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

Report on the Stakeholder Workshop of 19 April 2016 in Brussels

6 June 2016

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This report contains an overview of the opinions and views expressed during the Stakeholder Workshop and do not necessarily represent the views or propositions of the consultants.

In addition, unless otherwise stated, they do not necessarily represent any official view of the European Commission or any other organisation mentioned in this document.

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1 Overview

1.1 Background to the Workshop

This study is one of the key activities in support of the fitness check on chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, which the European Commission is conducting as part of its Regulatory Fitness and Performance Programme (REFIT).

The fitness check of chemicals legislation is a comprehensive evaluation of the policy area, assessing the relevance, coherence, effectiveness, efficiency and EU added value of the legislative framework for the risk management of chemicals. It also identifies excessive administrative burden, overlaps, gaps, inconsistencies and/or obsolete measures. This will promote better legislation, making it more responsive to current and future challenges and help improve implementation.

The scope of the fitness check covers chemical and chemical-related legislation, encompassing legislation governing hazard identification, classification, hazard communication and risk management measures for chemicals. This includes chemical-related provisions in worker safety legislation, transport legislation, environmental protection legislation and product safety legislation, as well as other supporting legislation. An indicative list of relevant legislation can be found in Annex 1 to this document. A fitness check roadmap will be published on the Commission's website[1]; a background document with key information on the fitness check is already available.[2]

The European Commission (DG GROW) commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to conduct the study. It focuses on the CLP Regulation[3] 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. Study tasks include the following:

- A thorough analysis of the different pieces and provisions of legislation, which in their interplay make up chemicals regulation, identifying gaps, overlaps and inconsistencies
- 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 or where the benefits are particularly significant compared to the costs
- The identification of gaps in health and environmental protection
- The identification of areas where the potential for improvement, modernisation and simplification has not yet been harnessed, and
- The identification of existing mechanisms and procedures that work well and that could be considered as a best practice.

The aim of the stakeholder workshop, which took place on 19 April in Schaarbeek, Brussels, was to provide an early check on preliminary study findings, identify potential gaps and opportunities for

[1] http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm

[2] http://ec.europa.eu/growth/sectors/chemicals/ec-support/index_en.htm

[3] 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.

further investigation and to collect ideas and information from stakeholders. The conclusions of the workshop will be taken into consideration in the final study report, which will be used in the preparation of the Commission Staff Working Document on the results of the fitness check.

1.2 The Workshop Format and Agenda

1.2.1 The Format

The workshop followed the "World Café" format and was structured around a number of break-out group discussions on relevant study topics. During six 30-minute break-out sessions, participants engaged in discussions focused around key questions, which were aimed at identifying both problem areas and good practices related to the discussion topics.

Registration for the Workshop was open to all, with a link to the registration website being available on the Commission's website as well as on RPA's website. The workshop was also announced through social media by DG GROW. Furthermore, an email invitation to register for the workshop was sent to stakeholders already contacted in the context of this study (with regard to either the case studies and/or the targeted data collection). The number of registrants exceeded the capacity of the venue (90 people) and a selection of registrants was invited to attend, ensuring a balanced representation of relevant stakeholder groups.

A list of participants is provided in Annex 2 to this report, together with the agenda for the day. A thought-starter paper was also sent out ahead of the Workshop, in preparation for the World Café format discussions[4].

For each discussion topic, there were two tables of a maximum 10 participants per table. There were two sets of break-out sessions, Part I and Part II, during which there was the potential to select three out of the four pre-planned discussion topics. As noted above, discussions on each topic were allocated 30 minutes. Participants select the three discussion topics they wished to discuss at the start of Part 1 and again at the start of Part 2.

The discussion topics were as follows:

- Part I (morning sessions):
  a. CLP classification rules and criteria
  b. Hazard assessment across chemicals legislation
  c. Transparency of assessment procedures
  d. Hazard communication to downstream users and consumers.

- Part II (afternoon sessions):
  e. Implementation of GHS
  f. Data quality requirements and test methods
  g. Downstream risk management measures
  h. SME awareness and engagement.

[4] This is available at: http://ec.europa.eu/DocsRoom/documents/16418/attachments/1/translations/en/renditions/native

The discussion topics and the associated discussion questions were identified from the work undertaken during the first stages of the study, based on literature review and legal analysis, targeted data collection and stakeholder interviews to date. The objectives of the workshop discussions were to identify what works well within the chemicals legislative framework and why and the associated impacts, as well as what does not work well, why not and the associated impacts.

2 The Workshop: Presentations and Discussion Topics

2.1 Setting the scene

2.1.1 Opening

The Workshop was opened by Carlo Pettinelli, Director for Consumer, Environmental and Health Technologies at DG GROW. Mr Pettinelli welcomed all participants who share an interest in Better Regulation, which is a key priority for the Commission and which aims to result in better rules with better results for Europe.

Mr Pettinelli underlined that chemicals legislation is a key area of interest under the REFIT programme. He indicated that better chemicals regulation is important to ensure the protection of human health and the environment in the EU, but also to ensure that these health and environmental goals are achieved in the least burdensome way for businesses. Mr Pettinelli pointed out that the REACH REFIT evaluation is conducted in parallel to the fitness check and that both activities will provide a comprehensive evaluation of the legislative framework. He stressed that stakeholder consultation is another pillar of the Better Regulation Agenda and that this is reflected in the consultation strategy of the fitness check, including a public consultation open to all stakeholders to participate, an SME panel and this workshop.

Mr Pettinelli encouraged participants to share their practical experience with chemicals legislation with a view to answering the questions 'what works well, and what does not work?' and 'What have we learnt and what can be improved?'.

2.1.2 Objectives of the study

Reinhard Büscher (Head of Unit, DG GROW) presented an overview of the objectives of the study. He explained that the study is one of a number of studies that will feed into the fitness check on chemicals legislation, resulting in a staff working document in the second half of 2017. The fitness check methodology applies to this study and the study aims to assess the chemicals legislative framework (excluding REACH) in terms of the five key evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value. Key to the fitness check exercise is the Open Public Consultation. All stakeholders are encouraged to participate in the Public Consultation which runs until 27 May 2016.

Mr Büscher also noted that the roadmap for the fitness check has not yet been published. However, the background document to the fitness check gives a solid outline of what is in the roadmap. The link to the document, published on the Commission's website, was sent to participants together with preparatory material for the Workshop.

2.1.3 Overview of the tasks and case studies

The study team is being led by Risk & Policy Analysts (RPA). Meg Postle of RPA gave a presentation outlining the main objectives of the study, the main tasks, the study approach towards obtaining data and stakeholder input to the study, and an outline of the case studies that are being carried out as part of the project work. This presentation is available in Annex 3 and has been posted on the Commission's website.

Ms Postle described how the work required for the study has been organised into four main tasks:

- **Task 1: Evaluating the implementation of CLP Regulation** – this includes consideration of the overall costs and benefits of CLP Regulation implementation; evaluation of the building block approach; comparing EU implementation to that in other countries; assessing the mechanisms within the CLP, such as the CLH process, the safeguard and urgency procedures, and the impact of transitional periods; and assessing the performance of the CLP Regulation against its objectives;

- **Task 2: Evaluating the horizontal links between EU legislation on hazard identification and communication –** this includes mapping of horizontal links between legislation; identification of gaps, overlaps, inconsistencies and other issues affecting the performance of the legislation; assessing mechanisms for adapting legislation, and assessing the relevance, effectiveness, efficiency, coherence and EU added value of hazard/risk communication;

- **Task 3: Evaluating the vertical links between the CLP Regulation and relevant EU and national downstream legislation identifying risk management measures based on hazard classification –** this includes mapping references in downstream legislation to the CLP and analysing what risk management measures are triggered in downstream legislation by CLP classification; assessing the relevance, coherence, efficiency, effectiveness and EU added value of mechanisms and procedures within downstream legislation, examining the costs and benefits of the main downstream legislative provisions and assessing any differences in the national transposition of relevant downstream Directives; and

- **Task 4: Organisation of a public consultation and workshop.**

Ms Postle also explained the importance of **case studies** work being undertaken as part of Tasks 1 to 3. The purpose of the case studies is to explore in detail some of the more pertinent issues associated with EU chemicals legislation, considering aspects such as the health and/or environmental benefits of key provisions, the costs to industry (whether direct or indirect) of the provisions and other regulatory costs (including the time taken and other impacts arising from the procedures that exist as part of the regulatory interface), transitional issues, etc. Importantly, the aim of the case studies is not to re-consider specific decisions that have already been taken; instead, it is to examine the mechanisms and procedures of the legislation and to assess whether the current linkages are appropriate (which may necessitate examining some of the impacts of past decisions).

The case studies currently being examined are listed below. These were chosen on the extent to which they fulfilled the following criteria: significance of the problem; sectoral representativeness; legislative scope; addressing evaluation criteria; potential significance of impacts; linkages to other case studies. Ms Postle noted that the descriptions provided in Table 1 of the thought-starter provide a first impression of the purpose and scope of the case studies.

