risk assessments carried out under the Biocidal Products and Plant Protection Products Regulations must consider multiple routes of exposure (inhalation, ingestion, dermal), for professional and general public users of such products (Annex IV, Section 3.2);

- The legislation works together to take into account the potential for exposures via multiple routes, e.g. by classifications for certain properties such as carcinogenicity triggering risk obligations under a suite of legislation (Annex IV, Section 3.2 and Case Study 11); while

- In other cases, such as under the Detergents Regulation, requirements are triggered if the combination of hazardous constituents exceeds a certain concentration; in this case labelling requirements are triggered if allergens and skin sensitisers individually or in combination exceed concentrations of either 0.1% or 1.0%, depending on the type of sensitiser (Annex III, Section 4.5).

More generally, 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"[18] which recognises that there is a gap with respect to 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). 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 highlights the significance of the problem and the areas where action is needed; it also sets priorities based on the recommendations of the main Scientific Committees (see Annex III, Section 4.6). 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.

[18] 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.

On the negative side, there are significant gaps in the extent to which both combination effects and multiple routes of exposure are addressed, which will be impacting on the effectiveness of the legislative framework. For example:

- There may be a need for greater hazard assessment of non-intentionally added substances (NIAS), which stem from chemical impurities, reaction and degradation products (Annex III, Section 4.6). This issue has been raised with respect to plant protection products, where the levels of these substances may be higher than pesticide residues. Such impurities, reaction and degradation products are also relevant in other regulatory contexts though and have driven risk management of industrial chemicals in the past (e.g. brominated flame retardants);

- There is a duty for employers to consider combined effects when preparing risk assessments 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, as SDS and exposure scenarios provided to downstream users are substance or mixture specific (Annex III, Section 4.6); and

- The lack of information on potential combination effects within the workplace may be linked to the significant level of on-going occupational health impacts. ETUI has estimated that 53% of occupational deaths were from cancer, with over 102,000 cases of occupational cancer occurring in the EU28 in 2011; occupational cancer is also responsible for 5.3-8.4% of all cancers[19]. Although most of these cancer cases will be linked to chemical exposures (with a significant percentage relating solely to asbestos), no assessment can be made as to the extent to which these impacts relate to a single carcinogenic agent or to multiple exposures or other combination effects.

ETUI note that REACH could improve the situation with occupational cancer[20], and this is likely to also be the case with respect to exposures of citizens. However, there is less information on the extent to which the simultaneous exposure of citizens to different hazardous chemicals via indoor air sources, use of consumer products, from use of plant protection or biocidal products, etc. may be giving rise to significant health effects. In this respect, significant gaps remain to be addressed. For example, there are gaps in the regulation of hazardous substances in consumer products which will impact on the extent to which multiple routes of exposure are being addressed. One response to difficulties in addressing this issue under the General Product Safety Directive has been to draw on the Article 68(2) fast track procedure under REACH. Although this may be fast and effective in addressing exposures, this approach also has the potential for giving rise to significant (and potentially) disproportionate costs (Annex III, Section 4.6).

The lack of assessment for combination effects and multiple routes of exposure is considered by stakeholders of all types to be a gap in ensuring a high level of protection to human health and the environment. Although it is acknowledged that there is not the technical capacity to assess combination effects and multiple routes of exposure to the full extent, it is also the case that

[19] ETUI (2015): Eliminating occupational cancer in Europe and globally. Available at http://www.etui.org/Publications2/Working-Papers/Eliminating-occupational-cancer-in-Europe-and-globally

[20] ETUI (2011): Occupational cancer: the main challenge for the new Community Strategy. Available at https://www.etui.org/content/download/7515/71981/file/Occupational+cancer++the+main+challenge+for+the+new+Community+Strategy.pdf

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).

3.2.5 Data quality and reliability

In general, the conclusions of the evaluation are positive with regards to the quality and reliability of the data used for classification purposes:

- The data requirements underlying the legislative framework are considered adequate to ensuring the protection of human health and the environment, taking into account the discussion provided above regarding the identification of properties;
- Where new tests are carried out, these adhere to the requirements of Good Laboratory Practice or, for certain tests, relevant standards (i.e. ISO 17025); older data are accepted where these are considered reliable (Annex III, Section 5.2);

- The test methods that currently provide the basis for identifying human health and environmental hazards are considered adequate and work is underway on agreeing alternative methods (work within both the OECD and the UN Sub-Committee of Experts on GHS is being undertaken to assess whether new classification criteria, based on alternative approaches, should be developed in the GHS) (Annex III, Section 5.2);

- Member States, scientific bodies and committees generally take both data generated by manufacturers for classification purposes as well as other scientific data into account when making classification and risk management decisions (Annex II, Section 5.5).

3.2.5.1 Good Laboratory Practice

As noted above, GLP compliant data underlies the CLP classification system in cases where new (eco-) toxicological tests are performed. GLP is a quality system and a management tool concerned with how safety studies are organised, planned, performed, reported, reviewed and archived. The main purpose of GLP is to have confidence in the data and to promote the development of quality test data. Comparable quality test data forms the basis for mutual acceptance of data among countries, and is therefore important not only for market harmonisation but also international trade purposes. It is also important as individual countries can confidently rely on test data developed in other countries, duplicate testing can be avoided, thereby saving time and resources. The only way this objective can be effectively achieved is by having an independent assessment of compliance by national monitoring authorities. Although it is important that all companies maintain their own quality systems and checks, the experience of GLP monitoring authorities is that self-regulation does not work particularly effectively (see Annex IV, Section 4.2).

There is concern though that this requirement for new tests to be carried out to GLP will mean that studies by academia and independent labs will not be taken into account, even though they may be undertaking more innovative studies aimed at testing for specific effects such as endocrine disruption. It is important to recognise though that these labs are carrying out scientific research rather than performing regulatory studies, thus, not being GLP compliant should not undermine the validity of their work. Even so, experiences in the UK have shown that academic labs working as small contract research organisations offering specialist services are able to apply GLP through a commitment to implementing management and quality systems.

3.2.5.2 Testing methods

One of the effectiveness questions concerns whether or not testing methods are adequate to identify all hazards to human health and the environment. Our key findings are as follows (see Annex III, Section 5 and Annex VI, Case Study 4).

- Overall, there are test methods available to identify the majority[21] of hazards to human health and the environment for substances. The picture is less clear with respect to mixtures, with authorities noting 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 believe that some test methods do not adequately identify certain hazards, e.g. irritation, sensitisation, and endocrine disruption in relation to legislation other than the CLP Regulation.

- In 2014, the Joint Research Centre (JRC) of the European Commission compiled a state-of-the-art review on alternative methods for regulatory toxicology, which found that a number of non-standard methods are available for most of the human health endpoints 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. 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.

- Work has been initiated within the UN Sub-Committee of Experts on GHS 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 initiative is a necessary step towards a further adaptation of the classification system into the technical progress.

3.2.5.3 Data used for scientific decisions

Evaluation of the quality and reliability of data used for scientific decisions must start by recognising variations in the allocation of responsibility for "data generation". This varies from responsibility being placed on manufacturers and formulators for self-classification (CLP) and preparation of risk assessments (Plant Protection Products Regulation, Biocidal Products Regulation, Cosmetic Products Regulation and Toy Safety Directive) to Member States (dossiers for harmonised classification and labelling) and scientific agencies and committees.

In general, the Member State competent authorities, scientific bodies and committees are considered to give proper scrutiny to different datasets and to weigh up differences in the quality of available data when making classification and risk management decisions. There is an industry concern, however, that there have been cases where the data generated by manufacturers for REACH have not been considered by authorities, for example, when preparing a harmonised

[21] For example, OECD's (2012) Detailed Review Paper (DRP) 178 on endocrine disruptors identifies a number of gaps with regards to human health impact pathways and testing methods related to endocrine disruption. There are also gaps in relation to immunotoxicology, epigenetics and terrestrial toxicity.

classification dossier for an industrial chemical[22] (Annex II, Section 5.5 and 5.6). If this is the case, it will be negatively impacting on the effectiveness of the legislative framework, as it ignores the regulatory basis of the data developed by industry, e.g. for REACH registration purposes and in accordance with GLP requirements (for new data). It also undermines the degree to which there is a level playing field and harmonisation across the single market, if data generated in line with regulatory requirements is accepted in some cases but not in others. This is not to say that other available data should not be considered, only that its quality should be compared to and weighted against that of the data developed specifically for regulatory compliance purposes. (See also Annex V, Section 3.15 and Annex IV, Section 4.2).

3.2.6 Communication measures

A range of different communication measures exist across the legislative framework:

- Labelling requirements under CLP and the legislation (Annex III, Section 4.2 for a list);
- Creation and operation by ECHA of the Classification and Labelling Inventory; and
- The obligations for communication of hazard and safety information on consumer mixtures to national poison centres.

Together these create a system which aims at ensuring that users (workers, professional users and consumers) of chemicals have the information needed to use substances safely and to make informed choices when selecting between chemical products. Because these requirements are harmonised across the single market, this helps ensure a level playing field in communication requirements across legislation for all manufacturers. Information on chemical hazards is also likely to increase competition within the market, providing an incentive to manufacturers to develop and market less hazardous products in response to consumer demands; although the effectiveness of such measures (and the framework more generally) in stimulating competition and innovation appear to not be that positive (Annex V, Sections 2.5, 3.7, 3.16 and 3.20).

3.2.6.1 Labelling requirements under the CLP Regulation

The purpose of the communication instruments in CLP 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. It is the general view of most stakeholders (e.g. industry, NGOs, and the Open Public Consultation) that hazard communication under CLP has had a positive impact on health and safety (Annex V, Section 3.14; Annex II, Section 7.3), due to improved access of labelling data and improved hazard communication (although this is also linked to better information being available through REACH). The picture is less clear in relation to the environment, with a much smaller percentage of stakeholders indicating that hazard communication on its own has benefited the environment (Annex II, Section 7.3).

A number of issues have been identified that are considered to be impacting the effectiveness of hazard communication measures. Evidence (Annex III, Section 7.3; Case Study 9) suggests that, in general, CLP pictograms are not well understood by the general public (in particular GHS04 (gas cylinder) and GHS07 (exclamation mark) pictograms, which may be due in part to a lack of differentiation between certain hazards (i.e. products may labelled with the same pictogram despite the actual hazards being markedly different). This may be leading to consumer confusion, and

[22] This is a legal requirement and is checked by ECHA during the accordance check. However, ECHA recognises that mistakes may have occurred especially for data rich substances, but notes that in such cases the registrant would have the possibility to submit information during public consultation.

result in consumers and downstream users not fully heeding the warnings related to certain products[23]. Workers are considered to have a greater understanding of hazard pictograms than consumers, due mainly to the training received from employers. 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 consumers.

The issue of inflationary labelling has also been raised by a range of stakeholders (including industry, consumer organisations, Member State authorities and the detergents sector) as impacting the effectiveness of hazard communication. A particular example is classification for corrosion. 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 in the CLP Regulation (Annex III, Section 7.3). This change in the classification criteria has had a considerable impact on product labelling, especially in the cleaning products sector (Annex VI, Case Study 5). As a consequence, mixtures (of unchanged composition) may now be classified with a more severe hazard and labelled with the matching hazard pictograms and hazard statements, leading to a situation where consumers assume the existence of new hazards because of new labelling (even though the risk has not changed). The concern is that widespread labelling on products can have a "habituation effect", i.e. labelling no longer has the intended effect of a warning for consumers.

Evidence from consultation indicates that labels can become overloaded with information, making it difficult for downstream users to focus on the essential hazard information, thus reducing the effectiveness of hazard communication. In particular, the long hazard (H) and precautionary (P) statements on multi-lingual labels can result in a significant amount of information that can become difficult to read and understand for downstream users and consumers. In the view of manufacturers, the space required to present such hazard information is greater under CLP. Member States also identify overcrowded labels as a concern, but note that this can result from manufacturers giving too much of the label space to promotional messages rather than the required hazard information (Annex III, Section 7.3; Case Study 5).

A potential way of reducing the level of information included on product labels while ensuring it remains available is through the use of innovative communication technologies, such as Q-R codes and bar codes. These find mixed support across stakeholders, however (Annex V, Section 2.5; Annex III, Section 7.5; Case Study 9), with the detergents sector being the most positive about their use and SMEs in general being more wary.

3.2.6.2 Labelling requirements under legislation with horizontal links to the CLP Regulation

An analysis of the labelling requirements under horizontal legislation with links to CLP found that many pieces of legislation (in particular those relating to consumer products and professional products) set out requirements for providing instructions on the use of different types of products (Annex III, Section 7.2), as well as contact details for traceability purposes. 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. There are also more limited communication requirements in environmental

[23] Note that a recent study carried out for DG Justice and Consumers has also examined factors relating to the design of pictograms for consumer understanding, and highlights the importance of consumer validation of pictograms.

protection legislation, and worker specific communications under occupational health and safety legislation.

In general, these labelling requirements are considered to be effective at communicating hazards and risks to workers, professional users and consumers. However, issues have been raised with regards to the communication requirements under certain pieces of legislation, in terms of both effectiveness and coherence (see also Section 6 of this report). With respect to effectiveness, currently there are no specific labelling requirements in the Toy Safety Directive specific 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 (Annex III, Section 7.2 to 7.4). This is 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. Issues have also been raised with regards to toy products not meeting the labelling requirements outlined in the Directive (see Annex VI, Case Study 8). These can represent significant issues as incorrect labelling can impact on product traceability and potentially for consumers' health if toys are not appropriately used.

Classification and Labelling Inventory

The Classification and Labelling Inventory (CLI), which holds data on substance classifications, is used both by industry and by ECHA and Member State authorities as a source of information. The key findings of the evaluation with respect to the CLI are that (Annex II, Section 8.2):

- The provisions in the CLP which created the CLI have been effective in providing a single, readily accessible source of basic classification and labelling data on hazardous substances;
- Some 123,000 substances have been notified to the database, with over 6.5 million notifications made in total; and
- The graphical presentations of hazard classes and regulatory profiles that ECHA now presents in the innovative Brief profiles, as well as the associated InfoCards, are welcomed as it makes the information on the differences among classifications more readily understood and provides industry with an overview of regulatory status.

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*".

Industry clearly uses it to check on the classifications being notified by others and to identify alternatives with a better hazard and, hence, regulatory profile (for example, through reference to the InfoCards). Member State authorities use the Inventory to assist in enforcement activities, to identify substances of concern, to respond to Helpdesk requests and for various other regulatory needs, while NGOs use it as a reference source (Annex V, Section 3.29 – 34; Annex II, Section 8.2). These uses are despite the concerns over the reliability of the data held in the CLI, which significantly affect its value and effectiveness as a communication tool (Annex V, Section 3.24 – 31; Annex II, Section 8.2).

There is a range of potential reasons underlying this lack of reliability, from differences in impurities or physical states, to differences in the availability of data for self-classification to different notifiers, or to importers not classifying according to CLP but to other national requirements. Unfortunately,

there is no legal obligation for companies to update notifications and ECHA is not legally allowed to correct or delete obvious mistakes. The result is that the CLI's effectiveness as a communication tool is limited as is its role in enhancing the single market, and contributing to competitiveness and innovation, as it may be giving incorrect signals as to the real hazard profiles of substances; indeed, there is a view amongst some stakeholders that companies have purposely under-classified their substances prior to notification (Annex II, Section 8.2).

There are several suggestions as to how the reliability of the tool could be improved, including giving priority to data from REACH registration dossiers and introducing obligations for notifiers to up-date their notifications. In ECHA's recent *Report on the Operation of REACH and CLP*[24], 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. If any such measures are introduced, consideration should be given to the cost versus data quality trade-offs involved, given the administrative burden that such obligations place on industry (estimated at between €49 and €63 million – see Annex II, Section 8.2).

3.2.6.3 Poison Centre reporting obligations

Obligations related to poison centres were one of the requirements under CLP that drew the highest level of concern from industry stakeholders, with these mainly related to the costs rather than the effectiveness of the obligations (see Section 5 below for a discussion on costs). Such reporting requirements were originally established under the Dangerous Substances Directive, but were not enforced across all Member States leading to considerable inconsistency. This both impaired the effectiveness of these obligations but also led to a lack of harmonisation across the single market.

Under CLP, new poison centres or receiving bodies have been established under a number of Member States: Czech Republic, Estonia, Germany, Greece, Ireland, Netherlands, Portugal, and Slovakia. In response to targeted consultation, several of Member State authorities indicated that the obligation to notify poison centres has had a large positive impact on human health and safety and the environment, with most of these being countries that did not enforce poison centre obligations prior to CLP. This highlights the perceived effectiveness of such obligations. Unfortunately, quantitative data specific to the benefits of poison centre obligations are not readily available across Member States and so it is not easy to quantify the magnitude of the impacts of these obligations.

3.2.7 Incentives to reduce exposures and access to substances with more favourable risk profiles

The findings of the evaluation are mixed as to whether or not the legislative framework incentivises industry and regulators to either reduce the use of, or reduce exposures to, hazardous substances, and the extent to which it promotes access to and the use of substances with a more favourable risk profile. For example, it is clear that a limited number of Member State authorities are responsible for developing most of the proposals for harmonised classifications to support authorisation of active substances under the Plant Protection Products and Biocidal Products Regulations or to support further regulation of industrial chemicals under REACH. Further incentives may be needed in this respect (Annex II, Section 5.3).

[24] https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

In contrast:

- Detergents manufacturers and other producers of consumer chemicals have reportedly reformulated their products in response to CLP resulting in more severe hazard classifications of some products (e.g. due to the change in classification criteria for skin corrosion/irritation), so as to ensure that certain types of products remain unclassified (Annex II, Section 4.3; Annex VI, Case Study 5);

- The generic, hazard-based triggers that apply under the Plant Protection Products and Biocidal Products Regulations have had an effect on the active substances being supported for approval by manufacturers. The existence of these triggers means that active substances are being or will be withdrawn from the market, unless manufacturers believe that a case can be made for exemption or derogation (Annex IV, section 6); and

- Under the Plant Protection Products Regulation, certain substances can be approved as candidates for substitution, allowing Member States to decide not to authorise products containing the substances if alternative products are available (Annex IV, Case Study 11).

