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

Stakeholder Workshop
Thought Starter

19 April 2016

1 Introduction: Context, Objectives and Approach

1.1 Policy context

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 added value of the legislative framework for the risk management of chemicals. It also identifies excessive administrative burdens, 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 and classification, hazard communication and governing 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 supporting legislation. An indicative list of relevant legislation can be found in Annex II 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) has commissioned a team led by Risk & Policy Analysts Ltd. (RPA) to conduct this study.

1.2 Objectives of the study

The objectives of the study are to identify and evaluate the implementation of the CLP Regulation and to evaluate its interface with other related chemicals legislation. Its main purpose will be to take a step back from the daily implementation of chemicals legislation and to evaluate whether that legislation, in its interplay, still fulfils its purpose in the best possible way, and to identify areas where, in a next step, gains in effectiveness, efficiency, coherence, relevance and EU added value can be achieved. The work is therefore to include:

- A thorough analysis of the appropriateness and proportionality of different pieces and provisions of legislation, which in their interplay make up chemicals regulation;
- The identification of areas where the cost of implementation is high compared to the benefits for health and the environment, as well as positive examples where the implementation is particularly efficient;
- The identification of gaps in health and environmental protection;
- The identification of areas where the potential for improvement, modernisation and simplification has not yet been harnessed; and
- The identification of mechanisms and procedures that work well and that could be considered as a best practice.

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

The aim of this stakeholder workshop is to provide an early check on preliminary study findings, identify potential gaps and opportunities for further investigation and to collect ideas and information from stakeholders. The conclusions of this 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.

1.3 Tasks

The work required for this study has been organised into four main tasks:

- **Task 1: Evaluating the implementation of CLP Regulation** – this includes assessing the overall costs and benefits of CLP Regulation implementation; evaluating the building block approach; comparing EU implementation to that in other countries; assessing the mechanisms within the CLP, such as the CLH process and urgency procedure, and the impact of transitional periods; and assessing the performance of CLP 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; identifying 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.**

Case studies are a key feature of the work to be undertaken in 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, both in relation to the impacts of implementing the CLP Regulation and the interface between this and other chemicals legislation. They will consider 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 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 by the study are set out in Table 1. 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; and linkages to other case studies. The descriptions in Table 1 provide a first impression of the purpose and scope of the case studies.

Case study	Case study title	Case study description
1	Impacts of differences in the uptake of **GHS building blocks** for costs, competitiveness health and the environment	Different countries have adopted different building blocks both in terms of hazards covered and sectors covered. Consideration will be given to differences in the potential costs and benefits for chemical suppliers, as well as for consumers (public health) and the environment. The focus will be on building blocks within the GHS which have (not) been implemented in the EU and North American countries and any differences in costs and benefits arising as a result.
2	Coherence in **parallel hazard assessments** under different legislation	Different bodies are responsible for the hazard assessment and classification of a substance/mixture under the CLP, Biocides and PPP. This case study focuses on the coherence of the parallel procedures under these three Regulations and –if feasible– other relevant legislation.
3	Relevance and coherence as regards the use of **test methods** and **data quality requirements** in chemicals legislation	The classification criteria under the CLP for some hazards are linked to the outputs from existing animal test methods, with these used to fulfil REACH information requirements. This case study would examine the relevance of the CLP classification criteria in terms of their ability to respond to changes in scientific methods, and the horizontal coherence of these also taking into account prohibitions on animal testing under the Cosmetic Products Regulation.
4	Coherence of classifications, definitions and the **labelling requirements for detergents**	This case study will explore the coherence in the definitions (e.g. 'placing on the market' and 'manufacturer') between different legislation, in particular the CLP Regulation, Detergents Regulation, Cosmetics Regulation and Biocidal Products Regulation.
5	Suitability of the CLP Regulation **classification criteria for metals**	It may be the case that there is a gap in the legislation as the CLP contains no criteria for the classification of metal alloys, with this potentially impacting on their treatment under other horizontal legislation, e.g. REACH, waste legislation, etc. The case study would investigate the classification of metal alloys and their treatment under different pieces of legislation. It also looks into classification rules under the CLP Regulation for metals more generally.
6	Inconsistencies in assessment procedures for **PBT and vPvB** as properties of concern	This case study considers the coherence between requirements for identifying PBT and vPvB properties in relevant EU legislation, namely the REACH Regulation, the Biocidal Products and Plant Protection Products Regulations. The case study will also consider differences in the way such criteria are applied, in terms of the evidence used to identify whether a substance is a PBT, and in the regulatory consequences.
7	**SME awareness** of ATPs and changes in classification and of labelling and packaging requirements	This case study focuses on the awareness of SMEs of the need to up-date their hazard classifications and labelling in line with revisions made to the CLP Regulation through the Adaptations to Technical progress, which occur on a regular basis. It will also look at awareness of SMEs in terms of the changes introduced by the CLP Regulation relating to labelling requirements.
8	Linkages between the **CLP and Seveso III** Directive, including risk management under Seveso III *(scope under discussion)*	This case study investigates the interface between CLP hazard classifications and Seveso requirements. It would consider the implications of newly agreed harmonised classifications for Seveso, as well as procedures within the Directive triggered by a CLP classification.