The case studies are:

- Impacts of differences in the uptake of **GHS building blocks** for costs, competitiveness health and the environment
- Coherence in **parallel hazard assessments** under different legislation
- Relevance and coherence as regards the use of **test methods** and **data quality requirements** in chemicals legislation
- Coherence of classifications, definitions and the **labelling requirements for detergents**

- Suitability of the CLP Regulation **classification criteria for metals**
- Inconsistencies in assessment procedures for **PBT and vPvB** as properties of concern
- **SME awareness** of ATPs and changes in classification and of labelling and packaging requirements
- Linkages between the **CLP and Seveso III** Directive, including risk management under Seveso III *(scope under discussion)*
- Awareness of Chemical Safety Assessment and labelling requirements for **Toys**
- **Consumer comprehension** of and relevance of safety information on product **labels**
- Interface between the **Fertiliser Regulation and chemicals legislation**
- Linkages with **Occupational Health and Safety Legislation** *(scope under discussion)*
- **Risk management procedures triggered by harmonised classifications** under the CLP Regulation

The presentation also set out the numerous research tools that are being used to obtain the wide range of data, information and feedback required to provide answers to the evaluation questions at the heart of the fitness check methodology. Besides this workshop and the case studies outline above, desk research and interviews of key stakeholders have been and are being undertaken. In addition, there has been a programme of **targeted data collection** (via online and written questionnaires) of key groups of stakeholders to ensure a wide range of response. Key stakeholder groups invited to participate in the targeted data collection include:

- Industry stakeholders:
  - Manufacturers and importers
  - Formulators: general industrial, plant protection, cosmetics, detergents
  - Distributors
- Consumer representatives
- Workers representatives
- Environmental and public health NGOs
- Member States, Competent Authorities, the Commission, Caracal, Agencies and international bodies
- Expert groups
- Member State Competent Authorities, the Commission, Caracal, Agencies, Committee/Expert Working Group members and international bodies

In addition, a questionnaire will be sent to the Commission's SME Panel, with high level questions specifically tailored to SMEs. The SME Panel aims to identify ways in which SMEs are impacted, and whether these impacts differ from those to larger enterprises.

The importance of responding to the Open Public Consultation (OPC) was once again also highlighted, together with an overview being given as to the issues addressed under the main evaluation criteria for the fitness check as well as study-specific concerns. These include:

- Effectiveness of EU chemicals legislation: human health, environment, risk management orientation, single market, competitiveness and innovation; decision making, procedures, implementation, hazard assessment, risk management, hazard communication, data quality requirements
- Efficiency: societal benefits and costs as well as potentially significant type of costs
- Relevance: substitution and emerging areas of concern
- Coherence: gaps overlaps and inconsistencies
- CLP related questions (study-specific).

2.1.4 Introduction to the break-out sessions

Maurits-Jan Prinz explained to participants how the break-out sessions would work. He briefly went over the discussion topics and suggested questions for the discussions. Annex 3 provides the handouts provided to participants on the day, to help focus the discussions held on each of the topics.

2.2 Break-out sessions Part 1: Discussion topics and conclusions

The following sections provide an overview of the opinions and views expressed by the participants at the Workshop.

2.2.1 CLP classification rules and criteria

Background

This discussion topic considered the extent to which default classification rules under the CLP Regulation are appropriate for the different types of substances and mixtures, and whether they may trigger under/over classification of substances and mixtures. One of the case studies being considered under this discussion topic is the appropriateness of classification rules for particular types of substances, e.g. metals in the massive form and alloys. Early findings suggest that there may be a gap in the CLP Regulation, due to the lack of specific criteria for the classification of metals. In addition, there are suggestions that the outcome of mixtures classifications more generally can depend on the choice of method.

The moderators for these sessions were: Roberto Scazzola, European Commission; Caroline Raine, NCEC of AEA-Ricardo.

Workshop questions

1) To what extent do you believe that current classification criteria are suitable to fully describe the hazard profile of substances and mixtures to an extent necessary for enabling appropriate risk management?
2) Does the classification system (including the rules, criteria, guidance documents) make it easy to correctly classify substances and mixtures?
3) What methods (rules, test data, bridging principles, weight of evidence) are being used most for mixture classification and are there any differences arising from the use of these different methods?
4) Are there differences in the approaches taken by SMEs versus large companies, and in the acceptability of different approaches at the Member State level?

Summary of break-out group discussions:

While CLP criteria were seen by participants as adequate to describe hazards, there were suggestions on additional hazard classes that could be included (hazard classes mentioned included EDs, PBT, and environmental classes such as for soil and sediment). The consideration of the physical state is important (e.g. for nanomaterials) for the identification of appropriate risk management measures. Various participants noted that maintaining the CLP system as purely hazard based is important. Some participants indicated that CLP mixture classification was not as problematic since industry was used to classifying mixtures under the DSD/DPD. However, it was accepted that there could be issues for SMEs and that some specific approaches under CLP may lead

to over-classification. According to some participants, consideration should be given to the way special matrixes are classified (alloys, polymers, glass, etc.), in particular when the harmful substance is embedded/blocked in the matrix and exposure is not possible or should be extremely limited.

Challenges mentioned included how to take into account potency for CMRs (participants expressed contradictory views on this due to potency being relatively new) and how to expand environmental classifications (e.g. to soil, sediment, etc.), as implementation is viewed as problematic. Another challenge discussed was over-classification for skin corrosion based on additivity (for example, for households detergents), which can lead to an ambiguous message to consumers (no difference is provided between "light" hazards versus "serious" hazards).

On guidance documents and the Classification and Labelling Inventory (CLI), participants noted that further improvements to the CLI are needed to support CLP implementation, and that while Guidance documents and Frequently Asked Questions (FAQs) are a good starting point and provide effective support to CLP implementation, it is important that they are updated regularly and that they are customised, for example, for SMEs. It was also suggested that guidance is required on how to consult the CLI. A decision tree would be helpful in this regard. Some industry initiatives aimed at supporting and facilitating classification, for example for the detergents sectors, were welcomed.

A number of points relating to the (lack of) consistency of national interpretation and/or enforcement were made. For example, recognition and acceptance of alternative testing data, the use of weight of evidence approaches and read across for classification decisions vary across Member States; as the outputs of such approaches are still subject to interpretation at the national level, this can result in an uneven playing field (e.g. national authorization for PPP, BP etc.). Increased consistency in the acceptance of such methods when applying the CLP criteria across EU countries would be of value. In particular, there appears to be a lack of consistency in the application of the CLP criteria with respect to the classification of mixtures across EU countries, and more consistency is needed in this respect if the single market is to be achieved. Furthermore, according to some participants, there is a need for more enforcement in general to encourage compliance.

2.2.2 Hazard assessment across chemicals legislation

Background

Responsibility for hazard assessment and agreement of harmonised classifications differs under different pieces of legislation (i.e. CLP, Biocidal Products (BPR) and Plant Protection Products Regulations (PPPR)). This discussion will focus on coherence across the different pieces of chemicals legislation in terms of the procedures for assessing hazards and classifying substances and mixtures, and their outcomes. It will also cover how such differences have been resolved and what types of impacts arise from any potential lack of coherence.

The moderators for this session were: Claire Dupont and Julia Lietzmann, Milieu; Johanna Bernsel, European Commission.

Workshop questions

1) What aspects of the procedures work well and what does not work well?
2) Are you aware of any examples of where different conclusions on the proposed classification of a substance have been reached? What impacts did this have? Have these differences now been resolved? To what extent are the different pieces of legislation (CLP, PPPR, BPR, etc.,) coherent in terms of the criteria for hazard identification and classification?

3) What are the incentives or disincentives for Member States to prepare CLH (Classification and Labelling Harmonised) dossiers, and should industry also be able to submit dossiers?
4) Are there steps that could be taken to help streamline the processes when they are running in parallel (e.g. CLH and an active substance under PPPR)? If not, how can the processes be managed better?

Summary of break-out group discussions

The discussions focused on BPR and PPPR. Participants noted that the diverging opinions issued by the different scientific bodies involved across the relevant chemicals legislation is an issue for industry, both regarding mixtures (product authorisation at member state level), and active substances (EFSA/ECHA). In terms of the roles of authorities and industry, it was acknowledged that there are resource constraints for member state authorities that impact on their ability to develop dossiers and move these through multiple processes (e.g. CLH and PPPR).

With respect to the potential for industry to submit CLH dossiers, participants (industry and CA) indicated that industry should be allowed to submit a CLH dossier for an Active Substance under PPPR, as this may help reduce differences arising within the two processes (and given that the data will be evaluated by the committees regardless of who submits it). A question regarding possible conflict of interest was raised, and the issue of the availability of industry resources to do this was also mentioned. It was further suggested that if ECHA waived fees for accepting a CLH dossier from industry, this would incentivise industry to submit their own CLH proposals. It was also noted that, under CLH, it is already possible for industry to submit a dossier for an industrial chemical. There was consensus that there should be a legal requirement under the PPPR for a member state to submit a CLH dossier for an active substance. There is currently a serious lack of incentives for MSs to submit CLH-dossiers, in particular since fees cannot be charged (as opposed to PPPR- and BPR-evaluations). Another problem is that the competent authority for CLP is not necessarily the same as those for BPR or PPPR within one MS.