Some care should be taken in interpreting such outcomes, in particular where there is the potential for unintended consequences. For example, the loss of certain active ingredients may lead to increased loading or application by farmers of other, less effective products, so as to retain crop quality and yields (Annex IV, Section 7.5). Such behaviour can result in worse environmental and health impacts overall.

In addition, as illustrated by recent concerns over the potential classification decision regarding lead metal, there is the potential for such decisions to have significant downstream implications (Annex VI, Case Study 12); in this case, applying the same stringent specific concentration limit for lead metal and lead powder, as was originally proposed, could have had serious implications for other metal sectors, as well as more general metals recycling activities within the EU. Although this may have reduced exposures to lead in articles at very low concentrations which would not have posed a significant risk to workers or citizens, industry believed that application of the lower specific concentration limit could have significantly impacted on some types of metals recycling, which in turn would have had significant implications in terms of the increased energy consumption associated with the production of new aluminium, for example. This would, in turn, have resulted in increases in atmospheric emissions leading to greater environmental and human health impacts than the risks to workers or citizens associated with the potential lead exposures. As different specific concentration limits were established for the metal and the powder, these impacts remain hypothetical, but the example highlights the potential effects of harmonised classification decisions.

3.2.8 Reductions in exposures and the incidence of accidents and diseases

Different pieces of legislation will work in different ways to reduce exposures to hazardous chemicals and the incidence of chemicals-related accidents – either minor ones in the workplace or more major industrial accidents - resulting in exposure/damage to human health and or the environment. For example, the ETUI has estimated that 53% of occupational deaths were from cancer. There were 102,517 cases of occupational cancer in the EU28 in 2011; and an estimated 95,000 fatal occupational cancer cases for the EU-27 in 2007. Occupational cancer has also been

found to be responsible for 5.3-8.4% of all cancers[25]. Statistics for allergies were given in Section 1 of this report, while other indicators are available from other studies[26].

In general, reductions in exposures and in the incidence of accidents and diseases stem from:

1) Classification of substances and mixtures leads to improved information on the properties of chemicals:
   - Through labelling requirements, this leads to improvements in consumer choice and potentially a shift in demand towards less hazardous products; labelling requirements also help reduce exposures of sensitive populations to substances such as allergens;
   - Information on the hazards of substances and mixtures should lead to improvements in the safe use and disposal of chemicals;
   - Packaging requirements linked to particular classifications help protect vulnerable populations from accidents;
2) Safeguard and urgency procedures provide a back-up mechanism for addressing emerging issues regarding the classification and safe use of substances and mixtures.
3) Agreement of new harmonised classifications by the relevant agencies, scientific bodies and committees provides the basis for risk management of chemicals. Under some legislation, generic risk approaches can lead to automatic bans on the use of substances having the following properties: carcinogenicity, mutagenicity and reprotoxicity; Persistence, Bioaccumulation and Toxicity and very Persistent and very Bioaccumulative; and endocrine disruption. Under other legislation, harmonised classification leads to specific risk assessments providing the basis for risk management, where the risk assessment is either carried out by authorities, agencies or scientific bodies or by economic operators.
4) Risk assessment or safety assessment requirements under sectoral legislation help ensure that exposures are reduced to safe levels.
5) Broader communication measures, such as the CLI and poison centre reporting obligations, reinforce and contribute to the effectiveness of the above activities.
6) Monitoring and enforcement activities of Member State authorities ensure the proper implementation of the legislation by economic operators.

These different requirements in combination deliver the benefits of CLP and the related chemicals legislation in terms of the extent to which the incidences of consumer, industrial worker and professional chemical-related accidents resulting in exposure and damages to human health and the environment have been reduced, as well as the incidence of occupational diseases and diseases within the general population. Quantitative estimates of benefits are discussed further in Section 5. It is clear though that there is the potential for the legislation to be more effective, with key areas for improvement set out below.

[25] ETUI (2015): Eliminating occupational cancer in Europe and globally. Available at http://www.etui.org/Publications2/Working-Papers/Eliminating-occupational-cancer-in-Europe-and-globally

[26] See the forthcoming Cumulative Benefits of Chemicals Regulation, or RPA et al (2016): Study on the calculation of the benefits of chemicals legislation on human health and the environment – Development of a system of indicators, for DG Environment. Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf

3.2.8.1 Legislative gaps

Gaps in the legislation framework which impact on its effectiveness include (see also Section 7):

- A lack of requirements under the Cosmetic Products Regulation for classification of intrinsic environmental hazards, leading to a lack of information for both consumers and authorities (Annex II, Section 3.2; Annex III, Section 7.4);

- The lack of classification obligations for food and feeding additives, resulting in a lack of information for employers and consumers on their intrinsic properties (Annex II, Section 3.2);

- A lack of information on hazard identification and communication, exposure assessment, identification of risk management measures, or the provision of transport information in relation to consumer articles under the General Product Safety Directive, such that economic operators are not provided with clear indications of the types of chemical hazards that should be considered when ensuring their products are safe (Annex III, Section 4.6);
- Lack of a definition of what constitutes an allergen in the Cosmetic Products Regulation, which is considered to lead to the potential for a (and indeed the expected actual) lack of harmonised application of the requirements across the single market (Annex III, Section 4.2).

3.2.8.2 Requirements regarding allergens

There are differences in the number of allergens that are regulated under different pieces of legislation; this may be appropriate given the different scopes of the legislation, but reason for the differences is not clear.

Currently, 26 fragrance allergens require labelling under the Cosmetic Products Regulation, with a further 11 being restricted from use. The Scientific Committee on Consumer Safety (SCCS)[27] has recommended, however, 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 has 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 (Annex III, Section 4.2). Member State authorities have also raised concern in response to this study, in particular with respect to leave-on products which are more stringently regulated under the Cosmetic Products Regulation.

With respect to effectiveness, then, it is clear that the SCCS has identified more fragrance allergens than are currently regulated in terms of labelling or other requirements. It also appears that the inclusion of fragrances within different products is increasingly being used as a means of market differentiation. In terms of effectiveness, increased labelling of fragrance allergens would allow consumers to make informed choices and, where necessary, avoid substances that they are allergic to (Annex III, Section 4.2).

The evaluation study undertaken by Technopolis *et al.* in 2015 of the Toy Safety Directive (Annex VI, Case Study 8) also identified the regulation of allergens as an issue.

[27] 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

3.2.8.3 Criteria for endocrine disruptors

The endocrine disruptors Roadmap[28] is focused on the setting of criteria for the Plant Protection Products Regulation and the Biocidal Products Regulation but highlights the differences in wording with respect to their regulation across the legislative framework. Most significant are the qualifiers that exist in the legislation in terms of the strength of the causal relationship, with approval under the Plant Protection Products Regulation and the Biocidal Products Regulation relating to those substances "that may cause" endocrine disrupting effects, while under the REACH Regulation and Medical Devices Directive it is those "for which there is scientific evidence of probable" effects. Where endocrine disruptors are addressed, they are managed in the same way as CMRs and PBTs, which is dependent on the legislation concerned. For consumer and professional products this is through risk management based on generic risk considerations with the possibility of derogation based on specific risk assessment (Annex IV, section 2).

These differences 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).

After significant delays, the Commission has now 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, therefore, the potential for criteria to be non-harmonised across the legislation raises concerns over coherence and costs. As a result, no judgement can be made as to the merit of also having a definition within CLP, although all stakeholders have argued for the need for a consistent set of criteria to apply horizontally across all legislation for endocrine disruptors (Annex III, Section 4.5).

The delays in establishing the appropriate criteria will have had impacts on the functioning of the legislation and its ability to ensure a high level of protection for human health and the environment. Due to the scientific uncertainties surrounding the effects of endocrine disruptors, stemming from a lack of evidence and difficulties in testing for effects, as well as differing scientific views on whether there is a threshold for effects or not due to repeated exposures, bioaccumulation and mixture effects, it is difficult to assess how significant this gap in available criteria has been in terms of the increased incidence of human health or environmental effects.

3.2.8.4 Generic risk considerations versus specific risk assessment

There are two approaches which can be taken for the risk management of hazardous substances: regulation based on generic risk considerations; or regulation based on specific risk assessment. When a substance is subject to risk management based on generic risk considerations, it is based on the intrinsic properties of the substance and generic assumptions regarding exposures and hence risks; the key properties triggering automatic bans are carcinogenicity, mutagenicity, reprotoxicity,

[28] 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

PBT properties (persistence, bioaccumulation and toxicity (PBT), and endocrine disruption. Chemical and use specific considerations are not taken into account. Although this lack of consideration of exposure may only be important in a small number of cases, it may still be important. It is presumed that the rationale for not taking account of information on the route and level of exposure is based on arguments over the need to be precautionary with respect to exposures over the life-time of the chemical (i.e. during use, for bystanders, via the environment and for the environment). However, this generic risk approach may be leading to over-regulation where the route of exposure (e.g. via oral route inhalation, inhalation, etc.) is not relevant to 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, even though there may be no potential for exposure via the relevant route from those mixtures (e.g. if inhalation is the issue but the end products would not be inhaled) or from other life cycle stages.

Under some legislation, generic risk considerations which result in bans on use (unless derogated) are automatically triggered as a result of a certain hazard classification or when certain properties are met. This is the case with legislation such as the Biocidal Products Regulation, Plant Protection Products Regulation and the Toy Safety Directive. Derogation or exemption from a ban may be granted under these different acts following the submission of a request for derogation and supporting information from industry (including a risk assessment and under the Biocidal Products Regulation potentially information on technical feasibility and social interest). Although such triggers may be effective in terms of avoiding future damages to human health or the environment, the impacts may be disproportionate (in cases such as ethanol where the only proven route of exposure to cause carcinogenic effects is the oral route) or may lead to 'regrettable substitutions' (i.e. substitutions to as hazardous or more hazardous alternatives or which give rise to other equally damaging human health or environmental impacts (see Annex VI and Case Studies 10 and 11; other references are cited in Annex IV).

Furthermore, the inability to take technical feasibility and social interest or socio-economic factors into account may impact on the functioning of the single market, as well as impact on EU competitiveness. In this respect, the potential for technical and/or socio-economic derogations is considered important to the overall effectiveness (and efficiency) of the legislation across all three of its main objectives, and for consistency and coherence in regulation across different pieces of legislation (e.g. industrial chemicals versus biocides and pesticides).

In other cases, a hazard classification leads to the need for further assessment, which generally takes the form of a specific risk assessment where exposures are taken into account as part of the analysis. An example of this approach to risk management is given by the Cosmetic Products Regulation, where a harmonised CMR classification triggers a specific risk assessment, the findings of which may or may not allow derogation. Other examples include the REACH Restriction and Authorisation processes, as well as the requirements placed on Member States under the Water Framework Directive and employers under the Chemical Agents Directive. Industry and some Member States favour this approach as they believe it does not lead to the removal of substances that do not pose a risk due to their use characteristics. This is despite the fact that further assessment can be a lengthy process; it also may mean that hazardous substances remain on the market until they are deemed unsafe following risk assessment.

3.2.9 Protection of vulnerable groups

Under the generic risk consideration approach, the automatic triggers linked to CMR classifications provide a means of protecting vulnerable groups, as well as reducing exposures of workers and the

general population to such substances. Under the specific risk assessment approach, the routes of exposure of a substance are assessed depending on those that are relevant to the use of the substance, such as: children under three years of age, as well as the unborn; the elderly; pregnant and breastfeeding women; people with a compromised immune system; etc. Risk management measures are then based on the risks to such vulnerable populations, as well as other exposed populations (workers, nearby residents, the general population).

More generally, and in addition to the issues highlighted earlier with regard to allergens, an NGO has noted that there is a gap in the legislative framework with respect to endocrine disrupting chemicals, and exposures for women for example (Annex V, Section 3.12). For instance, under the Pregnant Workers Directive (92/85/EEC) endocrine disrupting substances are not identified as a risk and there is no obligation on employers to reduce exposure (although there is such an obligation with respect to reproductive toxins). This highlights an issue that may be impacting on the effectiveness of the legislation at protecting human health (see also Annex IV, section 4.2.1 and 6.1.3)

3.2.10 Single market, competitiveness, innovation and international trade

As of yet, sufficient evidence to conclude on the effectiveness of CLP implementation on the single market, competitiveness, innovation and international trade is not available. It is clear though that CLP has resulted in greater harmonisation than existed under the preceding system under the Dangerous Substances and Dangerous Preparations Directives, which were impacted by greater differences in national interpretation and implementation.

In addition, although industry may have found re-classification of all mixtures in particular a challenge within the timeframes allowed under CLP, they rose to the challenge. Companies made full use of the range of approaches that could be applied under CLP for the classification of substances and mixtures and, in a few cases, sectors responded by developing sectoral approaches to CLP's requirements. For example, the detergents sector developed the DetNet system to assist smaller manufacturers in classification and labelling, while the aerosols sector developed a global agreement on the test information to act as the basis for classification (Annex II, Section 11).

Despite the general view of stakeholders that the introduction of CLP has had a positive impact on the functioning of the single market, the evaluation has identified several factors hindering the functioning of the single market with respect to implementation of the legislative framework at the Member State level:

- Differences across Member States in the acceptance of the use of different methods for the classification of mixtures (Annex II, Section 4.3, Annex VI, Case Study 5);
- Variations in the willingness of Member State authorities to support harmonised classification dossiers under the Biocidal Products Regulation and Plant Protection Products Regulation (Annex II, Section 5.3);
- Variations in Member States with regard to the classification of plant protection products, although this should be being addressed through the regional approach to agreeing on classifications (Annex III, Section 4.5);
- Variations in approaches to and levels of enforcement, which work against achievement of the single market and the establishment of a level playing field for companies (Annex II, Section 11; Annex VI, Case Study 5).

These variations in implementation and enforcement have a number of consequences for innovation within the European chemicals industry. For example, it fails to reward those companies that comply with the legislation and which develop new, innovative products in response to the incentives that the legislation provides for reducing the use of hazardous substances. Furthermore,

industry stakeholders have also suggested that the nature of some legislative procedures discourage competition (Annex V, Section 3.7). Indeed, a number of industry stakeholders commented that, in their view, impacts on competitiveness of EU industry are generally not considered as part 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, however, they may not be re-considered when the rules are finally adopted and become law or when they are implemented.

Moreover, looking at the framework as a whole, it is evident that there are significant cumulative costs for industry arising from the legislation (as outlined in the Cumulative Cost Assessment for the EU chemical industry study[29] and Section 7 of Annex IV). It remains to be determined to what extent these costs have affected the international competitiveness.[30]

The UN GHS is still in a period of revision and adaptation, and has not yet been adopted fully by all countries, nor adopted in a harmonised manner by those who have adopted it. Two key differences have been identified which significantly impact on the extent to which the desired benefits in terms of international trade and competitiveness have been realised (Annex VI, Case Study 1):

- Differences in the sectoral scope of implementation across countries, for example, the fact that there is no implementation of GHS for consumer products in North America;

- Differences in concentration limits as part of classification for some key hazard classes such as Reprotoxicity, Respiratory Sensitisation, STOT SE and STOT RE impact on the extent to which classifications are harmonised globally. Discussions with the US OSHA, for example, have indicated that such differences were critical to them, as they helped ensure that adoption of the GHS criteria did not lead to a lowering of protection. This position is understandable; nevertheless, the existence of such differences has an impact on the extent to which non-tariff barriers to trade have been reduced through the introduction of GHS;

- In addition, given differences in the adoption of building blocks by different countries, as well as differences in requirements under national legislation, significant differences in labelling requirements continue to exist. Many EU companies have identified these differences in labelling requirements as being the most significant driver of additional compliance costs arising from a lack of global harmonisation (although companies were unable to indicate the magnitude of such costs).

3.3 What are the consequences or effects not originally planned?

Legislation can lead to unintended consequences. On the positive side, this may include spurring on innovation into new products, increasing competition in an unexpected manner, creating new trade opportunities or generating human health or environmental benefits not initially anticipated. On the negative side, the reverse may be true, with legislation having knock-on effects for the users of chemicals which were not anticipated and which impact on all of the above aspects.

[29] Technopolis et al (2016): Cumulative Cost Assessment for the EU Chemical Industry. Available at: http://ec.europa.eu/growth/sectors/chemicals/ec-support_en

[30] As part of the fitness check, the Commission is undertaking a study on the 'International Comparison of Cumulative Regulatory Costs for the Chemical Industry – Considerations on competitiveness issues concerning the sector' (results pending).

It has been difficult to identify positive unintended consequences as these are not foremost in the mind of consultees and are rarely ever reported in the literature. The most significant positive unintended consequences that have been identified are as follows:

- The aerosols sectors has taken advantage of the introduction of CLP to agree at the global level what test methods will be used for classification purposes, with this helping to ensure that barriers to market entry in general are reduced. This type of sectoral level achievement was not originally planned for and is important for competitiveness and trade reasons.

- The potential increased trade opportunities for some European products, such as cosmetics, due to the automatic mechanisms triggered under the Cosmetic Products Regulation with regard to the presence of CMR substances. This has led to media campaigns by NGOs and companies within the US regarding the higher safety level of EU cosmetics. This may in turn have provided some market opportunities to the sector, although this has not been verified.

With respect to negative unintended consequences, these relate to unnecessary regulatory burdens as well as the effects of the generic and specific risk assessment approaches. They also include issues that have been addressed or are being addressed:

- The original obligations regarding poison centre notifications were not expected to lead to the high costs that companies later identified. This issue is now being addressed, but has been a major concern for industry (see Section 8.3.2 of Annex II for further details).

- A review of the ATP process finds that the EU has fully adopted and implemented changes made at the UN level into CLP up to the fifth revised edition of GHS (implementation of the sixth revised edition is currently on-going). This is consistent with the commitments stated in Recital (6) of CLP. However, many of the revisions carried out to date have been for clarification purposes, definitional purposes or have involved minor changes in the classification criteria or in the wording of various hazard and precautionary phrases. These are not considered to have significantly impacted on the quality of hazard communication, but at the same time have led to high costs to industry and a waste of labelling and in some cases packaging resources. Although there are unlikely to have been single market effects, there may have been impacts on EU competitiveness (see Section 9.3 of Annex II for further details).