Case study	Case study title	Case study description
9	Awareness of Chemical Safety Assessment and labelling requirements for **Toys**	The TSD lays down toy safety rules which include requirements for Chemical Safety Assessments, compliance with specific chemical requirements laid down in other legislation with a horizontal link to CLP (such as RoHS, WEEE, etc.), and the CLP Regulation. Specific requirements are set out in relation to CMRs and certain allergens, which can also lead to cosmetics-based labelling requirements. This case study would examine SMEs awareness of this range of obligations. The case study will examine the awareness of SMEs in of labelling requirements, including traceability requirements, labelling of manufacturer/importer contact details, CE marking, instructions for use, precautions and warnings.
10	**Consumer comprehension** of and relevance of safety information on product **labels**	The focus of this case study will be on the hazard pictograms that CLP introduced when implementing GHS. Research suggests that comprehension of the various pictograms amongst EU citizens is variable; findings indicate that a low percentage of citizens may understand all of the hazard pictograms or equally understand only a few of the pictograms. Some EU legislation uses different safety phrases and does not rely on the pictograms. Similarly, where the GHS building block for consumer products has not been implemented (e.g. North America) different communication tools may be used.
11	Interface between the **Fertiliser Regulation and chemicals legislation**	Within the current version of the Fertilisers Regulation there is no direct link to the CLP Regulation. However, the same substance may be assessed by SCHER in the context of the Fertilisers Regulation and by other scientific committees under other legislation. The inclusion of calcium cyanamide in Annex I of the Fertilisers Regulation, recently reviewed by SCHER, could be used a case study for the evaluation of coherence between the Fertilisers Regulation and other chemicals legislation.
12	Linkages with **Occupational Health and Safety Legislation** *(scope under discussion)*	The CLP Regulation and the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD) are closely interlinked. This case study may investigate the coherence between these different pieces of legislation in relation to substances not placed on the market, as well as actions triggered under occupational health and safety legislation due to a harmonised classification.
13	**Risk management procedures triggered by harmonised classifications** under the CLP Regulation	This is an overarching case study involving a comparative assessment of the procedures triggered by a CMR or other health classification (e.g. sensitiser). It will cover PPPR, BPR, cosmetics, toys, food contact materials and CMD. This case study will also consider selected substances, such as lead, borates, gallium arsenide, etc. This case study will also include a comparison between RMM based on generic risk considerations and specific risk assessment.

1.4 Stakeholder Consultation

Open Public Consultation: The open public consultation (OPC) was launched on the 4th March and will close on the 27th May. It is being hosted on RPA's website and is being implemented through the use of on-line questionnaires in English, French and German. The OPC asks a series of relatively high level questions relating to the chemicals legislative framework and it is intended to support the fitness check itself, rather than the study being conducted by the consultants. However, it is intended that the results of the OPC will perform an auxiliary function in the analysis conducted for the study on CLP and its interplay with other related legislation.

SME Panel: A questionnaire to be sent out to the SME panel is being developed. It consists of around 20 high level questions specifically tailored to SMEs. The purpose of the SME panel is to identify any ways in which SMEs are being impacted in a significantly different manner from larger enterprises.