It was also noted though that competent authorities within CARACAL are making an effort to streamline the procedures in relation to hazard assessment (a combined format for a CLH dossier and classification under BPR and PPPR have been developed). In addition, it was argued by a few that self-classification under these two regulations would be less burdensome for industry and for member states.[5] It was further argued that as CLP allows self-classification, there need to be real reasons for not also allowing it under BPR and PPPR; one potential reason suggested was that the authorisation procedure under BPR involves more than just hazard classification. Another was the importance of ensuring that classifications are based on robust data sets because of the potential spill-over effects on other manufacturers.

Greater dissemination and communication about on-going hazard evaluations was seen as being a useful improvement to the process and the importance of a robust data set was discussed, given the spill-over effects on other manufacturers.

One problem raised was the divergence of underlying data sets for the different evaluations. Data sets evolve over time, and become consolidated in REACH registrations. At the same time, for PPPR and BPR evaluations, old data sets from one applicant can be used, and established classifications can be re-discussed. The results can then spill over on manufacturers of the same substance for

[5] It is not clear whether it was recognised during the Workshop that this would result in responsibility for CMR classification being shifted completed to EFSA, as EFSA would still need to check the cut-off criteria based on the proposed self-classification.

other users. The transmission of the biocides file to ECHA, and the alignment with the CLP evaluations, was however seen as having improved transparency and predictability for manufacturers for other uses.

An additional point made during the plenary concerned the activities of SCOEL versus the RAC in setting OELs and DNELs. This was raised as an issue of incoherence, due to the different traditions of the Committees; although it is being picked up by a joint working group between RAC and SCOEL, it leads to confusion.

2.2.3 Transparency of assessment procedures and ability of stakeholders to contribute

Background

This discussion centred on the transparency of procedures within the chemicals legislative framework and the extent to which they allow for stakeholders to participate and contribute. Such procedures include the harmonised classification and labelling process under CLP, PPPR and BPR, as well as risk assessment processes and other Committee procedures (e.g. under Cosmetics, Toys, Fertilisers, etc.). The aim here was to identify good practices in enabling stakeholder involvement and consultation. Preliminary results from the targeted consultation indicate that the CLH procedure, for example, seems to operate in a transparent manner and that stakeholders feel able to contribute to it, although there are some concerns about the degree to which their submissions have been adequately taken into account.

The moderators for these sessions were: Eric Liégeois and Federico Musso, European Commission; and Antonia Reihlen of Oekopol.

Workshop questions

1) To what extent are stakeholders able to contribute effectively to the assessment procedures, in terms of content and level, timing and frequency of contributions? Are stakeholders sufficiently aware of the possibilities to contribute?
2) Are the procedures and timescales under the processes clear and reliable?
3) Are the procedures able to achieve consistent conclusions?
4) Is the level of stakeholder involvement balanced within and across legislation? Are some stakeholders (e.g. industry, NGOs) more involved than others? Are there measures to reach out to all stakeholder groups?

Summary of break-out group discussions

On the key question of transparency of procedures, in general, the participants agreed that transparency has increased with, for example, the publication of meeting documents, draft opinions and opinions of committees etc.

Nevertheless, this transparency may be more evident to those people who regularly deal with the assessment procedures than to those who do not. ECHA/RAC's transparency was perceived by participants as being very good for experts who are able to contribute via the public consultation process, or via direct participation or via the minutes of the meetings; however, there was considered to be less transparency for small(er) companies, Downstream Users (DU's), and trade unions. Participants were also generally in agreement that the timescales and procedures for contributing and providing feedback to the RAC are clear. COM processes (e.g. expert/working groups' activities, consultations) were seen by some participants as less transparent. Ideas that were

presented by participants as possible improvements included a check-list for end-points, and an overview of upcoming opinions.

With regard to the scientific committees and expert groups, it was commented that the decisions on the composition of some scientific committees are not transparent; in particular, this is considered to be the case where experts are not nominated by Member States but are selected by the Commission or by the Committee[6]. There is also some concern that not all of the expertise required to discuss a particular issue may be available within a particular Committee and/or that there might be conflicts of interests. Overall though, expert groups were perceived as a good model for ensuring transparency, because stakeholders can participate as observers / experts; for example, NGOs as they are often members of such groups.

However, it was noted that procedures that are clear to experts must be "translated" and "transported" (i.e. communicated) to those who are not "in the process" (e.g. SMEs), and that industry associations see this as part of their role. As regards SME participation in the processes, the issue of language being a barrier to participation was raised, as was the issue of a lack of resources, which is also relevant to NGOs and their ability to be represented in different fora. Because of the level of activity, just following the processes can be challenging for many stakeholders.

Participants commented that improvements could be achieved by keeping some of the existing tools (e.g. the Comitology register) up to date, and by improving other tools such as the early warning systems. In relation to consultations within the Committee processes (e.g. ECHA consultation periods on RAC draft opinions, etc.), timelines were considered to be too tight.

Other key points in relation to transparency include:

- It is difficult to understand / find information at which stage of a (regulatory process) a substance is. ECHA's website is good to prepare for involvement; early warning systems help but are not sufficient to prepare for consultations / other forms of participation
- The practice of listing consultation comments and replying to them in a consolidated document is regarded as good, for example, in ECHA's RCOM process; however, a reply on how the comments were taken on board or handled is missing;
- It is not always clear to all stakeholders what information can be submitted in a consultation, for example, on a proposed harmonised classification, or at what time different types of information can be submitted. There should be an opportunity to report information which is not directly related to the consultation topic (e.g. as part of the CLH process). It was mentioned that the COM consultation on SEA in relation to the prioritisation of substances for inclusion in Annex XIV was welcome, because stakeholders had a place to provide their concerns about consequences of the regulatory action. The implication is that they would also welcome such a consultation in relation to CLH proposals.
- There was criticism that the raw data / full studies underlying an opinion or CLH decision are not published, making it difficult for industry and NGOs to understand how an opinion was

[6] It was noted in discussions that RAC members are proposed by member states in an open and transparent procedure, while EFSA for example had a different working procedure that was considered less transparent. In addition, active participation of observers is only possible within EFSA's working procedure if they are invited to participate; one NGO participant at the Workshop believed that this has had an impact on some of the opinions produced by EFSA.

arrived at in those cases where it differs significantly from what they expected based on their interpretation of the data available to them;

- Consultation periods are seen to be very short (e.g. 45 days) by some stakeholders (industry) but making the consultation period longer (e.g. 6 months) would not be acceptable to other stakeholders (NGOs) as this could be seen as delaying the process;
- ECHA's communication tools in relation to PBTs is an example of what is being done well, in terms of disseminating information on on-going hazard assessments; and
- In contrast, the exclusion of industry from the CLP/ BPR/ PPPR alignment project for active substances is an example of a lack of transparency and appropriate stakeholder participation.

2.2.4 Hazard communication to downstream users and consumers

Background

Various tools are in place to communicate hazards to downstream users of chemicals and end consumers. Some are mandated by EU legislation, such as labelling requirements under the CLP Regulation, Detergents Regulation and Cosmetics Regulation; others are voluntary measures. The discussion will look at how effective and efficient these tools are, whether the labelling requirements are appropriate, as well as considering the potential role of technologies such as bar codes, Q-R codes, etc. for relaying important hazard information to downstream users.

The moderators for the session were: An Jamers, European Commission; and Linda-Jean Cockcroft, Risk & Policy Analysts Ltd.

Workshop questions

1) To what extent do you think that hazard communication (labels, pictograms) guides the awareness and risk management of downstream users?
2) To what extent is hazard communication coherent across sectors / products?
3) Do you believe workers have a sufficient understanding of pictograms and other information communicated on product labels?
4) Do you believe consumers have a sufficient understanding of pictograms and other information communicated on product labels?
5) Do you believe there is scope for greater use of technology (i.e. Q-R codes, barcodes, mobile phone apps) for communicating hazards to downstream users?

Summary of break-out group discussions

Participants agreed that labels form the cornerstone of hazard communication, but also noted that there is a different level of understanding of labelling information between workers and consumers. Workers generally seem to have a better understanding/awareness than consumers. There is an obligation on the part of employers to train their employees on hazard communication and employees should be trained regularly (not just once) to keep their knowledge up to date. This employer obligation to provide training is better at large companies than at SMEs and is not always enforced, which could be a point of improvement for worker communication. Pictograms are key for communication, also for workers, although some pictograms are confusing/problematic and need attention. Participants suggested that consumers may need different pictograms to workers.

Consumers were reported to (often) not read labels and, if they do, they stop because there is too much information and it is too confusing. However, a participant reported that a study by CEPE on the consumer use of paint labels found that around two thirds of paint users do read labels. This is

either because paint is an "infrequent use" product (as opposed to day-to-day household products) or because of consumer perceptions of the hazardousness of a product (e.g. dishwashing liquid is perceived as being "safe", while paint is perceived as being potentially "toxic"). Another participant recalled that an ECHA study on consumer comprehension of pictograms in 2011 showed that general knowledge of pictograms is low.