- Failure to bring forward criteria for identifying endocrine disruptors under the various pieces of EU legislation. The delay in bringing forward criteria will have led to on-going impacts to the environment and human health related to the continued use of endocrine disruptors; however, it has also impacted on regulatory certainty for those whose products may or may not be affected by the final criteria. Such regulatory uncertainty reduces the willingness of companies to invest in new product development given the high costs this can involve (see Sections 4.2.2 and 4.4.2 of Annex III and Section 3.5.4 of Annex IV).

- When endocrine disruptor criteria are finally agreed, the automatic triggers (generic risk considerations) that exist in the Biocidal Products and Plant Protection Products Regulations for these, as well as PBT and CMR properties, may in themselves lead to unintended consequences (e.g. impacts on the feasibility of growing certain crops, pesticide resistance, etc.). The extent to which this is the case will depend on the criteria, but also on the chemical products that are affected. The agricultural sector's fears regarding the loss of effective products to control pests, for example, and hence increases in crop damage and resistance may be well founded; similar concerns have been expressed by the coating sector,

which fears losing the ability to incorporate biocidal properties into water-based coatings, with potentially significant impacts for human health[31] (see Section 6.1 of Annex IV for further details).

- As discussed above, harmonised classification under CLP leads to automatic bans on the use of substances classified as CMR Cat 1A and 1B under a range of legislation based on generic risk considerations, but may also stigmatise a substance; together these can lead to impacts on downstream supply chains and associated unintended consequences, including regrettable substitutions, impacts on resource efficiency and on achievement of other goals such as recycling and the circular economy[32] (e.g. as highlighted by the lead case and the potential impacts of differences in the end classification, Annex VI, Case Study 11; see also Section 4.4 of Annex III and Sections 3.3, 6.1 and 6.2 of Annex IV). Failure for technical feasibility and socio-economic factors to be taken into account may lead to significant consequences not only for industry, but also human health and the environment. Various suggestions have been put forward as to steps that could be taken to address this issue, including the use of a form of Risk Management Option Analysis or adaptation of some of the downstream legislation to better enable technical feasibility and socio-economic factors to be taken into account following the use of specific risk assessments.

- Once a harmonised classification is agreed under CLP, a transition time of 18 months from its entry onto Annex VI is allowed for. This period is considered by industry to be too short for compliance with classification and labelling obligations within a complex supply chain. More importantly, though, it may also be too short for downstream users to identify how best to respond in the medium to long term. Identifying alternative substances or technologies may take longer than 18 months, however, the need to act quickly (e.g. to a substance newly being classified as a carcinogen) may instead lead to investment in short term solutions, such as increased personal protection, or to the adoption of another substance within the same family (i.e. to undertake a regrettable substitution) (see Section 5.4 of Annex II, and Case Study 10, Annex VI). Although users of a substance could establish that a substance is going through the classification process, as this information is available in the registry of intentions on the ECHA website, SMEs have shown a lack of awareness (Annex V, Section 2.6.3).

[31] 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 easy substitutes that can 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.

[32] See for example, Abelkop et al (2014), Lofstedt (2014) and EC (2012) which argue that adopting a precautionary approach 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.

3.4 What factors affect the correct functioning of the legislative framework for hazard identification and risk management?

3.4.1 Overview

A wide range of factors in isolation and in combination impact on the correct functioning of the chemicals legislative framework. We set out below what we believe are the most important factors having a positive impact and the most important having a negative impact. This does not mean that other factors do not affect its functioning, only that these are not considered as significant as those highlighted below.

The factors that have the biggest positive impact on the functioning of the legislative framework are the following.

- CLP provides the starting point for self-classification and the identification of properties of concern for almost all related legislation, with this establishing a harmonised basis for industry to meet its classification obligations under the various legislation and a consistent starting point for any subsequent risk management. In addition, the related legislation is generally coherent in terms of the criteria used to identify properties of concern, with inconsistencies being addressed by the relevant agencies and scientific bodies. There are some gaps, but this overall coherence lays the groundwork for the proper functioning of the legislation (see Section 4 of Annex III for further details).

- The agreement of harmonised classifications under CLP is one of the cornerstones of EU chemicals policy, with the processes and procedures introduced by ECHA and its Risk Assessment Committee helping to ensure that decisions are based on high quality data and that there is transparency for all stakeholders. As harmonised classifications provide the basis for risk management in downstream legislation this is essential. Although there is room for improvement across a number of aspects, this component of the system is generally held in good regard and must be considered to have a significant positive impact. This view is supported by the majority of stakeholders (see Section 3.3.10 of Annex V).

- The labelling requirements that apply across the legislative framework are viewed by all stakeholders as having had a positive impact on human health and the environment. This includes not only labelling as a direct result of CLP but also the additional labelling that exists under other legislation such as the Cosmetic Products Regulation (see Sections 7.3, 7.4 and 7.6 of Annex III). There are some gaps and potential overlaps in labelling, but these can be addressed (see Section 7.2 of Annex V and Section 7.5 of Annex III for further details).

- Finally, significant efforts have been put into the development of guidance, 'Frequently Asked Questions' and helpdesk support by Member States, Agencies and the Commission. This has been invaluable to stakeholders. The national helpdesks for CLP and REACH are highly appreciated by stakeholders and considered very effective, with their also being good cooperation between helpdesks, e.g. HelpNet (see Section 3.3.26 of Annex V).

The factors that in our view have the biggest impact on the negative functioning of the legislation are, in part, ironically also linked to the most positive factors. Starting with those that are separate from the factors listed above, we believe the following key factors having the greatest negative impact on the functioning of the legislation are as follows.

- The complexity of the legislative framework. The legislative framework includes linkages not only between CLP and other legislation with respect to the identification and communication of properties of concern and risk management considerations, but also between pieces of horizontally and vertically linked legislation. Although this may help ensure consistency, it also makes it difficult for some stakeholders, such as SME companies, to keep up to date with changing requirements and to participate in key processes. Perhaps more importantly, it leads to the potential for more than one scientific body to provide conflicting opinions regarding substance classification and hence risk management requirements for specific chemicals. In particular, issues arise with respect to the parallel hazard assessment processes undertaken by the RAC and EFSA, but differences in dose-response functions between the RAC and SCOEL also give rise to some confusion. So far there is only one case of conflicting opinions that need to be resolved, but a large number of CMR substances will come up for re-approval in the future (see Case Study 3, Annex VI). Efforts are being taken by the Commission to find ways of avoiding misalignment in the future (see Sections 6.4 and 6.5 of Annex IV and Case Study 3 in Annex VI for further details); this is important to avoiding potential for the uneven treatment of chemicals within the legislative framework.

- The 'effectiveness' and 'efficiency' of harmonised classifications for substances depends upon their scientific quality and integrity. Although most commentators agree that classifications are based on robust data and science, others believe that there have been weaknesses in some of the science used in the past. In particular, industry has raised issues regarding metals classification (see Case Study 2, Annex VI for further details), but there also have been cases where industry has questioned the science underlying classifications. Lead and gallium arsenide both provide examples of cases where industry strongly challenged original classification proposals on these grounds (see Case Study 2 in Annex VI).

- Related to the above and to the benefits of the harmonised classification process is the resource intensity of the process. This is currently limiting the extent to which all Member States are actively preparing dossiers. Constraints exist on the level of human resources but also on the expertise available within authorities to prepare such dossiers. The burden of such work is therefore falling disproportionately on a subset of Member State authorities, impacting on effectiveness (see Sections 5.3 and 5.4 of Annex II for further details).

- As noted in Section 3.2.6, there is a need to better optimise hazard communication to consumers as some CLP pictograms are deemed to be poorly understood. Many stakeholders have also highlighted that the increase in information included on product labels is an issue as it can make it difficult for downstream users to focus on the essential hazard information. There is agreement across different stakeholder groups that additional awareness raising campaigns would assist in increasing the understanding of hazard communication elements of product labels and that further investigation should be carried out into the potential use of innovative technologies (such as Q-R codes and bar codes) (see Sections 7.3, 7.4 and 7.5 of Annex IIII for further details).

3.4.2 Balance between risk management based on generic risk considerations and based on specific risk assessment

Hazard classification under CLP is considered to be an appropriate starting point for risk management decisions. The general consensus across all stakeholders is that it is appropriate for different pieces of legislation to adopt different approaches, as they are concerned with different sectors and end-users. The key question is whether the balance is right.

Risk management based on 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.

For example, the consumer sector contains 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. This may be important as it may not be possible to attribute health effects linked to CMR substances in all cases (health effects are most commonly attributed to workplace exposure) and it may not always be possible to ensure that consumers are not exposed through the use of products containing CMRs.

With regards to PBTs and vPvBs, market restrictions are precise and clear, relatively easy to implement (although search for alternatives can be more difficult due to the resources needed) and enforce. Conditions of use included in product authorisations are less easy to implement (see Section 6.2.2 of Annex IV for further details).

The specific approach to risk management is often dependent on lengthier assessment processes and expert judgement in the peer review following a risk assessment. This is not considered a negative by industry, 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 (see Section 6.4 of Annex IV for further details). 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 potential for significant socio-economic costs and unintended consequences.

In particular, the effectiveness of the automatic triggers in legislation that already requires detailed and extensive chemical-specific risk assessment requirements is questionable. These specific risk assessments should in themselves provide an indication of the level of risk associated with the continued use of a substance, across exposure scenarios. Furthermore, they should reflect the properties and modes of action which lead to the triggering of generic risk considerations (i.e. the potency of a carcinogen, the level of persistence or toxicity of a PBT, hazards related to only one route of exposure, endocrine disruption, etc.). 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 ensures that risk management decisions are based on the acceptability of residual risks. This reinforces that classification decisions remain fully science-based, avoiding the need to consider the downstream consequences at the classification stage or to introduce derogations.

NGOs in general hold an opposing view, arguing that where the generic risk approach has been adopted it is the most appropriate means of ensuring the protection of human health and the environment. 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 seeking a more risk assessment based approach across all downstream legislation (see Section 6.1 of Annex IV for

further details). Of course, many Member State authorities and NGOs also recognise that there is a need for both types of approach with it being more of a question as to which approach is most appropriate and when.

Derogations and exemptions can prevent the unnecessary removal of a substance from the market where it can be proven that under foreseeable conditions of use, the substance is considered to be safe. The additional derogation criteria that exist under the Biocidal Products Regulation could be extended to other legislation to address concerns over the lack of technically feasible alternatives or the societal interest in a chemical remaining available for use in products falling under sectoral legislation. This would help in adding balance to the use of this approach; it would also help address concerns over the potential societal impacts that the loss of key substances may have to other sectors, such as in relation to plant protection products.

More generally, substitution is considered to be a key risk management measure for protecting human health and the environment, although the requirements for substitution vary across the chemicals legislative framework. The majority of the pieces of legislation (the Biocidal Products Regulation, Cosmetic Products Regulation, Food Contact Materials – plastics, Plant Protections Products Regulation, Toy Safety Directive, Ecolabel, Industrial Emissions Directive, Carcinogens and Mutagens Directive, Chemical Agents at Work 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 (see Section 6.2.1 of Annex IV for further details).

3.4.2.1 Predictability of decisions of the two risk management approaches

There is no general consensus on the predictability of risk management decisions. Stakeholders have highlighted positives and negatives with respect to the predictability, consistency and transparency of decisions under certain pieces of legislation.

A generic approach to risk management can be considered to be more predictable than a specific risk assessment approach, as the risk management decision is clear and is not dependent on further assessment. Risk management decisions under the Biocidal Products Regulation, Plant Protection Products Regulation (marketing bans) are predictable because they are based on an identified status based on intrinsic properties, e.g. PBT/vPvB. Under the OSH legislation, it is clear what risk management measures must be undertaken in order to protect workers' health. Predictability and consistency is not an issue as certain classifications will require certain actions, such as a C or M classification requiring an employer to enact the risk reduction hierarchy as is feasibly possible (see Section 6.2 of Annex IV for further details).

Predictability of risk management decisions can be more difficult when it is based on the specific risk assessment approach and requires the input of a committee. The specific risk assessment approach can be lengthy and it may be 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). Transparency of committees can be key to predictability. Some committees, such as ECHA's Risk Assessment Committee are considered to be very transparent, while others are not considered to be as transparent and stakeholders have raised concerns over the consistency of decisions arising from committee opinions (e.g. EFSA) (see Section 6.1.2 of Annex IV for further details).

The findings of the Open Public Consultation indicate that stakeholders, in general, have a low level of satisfaction with regards to the predictability of outcomes from risk management processes from chemicals legislation with Group 1 (citizens) and Group 2 (industry) providing the lowest ranking (suggesting that they are least satisfied) (see Section 3.3.12 of Annex V for further details).

Offsetting this concern over predictability is the fact that specific risk assessment is more precise, as it takes into account the exposure scenario and risk of the specific substance.

3.5 To what extent are the main elements of the legislative framework effectively implemented across EU Member States?

The discussion provided above highlights the importance of harmonised implementation to the effectiveness of the legislative framework, across its three main objectives. This implementation relies on the activities of the Commission, different EU agencies and scientific committees, as well as the actions of Member State authorities. The discussion provided here focuses on implementation and enforcement activities rather than consistency in opinion forming or decision making for example, which is addressed in more detail in Section 7 on Coherence.

3.5.1 Consistency in implementation and enforcement

The evaluation has found that, in general, there is reasonable consistency in national implementation of the legislative framework (see Section 12.3 of Annex II for further details).

- Around half of industry respondents (54%) to the targeted consultation agreed that CLP is consistently implemented at the national level across the EU, although there are some sectors which would disagree with this statement (e.g. the detergents sector). Authorities also noted that the various agencies and the Commission generally implement the framework in a consistent manner, although some exceptions were also identified;

- Member States are increasingly working together to coordinate enforcement actions, although, as expected, differences exist due to differences in regimes, resources, etc.;

- Worker representatives and NGOs are less convinced that there is consistent implementation with respect to downstream legislation, although many of these issues relate to consistency with wider EU policies in achieving the three main objectives of chemicals legislation.

In addition, although there is significant variation in numbers across Member States, the 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 remained relatively consistent over the period from 2010 to 2014, increasing from 38,400 to 42,000; the total number of organisations subject to enforcement activities across the MS varied from 12 in Luxembourg and the UK to over 1.8 million in France (see Section 12.4, Annex II).

As noted earlier, though, variations in national implementation mean that the single market is not currently harmonised with respect to classification and labelling activities, nor in the enforcement of some of the downstream legislation that has vertical linkages to CLP. Respondents to the Open Public Consultation (see Annex V, Section 3) identified issues with regard to consistent enforcement of requirements under OSH legislation (Chemical Agents Directive and Carcinogens and Mutagens Directive), varying national interpretations of some of the requirements under the Biocidal Products Regulation (e.g. labelling, classification of biocidal products), differences in Member State implementation of the Seveso Directive, and differences in implementation of the waste legislation. Indeed, the existence of such national differences in the implementation of directives leads some consultees (see for example Section 3.3.31 of Annex V for further details) to suggest that the system should continue its move away from Directives towards Regulations (although presumably not away

from all Directives). Nevertheless, CLP has helped, in general, to ensure regulatory consistency and single market functioning within the EU, beyond that which could be achieved at the national level (as discussed further in Section 8).

In addition to issues raised earlier regarding mixture classification, amongst Member States, 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 such test data and fear accepting false negative results (see Section 5.2.5 of Annex III for further details). As a result, there is variability in the approaches of authorities on their acceptance or non-acceptance of non-animal test data under the different legislation.

3.5.2 Actions to support implementation and enforcement

It is clear that considerable effort has been expended at both the EU and the national level to ensure that there are measures in place to support implementation of the legislation and its enforcement.

- The CLEEN project report on e-commerce looks at trends in online chemicals trade in select European countries, noting the number of illegal offers and acts of non-compliance over the period from 2004 to 2012. The report notes that in 707 of the 1,289 cases identified, authorities had the offers removed from the Internet sites, which had the effect of intercepting and blocking the attempted sales.

- The EU's Rapid Exchange System for information on dangerous non-food products (RAPEX) had nearly 2,500 notifications in 2014. 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.

- Guidance has been developed to assist national authorities and industry in the implementation of the legislation. In some cases, further guidance may be needed with a focus on either specific issues (such as the bridging principles for mixture classification, guidance on metals classification, use of weight of evidence approaches, etc.) or to meet the needs of specific groups such as SMEs (see Sections 4.3 and 4.4 of Annex II and Section 5.2 of Annex III for further details).

- The FORUM is a good tool for discussions between Member States regarding enforcement actions and their comparability. In particular, the REACH EN-FORCE projects (which also cover CLP related issues) provide an effective tool for ensuring harmonised enforcement of the legislation (see Sections 12.3 and 12.4 of Annex II for further details).

- Enforcement networks exist under other legislation (e.g. biocidal products, toys, RoHS) which also help ensure that Member States are working towards a more harmonised approach (see Section 12.3.2 of Annex II and Section 8.3 of Annex IV).

- Country specific reporting requirements, for example, on CLP and REACH also provides a mechanism for regular monitoring and evaluation of the level of activities being carried out at the Member State level (see Section 12.4 of Annex II for further details).

The majority of stakeholders from each group (i.e. citizens, industry public authorities and NGOs/others) consider guidance documents and supporting materials to be effective in providing support and assistance in understanding the requirements of the legislation within the legislative framework. However, Member States suggested that there are areas where more guidance is

needed, for example, health classification of solid metals, strategy for classifying alloys (health and environment), bridging principles, weight of evidence, and a clearer definition of bioavailability. SMEs were also identified by authorities as needing further support, including from the Commission. It is particularly beneficial when guidance is made available centrally (via the Commission or ECHA) because it strengthens harmonisation and reduces work across Member State authorities (see Sections 3.3.12 and 3.3.26 of Annex V for further details).

Industry and Member State authorities also argue that the lack of clarity of legal texts has resulted in the need to produce large quantities of guidance documents. Even so, the amount of information that one needs to assimilate can make it difficult for stakeholders (and particularly SMEs) to fully understand the legislation due to a lack of time and resources.