Targeted Data Collection: Stakeholders have been invited to take part in targeted data collection exercises, which are focused on issues specific to their activities and/or concerns. These data collection exercises have involved the development of a series of surveys, containing overlapping and complementary information requests. They have been developed to contribute to the evaluation questions set out in the Roadmap and tailored to specific groups of stakeholders. The main groups of stakeholders who have been approached as part of these exercises are: industry associations and their members; non-industry (trade unions, worker representative organisations, consumer associations, environmental NGOs and health-related NGOs); and Member State Authorities.

Interviews: Interviews with a broad range of stakeholders are being used as an opportunity to further develop the research being conducted under the case studies, and to collect additional information relevant to the fitness check (e.g. consultation of Agencies, Committee/Expert Working Group members and international bodies). These interviews also allow stakeholders an opportunity to share their experiences of particular issues relating to the chemicals legislative framework. Interviews will also be used as a chance to follow up on comments made to the targeted data collection.

1.5 The Evaluation Questions

A wide range of evaluation questions have been set for the Fitness Check. These can broadly be summarised as follows, although there are around 120 questions in total, addressing both specific and overarching aspects of effectiveness, efficiency, coherence, relevance and EU added value.

Effectiveness

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

- What are the consequences or effects (whether socio-economic, environmental or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?

- What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right

choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?

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

Efficiency

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

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

Coherence

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?

- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlaps or missing links between different pieces of legislation? Are these leading to unintended results?

Relevance

- To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)

- To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?

- To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

EU Added Value

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

2 Themes for Discussion at the Workshop

The following key themes will act as the basis for discussion at the workshop. These themes and associated discussion questions have been identified from the work undertaken during the first stages of the study, based on literature review, targeted data collection and stakeholder interviews. The aim of the workshop discussions will be to identify what works well within the chemicals legislative framework and why, as well as what does not work well and why.

1. CLP classification rules and criteria

This theme considers 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 theme 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.

- 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 approaches taken by SMEs versus large companies, and in the acceptability of different approaches at the Member State level?

2. Hazard assessment across chemicals legislation

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). 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.

- 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?

3. Transparency of assessment procedures and ability of stakeholders to contribute

This discussion will centre 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, PPR and BPR, as well as risk assessment processes and other Committee procedures (e.g. under Cosmetics, Toys, Fertilisers, etc.). The aim here is to identify good practices in enabling stakeholder involvement and consultation. Preliminary results from the targeted consultation is that the CLH procedure, for example, does operate in a transparent manner and that stakeholders feel able to contribute to it, although there are some concerns over the degree to which their submissions have been adequately taken into account.

- 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?

4. Hazard communication to downstream users and consumers

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.

- 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?

5. Implementation of the GHS

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 theme will consider 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 will also consider 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.

- 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 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?
- 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 related adaptations 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?

6. Data quality requirements and test methods

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.

- 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? Can lessons be learned from such cases?

7. Downstream risk management measures

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 will focus on the appropriateness and impact of these linkages.

- 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?

8. SME awareness and engagement

This discussion will focus 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 to be discussed is the effectiveness of current methods for engaging with SMEs under the different processes of the chemicals legislative framework.

- 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.

Other issues can be raised during the plenary session, for example, regarding the coherence of the legislation, and any overlaps, gaps or synergies (complementarities) that impact on its effectiveness.

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

Consumer, Environmental and Health Technologies
Chemicals

Study on the regulatory fitness of chemicals legislation (excluding REACH), in particular CLP and related legislation

STAKEHOLDER WORKSHOP

19 April 2016

Diamant Conference Centre
Auguste Reyerslaan 80, 1030 Schaarbeek, Brussels, Belgium

AGENDA

	Registration	09:00 – 09:30
1.	**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.)*	
2.	**Introduction to the break-out sessions** *(Maurits-Jan Prinz, policy officer, DG GROW)*	10:20 – 10:30
	Coffee break	10:30 – 10:45
3.	**Break-out sessions** *(Part I)* (5 min. introductions & 3*x* 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
4.	**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
5.	**Feedback from the break-out sessions & discussion** *(Maurits-Jan Prinz, policy officer, DG GROW)*	15:15 – 16:40
6.	**Conclusions and next steps** *(Otto Linher, deputy Head of Unit, DG GROW)*	16:40 – 17:00

STAKEHOLDER WORKSHOP – SCHEDULE OF BREAK-OUT GROUPS

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	

Annex II: Legislation under scope of fitness check

The following pieces of legislation fall under the scope of this fitness check on chemicals legislation.

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.