Thus, according to participants, although pictograms are considered the most informative part of label, there is some room for improvement. Some are not clear (exploding chest, exclamation mark), and it was noted that pictograms were not originally designed for consumers. In terms of other icons, some labels are better known than others (e.g. Ecolabel) and certain "safe use" icons developed by industry (e.g. by the detergents industry) are more informative and communicate more clearly with consumers than pictograms do. As regards pictograms, participants noted the need for training and education and awareness raising of consumers of all ages (the Hungarian project to educate children and a new project in Belgium involving a game for children aged 10-14 were mentioned).

Participants agreed that technology has a clear role to play: bar codes, Q-R codes, toxfox (DE), and programs in Demark and Norway were all seen as having added value. The feasibility of simplifying labelling by using technology in addition to (but not instead of) the label was discussed. This could be a way to reduce information overload due to requirements from multiple legislation. The issue of language was also raised, with the suggestion that all EU languages should be included on a fold-out label to ensure all EU consumers are able to access the necessary information.

However, there was some discussion as to what is "meaningful" communication with consumers via a label. Some participants preferred keeping the existing labels, and suggested that it should be very clearly stated on the label where additional information on a product can be found (a link to a website is not enough) and a Q-R code for example could provide a direct link to this information. In this respect, it was suggested that specific information should be readily available on the manufacturer's website while general information could be held on the websites of authorities or ECHA.

It was also noted that not everyone has a smartphone, so care was need to make sure that there were alternative methods of communication and dissemination.

Thus there appears to be agreement that hazard information has to be retained on labels, with more innovative technologies used to provide supplementary information requirements. More generally, labels are perceived as being overloaded, and there needs to be a smart integration of communication requirements across legislation. In addition, there are innovative projects in several member states aimed at educating children and the public, and perhaps more effort should be put into education.

2.3 Break-out sessions Part 2: Discussion topics and conclusions

2.3.1 Implementation of the GHS

Background

The EU has adopted all four major building blocks of the GHS, and to date has adapted CLP in line with changes to the GHS. This discussion topic considered the impacts of the EU adoption of GHS vis a vis other nations with respect to the single market, international trade, and human health and environmental protection. It also considered issues arising from the timing of adaptations of CLP (including transition times), and the extent to which aspects of the Regulation lead to disproportionate effects.

The moderators for this session were: Fabrice Broeckaert, European Chemicals Agency, and Roberto Scazzola, European Commission; Linda-Jean Cockcroft, Risk & Policy Analysts Ltd.

Workshop questions

1) Has implementation of the GHS resulted in any differences in terms of the international trade in chemicals? If so, for which markets, and has it had a positive or negative impact?
2) What issues have arisen at the international level from the adoption of different building blocks or the divergent implementation of building blocks? To what extent has this affected international trade?
3) Although the EU adopted all of the GHS hazard classes, it did not adopt all of the hazard categories. Has this led to any significant impacts? Have all of the appropriate hazard classes and categories been adopted in the EU?
4) Are the timings of the GHS revisions and the related adaptations of CLP, including the transition times allowed to implement these changes into national/EU legislation, appropriate?
5) To what extent are the impacts of GHS taken into account in the revision process?

Summary of break-out group discussions

The timing of GHS implementation was viewed overall in a positive manner as an adequate time was given for making the adjustment to GHS; in this respect, predictability is important for companies. However, the flexibility in the way GHS can be implemented can result in different approaches at the regional (national) level, which in turn reduce the potential benefits of there being a globally harmonised system. This leads to different classification decisions and undermines global GHS effectiveness (consumer vs workers applicability, optional categories, building blocks, etc.).

The EU approach of having an 18 month transitional period for applicability of GHS updates is generally perceived as being sufficient (depending on a company's position in the supply chain) but the constant need to re-label is a cost. (It was also noted that GHS brings changes to the transport orange book.) Minor changes ("nice to have" rather than "need to have" changes such as editing changes, e.g. wording clarification, etc.) have no real benefits but can have significant negative impacts due to re-labelling requirements. In this sense, a longer transitional period or longer delay in the EU adoption of minor changes would be desirable. Proportionality and assessment of the costs and benefits of proposed changes could support this analysis.

Other suggested improvements to the current system included assessment and possible amendment of the two years' working programme. However, some participants were afraid that this could

undermine the system. The implementation of a global list for the classification of hazardous substances (e.g. similar to Annex VI CLP) could be a powerful tool to enhance GHS applicability.

In general, being a forerunner of GHS implementation was seen to have positive effects in the EU. However, clearly GHS is neither global nor harmonised internationally, as different regions implement different building blocks at different times. Participants discussed what could be done to promote the uptake of building blocks in other regions. Suggestions included providing capacity building and technical support and training to India (an example of a country known to be open to such support). In particular, participants mentioned that differences in consumer and environmental building block uptake results (notably in the United States and Canada) in regional differences. For example, environmental building block uptake determines what can be transported and how internationally, and it was observed that this could in the future result in a disadvantage for the EU if waste (tomorrow's raw materials in a circular economy) cannot be imported/exported due to transport restrictions resulting from environmental regulation.

One interesting example of an industry sector working together globally to harmonise their C&L approach was given by the Aerosol sector, which worked at the UN level to ensure global adoption of the same classification criteria and test methods. This included development of new tests that agreement on classification rules that reflected an increase in requirements across all regions, so as to ensure that an aerosol supplier producing a new formulation would meet the requirements for classification in any region if they followed GHS based requirements.

Additional or reiterated points within the plenary included the following (in order of discussion):

- From an NGO perspective, implementation of GHS has resulted in significant health and environmental benefits, and that these should be recognised; and
- The need to consider the costs and benefits of alignment of CLP with all GHS changes was re-iterated.

2.3.2 Data quality requirements and test methods

Background

The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. A key issue moving forward is whether the CLP classification criteria can be adapted to changes in scientific methods for testing and rules regarding animal testing. It will also consider, more broadly, whether new test methods are sufficiently able to identify combination effects of mixtures and whether these effects are taken into account in classifying substances and mixtures. A related issue is the relevance and coherence of data quality requirements, in particular on Good Laboratory Practice (GLP), across chemicals legislation, as well as the extent to which non-GLP data can be taken into consideration for the risk management of chemicals.

The session was moderated by: An Jamers, European Commission; and Antonia Reihlen, Oekopol

Workshop questions

1) To what extent do you believe that current data quality requirements, in particular GLP, can be applied to novel, non-standard animal testing methods and related information? Do they hinder use of "all available" data and, if so, what consequences does this have?
2) To what extent do you believe that data quality requirements, in particular GLP, pose an (un)necessary burden to businesses and to what extent are they consistently enforced?

3) To what extent do you believe that there is consistency across legislation in the use and interpretation of data? Are there significant differences that lead to inconsistencies in risk management, for example?
4) What challenges arise in using hazard data from new test methods or other sources, such as QSARs, for classification?
5) Are there cases where the use of data generated from new methods has been readily accepted by all stakeholders? Can lessons be learned from such cases?

Summary of break-out group discussions

The discussions were divided into three aspects: data quality issues; the use of non-animal test data as a source of classification data; and issues regarding toxicity. A summary of the key points made in relation to each is provided below.

- There was general agreement that high quality data is needed to ensure a sound basis for regulatory decisions making. In this respect, the GLP requirement ensures that there is a rigorous documentation of how a study was conducted and that allows the checking of study details which may be required for e.g. classification. However, GLP on its own does not help in ensuring that a scientific study is of high quality or is of high accuracy. Stakeholders had divergent views on the relevance of GLP: some consider it outdated, as the problems that lead to it do not exist anymore; while others consider it helpful in ensuring that available toxicological and ecotoxicological data that meets data quality requirements is used, with this in turn helping to ensure that no unnecessary animal tests are conducted (due to the mutual recognition of data).
- GLP is good to have as it demonstrates reproducibility but it is not sufficient to ensure high scientific quality, implying that GLP may be best used as a quality guarantee for established test methods, and
- Nevertheless, non-GLP data can also be valuable, for example, as often toxic chemicals are first picked up in scientific research and reported upon in scientific literature. While the research is not always done according to GLP, the information is still very valuable and should not be disregarded.

In particular, requirements on GLP for physical-chemical data were questioned, as no animal tests are carried out, there is considerable information that was generated pre-GLP and that is still applicable, meaning that there are no added benefits of now requiring new testing to be carried out which meets GLP requirements. It was also noted that nowadays most commercial laboratories implement GLP for most endpoints, but that this is less often the case for academic labs; some stakeholders think that the GLP requirement therefore excludes the use of data from academia (although one could argue that there is nothing stopping academia from also adhering to the principles). GLP does create costs but there was no clear conclusion on whether these are proportionate to an expected benefit regarding increased quality / acceptance of data. It was also suggested though that the CRED system recently introduced under the WFD could be an approach to ensure quality independently of Klimisch criteria and/or GLP.