3.5.3 Use of the safeguard and emergency procedures under CLP

Much of the legislation considered in this study has provisions which equate to a safeguard clause or an urgency procedure, to enable Member States to address situations where they believe there is a serious risk to human health or the environment. The safeguard procedure in CLP has been used only once, with this being the Netherlands Decree regarding the packaging and labelling of electronic cigarettes and refillable cartridges, in order to protect small children from poisoning incidents and those who may become addicted to nicotine. No other authorities have considered use of the safeguard procedure. Member State views on its appropriateness are mixed; some see it as an important instrument which enables emerging issues to be addressed quickly and others believe its use can lead to a lack of harmonisation across the single market and should not be needed if the legislation is functioning properly (see Section 10.2 of Annex II for further discussion).

Under Article 54(4) of the CLP Regulation, an urgency procedure is provided for when "*the normal time limits for the regulatory procedure with scrutiny cannot be complied with, …".* Commission Regulation (EU) No 1297/2014[33] (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 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).

3.5.4 Enforcement of risk management measures

No strong conclusions stem from the evaluation research regarding the enforcement of risk management measures under downstream legislation, other than those that are implied from the findings regarding a lack of harmonised enforcement (further details are provided in Sections 3.3 and 8 of Annex IV). The lack of harmonised enforcement stems from both different approaches to enforcement, as well as varying levels of resources. As indicated in Section 12.4 of Annex II, some Member States have highlighted difficulties associated with enforcement with these including constraints on human and financial resources, difficulties in finding testing facilities and problems with obtaining information from long supply chains (particularly those outside of the EU).

[33] 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

4 Efficiency

4.1 Introduction

As noted in Section 2 (and Annex I), efficiency concerns the relationship between the inputs to and the outputs of the chemicals legislation framework, as well as whether there may be more efficient (i.e. less costly) ways of achieving the objectives of the legislative framework. The two core questions to be addressed by the analysis are:

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 drivers 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?

As for the other criteria, there is a series of more detailed questions supporting each of these (see Table A2-2 of Annex I). It is of note that some of these more detailed sub-questions on efficiency overlap with questions on effectiveness. Where this is the case, we have reported on the findings under the most appropriate criterion.

4.2 The costs and benefits associated with the implementation of the legislative framework for chemicals

4.2.1 Overview

The Commission identified a range of evaluation questions as being relevant to efficiency with respect to the costs and benefits associated with the legislative framework. The most important of these in our view are:

- 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?
- What are the costs associated with the chemicals legislative framework for: regulators at EU and national level; industry, including SMEs; workers; consumers; society / economy in general?
- What are the benefits associated with the chemicals legislative framework for: regulators at EU and national level; industry, including SMEs; workers; consumers; society / economy in general?
- To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits?

The starting point for the assessment of costs and benefits are the categories as defined in the Better Regulation Toolbox. This defines the following types of costs:

- **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 set out under the legislation. ***Hassle costs*** include the costs associated with corruption, annoyance and waiting times;

- **Indirect Costs:** these are costs 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. For the purposes of this study, our attention was 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; and
- **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.

Benefits are defined in terms of the following:

- **Direct Benefits:** these relate to the direct benefits of the regulatory measures for the well-being of individuals; 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 through as improved market efficiency and better functioning of the single market, and associated cost savings due to the removal of any non-tariff barriers to trade; and
- **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 Gross Domestic Product (GDP), etc.

Given the scope of this study, it has not been possible to assess all of the costs and benefits associated with CLP and related chemicals legislation. Instead, and as required under the terms of reference, the work has focused on estimating the transition costs of moving from the Dangerous Substances Directive and Dangerous Preparations Directive to CLP, as well as the ongoing costs associated with CLP compliance. These costs are estimated on the basis of a "no legislation" counterfactual, rather than on the basis of what Member States may have implemented in the absence of EU legislation. Where available either from impact assessments, research reports or responses to the consultation carried out for this study, additional information on the costs and benefits under other legislation are also reported.

Quantification has been carried out to the extent possible. In the case of benefits, quantitative estimates have been developed for the reduction of certain types of diseases, as well as in poisoning incidents. Additional benefits data are provided where available from existing studies.

4.2.2 Transition costs of moving to CLP

A number of different sources of information have been used to support estimation of the transition costs of moving to CLP. These included for example the 2006 Impact Assessment carried out prior to the adoption of CLP, Eurostat data, the Classification and Labelling Inventory, data from other REACH related studies, and data collected from the targeted industry consultation carried out for the purposes of this study. These different sources are reported on in detail in Annex II.

Drawing from these sources, transition costs were estimated based on a series of assumptions as to the percentage of substances and mixtures that would require classification (i.e. would meet the criteria for being hazardous) and which would not have otherwise been classified according to CLP for export purposes. The sensitivity of the cost estimates to different assumptions has been assessed and estimated errors/cost ranges have been provided alongside the cost estimates. The types of costs taken into account include those related to classification, labelling, SDS revision and distribution, packaging costs, upgrading IT systems, staff training, CLI notification costs and costs associated with reformulation or the withdrawal of products.

Based on Eurostat data and assumptions regarding the sectors that are assumed to have incurred transition costs under CLP, estimates of the number of companies likely to have been affected were developed. These are as set out in Table 4-1 below. Note that the sectors assumed to be affected include those covered by the Cumulative Cost Assessment study[34] and the study on Inspection requirements for REACH and CLP[35]; these are the sectors which are directly impacted by the transition to CLP.

Table 4-1: 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**

4.2.2.1 Costs of classification, labelling, SDS revision, IT systems and staff training (CAPEX[36])

Based on estimates for the number of substances (over 99,000) and the number of mixtures also (with a lower bound of 2 million and an upper bound of 2.5 million) subject to reclassification, labelling and SDS preparation, as well as the costs of updating or purchasing new IT systems and undertaking staff training regarding the transition, total costs for the transition from the Dangerous Substances Directive/Dangerous Preparations Directive to CLP by 1 December 2010 for substances and by 1 June 2015 for mixtures were calculated. These costs are based on the approach set out in the Standard Administrative Cost Model. The total costs and ranges are as follows:

- 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).

These estimates are significantly higher than those developed for the 2006 Impact Assessment. Taking the most appropriate scenario from the 2006 study, total costs were estimated at 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

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

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

[36] CAPEX refers to capital expenditure and entails the costs incurred by companies on human and physical capital in complying with the legislation.

figure of 99,000 assumed in this study). This difference will have a significant effect 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; this has a significant effect on the mixture-related costs. The per unit costs for both studies show a strong correspondence (Section 6 of Annex II provides further details).

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 on the losses associated with the removal of these products. Although one can assume that any product removed from the market is substituted with another, 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 issues were not explored in detail for this study, but other research in the context of REACH will provide further discussion and examples.

4.2.2.2 Administrative burden of first time notification to the Classification and Labelling Inventory

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. 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.

As of May 2016, information is held on over 123,000 notified and registered substances on the database and, in total, ECHA indicates that more than 6.5 million separate notifications have been made to the CLI. The estimated administrative burden associated with industry fulfilling these notification obligations is between €49 million and €63 million (Section 8.2 of Annex II provides further details).

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. 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. ECHA has taken measures to reduce the burden for potential notifiers but also notes that it is the obligation of notifiers and registrants to improve the reliability and the convergence of the classification data.

4.2.2.3 Transition costs to other stakeholders

The total capital costs (CAPEX) to ECHA of developing the CLI were in the range of €1 million, with annual operating expenditure (OPEX) of around €0.2 million (see Section 8.2 of Annex II for further details).

Other stakeholders will also have incurred transition costs with the move to CLP. For example, Member States will have incurred costs in adopting the Regulation and removing previous national legislation from their books. They will also have incurred costs in familiarisation with and training on CLP, so as to understand differences. Similarly, citizens and NGOs will have incurred costs in familiarisation and training, as will industry associations which will also have developed training programmes for their members (see Section 6 of Annex II for further details). No estimates are available on the likely magnitude of such costs.

4.2.3 Ongoing costs associated with the legislative framework

There will be a range of ongoing or recurring costs (and benefits) associated with the legislative framework. This includes costs to regulators at the EU and national level, to industry, to workers, to consumers and to society / the economy more generally. It is impossible within a study such as this to capture all such costs. The best that can be achieved is to try and identify the range of costs and benefits that are of relevance, to provide quantitative estimates where possible and indications otherwise of the likely significance in qualitative terms. As mentioned above, the costs being estimated here are based on a counterfactual of "no legislation" rather than what Member States may have implemented in the absence of EU legislation.

4.2.3.1 Responses to the Open Public Consultation and SME Panel on costs and benefits

The Open Public Consultation asked questions about the significance of different types of costs and benefits, to gain qualitative views from across the range of stakeholders. These results are discussed in detail in Annex V, with responses summarised in Table 4-2.

Table 4-2: Percentage of respondents indicating different types of costs were likely to be significant for companies (n=269)

Cost	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]
Classification requirements for substances and mixtures	6	25%	100	57%	12	36%	7	18%
Chemical labelling and packaging requirements	6	25%	102	59%	8	24%	9	24%
Risk management measures under the different legislation	1	4%	127	73%	14	42%	16	42%
Understanding and keeping up-to-date with changes in legal requirements	5	21%	147	84%	9	27%	16	42%
Training staff to ensure compliance with legal requirements	3	13%	106	61%	8	24%	9	24%
Inspections and administrative requirements	1	4%	100	57%	6	18%	9	24%
We do not view the business costs of meeting EU chemicals legislation to be significant	2	8%	2	1%	2	6%	9	24%
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'

As might be expected, industry perceptions of the significance of different types of costs vary considerably from those of other stakeholders. Perhaps more interesting is the fact that "understanding and keeping up-to-date with changes in legal requirements" is identified as a significant driver of costs by the highest number of companies (84%), followed by the costs of risk management under the different legislation. To a degree, this reflects the fact that all companies have to keep up-to-date with requirements, while only a sub-set will be affected by risk management obligations.

Similarly, some 60% of SME respondents to the SME Panel Survey identified that they incurred significant costs on an annual basis in complying with CLP and/or other chemicals legislation (other than REACH). The most common response was training of staff to ensure compliance with legal requirements, with 48% of SMEs incurring such costs on an annual basis; 45% of respondents also identified annual costs in understanding and keeping up-to-date with changes in legal requirements.

4.2.3.2 Costs to industry - CLP

Using data collected from the targeted questionnaire and previous studies, estimates have been derived for the costs of the ongoing implementation of CLP, with these defined in Table 4-3 below. These costs are expressed as per company, per annum costs (OPEX), except for the annual costs of employing FTEs and the costs of reformulation. Total annual costs are calculated by multiplying the relevant per unit figure by the number of companies or products that would be affected. The central estimate for total cost is associated with a range of ±30%. Again, 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 the cost burden it should be borne in mind that, in the absence of CLP, equivalent national Member State legislation might otherwise have been in place. There is, however, no means of gauging what this would have been and the cost burden associated with it (Section 7.2 of Annex II provides further details).

Table 4-3: Data collected for each cost type for ongoing costs	
Direct Costs	**Cost elements for which estimates have been generated**
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	Poison centre reporting obligations
Hassle Costs	Costs of checking CLI
Indirect Costs	
Indirect compliance Cost	Opportunity cost of removing a product line from the market

The central estimate of total annual costs across substance and mixture manufacturers is €1.3 billion per annum (with a range of €0.97-1.7 billion) without poison centre reporting obligations. The best (central) estimate of the costs of poison centre reporting are given as €1.7 billion (€1.2-2.2 billion), assuming the Commission's September 2016 proposal to harmonise information requirements.[37] Together, this leads to a grand total (CAPEX and OPEX) central estimate of costs of around €3.0 billion (within the range of €2.1-3.9 billion).

[37] 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).

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). Note that the per company figures should be treated very much as being indicative, especially for SMEs, as there will be wide variations in the actual incidence of these costs across different types of companies (e.g. a fertiliser manufacturer with only a few products in his portfolio versus a formulator serving the industrial and consumer sectors).

Furthermore, it ought to be noted that, in the absence of CLP, those companies placing products in multiple Member States would have incurred costs of a similar (if not larger) magnitude in order to comply with the different national legislative requirements relating to classification and labelling in each Member State.

It is also important to compare these figures to those derived for the Cumulative Cost Assessment (CCA) study[38] was commissioned by DG GROW with the aim 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 CCA 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. The study estimated that REACH, the Plant Protection Products Regulation and the Biocidal Products Regulation 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. Note that the CCA will have classed poison centre reporting requirements as an administrative burden (as done for this study), with these estimated by the CCA to equate to roughly €780 million across all sectors. This is below the estimate of €1.7 billion quoted by the poison centre study carried out by Kirhensteine et al (2015) (see Section 7.2 of Annex II for further details).

4.2.3.3 Costs to industry – related chemicals legislation

Three different approaches to risk management exist within the legislative framework:

- Possibility 1: risk measures are triggered automatically under the generic risk approach;
- Possibility 2: risk measures are triggered only after further assessment;
- Possibility 3: risk measure is defined following further assessment by Member States or economic operators.

The case study work (Annex IV, Case Study 11) illustrates the potentially significant costs that can arise to businesses as a result of linkages between downstream legislation and CLP. For example, it highlights the role of legislation which relies on possibility 2 or 3, for example the Carcinogens and Mutagens Directive, in driving substitution and controls on exposures while allowing the continued use of CMRs and other hazardous substances, where this is critical (Gallium Arsenide, Case Study 11) or where alternatives may also pose risks (Formaldehyde – see also Case Study 10). The case study

[38] 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

work also highlights the potentially significant impacts that may arise to manufacturers, downstream users and society when using generic risk considerations, if there is no potential for derogation (MBM, Case Study 11). Even where there are direct risk management requirements, indirect effects due to market perceptions may result in significant impacts, for example due to the impacts of a change in labelling on the acceptability of a product to consumers. Case Study 11 illustrates this using data produced by industry in relation to lead, but this point is also made clearly by the detergents sector; numerous respondents noted that they had undertaken reformulation activities in order to avoid placing products on the market with a hazard classification (any or an increasingly stringent one) due to consumer perceptions.

As noted above, the CCA considered not only the costs related to CLP, but also other chemicals legislation. Overall, the study found that, during the period 2004-2014, the cumulative costs for the EU chemical industry due to legislation approaches €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, chemicals legislation around 29% (as discussed above) 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% (see Section 7.5 of Annex IV for further details).

Although the study provides estimates (in terms of percentages of the total cost) of the costs attributable to the different legislative packages, it is not possible to estimate share associated with 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 under previous legislation, e.g. for Plant Protection Products and Biocidal Products Regulation.

A range of additional information was collected from literature review and from consultation, and in particular from responses to the Open Public Consultation, with respect to the costs to industry arising due to either generic risk considerations or the specific risk assessment approach. Detailed discussion of the qualitative and quantitative evidence is presented in Annex IV. Table 4-4 presents the quantitative estimates from the literature review for specific pieces of legislation.

Table 4-4: Costs of legislation reported in previous studies - See Annex IV, Section 7 for further details

Legislation	Estimated costs	Source
The Seveso Directives	One-off costs: **€22.4m - €54.9m** Annual costs: **€5.1m - €7.5m** Annual cost savings: **€0.5m**	Seveso III Impact Assessment - estimates administrative costs only
	€0.1m - €100m (not specified if this is annual or one-off)	Stakeholder consultation
	One-off costs: **€0.05m - €0.1m**	Case study 13
Plant Protection Products Regulation and Biocidal Products Regulation	Total cost of yield loss for 7 staple crops owing to ban of 75 substances: **€14.3bn**[1]	Cumulative Impact of Hazard-Based Legislation on Crop Protection Products in Europe (2016)
	Total costs (spread over 10 years): **€193.6m - €706m** Total cost savings (spread over 10 years): **€2.7bn - €5.7bn**	BPR Impact Assessment (2009)
	Cost of discovering, developing and registering a pesticide active ingredient: **€320 million**	Study by Phillips McDougall

Table 4-4: Costs of legislation reported in previous studies - See Annex IV, Section 7 for further details		
Legislation	**Estimated costs**	**Source**
Cosmetic Products Regulation	Cost of reformulating and remarketing a product due to a change in a key ingredient: **€12,000** - **€920,000** depending on role of ingredient, availability of alternatives, etc.	Study for US Food and Drug Administration
Carcinogens and Mutagens Directive	Variable across individual substances; in total **€17-60 billion**	Impact assessment for proposal to establish new or revised OELs for 13 priority chemical agents (2016)
Toy Safety Directive	Option 3, banning allergenic substances and all CMR cat 1 and 2 unless derogated: **€15,859** million	2008 Impact Assessment
Note: [1] This figure concerns the full risk assessment; it is not possible to isolate the costs attributable to CLP.		

4.2.3.4 Costs for national authorities

56% of Member State authorities responding to the open public consultation indicated that there are requirements in the chemicals legislative framework that lead to significant costs. These include costs associated with implementation activities, compliance monitoring and enforcement activities, as well as reporting activities. Although no quantitative estimates of costs have been provided, key remarks regarding the types of costs incurred by authorities are given below (see Section 3.3.18 of Annex V for further details).

Implementation of the legislation

Implementation activities include for example participation in expert groups and scientific bodies, undertaking own research and bringing forward regulatory proposals, as well as fulfilling risk assessment and other obligations such as those under the Biocidal Products Regulation and Plant Protection Products Regulation as part of the authorisation of active substances. With regard to costs, Member State authorities note:

- Risk assessments are very costly, especially when the burden of proof is on authorities and not on industry (and that this is not in line with the polluter pays principle);
- The so-called "unless-clause" in the uniform principles for decision-making in the framework of the authorisation of plant protection products opens the floodgates to an excessive use of more and more complex and extensive higher tier methods by applicants in their dossiers. This has led to a considerable increase in the expenditure of competent authorities in the risk assessment, partly exceeding the limits of their capacity;
- RoHS exemption renewals and applications consume a significant amount of resources and time for authorities because of the open scope under current RoHS legislation; and
- The implementation of chemicals control legislation is time- and resource-intensive. 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 as a result.

The latter point is illustrated by looking at the involvement of different authorities in bringing forward dossiers for the harmonised classification and labelling of substances; the majority have been prepared by only a subset of Member States, with other authorities acknowledging that they do not have the resources or in some cases expertise.