The existence of test guidelines were considered to be an important factor for quality assurance; in this respect, some participants suggested that it is more relevant that test guidelines are followed than that GLP is implemented. However, it should be noted that test guidelines do not ensure the reproducibility of the data, as guaranteed by GLP. According to some participants, it is also important that test guidelines are agreed at the OECD level as this ensures international recognition of study results.

The lack of test guidelines is seen as one of the constraints to greater acceptance of non-animal test data or non-test data. Starting with non-animal test data, in-vitro methods (replacing animal tests and creating new (types) of information) are hardly used at present, as methods are only available for some end-points, and that this discourages use.

Stakeholders also indicated that the legislative framework, in particular CLP, does not encourage use of in-vitro methods, as criteria / cut offs are targeted to animal test results, and there are no clauses referring to such methods in the legislation (reference to weight of evidence would be relevant but is not considered to be sufficient). In addition, one stakeholder indicated that a possible downside of in vitro test results is that one may only obtain a binary response; where this is the case, no dose-response data would be available from the test results, and weight of evidence methods must then be relied upon[7]. However, another participant argued that, in some cases, in vitro test systems may actually be more fit for purpose and more reliable than animal test results (e.g. when looking at a particular metabolic pathway or mechanism of action).

It was also suggested though that there may be particular value to allowing the use of in vitro data in relation to mixtures. Little testing of mixtures is carried out at present, although this is allowed under CLP where mixture test data prevails over calculations (which is good). If there were accepted in vitro methods, then they could be used to improve current datasets.

More generally, it appears that authorities and industry regard the general level of confidence that can be achieved from in-vitro testing as lower than that from animal tests; i.e. it is difficult to achieve similar protection as if animal tests were used. As a result, acceptance of their use is uncertain in the absence of agreed rules or test methods. In this respect, it was agreed that in order to gain greater acceptance of non-animal test methods, translation rules are needed to enable one to move from the results of in-vitro tests to e.g. classification endpoints. Ideally, the development of such rules or of methods at OECD level will ensure acceptance of non-animal data.

With respect to non-test methods, stakeholders felt that the guidance on how to use QSARs and *in silico* methods is not sufficient (for example, how does one treat negative results). In particular, it was argued that the misuse of QSARs is possible, e.g. to avoid generation of new test data despite the fact that the resulting information is not of good quality. It was also argued that there is too little information on the validity and applicability of *in silico* models in the context of filling data gaps.

Overall, it was agreed that the development of new methods is a long and time consuming process. It does not appear necessary to have a "revolutionary" change but for the time being it is more appropriate to move in small steps as methods become available (in vitro and in silico) and gain in acceptability. It is unclear though if and when new methods will really become available and accepted for more complex end-points, such as carcinogenicity. When they do, CLP classification criteria would have to be adapted.

[7] The European Commission notes, however, that this depends on the design of the in vitro method – many involve testing at multiple concentrations and thus result in the generation of concentration-response data. Such data can then be used for potency estimation as well as hazard classification.

Additional or reiterated points within the plenary included the following (in order of discussion):

- The importance of flexibility but also conversely that there is confidence that a comparison of data is based on a like for like basis;
- The fact that academics have moved away from testing to the current classification criteria, with this suggesting that there is a need for new criteria that are more suited to non-animal testing; and
- There is a need to distinguish between PPP and BP compared to industrial chemicals within such discussions (due to differences in endpoints and hence testing requirements at present).

2.3.3 Downstream risk management measures

Background

There are many pieces of downstream legislation, such as the Toy Safety Directive, Plant Protection Products Regulation, Biocidal Products Regulation, Cosmetics Regulation, as well as occupational health and safety legislation, which are affected by harmonised classifications under CLP and that trigger risk management requirements. In some cases, a harmonised classification under CLP automatically triggers the need for risk management, while in others it is based on further assessments. The discussion focused on the appropriateness and impact of these linkages.

The moderators for these sessions were: Eric Liégeois and Johanna Bernsel, European Commission; and Julia Lietzmann, Milieu.

Workshop questions

1) Which circumstances justify automatic triggers for risk management measures in downstream legislation (e.g. use restrictions, personal protective equipment)?
2) What are the advantages / disadvantages of a risk management approach based on automatic consequences of a hazard classification (with or without derogations) over an approach involving a risk assessment procedure?
3) In which cases do you think that the links between a hazard classification and a downstream risk management measure are (dis)proportionate or (in)effective?
4) Are there cases where derogations under the legislation are needed on a regular basis?
5) Are there missing links between risk management measures and hazard classifications?
6) Are there cases where there are differences in national interpretation and enforcement?

The advantages of automatic triggers are seen by some participants as providing legal certainty and a quick, high level of protection (particularly for cumulative risks). One participant noted that the focus should be on when the use of hazardous chemicals should be allowed (for example, when exposure is controlled), rather than the other way around, meaning an automatic ban with possible derogations is preferable. Another participant noted that for some classifications there should be no derogation. Other participants, however, expressed severe criticism against hazard-based risk management measures, which was seen as giving the European industry a competitive disadvantage vis-à-vis the rest of the world. In this respect, some argued that any hazard should only trigger risk assessment, with RMMs then identified based on this. Consequently, if there is a change in the hazard classification the RMM currently required should be re-assessed. There are also arguments in favour of a more mixed approach, which would allow for automatic triggers appropriate under some legislation (where justified) but not under other legislation.

In some legislation, derogations from automatic triggers are the exception rather than the rule (BPR, PPPR, Toys); in others, derogations are case by case based on contact or exposure/risk assessment (Seveso III); while in others, they are based on societal interests (BPR, PPPR, Medical devices,…). An industry representative acknowledged that there are hazards that should be addressed automatically, but also noted that for the Cosmetics Regulation (CR), industry struggles with the 15-month deadline to apply and obtain a SCCS opinion for a derogation and with knowing what information must be provided. There is also uncertainty about the timing of a ban of a new CLH substance under the CR: is it when the substance is classified under CLP or when it is formally added to the CR Annex.

Participants mentioned the following legislations as missing a link between hazard classification and risk management measures: general product safety legislation, textiles, food contact materials, and furniture.

Derogations are seen as difficult to apply and the costs are not always proportionate to the risks, e.g. Seveso, where the example of nitric acid was considered by some participants to demonstrate a problem with the automatic trigger. Stakeholders noted that there is difficulty obtaining a 'derogation' under Seveso, as this requires an exclusion from the scope of the Directive: this can take 5-7 years to obtain and there is a need to prove that the requirements to obtain a derogation are met throughout the EU.[8] If derogations are difficult to obtain or cannot be obtained, then the resultant impacts could affect the integrity of CLH discussions, which are currently based on scientific evidence only.

In addition, Ethanol was raised as a case in point, where it was highlighted that classification of the substance as a CMR would trigger a range of downstream consequences under different pieces of legislation, which would be significant.

Finally, mention was made of national discrepancies in approaches to dealing with waste.

2.3.4 SME awareness and engagement

Background

This discussion focused on the problems faced by SMEs in understanding and complying with chemicals legislation. This includes their ability to respond to the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years, as well as to respond to the introduction of new harmonised classifications. Also of importance is the level of support available to SMEs to help them understand and respond to these and other obligations under other related chemical legislation. Also for discussion was the effectiveness of current methods for engaging with SMEs under the different processes of the chemicals legislative framework.

The moderators for the sessions were: Federico Musso, European Commission; and Caroline Raine, NCEC of AEA-Ricardo.

[8] Unlike derogation mechanisms which are typically addressed by Implementing Decisions, an ordinary legislative procedure has been required by the legislator in the case of Seveso. It should also be noted that the Union is bound by international agreements in this area.

Workshop questions

1) What problems do SMEs face in understanding and complying with chemical and chemical related legislation?
2) What aspects of the chemicals legislation framework cause the most difficulties for SMEs?
3) How do SMEs keep up to date? Do they rely on external service providers, trade associations, guidance from Member States?
4) Is sufficient support or consideration given to SMEs in aiding their compliance with CLP and other chemicals legislation?
5) Are SMEs able to effectively and efficiently engage in the various processes in the chemicals legislative framework? If not, what actions could help address the difficulties they face.

Participants discussed that the complexity of legislation as well as the fact that legislation is frequently inter-linked present difficulties for SMEs. This complexity adds to frustration and can be a barrier to innovation. While information is available, it can be difficult to find and hard to understand, particularly as the information is frequently available only in English; in addition, webinars and conferences are often only in English. Other difficulties discussed include transition times to implement new or changes to legislation, language and knowing what legislation actually applies to their business.

A number of SME-specific challenges and opportunities were raised. Challenges included the lack of resources internally, as often the person responsible for chemical regulations is doing other roles, therefore has too much to do, and can struggle to find others to talk to for advice and or a reality check. For SMEs, it is difficult to find the time and money to attend workshops, webinars, conferences etc., and to find time to track, understand and implement changes. In addition, the lack of a large legal team to make decisions was mentioned as a challenge.

From an authority and industry association perspective, it can be difficult to reach small companies. Associations often don't know that they exist (and this may be a problem for authorities too). SMEs may not realise the regulations apply to them, and industries that are not necessarily perceived as chemical industries fall under the regulations (e.g. candle makers). SMEs may only realise the impact of chemicals legislation on their business when there is an inspection or complaint being investigated. Not all SMEs belong to a trade association or similar group. There can also be cultural differences, with some people not liking to ask for help, or to pay for help. Compliance software was discussed and it was agreed it is too expensive and creates a significant cost burden.

A number of opportunities for improvement were also raised. In the area of training and education, training courses are needed on the basics. Top tips and tricks would be helpful, along with simple guidance in layman's terms.

Benchmarks would be helpful so as to be able to understand what are other similar companies doing. On CLP, it was suggested that contact details could be added to the CLI so that companies could discuss classifications. In addition or alternatively, a forum to discuss openly classifications was mentioned as beneficial. Downstream users (SMEs) may have very little time to make labelling changes as suppliers upstream provide details late, or when it is convenient for them to make changes. It was noted that SMEs often rely on the downstream SDSs and, for articles, it becomes difficult as the flow of information often stops. It was also noted that SMEs need help to interpret SDSs.

It was considered that Member States need to do more. One suggestion was that each government/Member State contributes to a pot of money that is then used to educate SMEs. Some Member States do provide support, with the following mentioned: Ireland has released online e-

learning modules; Finland offers seminars; France has newsletters, bimonthly publications, information emails that can be subscribed to; Germany runs a SME discussion forum.

In the plenary session there was a request for a stand-alone mapping of the horizontal and vertical links between CLP and other chemicals legislation to be one of the outputs of the study, as this may be of enormous help to SMEs, who want to make sure that they understand the complexity of the legislative framework.

2.4 Conclusions and next steps

The rapporteurs gave feedback from their discussion groups to the plenary. The discussions during the plenary session picked up various points from the individual breakout sessions. Additional or reiterated points made within the plenary session have been included in the discussion of each of the topics set out above.

Finally, Otto Linher made the concluding remarks. He thanked those involved in organising and running the workshop, the rapporteurs and the participants. He reminded everyone of the importance of participating in the Open Public Consultation on the fitness check of chemicals legislation (excluding REACH) which closes on 27 May 2016.

Annex 1 Legislation under the scope of the fitness check

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 (Directive 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
General product safety (Directive 2001/95/EC) 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 regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision) Aerosol dispensers (Directive 75/324/EEC) Explosives (Directive 93/15/EEC) 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)
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)

[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.

Annex 2 Workshop Agenda and Participant List

Date & time: 19 April 2016, 09:30-17:00
Location: Diamant Conference & Business Centre
Auguste Reyerslaan 80, 1030 Schaarbeek, Brussels, Belgium

Registration 09:00 – 09:30

Setting the scene 09:30 – 10:20

i. **Opening**
(Carlo Pettinelli, Director, DG GROW)

ii. **Objectives of the study**
(Reinhard Büscher, Head of Unit, DG GROW)

iii. **Overview of the tasks and case studies**
(Meg Postle, Risk and Policy Analysts, Ltd.)

Introduction to the break-out sessions 10:20 – 10:30
(Maurits-Jan Prinz, policy officer, DG GROW)

Coffee break 10:30 – 10:45

Break-out sessions *(Part I) (5 min. introductions & 3x 30 min.)* 10:45 – 12:20

a. CLP classification rules and criteria
b. Hazard assessment across chemicals legislation
c. Transparency of assessment procedures
d. Hazard communication to downstream users and consumers

Lunch 12:20 – 13:25

Break-out sessions *(Part II)* (*5 min. introductions* & 3*x* 30 min.) 13:25 – 15:00

e. Implementation of GHS
f. Data quality requirements and test methods
g. Downstream risk management measures
h. SME awareness and engagement

Coffee break 15:00 – 15:15

Feedback from the break-out sessions & discussion 15:15 – 16:40
(Maurits-Jan Prinz, policy officer, DG GROW)

Conclusions and next steps 16:40 – 17:00
(Otto Linhe, deputy Head of Unit, DG GROW)

Morning schedule:

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8
Round 1: 10:45-11:20	Table A1	Table B1	Table D1	Table C1	Table A2	Table B2	Table C2	Table D2
Round 2: 11:20-11:50	Table B1	Table A1	Table C1	Table D1	Table B2	Table D2	Table A2	Table C2
Round 3: 11:50-12:20	Table C1	Table D1	Table A1	Table B1	Table C2	Table A2	Table D2	Table B2
Not discussed:	*D: Hazard communication*	*C: Transparency*	*B: Hazard assessment*	*A: CLP classification*	*D: Hazard communication*	*C: Transparency*	*B: Hazard assessment*	*A: CLP classification*

Afternoon schedule:

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8
Round 1: 13:25-14:00	Table E1	Table F1	Table H1	Table G1	Table E2	Table F2	Table G2	Table H2
Round 2: 14:00-14:30	Table F1	Table E1	Table G1	Table H1	Table F2	Table H2	Table E2	Table G2
Round 3: 14:30-15:00	Table G1	Table H1	Table E1	Table F1	Table G2	Table E2	Table H2	Table F2
Not discussed:	*H: SME engagement*	*G: Down-stream RMM*	*F: Data quality & methods*	*E: GHS implementation*	*H: SME engagement*	*G: Down-stream RMM*	*F: Data quality & methods*	*E: GHS implementation*

Morning				**Afternoon**		
Table	**Facilitator(s)**	**Topic**		**Table**	**Facilitator(s)**	**Topic**
Table A1	R. Scazzola	CLP classification rules and criteria		Table E1	F. Broeckaert & L-J. Cockcroft	Implementation of GHS
Table A2	C. Raine			Table E2	R. Scazzola	
Table B1	J. Lietzmann	Hazard assessment across chemicals legislation		Table F1	A. Reihlen	Data quality requirements and test methods
Table B2	J. Bernsel			Table F2	A. Jamers	
Table C1	E. Liegeois	Transparency of assessment procedures		Table G1	J. Bernsel & J. Lietzmann	Downstream risk management measures
Table C2	F. Musso & A. Reihlen			Table G2	E. Liegeois	
Table D1	L-J. Cockcroft	Hazard communication to downstream users and consumers		Table H1	C. Raine	SME awareness and engagement
Table D2	A. Jamers			Table H2	F. Musso	

Workshop on the regulatory fitness of chemicals legislation (excluding REACH), 19 April 2016, Schaarbeek, Brussels

LIST OF SPEAKERS, MODERATORS AND PARTICIPANTS

Disclaimer: This list contains the names of all workshop participants, excluding those who objected to the publication of their names in this list. The European Commission does not assume any responsibility for the accuracy of its contents.

Speakers and moderators

Speaker name	Organisation
Carlo Pettinelli	European Commission
Reinhard Büscher	European Commission
Meg Postle	Risk & Policy Analysts Ltd
Maurits-Jan Prinz	European Commission
Otto Linher	European Commission

Moderator name	Organisation
An Jamers	European Commission
Antonia Reihlen	Ökopol
Caroline Raine	NCEC
Eric Liegeois	European Commission
Fabrice Broeckaert	European Chemicals Agency
Federico Musso	European Commission
Johanna Bernsel	European Commission
Julia Lietzmann	Milieu
Linda-Jean Cockcroft	Risk & Policy Analysts Ltd
Roberto Scazzola	European Commission

Registered participants

Name	Organisation	Position	Country
A. Michael Warhurst	CHEM Trust	Executive Director	United Kingdom
Alain D'Haese	FEA - European Aerosol Federation	Secretary General	Belgium
Aleksandra Terzieva	Center for International Environmental Law	Campaign Consultant	Belgium
Alex Föller	Verband TEGEWA e. V.	General Secretary	Germany
Alexander Molterer	The Dow Chemical Company	Lead Government Affairs Specialist Europe	Other
Ana Maria Blass Rico	European Commission	Senior Scientific Officer	Belgium
Andreas Fleischer	BAuA, Federal Institute for Occupational Safety and Health		Germany

Name	Organisation	Position	Country
Andrew Worth	European Commission (JRC)	Senior Scientific Officer	Italy
Anette Ejersted	Danish Environmental Protection Agency	Deputy head of division, Chemicals	Denmark
Anthony C Tweedale	R.I.S.K. Consultancy	Principal	Belgium
Aurélie Dussart	FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu, Belgium		Belgium
Barbara Dallinger	UEAPME/Austrian Economic Chamber		Austria
Bernd Berressem	Verband der Chemischen Industrie	Referent Produktsicherheit/CLP-VO	Germany
Bernd Glassl	Industrieverband Körperpflege- und Waschmittel e.V. (IKW)	Head of Department of Home Care	Germany
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Katinka van der Jagt	European Commission	Policy officer	Belgium
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Majella Cosgrave	Health and Safety Authority	Inspector	Ireland
Marc Pirrung	European Commission	Team Leader IA	Belgium
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Annex 3 Presentations and Workshop Handouts