Compliance monitoring, inspection and enforcement

Compliance monitoring and inspection are carried out at the national level, and the associated costs will depend on the way in which it has been organised and the approach of the Member State. These costs will also include those incurred in undertaking enforcement actions such as levying fines or taking offenders to court. Data available from the REACH-EN-FORCE projects indicates that on average over 2,000 inspectors are trained on REACH and CLP per annum, at an annual cost of around €1.7 million; this figure would clearly be higher if training inspectors to meet the needs of other legislation was included.

Regimes are also in place under the related chemicals legislation. For example, for plant protection products there are audits of Member States' enforcement of obligations throughout the distribution chain at farm level, etc., with these audits carried out by the Commission (although reports on these audits do not provide any data on the costs incurred by Member States as part of enforcement[39]).

Respondents note that meaningful inspection regimes to ensure legislation is being properly implemented require staff who are scientifically and technically competent in the industry being regulated. For example, for the Water Framework Directive, significant skills are required in sampling, sample management followed by analytical capability and capacity.

(Industry's perspective is that not enough is being spent on market surveillance and enforcement, in order to stop non-compliant goods, such as dangerous toys, from entering the EU. They view the current market surveillance system as ineffective and inefficient; some note that the EU must urgently unblock the product safety and market surveillance package to create a more harmonised system which equips market surveillance authorities with better financial and human resources).

Reporting obligations

Member State authorities note that there are substantial costs to the enforcement agencies related to unnecessarily bureaucratic reporting duties. For example, respondents to the Open Public Consultation noted that chemical data needs to be reported to numerous authorities due to numerous requirements. This includes the potential need for a company to undertake reporting to ECHA, the Commission (ozone depleting substances, etc.), to other national authorities (workers' safety, Seveso, the environment, VOCs, fluorinated gases, etc.). This leads to costs both for authorities and for enterprises, which are significant. Note that it is understood that this issue is being examined as part of DG Environment's fitness check on environmental monitoring and reporting[40].

4.2.3.5 Costs to ECHA

Data taken from the publicly-available reports setting out ECHA's budgets indicate that 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. (see Annex II). 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.

[39] http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

[40] http://ec.europa.eu/environment/legal/reporting/fc_overview_en.htm

4.2.3.6 Costs to consumers and citizens

The main 'costs' for consumers and citizens identified for this study include those related to inaction, stemming from ongoing risks to human health or the environment from chemical exposures. Three areas have been highlighted below where these remain a concern, although there will be others. It should be recognised though that consumers and citizens may also be impacted by the following:

- Loss of consumer products due to bans or restrictions on the use of substances, and where there is no technically feasible or cost-effective alternative;
- Loss in the quality of consumer products, where alternatives are less efficacious;
- Impacts on the availability but also quality of jobs, stemming from the loss of production activities within the EU; and
- Loss of competitiveness, where EU production costs rise compared to those for operators outside the EU.

Several different sectors have raised qualitative arguments with respect to the above. For example, the EU toy sector has argued that while it supports in general the legislative requirements under the Toy Safety Directive, the lack of enforcement of restrictions on the use of certain substances for imports puts them at a competitive disadvantage. Studies prepared for the crop protection sector have also argued that the potential loss of pesticides within the EU due to generic risk considerations will put the EU agricultural sector at a disadvantage compared to producers outside the EU, with knock-on effects for land use and food security.

Carcinogens

In 2008, 2.45 million people were diagnosed with cancer and 1.23 million died of cancer in the then EU-27 countries. The estimated costs of cancer in the EU were put at €126 billion in 2009, with health care accounting for €51.0 billion (40%), productivity losses due to early death accounting for €42.6 billion, lost working days accounting for €9.43 and informal care accounting for €23.2 billion. Lung cancer had the highest economic cost (€18.8 billion), followed by breast cancer (€15.0 billion,), colorectal cancer (€13.1 billion) and prostate cancer (€8.43 billion).[41] In 2012, it was estimated that cancer caused the death of 1.75 million people in the EU, affecting around 980,000 men and 780,000 women. In the same year, approximately 3.45 million new cases of cancer were predicted.[42]

The fraction of cancers attributable to working conditions – i.e. occupational cancers – is estimated at between 4% and 8-12%[43]. In the UK for example, 5.3% of cancer deaths were attributable to occupation (8.2% in men and 2.3% in women) in 2005, with this equating to over 8,000 people (over 6,360 men and around 1,660 women).[44]

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[41] Luengo-Fernandez et al (2013): Economic burden of cancer across the European Union: a population-based cost analysis, Published online October 14, 2013, www.thelancet.com/oncology, http://dx.doi.org/10.1016/S1470-2045(13)70442-X)

[42] Ferlay et al (2013): Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012, European Journal of Cancer, 49, pp. 1374–1403.

[43] http://www.etui.org/content/download/7515/71981/file/Occupational+cancer+the+main+challenge+for+the+new+Community+Strategy.pdf

[44] Rushton et al (2010): Occupation and cancer in Britain. British Journal of Cancer, April 27;102(9):1428-37.

Endocrine disruptors

A number of studies have developed estimates of the costs to society in relation to male reproductive health and other endpoints associated with exposures to endocrine disruptors. By way of illustration, the recent study on "The Costs of Inaction"[45] developed estimates of the total tangible and intangible costs to society in relation to male reproductive health, with costs calculated at around €59 million for an assumed 2% of the diseases covered being directly attributable to chemical exposures (higher attributable fractions were also considered but there will be much greater uncertainty linked to such estimates, particularly as the assumed fractions are not consistent with those used by the World Health Organisation or OECD). At this point in time, there is clearly considerable scientific uncertainty regarding the true magnitude of such impacts, although this study highlights their potential significance. Indeed, other studies[46] have put the figures at much higher values, in part because they cover more diseases but also due to the scope of the substances which are considered (including substances which have been banned in the EU for several years) and other methodological aspects. In addition to the human health impacts considered by such studies, there will also be impacts on the environment, including impacts on particular species and on ecosystems more generally.

Allergens

Allergens are also an important issue as an estimated 1-3% of the EU population has a skin allergy to fragrances, with the Scientific Committee for Consumer Safety (SCCS) reporting that around 16% of eczema patients in the EU being sensitised to fragrance ingredients. 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[47]. It is the most common chronic disease in the EU at a prevalence of greater than 20% of the population[48], with this predicted by the European Academy of Allergy and Clinical Immunology to rise to around 40% of the European population having an allergic predisposition by 2040. In terms of the associated economic costs, in the UK alone, an estimated £900 million per annum was spent on primary care related to allergens in 2004[49]. As a range of factors have been identified as possible causes (increased diagnosis, increased allergen exposure, excessive cleanliness, sedentary lifestyle, etc.), it is not possible to link changes in chemicals regulation to trends in the prevalence of allergies. However, the figures highlight the potential significance of ongoing allergenic effects, where these can be linked to chemical exposures (see Section 4.4 of Annex III for further details).

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[45] Olsson, Ing-Marie et al (2014): The Costs of Inaction: A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Norden.

[46] Rijk et al (2016): Health cost that may be associated with Endocrine Disrupting Chemicals. Institute for Risk Assessment Sciences, Utrecht University. Available at http://www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf

[47] 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

[48] 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

[49] 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

Persistent, Bioaccumulative and Toxic (PBT) chemicals

Different studies place varying figures on the number of substances that may meet criteria for being PBT, with a percentage of around 3% of industrial chemicals often cited as an upper bound based on screening studies, and lower bound estimates putting a much lower figure on the total number (e.g. below 100). Given the nature of these substances and the fact that they persist within the environment, there is no easy way of placing an economic value on the damages that they cause. A recent study carried out for ECHA's Socio-Economic Analysis Committee developed benchmark costs of somewhere between €1,000 and €50,000 per kg PBT substituted, remediated or emission reduced.[50] Clearly this is a very wide range, illustrating the difficulties involved in estimating the damage costs associated with ongoing emissions for this set of substances.

4.2.4 Ongoing benefits of CLP and related chemicals legislation

As for costs, there will be a range of benefits associated with the legislative framework, including benefits to regulators at the EU and national level, to industry, to workers, to consumers and to society / the economy more generally. A summary of these is provided below. It is impossible to attribute benefits of the availability of classification and labelling information solely to CLP, as it is the requirements of downstream legislation which result in risk management measures being taken. Similarly, rarely is it possible to attribute a disease to a sole source of exposure.

4.2.4.1 Responses to the Open Public Consultation on benefits

It is clear from the responses that most respondents believe there have been significant benefits from the legislative framework in terms of reducing exposures of consumers, citizens more generally, workers and the environment to hazardous chemicals (as indicated in Table 4-5, overleaf). The reverse is true with respect to 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 (with the exception of NGOs and others); stimulating competition and trade within the EU single market; or stimulating international trade between the EU and other countries (Section 3.3.15 of Annex V provided further details). The latter two types of benefits in particular are not considered to be significant drivers of benefits.

4.2.4.2 Benefits to industry

Table 4-5 indicates that industry believe there have been benefits from the legislative framework related to reductions in human health and environmental impacts which not only accrue to individuals and society more generally, but also to businesses. Reductions in lost working days due to occupational diseases can lead to significant reductions in employee sickness related costs. The magnitude of these potential savings were illustrated earlier). Similarly, a cleaner environment can reduce the costs that companies face, e.g. in water purification to ensure that it is of an appropriate quality for manufacturing purposes.

[50] IVM Institute for Environmental Studies (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances - a report for the Dutch Ministry of Infrastructure and the Environment; by Oosterhuis, F & Brouwer, R - Report R-15/11, 21 September 2015. http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

Table 4-5: Percentage of respondents indicating different types of benefits (n=284)								
Benefit	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]
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%
Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.	14	54%	151	85%	34	92%	40	91%
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%
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%
Stimulating competition and trade within the EU single market	1	4%	8	5%	8	22%	8	18%
Stimulating international trade between the EU and other countries	2	8%	7	4%	7	19%	4	9%
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'								

In addition, the harmonisation introduced by the legislative framework provides benefits to industry; for example, it provides legal certainty, which in turn helps industry prioritise its own production, research and development activities. In this respect, legislation can also act as a driver of innovation. Furthermore, harmonisation also helps ensure that there is a level playing field across the single market, reducing intra-EU barriers to trade. This also increases competitiveness within the market, leading to benefits to consumers.

As indicated in Table 4-5, however, not all benefits are viewed as significant by most industry respondents to the Open Public Consultation: only 10% of respondents identified innovation as a benefit whilst only 4% and 5% identified benefits relating to the stimulation of extra-EU trade and competition and trade within the single market, respectively (further details are provided in Section 3.3.15 of Annex V). The findings of Case Study 1 also support these responses, concluding that the implementation of CLP in the EU and GHS in other countries has not impacted either negatively or positively on international trade or the competitiveness of the EU chemicals industry.

4.2.4.3 Benefits to regulators

The framework will also reduce some of the burden faced by Member States, by enabling them to share efforts (and hence resources) at the European level in the implementation of the legislative framework. These benefits have not been quantified, but it is clear that they will be particularly significant for those Member States that have lower levels of resources and who may find it difficult to put in place effective national systems covering all of the areas addressed by the chemicals legislation covered by this study.

In addition, Member States will benefit from reductions in the damage costs associated with chemical exposures. For example, health care systems will face lower costs as levels of occupational and other diseases attributable to chemical exposures continue to reduce. National, regional and local authorities will face lower costs where accidental releases to the environment of hazardous substances reduce the need for costly remediation and clean-up activities. Similarly, improvements in environmental quality may reduce the costs to public authorities for the provision of drinking water supplies. There will obviously be other such examples (see Section 7.3 of Annex II and Section 7 of Annex IV for further details).

4.2.4.4 Benefits to consumers and citizens

The main benefits considered in this study are those related to reductions in chemicals exposures that arise from the CLP Regulation and the role that classification and labelling data plays in reducing 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.

4.2.4.5 Quantified benefits

Although trying to quantify such benefits is not straightforward, indicative figures have been developed for a subset of the likely actual benefits that can be estimated and expressed in monetary terms (see Sections 7.3 and 7.4 of Annex II for further details). Estimation is limited to a subset of human health parameters and benefits because quantification of several (indeed most) human health parameters and all 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.

As with the ongoing costs (OPEX), the benefits have been calculated on the basis of a 'null counterfactual' reflecting a present where there is no regulation. Owing to the paucity of data before 2000 and the timing of the changes and extensions made to the system of classification, packaging and labelling under the DPD 1999/45/EC, the year 2000 has been taken as the baseline but benefits since 2008 (and CLP) have also been estimated. Table 4-6 below provides a summary of the human health benefits for which monetary valuation can be attempted (a full description of the estimation of the benefits is provided in Section 7.3 of Annex II). 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. As noted above, 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 benefit 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. Rather, these represent the (continuing) benefits of a system of classification, packaging and labelling in combination with those realised due to the linkages between CLP and related chemicals legislation.

Table 4-6: 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 (consumers and general public)	€ 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 (consumers and general public)	€ 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**

In addition to the benefits captured within the above estimates, studies carried out on the relevant downstream legislation have also provided estimates of benefits, which are relevant. For example, a recent study carried out by the UK HSE provides an analysis of the potential economic impacts of accidents at major hazard sites and finds that the costs of an accident could be significant (demonstrating the value of their avoidance through legislation such as Seveso). The HSE work

performed modelling for all 1,700 major hazard sites in Great Britain[51] for three main hazard types associated with overpressure, flammable and toxic effects. Analysis followed an impact pathway approach, and considered the potential accident related 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 should an accident occur are €153 million (mean) and €36 million (median), with the results varying significantly by type of activity (e.g. chemicals used on site and processes). These figures stand up well against the estimated damage caused by the major accident at Buncefield.

Unfortunately, neither the impact assessment for the Plant Protection Products or for the Biocidal Products Regulations provide a quantitative assessment of benefits, although qualitative assessments suggested that there would be significant environmental and human health benefits. The more recent impact assessment for this legislation and definition of criteria for endocrine disruptors does provide some estimates, as indicated in the table below (and based on the Cost of Inaction study referred to earlier). Additional estimates are given for the Toy Safety Directive and the Carcinogens and Mutagens Directive.

Table 4-7: Benefits of legislation reported in previous studies – for further details see Annex IV, Section 7

Legislation	Estimated benefits	Source
Plant Protection Products Regulation and Biocidal Products Regulation	Cost savings (tangible and intangible) relating to male reproductive health: **€59m as a lower bound**	Defining criteria for endocrine disruptors in context of PPPR and BPR - Impact assessment (2016)
Toy Safety Directive	Option 2 banning allergens and CMR Cat 1 and 2: **€14,755 million**	Toy Safety Directive - Impact assessment (2008)
	Option 1: **€31bn** Option 2: **€29.4bn**	Impact assessment study on the health costs due to children's exposure to lead via toys and on the benefits resulting from reducing such exposure
Carcinogens and Mutagens Directive	Variable across individual substances; in total **€35-90 billion**	Impact assessment for proposal to establish new or revised OELs for 13 priority chemical agents (2016)

4.2.5 Are costs proportionate to benefits?

Given the difficulties surrounding quantification of the benefits of the chemicals legislative framework, it is hard to make strong conclusions regarding the extent to which costs are proportionate to benefits.

On the positive side:

- It is clear that the legislative framework is reducing the burden of occupational diseases and is impacting on the number of annual poisoning incidents, with the benefits quantified by this study equating to between €217 to €338 million per year quantified health benefits. These estimates do not take into account the potential damage costs associated with exposures to endocrine disruptors and allergens, and only reflect a very small proportion of

[51] Great Britain consists of England, Scotland and Wales, but not Northern Ireland.

the costs that are predicted as being attributable to the occupational cancer burden. In addition will be the environmental benefits from reduced chemical exposures;

- The annual costs are higher than anticipated in the original CLP impact assessment, however, some proportion of these will reduce over the next few years as the REACH 2018 deadline passes. One would expect classification, SDS and labelling costs to decrease after 2018 to a lower level annually (this also applies to the estimates reported under the CCA);

- Some of the decisions taken at the time of adopting CLP relating to the choice of GHS building blocks (hazard classes and categories) will have reduced the cost burden of its requirements. In particular, the benefits of adopting the following categories would have been unlikely to outweigh the costs: Acute toxicity, cat 5; Skin corrosion/irritation, cat 3; Aspiration hazard, cat 2B; and Acute hazards to aquatic environment, cat 2 and cat 3;

- Some of the legislation does effectively include provisions which help ensure that actions required under the legislation are either cost-effective or proportionate. The Water Framework Directive is a prime example.

On the negative side:

- The extent and complexity of the legislative framework impacts on the costs incurred by industry and will continue to be a factor in terms of both the number of FTEs required by companies to comply with the legislation and/or the "hassle costs" of keeping up-to-date and understanding the legislation due to its complexity;

- The anticipated benefits with respect to international trade have been realised by only a small percentage of companies, with classification and labelling differences (in particular) across different jurisdictions continuing to pose non-tariff barriers to trade for most sectors. The extent of the differences has decreased, but this has not yet translated to significant reductions in costs. SMEs in particular have not realised such benefits. Given that GHS is still at an early stage in the global implementation, these findings are not unexpected;

- The EU's decisions under the 2nd and 4th ATPs to adopt minor changes in labelling requirements (in line with their adoption at the UN GHS level) have led to disproportionate costs. The health and environmental benefits associated with such changes are considered to be marginal at best, while industry incurred significant costs in making such changes. In particular, sectors with long product lives or which print labels directly onto packaging (such as aerosols) will have been impacted. Although there are unlikely to have been single market effects, there may have been impacts on EU competitiveness (Section 9.3 of Annex II provides further details);

- To date, transition periods of 18 to 24 months have been allowed under the various ATPs. These appear to be too short for many 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. These time frames are particularly difficult for long supply chains (see Section 9.3 of Annex II);

- With respect to transition times linked to the entry into force of a harmonised classification, these again may be too short in that they may result in regrettable substitutions or companies adopting risk management measures in the short term based on readily

identifiable actions rather than more fundamental research into alternative technologies or processes. In other cases, they may be too short to enable companies to respond to the need to submit additional risk assessment information (e.g. in relation to the use of a carcinogen under the Toy Safety Directive);

- While further consumer research is needed to verify the response to CLP labels, the high presence of pictograms and hazard/precautionary statements on consumer goods is likely to lead some consumers to become inured to the hazards that mixtures (mainly) pose, reducing the ability of the hazard communication to deliver its intended benefits. As a result, the legislation will be both less effective and efficient than it should be in meeting its objectives.

- The automatic triggers that exist as part of generic risk considerations may lead to disproportionate effects, given that they do not take into account substance and exposure specific factors, or technical and economic feasibility. In this respect, derogations (and exemptions) are important to ensuring that proportionality is a consideration within risk management; for example, a derogation has been granted in the past under the Toy Safety Directive for the use of nickel with this justified on risk grounds. In particular, the lack of derogations under the Plant Protection Products Regulations (and which is inconsistent with those for biocidal active substances) may result in disproportionate costs. In the case of cosmetics, the timeframe for submitting evidence for and gaining the opinion of the SCCS for a derogation has been highlighted as a concern. Stakeholders do not believe that there is enough time to complete this process before a CMR substance enters in to Annex II and is banned, with this possibly leading to disproportionate impacts (see Section 6 of Annex IV, and Case Study 11, Annex VI for further details).

4.3 What aspects of the functioning of the framework are the most and least efficient?

The efficient functioning of the legislative framework depends not only on whether the costs and benefits arising from it are proportionate, but also where the processes and procedures are efficient, whether the same results could have been achieved in a more cost-effective way, whether other tools could have improved the efficiency of risk management and whether there are significant differences as regard the benefits, costs and administrative burdens.

In terms of those aspects that contribute the most to the efficient functioning of the framework:

- The reliance of CLP as the basis for classification across almost all other legislation will have increased the efficiency of the legislative framework; requiring classification for identified properties not covered by CLP only in that legislation where those properties are relevant to legislative action is also likely to have helped maintain the proportionality of the costs and benefits (see Section 4 of Annex II for further details);

- The level of coherence that exists with respect to the criteria for identifying properties of concern is also considered to help ensure the efficient functioning of the framework. In particular, this relates to CMRs, PBTs and allergens, and to endocrine disruptors with respect to biocidal products and plant protection products (as currently proposed). This should increase efficiency for both industry and for the regulatory bodies involved in the legislation (ECHA, EFSA, SCCS, etc.) (see Section 3.7 of Annex IV for further details);

- Because of the above aspects, together with requirements for new testing being done to GLP standards, data can be shared across legislative acts. Although undertaking new tests to GLP standards can increase costs by up to 30%, it helps ensure regulatory acceptance of test data and the avoidance of further testing requirements. Together, these should help reduce the costs to industry of meeting data and risk assessment requirements (see Section 5.2 of Annex III for further details);

- Guidance and IT systems exist to assist companies in meeting their classification and labelling obligations, as well as risk assessment related obligations. Although some commentators complain about a "plethora" of guidance, others praise the efforts that have been made to produce guidance at the EU level (reducing the efforts needed by Member States), to make it accessible and to take into account the needs of SMEs. In some cases, further guidance may be needed (with simpler flow charts, etc.), but such efforts help improve the harmonised application of the legislation as well as the ease of compliance (see Section 5.2 of Annex III for further details); and

- The existence of the risk management based on generic risk considerations (triggered by a hazard) contributes to the efficient functioning of the legislative framework in terms of the clear signal it provides on the types of hazardous substances which should be avoided under sectoral legislation; however, it also works against the efficient functioning of the system in that it may lead to unjustified (in economic efficiency terms) outcomes based on risk assessment and socio-economic considerations. This may be appropriate where vulnerable populations are at risk (e.g. children under the Toy Safety Directive), but less appropriate in other cases, especially where exposures are minimal or would not occur through the route of concern (see Section 6 of Annex IV for further details).

With regard to the least efficient aspects of the legislation, the key findings are as follows:

- The implementation of CLP across the Member States is still not fully harmonised. This leads to costs for Member State authorities in discussing reasons for differences with industry, as well as increased costs for industry in having to meet varying national requirements. This lack of harmonised implementation relates mainly to mixture classification and the acceptability of the use of different principles, but also applies to other aspects such as the use of fold-out labels. Only 50% of SMEs responding to the SME Panel survey were positive in terms of the extent to which there was a harmonisation of chemicals legislation across Member States (see Section 2.6 of Annex V for further details). Responses to the targeted consultation and Open Public Consultation were even less positive.

- Related to the above, most industry stakeholders (64%) and a significant percentage (one third) of other stakeholders believe that enforcement of CLP is not harmonised across all or most Member States. This lack of harmonisation in enforcement will impact on the efficiency of CLP implementation for Member States (i.e. it may increase the overall level of enforcement required) and industry, in terms of the extent to which the intended benefits are realised across the single market (see Section 12.3 of Annex II for further details);

- The potential for disagreement between the RAC and EFSA regarding the proposed classification of an active substance used in plant protection products can have significant impacts for industry due to the uncertainty that it creates. If it was clear from the start what the harmonised classification of a substance would be, then stakeholders may not go through the expense of trying to renew their approval (see Section 6.2 of Annex III and Section 3.7 of Annex IV for further details);

- The pace of agreeing harmonised classifications, given that these are the cornerstone of the legislative framework. ECHA has taken action in this regard, for example, to speed up the process for agreeing non-controversial classification proposals. This should be welcomed by both Member States and industry, who have expressed concern 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 have to be processed (see Section 5.2 of Annex II). However, the evaluation also finds that the burden of developing harmonised classification dossiers currently falls on relatively few Member States;

- In line with the above, the length of time that it is taking for some elements of the legislation to address health and environmental impacts results in the legislation being inefficient in addressing such effects – one could also argue that this is one of the reasons that some stakeholders are so strongly against removal of risk management triggers based on generic risk considerations. The key example cited is the timeline for endocrine disruptors. If the legislative process were more responsive, there may be less demand for generic, hazard-based triggers (see Section 3.5 of Annex IV for further details);

- The lack of a consistent set of criteria for the classification of metals (massive versus powder) and their alloys is leading to inefficiencies in the classification process and additional cost burdens. Addressing this issue will reduce such burdens and provide industry with greater certainty across a range of legislation given the importance of classification decisions to downstream legislation (see Case Study 2 in Annex VI for further details);

- Some of the timelines within the processes lead to inefficiencies, as they impact on the extent to which stakeholders (industry and non-governmental) are able to participate or interact. As discussed above, too short timelines may impact on companies' ability to apply for derogations and for these to be processed (e.g. under the Cosmetic Products Regulation) may also lead to inefficient final decisions. Timelines for decision making have also been identified as a source of inefficiency, in particular, after decisions regarding a harmonised classification have been passed from ECHA to the European Commission;

- The allocation of the burden of work is currently inefficient. The bulk of harmonised classification obligations are falling on a subset of Member States, which impacts on the extent to which classifications are being agreed in a timely manner for biocidal products, plant protection products and industrial chemicals. Several Member States believe that responsibility for producing harmonised classification dossiers under the Biocidal Products and Plant Protection Products Regulation should be shifted to industry; they argue this would speed up the process and would not impact on effectiveness given that such dossiers are subject to review by ECHA in any event. DG SANTE dispute this view as they believe that dossiers produced by Member States help guarantee the quality of the CLH dossier and that there are resources available to minimise the burdens placed on Member States. EFSA is also of the opinion that the current system does not need to be changed. However, it is clear that Member States do not always take forward a CLH dossier prepared by industry (see Section 6.4 of Annex III for further details);

- There are currently inefficient reporting obligations under the CLP, with obligations regarding the notification to the Classification and Labelling Inventory (other than as part of REACH registration) representing an inefficiency given the quality of the data and its low reliability. Of more importance, however, are reporting obligations with respect to poison centres. Assuming that the estimate of €1.72 billion is correct, then this obligation has very high costs which compared to other CLP obligations, although its contribution to benefits is

unlikely to be as important as CLP's classification and labelling requirements (see Section 8 of Annex II for further details); and

- 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. In addition, there is currently no official approach under the Regulation for undertaking an assessment of the risks associated with the use of a fertiliser. This creates an issue from the perspective of the regulator because there is no efficient approach to removing a substance from the approved list (see Section 6.5 of Annex III and Section 6.1 of Annex IV for further details).

5 Relevance

5.1 Introduction

The relevance of the legislative framework is evaluated here in terms of whether or not the identified problems that necessitated the introduction of the legislation still exist. It considers the extent to which the activities required under the legislation actually addresses the identified needs. It may be the case that the problems the legislation initially sought to address are no longer relevant or no longer exist, or that the objectives of the legislation no longer accord with the wider goals of the EU chemicals legislative framework.

The three core questions with respect to relevance are as follows:

- 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?

Each of these is examined in more detail below.

5.2 Do the objectives meet current needs?

5.2.1 Introduction

Fundamental to evaluating the relevance of the legislative framework is understanding whether or not it meets current needs. Evaluation of this overarching question is based on a series of further sub-questions. To avoid repetition, we focus on the following sub-questions:

- Do the original needs still exist or are parts of the chemicals legislative framework now redundant? Have new needs emerged in relation to the risk management of chemicals? If yes, what are they?
- To what extent do the objectives of the legislative framework meet the need for enabling/promoting the circular economy? Are there conflicting objectives and how can they be solved? Are there synergies? Which of the risk management approaches is more effective and efficient in enabling/promoting circular economy?
- Does the chemicals legislative framework reflect and implement the basic principles of EU environmental policy stated in article 191 of the Lisbon Treaty (the principles of precaution, substitution, polluter pays and rectification of environmental damage at source)?
- 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)?

- To what extent are the chosen approaches to risk management (based on generic risk considerations or specific risk assessment) still relevant?

- To what extent does the legislative framework allow for innovative approaches to hazard and risk communication?

5.2.2 Do the original needs still exist?

The main objectives of the EU chemicals legislative framework is 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 given that the reduction of exposure to hazardous chemicals remains important, while at the same time recognising that chemicals will remain fundamental to economic activities within the single market and be present in day to day products. Ensuring that legislative requirements are harmonised across the single market helps ensure that all citizens of the EU benefit, as well as ensure that there is a level playing field for companies placing products on the EU market. This is also important for competitiveness and innovation. As such, the original needs of the EU chemicals legislative framework remain.

Some gaps remain within the legislative framework, however, meaning all relevant 'needs' may not have been addressed. The most important relates to having a better legislative means of ensuring that the use of hazardous substances in consumer products is minimised, either through modification of the General Product Safety Directive, the introduction of horizontal legislation spanning the consumer product sectors not already covered by chemicals specific requirements (see Section 7.3.1 below and Section 4.6 of Annex III), or another approach. In addition, there is a general view amongst all stakeholder groups that the combined effects of chemicals are not sufficiently taken into account within the legislative framework. As indicated in Section 4.2.4 above, this issue was identified by the Commission in 2012[52] based on findings that current EU legislation does not provide for a comprehensive and integrated assessment of the cumulative effects of chemicals, for example, through an integrated and co-ordinated assessment of mixtures across the different pieces of legislation. The communication also concludes that while methodologies for the identification of chemical mixtures of potential concern 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. There is also a lack of test methods for identifying combination effects (see Section 4.6, Annex III and Section 3, Annex IV). As discussed below, there are also gaps related to classification for environmental hazards, e.g. to the terrestrial compartment.

5.2.3 Do objectives meet the need for enabling the circular economy?

Assessing the interaction between the EU chemicals legislative framework and the circular economy is a large task. 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[53].

[52] 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.

[53] Ellen MacArthur Foundation (2015) Available at: https://www.ellenmacarthurfoundation.org/circular-economy/overview/concept

The material flows within such a system 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 – the generic risk or specific risk approach – is the most efficient, effective and relevant, as they both may have advantages and disadvantages. On the one hand, NGOs, some Member States and some in industry stakeholders argue that a generic risk approach has advantages in that it ensures that hazardous substances are removed from products, facilitating their recycling. On the other hand, stakeholders from these same groups recognise the generic approach may 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 approach based on risk assessment 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 (further details are provided in Section 3.6, Annex IV).

5.2.4 Does the legislative framework implement the basic principles of EU environmental policy?

Article 191 of the Lisbon Treaty lays out the objectives for environmental policy in the European Union, with this based on 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 has a generic approach to risk management, consistent with this principle, and which bans their use in biocidal products and plant protection products, unless the derogations can be met (see also Section 3 of Annex IV). Similarly, legislation such as the Waste Framework Directive is based strongly on Article 191 of the Lisbon Treaty, and is also clearly relevant to achieving circular economy goals. For example, it 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 (e.g. extended producer responsibility)[54]".

It should be noted though that the environment is not considered in all pieces of chemicals legislation. Cosmetics and toys do not have a focus on the environment. As discussed in Section 7.3 (and Section 7.4.2 of Annex III), there is an argument for not considering the environment in cosmetics legislation, but there is also a strong argument for including it.

5.2.5 Relevance of risk management approaches

The different stakeholder groups have varying views on the appropriateness of risk management based on generic risk considerations compared to specific risk assessment, for substances of very high concern, such as CMRs. In this respect, it must be noted that these views can vary by piece of legislation, e.g. industry are not always in favour of specific risk assessment and Member States are not always more in favour of generic risk considerations; similarly, some in civil society are pro specific risk assessment while others are strongly pro generic risk considerations.

The evaluation finds that the approaches to risk management adopted within the different legislation are generally relevant, and that they take into account the different population that may

[54] 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

be affected and associated exposure scenarios. In this respect, generic risk considerations and specific risk assessment approaches are relevant (see Section 6 of Annex IV), if not necessarily efficient.

However, the evaluation also highlights the importance and relevance of there being derogations from the automatic bans on use in order to prevent the removal of a substance when this may not be warranted when exposure and risks are taken into account, when there are no feasible alternatives and where there would be significant social/socio-economic implications. At present, most derogations are risk-based, with limited potential for derogation on technical feasibility and social interest grounds (see Annex VI, Case Study 11). The potential for derogation allows substances which do not pose a significant risk in use or are essential to continue to be used; they may also be important to avoiding 'regrettable' substitutions and ensuring that unintended effects do not arise. The use of TCEP as a flame retardant in children's toys is an example of regrettable substitution (see Annex VI, Case Study 11), although others can be found in the literature[55]. It replaced other flame retardants subject to risk management in the EU, even though it is itself a carcinogen category 2 and a reprotoxin category 1B.

There is also concern, mainly from industry but also some authorities and citizens, that automatic triggers are not appropriate in all circumstances, for example, where it would result in the removal of a substance which only poses a risk via one exposure pathway which is not relevant to the use of the substance. An example of this is given by ethanol, which has only one route of carcinogenic effect, but which is not relevant to its uses in cosmetics or biocides; yet both may be impacted if it is given a harmonised classification as a carcinogen. In such cases, a specific risk approach would enable the use of the substance and the associated exposure routes to be taken into account. This would include consideration of all populations relevant to the use of the substance, such as children under three years of age; the elderly; pregnant and breastfeeding women; and people with a compromised immune system, for cosmetic products and pregnant and nursing women; the unborn; infants and children; the elderly; workers; and residents, for plant protection products. The need for the co-existence of both approaches is also recognised by environmental NGOs, with one noting 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*".

5.2.6 Relevance of hazard classes and substitution of hazardous chemicals with safer alternatives

As part of the open public consultation process, stakeholders were asked whether the hazard classes in the CLP Regulation cover all relevant hazards (see Section 3.3, Annex V). In particular respondents were asked to consider whether hazard classes for environmental risks, physical risks and human health risks cover all relevant hazards. The responses received indicate that the majority of industry and national authorities believe they do, and that CLP acts as a consistent and appropriate basis for the identification of properties of concern under linked legislation.

NGOs also agree in the case of physical hazards and consider the hazard classes for physical hazards to be adequate and cover all relevant hazards. However, the majority of NGOs disagree with the views of industry and most public authorities, as they do not consider the hazard classes for

[55] Fankte et al (2015): From incremental to fundamental substitution in chemical alternatives assessment, Sustainable Chemistry and Pharmacy, Vol 1, pgs 108. Available at: http://www.sciencedirect.com/science/article/pii/S2352554115300024

environment and human health to cover all relevant hazards. In particular, these stakeholders believe that there is a need for further criteria related to endocrine disruptors and PBTs, but also the terrestrial environment. Citizens expressed concerns over allergens in addition to fragrance allergens, although it is not clear to what extent they realise that classification is undertaken for sensitisers and irritants under CLP (see also Sections 3.2 and 6.3).

Stakeholders were also asked to what extent the legislative framework for chemicals has contributed to a reduction in the use of hazardous chemicals and/or substitution with safer alternatives (see Section 3.3 of Annex III). It is clear from the responses that, in general, the majority of respondents from all groups consider the framework to have had a positive contribution to reducing the use of hazardous chemicals and substitution with safer alternatives (although strength of support decreases moving from national authorities, to industry, to NGOs and then citizens).

5.2.7 Does the framework allow innovative approaches to hazard and risk communication?

The main communication measures within the legislative framework consist of:

- The use of Safety Data Sheets (SDS) for communication of information on chemical properties and exposure scenarios to downstream users;
- Labelling of substances and mixtures in accordance with CLP and additional or alternative sector specific legislative requirements (e.g. for toys and cosmetics);
- Tools such as the Classification and Labelling Inventory (CLI) which is operated by ECHA; and
- Reporting obligations such as those related to the provision of mixture information to national poison centres.

SDS requirements are set under REACH and are therefore outside the scope of this study. The main requirements for labelling are set out in CLP and are linked to requirements within the UN GHS. In this respect, the requirements are fixed and could not be met through the use of more innovative approaches. However, it is clear that industry (and in some cases authorities) has developed its own voluntary icons to provide further information on safe use, with this highlighting that there is the potential for the use of additional communication measures. For example, there is clearly the potential for the use of more innovative techniques such as Q-R codes, to convey additional information to both professional users and consumers. This could include mandatory requirements under sectoral legislation, or voluntary actions to provide consumers with greater information on ingredients, their properties, etc. (see Section 7.5 of Annex III for further details).

The CLI is actively being developed by ECHA since its first introduction to provide improved information on substance properties. This has included the development of Brief profiles and Infocards for individual substances, which set out basic information about the substance and relevant regulatory activities. The CLI is also searchable, which enables its use for regulatory and research purposes. The creation of this database is obviously an innovative communication tool; unfortunately it suffers from data reliability issues, which affect its true value from being realised (see Section 8.2 of Annex II for further details).