Regulatory fitness check of chemicals legislation

Stakeholder Workshop

Diamant Conference Centre, Brussels

19 April, 2016

Meg Postle, Risk & Policy Analysts Ltd

milieu

Ökopol
Institut für Ökologie und Politik GmbH

RICARDO-AEA

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Summary

- **Aim**: Identify and evaluate the impact and consequences of implementing the CLP and examine the way it interacts with other chemical legislation

- **Specific Objectives**: The study involves four key tasks:

  1. Evaluate the implementation of the CLP
  2. Evaluate horizontal links between different pieces of EU legislation on hazard identification and communication
  3. Evaluate the vertical links between the CLP and relevant EU and national downstream legislation identifying risk management measures based on hazard classification
  4. Support the Commission in organising a public consultation and workshop

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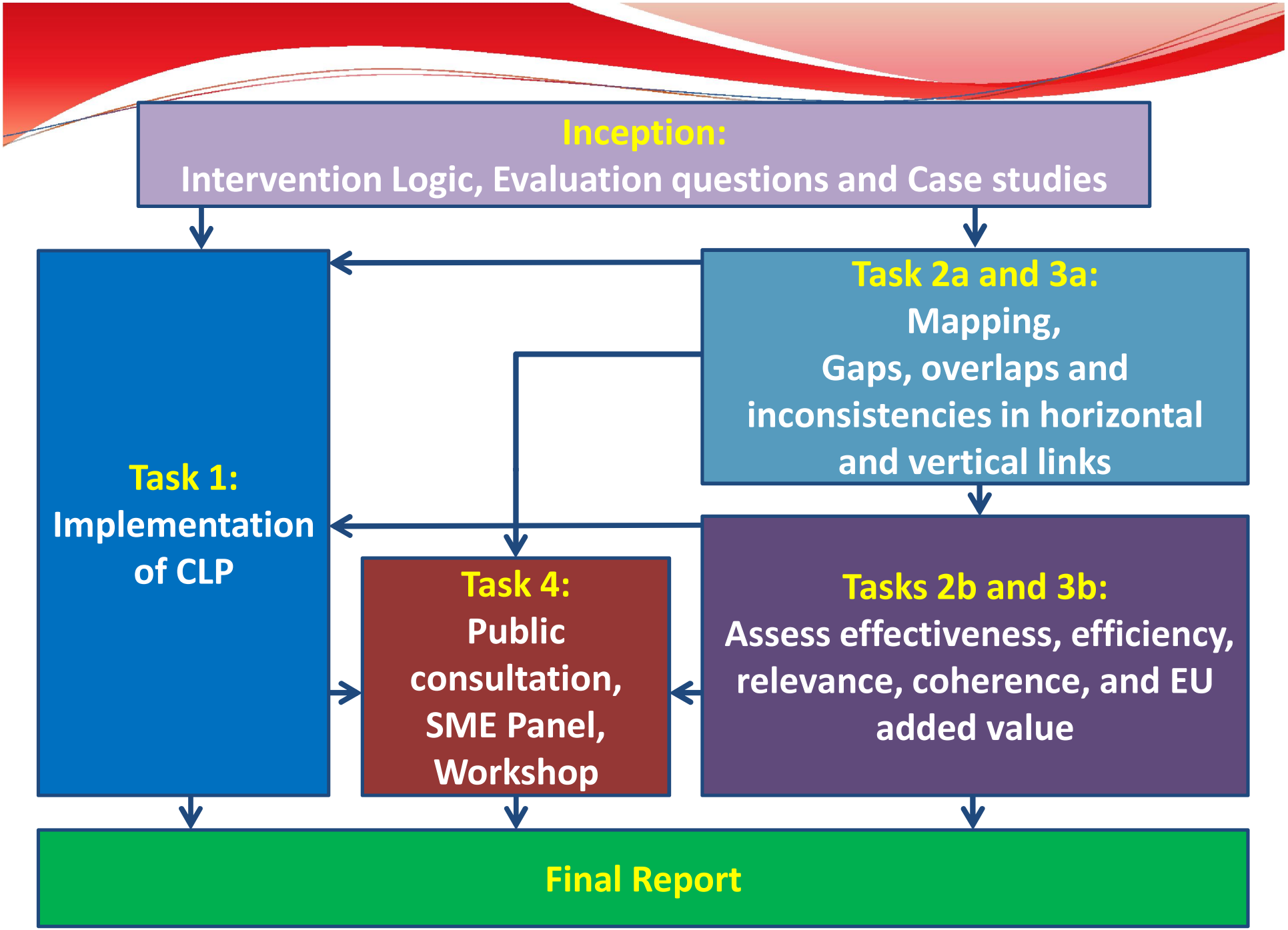
Inception:
Intervention Logic, Evaluation questions and Case studies
Task 1:
Implementation of CLP
Task 2a and 3a:
Mapping,
Gaps, overlaps and inconsistencies in horizontal and vertical links
Task 4:
Public consultation, SME Panel, Workshop
Tasks 2b and 3b:
Assess effectiveness, efficiency, relevance, coherence, and EU added value
Final Report

Overview of approach to study

- Intervention logic and agreement of evaluation questions
  - Effectiveness, efficiency, relevance, coherence, EU added value
- Legislative mapping work
- Desk research and further legal analysis
- Targeted consultation activities
- Case studies
- Open public consultation and SME Panel
- Stakeholder Workshop

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Methodology - Task 1

- Task 1 - i: Impacts of CLP implementation
- Task 1 - ii: EU take-up of building block approach
- Task 1 - iii: Comparison of EU implementation versus that in other countries
- Task 1 - vi: Assessment of harmonised classification procedure
- Task 1 - v: Urgency procedure and safeguard clause
- Task 1 - vi: Evaluation of performance of CLP

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Methodology - Task 2

- Task 2a-i & ii: Mapping horizontal links between CLP and legislation identifying properties of concern, with communication obligations and packaging requirements
- Task 2a-iii: Gaps/overlaps/inconsistencies
- Task 2a-iv: Assess adaptations to technical progress
- Task 2a-v: Case studies on inconsistencies and gaps
- Task 2b-i: Understanding of communication obligations
- Task 2b-ii: Strengths and weaknesses of downstream communication

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Methodology - Task 3

- Task 3a-i: Mapping vertical links with downstream legislation
- Task 3a-ii: Identification of automatic versus further assessment based risk management, and frequency of risk management measures
- Task 3b-i/ii: Assess vertical links in mechanisms and procedures, including stakeholder involvement
- Task 3b-iii: Costs and benefits of the main legislative provisions on risk management measures
- Task 3b-iv: Case studies
- Task 3b-v: National transposition of downstream EU Directives and differences in requirements triggered by CLP classifications

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Horizontal mapping – 15 pieces of legislation

Properties only

WFD, EQS, Watch list, CAD and OELs, CMD

Properties, Communication and Packaging

Tobacco, Plant Protection, Biocidal Products, Fertilisers , Explosives

Communication only

Toys, Food Information, Food Additives, Medical Devices, Pressure Equipment, Construction Products, ELV, Batteries, Waste Shipment, Transport, Safety Signs

Properties and Communication

REACH, Cosmetics, Detergents, Vet Meds, Medicinal Products

Communication and Packaging

Aerosols, Waste Directive, PIC

Vertical mapping – 20 pieces of legislation

Automatic Triggers

Cosmetics, Toys, Tobacco, Ecolabel, Intelligent Materials, Food Contact Materials Information, Plant Protection, Biocidal Products, Pressure Equipment, Waste Directive, Landfill Directive, ELV, Waste Shipments, Environmental Liability, Safety Signs

Risk Management Measures with Further Assessment

Cosmetics, Toys, Ecolabel, Plant Protection, Biocidal Products, Landfill Directive, Young Workers Pregnant Workers, CAD, CMD

Risk Management Measures after Further Steps

Plant Protection, Biocidal Products, Seveso III, IED, CAD, CMD, Pregnant Workers

Case studies

- Task 1:
  - Impacts of differences in the uptake of **GHS building blocks** for costs, competitiveness, health and the environment
- Task 2:
  - Coherence in **parallel hazard assessments** under different legislation (CLP, BPR, PPPR)
  - Relevance and coherence as regards the use of **test methods** and **data quality requirements** in chemicals legislation
  - Coherence of classifications, definitions and the **labelling requirements for detergents**
  - Suitability of the CLP Regulation **classification criteria for metals**
  - Consistency in assessment procedures for **PBT and vPvB** as properties of concern

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Case studies

- Task 2:
  - Linkages between the **CLP and Seveso III** Directive, including risk management under Seveso III *(scope under discussion)*
  - Awareness of Chemical Safety Assessment and labelling requirements for **Toys**
  - **Consumer comprehension** of and relevance of safety information on product **labels**
- Task 3
  - Interface between the **Fertiliser Regulation** and CLP
  - Linkages with **Occupational Health and Safety Legislation** *(scope under discussion)*
  - **Risk management procedures triggered by harmonised classifications** under the CLP Regulation

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Targeted data collection - Tasks 1, 2 and 3

- Industry stakeholders:
  - Manufacturers and importers
  - Formulators – general industrial, plant protection, cosmetics, detergents
  - Distributors
- Consumer representatives
- Workers representatives
- Environmental and public health NGOs
- Member States
- Expert Groups

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On-line Open Public Consultation

- Effectiveness of EU chemicals legislation:
  - Health and the environment, and orientation in terms of risk management
  - Single market, competitiveness and innovation
  - Decision making, procedures, implementation, hazard assessment, risk management, hazard communication, data quality requirements
- Efficiency:
  - Societal benefits and costs, as well as potentially significant types of costs
- Relevance:
  - Substitution and emerging areas of concern
- Coherence – gaps, overlaps and inconsistencies
- CLP related questions

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Thank you!