The poison centre communication requirements are not necessarily innovative but they are relevant and important, given the significance of chemical poisonings to the human health impacts associated with hazardous chemicals. Steps are being taken to reduce the costs of such reporting requirements, and this is an area where consideration of future innovative approaches may give rise to significant efficiency gains.

5.3 Does the legislative framework take into account consequences of relevance for citizens and stakeholders?

One of the key issues identified from stakeholder consultation is the division that exists between different stakeholder groups regarding the information that is taken into account in the implementation of different legislation. The aim of this evaluation question is to examine this issue as well as two further issues with regard to relevance. The three sub-questions are as follows:

- 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?
- To what extent are the information requirements in the current legislative framework adequate to enable informed choices, the promotion of safer alternatives, safe handling and use through the life-cycle of chemicals and products/articles?
- To what extent are socio-economic consequences of relevance for citizens and stakeholders taken into account in the implementation of the legislative framework?

These questions also overlap with some of the effectiveness considerations already discussed in Section 4 of this report. For completeness, we provide a summary of our key conclusions to each of these questions below.

5.3.1 Is information relevant and understandable?

There are 14 different pieces of EU legislation in addition to CLP that contain hazard communication obligations (see Annex III, Section 2). Considering the legislation as a whole, the general conclusion is mainly positive but mixed, with there being several examples of where the information is relevant but not sufficient or is not understandable. In some of these cases, there may be the potential for the use of new technologies to facilitate more targeted and relevant communication.

As noted in Section 3.2.6 of this report, workers are considered to have a greater understanding of hazard pictograms than consumers, mainly due to the training received from employers, with concerns mainly over the extent to which some CLP pictograms are understood by the general public. Further education programmes may be needed at the national level to ensure that labelling is understood to ensure the effectiveness of these hazard communication provisions (see Section 7.3 of Annex III for further details). Several stakeholders, mainly industry but also some Member State authorities, have also expressed concern that labels can become overloaded with information, making it difficult for downstream users to focus on the essential hazard information, thus reducing the effectiveness of hazard communication (see Sections 7.4 and 7.5 of Annex III for further details).

With respect to other legislation, 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 (see Section 7.4.4 of Annex III for further details).

Additional issues have been raised where the information being provided to professionals and citizens is not complete from their perspective (Section 7.4 of Annex III provides further details). These relate to labelling of allergens, classification of cosmetic products for environmental hazards and provision of information on safe use to cosmetics professionals. These have been discussed in Section 4 above under effectiveness.

5.3.2 Are the information requirements adequate to enable informed choices?

The question of whether or not information requirements enable informed choices, promote safer alternatives and safe handling and use is complex. In general, the labelling information required under legislation is deemed to be appropriate to enable downstream users and consumers to make informed choices regarding the products they purchase and use. Positive examples in this respect are requirements in relation to cosmetics and personal care products, where ingredient lists are obligatory. It is also clear that the importance of hazard labelling within the consumer products sector is viewed by manufacturers (e.g. within the detergents sector) as playing a role in product purchasing decisions. On its own, this highlights that the information impacts on consumer choices and leads to both the development and promotion of safer alternatives.

However, as also discussed in relation to effectiveness, the information may not always be sufficient or may not be clear enough (see Section 7.3.5 of Annex III for further details):

- Some consumers have indicated that the lack of detailed ingredient lists (e.g. in relation to detergents, biocidal products, cosmetics but also toys) restricts the ability of consumers and downstream users to make informed decisions and thus avoid products containing certain substances. In some cases, advice on safe use (e.g. biocidal products) is also missing. A similar issue is raised over the consistency in the labelling of allergenic substances on product labels, which causes difficulties for consumers that are actively trying to avoid products containing specific allergenic substances (see Section 4.2.8.2 above);

- NGOs have suggested that consumer articles should be labelled for the presence of SVHC, and 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;

- A range of stakeholders have also raised the issue of inflationary labelling (including industry, consumer organisations, Member State authorities and the detergents sector), due to the general concentration limits for the classification of mixtures – as regards irritant and corrosive effects on skin and eyes – being lowered considerably in the CLP Regulation (further details provided in Section 4.2.6); and

- The lack of labelling requirements under the CLP Regulation for PBT and endocrine disrupting properties is considered by some stakeholders to reduce the effectiveness of the Regulation in hazard communication terms with respect to industrial chemicals, however, labelling for these purposes would only be relevant if they are otherwise unregulated (given the automatic triggers that exist for substances with these properties under certain legislation).

Finally, it is important to remark on the interplay between CLP and some of the additional voluntary safe use icons that are included on certain types of consumer products. Although recent research by the detergent sector via AISE has found that consumers understand these icons better than CLP pictograms, the voluntary inclusion of such pictograms on some products but not others may be confusing. How is a consumer to interpret product labels for one product having the 'corrosive' pictogram but no icons, and another having icons but no pictogram? This may lead to confusion and an incorrect interpretation of the relative safety of the products. Such confusion could be exacerbated by the existence of multiple voluntary safe use icons being developed across different consumer product sectors.

5.3.3 To what extent are socio-economic consequences of relevance taken into account in the implementation of the legislative framework?

In order to answer the above evaluation question, one must first define what is meant by socio-economic consequences of relevance. This is not trivial, as the term is used differently by different stakeholder groups. Although a simplification, for industry, the term relates to the need to consider economic impacts on businesses, from the top of the supply chain to the bottom, including into the waste phase, where recycling and re-use are important aspects of overall efficiency and a circular economy. For environmental and public health NGOs, the term relates to human health and environmental impacts for current and future generations, also capturing concepts such as ensuring a non-toxic environment. Member State authorities generally use the term to refer to both sets of effects, although there is also a tendency for socio-economic impacts to be linked more to health and environmental effects than to costs to businesses. Broadly speaking, a holistic view of what the term should capture is rarely reflected[56].

We therefore define what we mean here. From our perspective, socio-economic consequences of relevance for both citizens and other stakeholders are linked and include:

- Impacts on businesses arising from the loss of substances, the need to shift to new alternatives or technologies, the need for new investment to comply with regulatory obligations, as well as increases in administrative costs and the 'hassle costs' of on-going compliance;

- The magnitude and severity of such impacts on businesses, which may have an impact on consumers in terms of changes in end on product prices and product availability, as well as potential impacts on jobs; it also impacts on research and development activities and, hence, innovation and competitiveness;

- The human health impacts that may arise from chemical exposures in the workplace, in the environment, from consumer products or from accidents; these not only negatively impact on individuals within society but also place significant demands on health care and other resources; they also impact on the costs of doing business due to employee absences, for example;

- The environmental impacts that may arise from chemical exposures linked to production activities, emissions from products while in use, waste disposal activities and accidents. These not only impact on the quality and state of the environment in terms of its 'health' and resilience, but also on the 'ecosystem services' that it can deliver, which in turn impacts on the costs of doing business; and

- The impacts on authorities with respect to monitoring and enforcement, and national governments, for example in relation to health care and other services.

These are not just first order effects. Changes in legislative requirements which affect the use of a chemical can lead to unintended consequences across all of the above. One example is where legislation impacts on the ability to use recycled materials or on recycling activities. Not only does this have resource efficiency implications (particularly given the criticality of some raw materials),

[56] With a notable exception to this being SEAs prepared under REACH.

but the production of virgin materials is often more energy intensive, with this giving rise to energy emissions related human health and environmental impacts.

On the question of whether the framework takes such consequences into account, the findings of the evaluation are mixed. On the positive side:

- The legislative framework does take into account the key properties of concern to civil society and to workers, with legislation in place to trigger risk management either based on generic risk considerations or specific risk assessment;

- As generic risk considerations are based on concern over anticipated consequences with respect to human health and the environment, these address part of the consequences of relevance for citizens;

- The potential for derogations under some of the key legislation applying generic risk considerations (Biocidal Products Regulation) enables socio-economic impacts stemming from technical feasibility and production related effects to be taken into account; in other cases, risk assessments are used to enable arguments to be made for continued use where a substance is of economic importance to manufacturers (e.g. under the Cosmetic Products Regulation, the Toy Safety Directive and the Carcinogens and Mutagens Directive);

- Inherent in some of the legislation, such as the Water Framework Directive, are the concepts of cost-effectiveness and disproportionate costs, which clearly provides a means for taking the range of socio-economic consequences into account.

On the negative side:

- The potential for risk, technical feasibility, or economic derogations from automatic bans triggered by generic risk considerations does not exist under all legislation (e.g. the Plant Protection Products Regulation, REACH in relation to CMRs in consumer products). As a result, socio-economic consequences with respect to economic growth and job security are not adequately taken into account for decisions regarding specific substances, in addition to any concerns of individual businesses over costs. As noted elsewhere in this summary, this gives rise to the potential for regrettable substitutions and unintended consequences; and

- As noted in Section 6.2.2 there is a gap in the legislation governing the safety of consumer products, as there are no specific requirements aimed at manufacturers in relation to hazardous chemicals; this can only be viewed negatively in terms of the extent to which this legislation takes into account the consequences of relevance for citizens.

5.4 Are current procedures transparent and robust enough?

The aim of this question is to address whether or not processes are in place to ensure that decisions are based on up-to-date and relevant evidence. Two sub-questions guide this component of the evaluation:

- To what extent do the risk assessment procedures and risk management decisions take into account the latest scientific findings?
- To what extent are the procedures implementing the framework transparent enough and take into account stakeholder input?

5.4.1 Do findings take into account latest scientific findings?

With respect to the first question, the findings of the evaluation are positive. A legal analysis of the Cosmetic Products Regulation, Detergents Regulation, Biocidal Products Regulation, Plant Protection Products Regulation and Fertilisers Regulation undertaken as part of the study also looked at identifying whether the regulations take into account scientific and technical developments. In general, these regulations are considered to take adequate account of scientific and technical developments and no significant issues have been identified in terms of the existence of mechanisms to adapt to new developments. Also, the mechanisms in place 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. The exception is the current version of the Fertilisers Regulation (as discussed below) (further details are provided in Section 6.3 of Annex III).

The availability of data in general depends on the legal framework with CLP 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.

In general, the responsible agencies and scientific bodies do take into account the latest scientific findings as part of their classification, risk assessment and risk management decision making. Although some stakeholders argue that more priority should be given to innovative academic studies than to the results of new testing carried out to GLP requirements, for example, it is clear that the various bodies take both sets of information into account. From their perspective, industry is concerned that too great a preference is sometimes given to academic studies over rigorously produced regulatory test data.

With respect to the up-dating of procedures, in some of the key legislation reviewed by the assessment (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 risk assessment requirements and other procedures. Mechanisms are in place, however (see Section 6.3 of Annex III for further details), for these purposes.

- The Annexes of the Cosmetic Products Regulation are regularly amended by the Commission following the safety evaluation of the Scientific Committee on Consumer Safety (SCCS) with regard to the potential need for legislative action. 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.

- In the case of the Detergents 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 detergents 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.

- In the case of the Biocidal Products Regulation and the Plant Protection Products Regulation there is no fixed frequency for the review of the Regulation itself, but decisions under the Regulations (approval of active substances and authorisation of plant protection products) are regularly reviewed.

In contrast, the Fertilisers Regulation lacks specific data requirements and the risk assessment process is not deemed sufficient to ensure risk assessment is based on the latest state-of-the-art methods. 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 and process for undertaking a risk assessment (and removal of a fertiliser type from the approved list (Annex I of the regulation) where relevant). It is therefore currently difficult to formulate coherent conclusions about the validity of the existing type-approvals. Arguably, the requirements of the current regulation are not sufficient to ensure risk assessment on the basis of the latest state-of-the-art methods (see Section 6.3 of Annex III and Section 6.1.1 of Annex IV for further details).

5.4.2 Are the procedures implementing the framework transparent enough and take into account stakeholder input?

In terms of transparency and the extent to which procedures take into account stakeholder input, the findings of the evaluation are mixed (see Section 5.4 of Annex IV for further details). For most of the legislation, procedures appear to be well understood and there is no lack of transparency. In two cases, the evaluation findings are particularly positive:

- The CLH process is generally considered to be well understood, and ECHA's efforts to provide transparency on where substances are within the various regulatory processes have been well received. Key stakeholders are able to participate in the process, although this may be more difficult for SMEs with fewer resources and less knowledge on how the system works; and

- Similarly, the process surrounding the development of binding and indicative occupational exposure limit values is considered to be transparent and well understood. In this case, the social partners dialogue ensures that there is transparency and that stakeholders are able to provide input into the decision making process (even if progress has been slow to date[57]).

On the negative side, the evaluation has also identified areas where further improvements could be made:

- Within the CLH process, there is more transparency in the process up to the RAC's opinion forming than there is after the opinion has been sent to the Commission. This lack of transparency results, in part, in industry submitting other (e.g. socio-economic) information into the process. In addition, long time periods for final decisions can lead to questions over the objectivity and predictability of the process from both industry and NGOs.

[57] 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

- However, companies have also raised issues with regard to the extent that Member State authorities communicate with them when preparing a CLH dossier. Some industry stakeholders note that they were not contacted by the authorities preparing a dossier, with the result that the authority did not use data held in the REACH registration dossier as would be expected. They have also noted that there can be a lack of clarity as to what information was taken into account when making a decision, as well as a lack of any proper formal response to comments submitted by industry during some parts of the process.

- Member States have highlighted issues with regard to the transparency of the processes under the Plant Protection Products Regulation. In particular, Member States have noted that there can be a lack of communication between EFSA and the Member State Rapporteur when concluding on the classification of an active substance.

6 Coherence

6.1 Introduction

The coherence of the legislative framework is evaluated in terms of the extent to which the legal acts are consistent in how they attempt to reach their stated objectives and whether there are inconsistencies, contradictions, duplications, overlaps or missing links that are having (positive or negative) unintended consequences.

The two core questions with respect to coherence are:

- 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, overlaps or missing links between different pieces of legislation? Are these leading to unintended results?

Each of these is examined in more detail below. It should be noted that some of the points discussed in this section also directly and indirectly impact on the effectiveness and efficiency of the legislative framework. Therefore, there is a degree of inevitable overlap between coherence and effectiveness and efficiency; where this is the case, the findings have been reported under the most appropriate criterion.

6.2 Consistency of the legal acts in reaching the stated objectives

The legal acts of the chemicals legislative framework all have the same objective of ensuring a high level of protection to human health and the environment, ensuring the efficient functioning of the single market and enhancing innovation and competition. Each of the pieces of legislation covered by this study takes steps to meet these objectives. With respect to protection of human health and the environment, this is either through generic, hazard-based measures banning the use of hazardous substances (in particular those considered in Annex IV), or the specific case-by-case assessment of substances in order to assess whether they are safe to use.

Although the criteria for exemptions or derogations within the different legislation differ, many require the opinion of a scientific committee on the safe use of a substance. The opinions of the technical and scientific committees for a given substance may vary, in part due to differences in the use of concern, but also due to different expertise and approaches of the committees. It should be noted though that stakeholders from all groups (industry, Member State authorities, etc.) believe that harmonisation of data requirements for risk assessment would ensure better coherence of the work and hence conclusions of different agencies, and that it could be beneficial to meeting the objectives of the EU chemicals legislative framework (Section 3.7 of Annex IV provides further details).

It is very difficult to assess whether the framework meets its objectives with regards to a substance that has multiple uses or uses under multiple sectors, 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. This does not necessarily reflect a lack of coherence between legislation, however, as the use and exposure to a substance (and thus risks) may vary across sectors (see Section 3.7 of Annex IV for further details).

It is generally well established across the chemicals legislative framework that industry are responsible for providing correct and adequate data when they are seeking a derogation or the approval of a substance for use, and that Member States or scientific bodies are responsible for processing these dossiers. Occupational safety and health, major accident and waste legislation is different from professional and consumer product legislation, as it is the responsibility of the employer/producer to ensure that risk management is undertaken and assessments are carried out (rather than by an external committee or agency). Member States are responsible for enforcement of all legal acts, although there may be Union wide enforcement as well (e.g. through the European enforcement network or CPC Network[58], which identifies common enforcement priorities and carries out specific activities) (see Section 3.7 of Annex IV for further details).

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 (from industry and Member State authorities) generally believe that the link is clear and there is no confusion as to which piece of legislation is applicable, suggesting a high level of coherence (see Section 3.7 of Annex IV for further details).

6.2.1 Coherence of criteria for hazard identification and data requirements

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 may no longer be 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 (see Section 4.3 of Annex III).

6.2.1.1 PBTs/vPvBs

The CLP Regulation does not include a hazard class for PBT/vPvB properties and, hence, lacks any respective criteria or any labelling provisions. 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 (see Annex VI), several pieces of legislation include criteria and procedures to identify PBT and vPvB substances. Also, within the scope of the Water Framework Directive[59], PBTs/vPvBs may be identified as priority hazardous substances.

[58] European Commission (2016): Enforcement. Available at: http://ec.europa.eu/consumers/enforcement/

[59] 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

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 differences are not significant, however, with the numeric criteria that establish whether or not a substance meets PBT or vPvB criteria considered to be coherent, as most legislation draw on the criteria set out in the REACH Regulation. Most stakeholders looking at this issue are of the opinion that any differences in PBT conclusions across the legislation mainly originate from the variations in the use of a weight of evidence approach, in particular when many different and/or contradicting test results are available. In this respect, it is of note that PBT data requirements are essentially harmonised across the legislative framework and the consistency of conclusions is high. The few inconsistencies that have been identified appear to arise due to the timing of the decision making on PBTness (see Case Study 6, Annex VI).

The ability to use a weight of evidence approach under the REACH Regulation to assess the PBTness of a substance is considered to be particularly unclear. Some believe that it decreases the predictability of the PBT assessment and could lead to inconsistent conclusions because of the expert judgement involved. Industry has proposed development of a consistent EU-wide weight of evidence methodology (clear and transparent), including scoring methods to allow identification of the (most) reliable and relevant data of sufficient quality for use in the assessment.

6.2.1.2 Endocrine disruptors

There are some differences in the data required under the different legislation for assessing endocrine disruption; however, at present there is no evidence to suggest that this has had a significant impact on the coherence of the legislation with respect to the identification of this as a property of concern.

However, greater harmonisation of the data requirements would help ensure consistency. All stakeholders have argued the need for a consistent set of criteria to apply horizontally across all legislation for endocrine disruptors. Multiple Member State authorities have suggested that criteria for endocrine disruptors should be included in Annex I to the CLP Regulation. 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 (and authorities) associated with the 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 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[60] which calls on the Commission to adopt horizontal criteria for endocrine disruptors. If varying definitions are to be adopted for different pieces of legislation, the reason for such differences should be clearly communicated.

[60] European Parliament (2015): Resolution – horizontal criteria for endocrine disruptors. Available at: http://www.endseurope.com/docs/150126a.pdf

6.2.1.3 CMRs

In terms of CMR properties, the CLP Regulation sets out clear criteria for the classification of CMRs, and the Plant Protection Products Regulation, Biocidal Products Regulation and Toy Safety Directive all refer to CLP for classification of these properties. However, there is legislation that does not refer to the CLP CMR classification criteria, notably the OSH legislation (see Section 4.2.3 of Annex III).

The Carcinogens and Mutagens Directive sets out definitions for what constitutes a carcinogen or a mutagen for its purposes. The definition of a mutagen draws only on CLP, while the definition of a carcinogen is broader and 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 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 be classified under the CLP Regulation but that workers might still be exposed to in the workplace (Section 4.2.3 of Annex III provides further details).

With regard to CMR classification decisions, multiple industry respondents to the targeted consultation (both associations and individual companies) noted that they believe that some substances are now being classified as CMR category 1B by the RAC for REACH purposes on a precautionary basis rather than on a robust, transparent weight of evidence approach. They suggest that new harmonised classifications are often overly conservative and do not always follow the EU guidelines. In addition, they suggest that the overly conservative classifications are often in contradiction with other EU goals, e.g. relating to increased trade and resource efficiency (especially where the classification could have an impact on the recyclability of materials. However, professional toxicologists and other industry observers have noted that there are probably as many carc. cat 1B proposals that are finally classified as cat 2, as there are cat 2 proposals that are finally classified as cat 1B (see Section 4.4.3 of Annex III for further details).

Differences in the approaches adopted by RAC and SCOEL have also been highlighted as leading to inconsistencies; these become 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 for proposals on Binding Occupational Exposure Limit Values (BOELVs) (Section 4.4.3 of Annex III provides further details).

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 that exist between ECHA and EFSA in establishing a substance 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 as to whether the active substance "is not or has not to be classified"[61] 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 Annex VI). 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. An attempt is being made by the Commission to prevent this by encouraging Member States to submit their harmonised classifications dossiers under CLP before they go to EFSA with an active substance approval dossier. A harmonised format is

[61] Regulation (EC) No 1107/2009, Annex II, 3.6.2, 3.6.3, 3.6.4

being developed which means that one document can be sent to both RAC and EFSA, to allow for RAC to develop the dossier while EFSA carries out its risk assessment review.

6.2.2 Coherence and adequacy of data requirements

There is currently a high level of coherence in data requirements and the use of data within the legislative framework. An exception is 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. 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, the Plant Protection Products Regulation, Biocidal Products Regulation or other legislation. 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 (see Section 5.2.1 of Annex III and Case Study 4 for further details).

6.2.3 Coherence of risk management approaches

The approaches towards risk management of CMRs, PBTs/vPvBs and endocrine disrupting chemicals are generally coherent, as they are automatically prohibited for use in professional and consumer products. The potential for derogations or exemptions from the automatic bans or restrictions vary between legislation, however, with this demonstrating a degree of incoherence. Although risk assessment may be a potential means of gaining a derogation or exemption, technical feasibility and socio-economic considerations are missing as potential criteria. Only the Biocidal Products Regulation includes such considerations – technical feasibility and social interest – as valid reasons for derogation (see Annex VI, Case Study 11 and Annex V, Section 6). This lack of consideration of technical feasibility and socio-economic factors is a lack of coherence within the legislation considered by this study; it also results in a lack of coherence with the REACH Authorisation process, where these factors provide the basis for applications for and decisions on the continued use of a substance.

In contrast, there is also considered to be an appropriate level of coherence in the factors taken into account in risk management decision making based on specific risk assessment. Vulnerable populations are considered in all legislation, to varying degrees, with the Cosmetic Products Regulation and the Toy Safety Directive paying particular attention to children. The characteristics of a substance are also considered to be given adequate weighting in decision making. This is also the case under OSH legislation which requires special attention for pregnant workers and young workers as vulnerable populations (see Section 6.1.3 of Annex IV for further details).

Socio-economic factors, as well as technical feasibility, can be taken into account in much of the specific risk assessment based legislation, for example by employers when deciding how to reduce risks to their workforce and by national authorities under the Water Framework Directive. In this respect, there is coherence amongst this set of legislation (Section 6.1.3 of Annex IV provides further details).

6.2.4 Lack of consistent definitions

In general, there is considered to be consistency in the definitions used in the various legal acts. A few inconsistencies have been identified, however, that are preventing the legislative framework from being fully coherent in meeting its objectives (see Section 3 of Annex IV for further details). The most significant of these relate to the definition of allergens and 'treated articles'.

6.2.4.1 Allergens

Under the Cosmetic Products Regulation, there is no definition of what constitutes an allergen. Whilst labelling of certain substances that 'may cause allergenic reactions' is required under the Regulation, allergens are not specifically defined. This is considered by a number of stakeholders to lead to the potential for a (and indeed the expected actual) lack of harmonised application of the requirements across the single market, impacting on the legislation's ability to also enhance competitiveness and innovation, or ensure a high level of protection of human health and the environment. In this case, the perception of consumers is important to their purchasing decisions, and the lack of a specific definition may impact on the extent to which consumers' information needs are properly met (with this considered to be a gap which may impact on the communication of chemical hazards to consumers).

6.2.4.2 'Treated' articles

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 (i.e. most waterborne paints) 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 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.

6.3 What are the inconsistencies, contradictions, overlaps or missing links between different pieces of legislation?

6.3.1 Legislative gaps

In general, the chemicals legislative framework is coherent in its requirements for ensuring that human health and the environment are adequately protected. However, the research (including stakeholder consultation) undertaken as part of this study has highlighted a number of gaps,

overlaps and inconsistencies with regards to the legislation with horizontal linkages to the CLP Regulation (see Section 7.2 of Annex III for further details).

6.3.1.1 Allergens

As indicated in Section 3.2, in the case of the Toy Safety Directive, allergens are considered to be inadequately regulated. This is because the list of sensitising fragrances set out in the Directive does not take account of the SCCS opinion[62], which suggests that this list is "clearly outdated". The evaluation of the Toy Safety Directive undertaken by Technopolis *et al.* in 2015 therefore suggests that the 129 contact allergens identified by SCCS in its opinion should be banned from toys (Technopolis et al., 2015).

In addition, consumer associations and six Member States expressed concerns over 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 not present a risk of adverse effects to human health*"[63] (Technopolis et al., 2015).

Consultation undertaken as part of this fitness check study has indicated 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) (see Section 7.2.11 of Annex III for further details).

Toy Safety Directive – exemption of rules outlined in the Biocidal Products Regulation

Concerns also have been raised by some Member State authorities 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. 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"* ((EC) No 528/2012) was approved. This means that biocides used in toys do not need to be authorised or declared. This may be impacting on the effectiveness of the legislation in protecting consumers, but also on the value of information provided to consumers and their ability to make informed choices on the products they purchase for children (see Section 7.2.11 of Annex III and Case Study 8 for further details).

6.3.1.2 Lack of requirements under the Cosmetic Products Regulation for classification for intrinsic environmental hazard properties

NGOs and Member States have raised the issue of the inconsistent treatment of substances and mixtures across the legislative framework, where use is authorised or allowed under one regime but not another. Such comments reflect the fact that different hazardous properties are taken into account under the different legislation. A particular issue has been identified relating to the lack of requirements under the Cosmetic Products Regulation and classification for intrinsic environmental

[62] 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

[63] 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

hazard properties (although ingredients should have been registered under REACH). There is also a gap with respect to the labelling of cosmetics for environmental hazards, as cosmetics often contain environmentally hazardous substances, are used in high amounts, and have a wide dispersive use pattern, and may often reach the environment or at least wastewater treatment plants. Indeed, a range of cosmetic ingredients, ranging from siloxanes, triclosan, synthetic fragrances, UV filters[64] etc., have been identified as having significant impacts on the environment. It could therefore be argued that these gaps are impacting the extent to which the legislative framework meets its objective of protecting the environment from the use of chemicals (Sections 4.5.5, 7.2.2 and 7.4.2 of Annex III for further details).

6.3.1.3 Lack of hazard criteria under the General Product Safety Directive

As noted in Section 5.2.2, 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, air fresheners, tattoo inks, childcare articles and construction materials.

The General Product Safety Directive requires that products are safe for consumers but it does not provide for specific criteria to be used by manufacturers in establishing whether the presence of hazardous chemicals makes the product unsafe under normal conditions of use. This can be seen as a major gap within the horizontal legislative framework for consumer products, as manufacturers of products are not given clear indications of the types of chemical hazards that 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 over long periods for vulnerable populations such as children.

As it currently stands, the only means of addressing the risks from substances in consumer products is through the REACH Regulation, via Restriction or the Article 68(2) fast track Restriction procedure. The full restriction procedure takes time and is substance specific (or applies to a small number of related substances); it is also limited to certain products. The fast track procedure may provide a mechanism for addressing such issues more quickly, with the example being its application to CMR substances in textiles consumer articles. As REACH is outside the scope of this study, the use of these procedures has not been examined in detail here. It is of note though that NGOs such as ChemSec have supported the fast track procedure and called for it to be applied to further sets of substances[65], while industry has protested against this approach by EU industry on the basis that it is not evidence (specific risk) based and contradicts the principles of 'Better Regulation'.

On balance, it would clearly be more efficient and effective if manufacturers of consumer articles were required to consider chemical hazard issues earlier on and based on clearer rules on what is considered safe, 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, by reducing the need to use either the REACH fast track or full Restriction procedure (see Section 6.2.1 of Annex IV for further details).

[64] Sobek 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.

[65] ChemicalWatch (2016): Fast tracking CMR restrictions sets 'dangerous precedent'. Available at: https://chemicalwatch.com/45962/fast-tracking-cmr-restrictions-sets-dangerous-precedent

6.3.1.4 Gaps in the protection of professional users under the Cosmetic Products Regulation and the Regulation on food additives

As noted earlier, Member State authorities have identified a gap in the protection of professional users under the Cosmetic Products Regulation and the Regulation on food additives, with authorities suggesting that cosmetics and food additives should be labelled according to the CLP Regulation, to ensure sufficient protection for professional users. Other authorities have noted that employers and professional users also need more specific information, such as a SDS, in order to meet their obligations in the workplace and to enable them to substitute to less hazardous products. 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 (Sections 7.2.2 and 7.4.2 of Annex III provide further details).

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 listed on packaging of products and determine their hazards and the procedures for ensuring safe use.

6.3.2 Legislative overlaps

6.3.2.1 Labelling of allergens

Information received from AISE and other 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.

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 and labelling 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 the Cosmetic Directives (Annex III, Part 1 of Directive 76/768/EEC and Directive 2003/15/EC, which have been replaced by the Cosmetic Products Regulation) that exceed concentrations of 0.01% by weight require labelling under it.

The case study focusing on the detergents sector (see Case Study 5 in Annex VI) 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.

6.3.2.2 Overlaps between the CLP Regulation and international transport rules

Several stakeholders have identified an 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 and could therefore have consequences for health and safety if the hazards associated with a particular package are not understood and incorrectly handled/stored (see Section 8.2.2 of Annex III for further details).

6.3.3 Inconsistencies and contradictions

6.3.3.1 Inconsistencies in classification of substances under Plant Protection Products and CLP

Case Study 3 (Annex VI) examines issues regarding the parallel hazard assessment process that exists for the classification of substances under the Plant Protection Products Regulation and the Biocidal Products Regulation and under CLP Regulation. Article 36(2) of the CLP Regulation notes that a substance that is an active substance should normally be subject to harmonised classification and labelling. Therefore, it is intended that all active substances under the Plant Protection Products Regulation and the Biocidal Products Regulation should 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 under CLP, companies are required to 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. During the procedure for approval of the active substance, the applicant, the rapporteur Member State and EFSA (the relevant authority) 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 – EFSA under the Plant Protection Products Regulation and ECHA's Risk Assessment Committee under CLP – under different procedures and timescales. A number of examples have been identified where different conclusions on classification of an active substance have been reached under the Plant Protection Products Regulation and separately under the CLP Regulation (e.g. Amitrole, Isoproturon and Flutianil).

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 be the first case where a resolution will have to be found. 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. As noted earlier, in order to avoid divergence of opinions between the procedural steps and timelines as set out under the CLP Regulation and the Plant Protection Products Regulation, for the CLH and active substance approval process respectively, 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) (see Section 6.2 of Annex III, and Case Study 3, Annex VI for further details).

6.3.3.2 Inconsistencies between Member States in Plant Protection Product classifications

Targeted consultation with formulators that specialise in plant protection products indicates that many have experienced cases whereby the rapporteur Member State and EFSA have not agreed on the proposed classification of an active substance. Considerable internal resources are needed to handle these discrepancies which may lead to the need for additional vertebrate studies. It may also lead to the potential for non-renewal or delay of active substance approval, which can lead to a competitive disadvantage in some Member States.

Respondents also noted that plant protection products (rather than the active ingredients) can have different classifications (resulting in different labels) in different Member States. 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.

It should be noted that Member States discuss classifications as part of the zonal evaluation[66], 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 (see Section 7.2 of Annex III for further details).

6.3.3.3 Inconsistencies in classification

It is clear from the research undertaken for this study that inconsistencies in the classification of substances can result in confusion for downstream users, and may impact on the functioning of the internal market.

For example, it was reported that inconsistencies between classifications provided by suppliers can lead to situations where similar establishments that handle the same substance are not covered in the same way under Seveso (see Annex VI, Case Study 8). One establishment could be covered because the operator has received a relevant classification, while the classification provided to another operator is less strict for the same substance and the site is therefore not covered by Seveso. 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. Although this problem will not be unique to regulation under Seveso, and will also arise under other downstream legislation, the issue was highlighted with respect to Seveso.

[66] 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 plant protection product on behalf of the entire EU.

Inconsistencies in the treatment of similar products under different legislation

Consultation has highlighted inconsistencies in the treatment of products that fall under the scope of different pieces of legislation within the chemicals legislative framework. An example of inconsistencies cited by industry is the case of shampoo and hand washing-up liquid, which are almost identical formulations falling under different pieces of legislation. Shampoo is a cosmetic product and therefore falls under the scope of the Cosmetic Products Regulation; shampoo products do not require hazard pictograms (as cosmetics are exempt from the CLP labelling requirements), but are required to be accompanied by safe use instructions. Washing-up liquid is very similar to shampoo but falls under the scope of the Detergents Regulation and therefore is subject to CLP labelling requirements. Washing-up liquid can (via the calculation route) be classified as being corrosive to the eyes resulting in the need for either a 'corrosion' pictogram meaning "causes severe burns or eye damage", or (where demonstrated by test results) the 'exclamation mark' pictogram, which means "causes serious eye irritation" and "harmful in contact with skin", as well as relevant P statements. A similar example was provided by the animal skincare products sector, which noted the difference in treatment between shampoos placed on the market for use on animals which are labelled under CLP versus shampoos falling under the Cosmetic Products Regulation.

This therefore highlights the different classification and labelling requirements that apply (and potential inconsistencies in how products are treated) for very similar products that are regulated under different pieces of legislation (see Case Study 5 in Annex VI for further details).

7 EU added value

7.1 Introduction

This section considers the value that the legislative framework has provided in the context of the EU compared to a regulatory situation at the national level. In other words it considers the extent to which the legislative framework has provided added value in meeting its fundamental objectives (as discussed in sections 4 to 7) and whether this is likely to have resulted in additional value/benefits compared to a national regulatory system.

The core question with respect to EU added value is therefore:

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

7.2 Has the legislative framework provided added value?

Based on information obtained from the desk-based research and stakeholder consultation it is clear that the chemicals legislative framework operating at the EU level rather than the national level does provide added value.

In general, stakeholders from all groups 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. For example, the majority of industry respondents (manufacturers, importers, distributors and formulators) to the targeted consultation agree that CLP is consistent with wider EU policies in achieving the same general objectives (i.e. increased trade, protection of health and the environment) and that EU-level intervention is necessary to achieve these benefits.

Similarly, responses to the Open Public Consultation indicate that respondents from all stakeholder groups generally agree that the EU chemical and chemicals-related legislation is necessary and provides added value. Respondents were asked to assign a score from 1 (no value) to 5 (very high added value) as to whether they consider the EU chemical and chemicals-related legislation has had an added value above what could have been achieved through action at the national level. The weighted scores give an indication of the overall score from each group. These show that industry, national authorities and NGOs are equally positive about the added value of the EU chemicals legislation with scores of 4.0, with citizens less positive (with a weighted score of 3.3) (see Section 3.3.8 of Annex V for further details).

It should be noted that authorities believe that national measures work for certain aspects, such as Occupational Safety and Health legislation, because an enforcement agency in a Member State will be more conscious of their market and the current climate within the country; this provides part of the justification for allowing different countries to set varying occupational exposure limit values when an indicative value has been set under the Chemical Agents Directive.

More generally though, 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 the Union level so that there are no barriers to trade which may occur if there are national differences. If an EU intervention was substituted for a national approach then manufacturers, producers, distributors and importers may face barriers to trade where different countries adopt different approaches to risk management, identify different properties of concern

for regulation in their country or set different criteria for triggering risk management. This could impact significantly on the internal market, as well as on competitiveness and intra-EU trade. It would also impact on the efficiency of chemicals legislation for all stakeholders. 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.

As noted in the preceding sections, stakeholders have indicated the need for greater EU-wide action on a range of fronts (e.g. food packaging, classification of plant protection products, etc.) in order to better meet the objectives of the legislative framework, and to avoid inconsistencies arising due to differing interpretations of approaches across Member States. The comments received from industry and NGOs as part of this study regarding the lack of consistency in the implementation and enforcement within the current system and the complexity of the framework suggests that regulation at the Member State level would magnify these issues, thus resulting in a less consistent and coherent regulatory approach compared to the current situation.

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