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A: CLP classification rules and criteria

The session will cover:

- The extent to which default classification rules under the CLP Regulation are appropriate for the different types of substances and mixtures
- Whether the classification rules trigger under/over classification of substances and mixtures, e.g. metals in the massive form and alloys
- Whether classification rules are appropriate for the for particular types of substances
- Whether there are any gaps in the CLP Regulation
- Whether mixture classifications are more generally dependent on the choice of method

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A: CLP classification rules and criteria

Workshop questions:

- To what extent are the current classification criteria suitable to fully describe the hazard profile of substances and mixtures to an extent necessary for enabling appropriate risk management?
- Does the classification system (including the rules, criteria, guidance documents) make it easy to correctly classify substances and mixtures?
- What methods (rules, test data, bridging principles, weight of evidence) are being used most for mixture classification and are there any differences arising from the use of these different methods?
- Are there differences in the acceptability of different approaches at the Member State level?

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B: Hazard assessment across chemicals legislation

The session will cover:

- The differences in responsibility for hazard assessment and agreement of harmonised classifications varies under different pieces of legislation, i.e. CLP, Biocidal Products and Plant Protection Products Regulations
- The coherence across the different pieces of chemicals legislation in terms of the procedures for assessing hazards and classifying substances and mixtures, and their outcomes
- Examples of how such differences have been resolved and what types of impacts arise from any potential lack of coherence

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B: Hazard assessment across chemicals legislation

Workshop questions:

- What aspects of the procedures work well and what does not work well?
- Are you aware of any examples of where different conclusions on the proposed classification of a substance have been reached? What impacts did this have? Have these differences now been resolved? To what extent are the different pieces of legislation (CLP, PPPR, BPR, etc.) coherent in terms of the criteria for hazard identification and classification?
- What are the incentives or disincentives for Member States to prepare CLH dossiers? Should there be a requirement under CLP, BPR and PPPR for MS to prepare and submit a CLH dossier?
- Should industry also be able to submit CLH dossiers?
- Are there steps that could be taken to help streamline the processes when they are running in parallel (e.g. CLH and an active substance under PPPR)? If not, how can the processes be managed better?

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C: Transparency of assessment procedures and ability of stakeholders to contribute

The session will cover:

- The transparency of procedures within the chemicals legislative framework and the extent to which they allow for stakeholders to participate and contribute. Such procedures include the harmonised classification and labelling process under CLP, PPR and BPR, as well as risk assessment processes and other Committee procedures (e.g. under Cosmetics, Toys, Fertilisers, etc.)
- The extent to which stakeholders can contribute
- Whether the ability of stakeholders to contribute is balanced
- And whether there are good practices that exist within the framework that could be adopted elsewhere

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C: Transparency of assessment procedures and ability of stakeholders to contribute

Workshop questions:

- To what extent are stakeholders able to contribute effectively to the assessment procedures, in terms of content and level, timing and frequency of contributions? Are stakeholders sufficiently aware of the possibilities to contribute?
- Are the procedures and timescales under the processes clear and reliable?
- Are the procedures able to achieve consistent conclusions?
- Is the level of stakeholder involvement balanced within and across legislation? Are some stakeholders (e.g. industry, NGOs) more involved than others? Are there measures to reach out to all stakeholder groups?

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D: Hazard communication to downstream users and consumers

The session will cover:

- The tools in place to communicate hazards to downstream users of chemicals and end consumers
- The effectiveness and efficiency of those tools that are mandated by EU legislation, such as labelling requirements under the CLP Regulation, Detergents Regulation and Cosmetics Regulation, as well as the effectiveness and efficiency of tools that are voluntary measures
- Whether labelling requirements are appropriate
- The potential role of technologies such as bar codes, Q-R codes, etc. for relaying important hazard information to downstream users

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D: Hazard communication to downstream users and consumers

Workshop questions:

- To what extent do you think that hazard communication (labels, pictograms) guides the awareness and risk management of downstream users?
- To what extent is hazard communication coherent across sectors / products?
- Do you believe workers have a sufficient understanding of pictograms and other information communicated on product labels?
- Do you believe consumers have a sufficient understanding of pictograms and other information communicated on product labels?
- Do you believe there is scope for greater use of technology (i.e. Q-R codes, barcodes, mobile phone apps) for communicating hazards to downstream users?

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E: Implementation of GHS

This session will cover:

- The extent to which differences in adoption of GHS building blocks lead to variations in impacts across different countries in terms of human health and environmental protection
- The effects of GHS implementation via CLP on the single market international trade
- The approach taken by the EU in adapting CLP in line with changes to the GHS
- Any issues arising due to the timing of adaptations of CLP (including transition times) including, for example, disproportionate effects on industry

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E: Implementation of GHS

Workshop questions:

- Has implementation of the GHS resulted in any differences in terms of the international trade in chemicals? If so, for which markets, and has it had a positive or negative impact?
- What issues have arisen from the adoption of different building blocks at the international level?
- Although the EU adopted all of the GHS hazard classes, it did not adopt all of the hazard categories. Has this led to any significant impacts? Have all of the appropriate hazard classes and categories been adopted in the EU?
- Are the timings of the GHS revisions and the adaptation of CLP, including the transition times allowed to implement these changes into national/EU legislation, appropriate?
- To what extent are the impacts of GHS taken into account in the revision process?

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F: Data quality requirements and test methods

The session will cover:

- Whether the classification criteria under the CLP regulation for some hazards are linked to the outputs from existing animal test methods, which are used to fulfil REACH information requirements
- Whether the CLP classification criteria can be adapted to changes in scientific methods for testing and rules regarding animal testing
- Whether new test methods are sufficiently able to identify combination effects of mixtures
- Whether these effects are taken into account in classifying substances and mixtures
- To what extent is non-GLP data is taken into consideration for the risk management of chemicals

F: Data quality requirements and test methods

Workshop Questions:

- To what extent do you believe that current data quality requirements, in particular GLP, can be applied to novel, non-standard animal testing methods and related information? Do they hinder use of "all available" data and, if so, what consequences does this have?
- To what extent do you believe that data quality requirements, in particular GLP, pose an (un)necessary burden to businesses and to what extent are they consistently enforced?
- To what extent do you believe that there is consistency across legislation in the use and interpretation of data? Are there significant differences that lead to inconsistencies in risk management, for example?
- What challenges arise in using hazard data from new test methods or other sources, such as QSARs, for classification?
- Are there cases where the use of data generated from new methods has been readily accepted by all stakeholders? Lessons?

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G: Downstream risk management measures

This session will cover:

- The linkages between downstream legislation, such as the Toy Safety Directive, Plant Protection Products Regulation, Biocidal Products Regulation, Cosmetics Regulation, Seveso Directive, as well as occupational health and safety legislation, which are affected by harmonised classifications under CLP and that trigger risk management requirements
- The appropriateness of these linkages, where the triggers are automatic in terms of requiring risk management
- The advantages and drawbacks of automatic triggers versus risk management based on risk assessment
- Effectiveness, efficiency and coherence of these different linkages

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G: Downstream risk management measures

Workshop questions:

- Which circumstances justify automatic triggers for risk management measures in downstream legislation (e.g. use restrictions, personal protective equipment)?
- What are the advantages / disadvantages of a risk management approach based on automatic consequences of a hazard classification (with or without derogations) over an approach involving a risk assessment procedure?
- In which cases do you think that the links between a hazard classification and a downstream risk management measure are (dis)proportionate or (in)effective?
- Are there cases where derogations under the legislation are needed on a regular basis?
- Are there missing links between risk management measures and hazard classifications?
- Are there cases where there are differences in national interpretation and enforcement?

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H: SME awareness and engagement

The session will cover:

- The problems faced by SMEs in understanding and complying with chemicals legislation
- The ability of SMEs to respond to the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur every two years, as well as to respond to the introduction of new harmonised classifications
- The level of support available to SMEs to help them understand and respond to these and other obligations under other related chemical legislation
- The effectiveness of current methods for engaging with SMEs under the different processes of the chemicals legislative framework

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H: SME awareness and engagement

Workshop questions:

- What problems do SMEs face in understanding and complying with chemical and chemical related legislation?
- What aspects of the chemicals legislation framework cause the most difficulties for SMEs?
- How do SMEs keep up to date? Do they rely on external service providers, trade associations, guidance from Member States?
- Is sufficient support or consideration given to SMEs in aiding their compliance with CLP and other chemicals legislation?
- Are SMEs able to effectively and efficiently engage in the various processes in the chemicals legislative framework? If not, what actions could help address the difficulties they face?

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