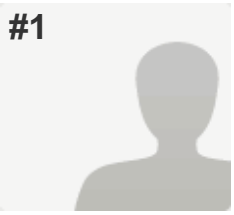

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Last Modified: Friday, May 27, 2016 12:22:27 PM
Time Spent: 00:30:44
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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	
Organisation/company	
Country	Finland
Email Address	
Q2: **If you have a Transparency Register ID number, please provide it below. If your organisation is not registered, you have the opportunity to register now by following this link. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and, as such, will publish it separately.**	
Q3: **Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.**	My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: **We might need to contact you to clarify some of your answers. Please state your preference below:**	I am available to be contacted
Q5: **Please indicate whether you are replying to this questionnaire as:**	A business
Q6: **If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:**	Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1) , Manufacture of other chemical products (C20.5)

Q7: For businesses, please indicate the size of your business:The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm	Large company (250 employees or more)
Q8: Please indicate the level at which your organisation is active:	Global

PAGE 3: Part II – General Questions

Q9: How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)*This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.**

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	4

Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	1

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Ensuring a well-functioning internal market	The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	5

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

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),

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),

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),

Packaging and Packaging Waste (Directive 94/62/EC)
,

Export and import of hazardous chemicals (Regulation No 649/2012)
,

Persistent organic pollutants (Regulation (EC) 850/2004)
,

EU Ecolabel (Regulation (EC) 66/2010),

Safety of toys (Directive 2009/48/EC),

Drinking Water (Directive 98/83/EC),

Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
,

General Product Safety (Directive 2001/95/EC),

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)

PAGE 5: Effectiveness

Q14: In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical. In your view, do you think EU chemical and chemical-related legislation should, in general:

a. Be more oriented towards specific risk assessments (i.e. differentiate more between chemicals depending on their use despite the possibility of prolonged discussions and implementation delays)
,

If you answered a or b, please explain
The risk associated with a chemical is very much dependending on the specific use for which it is intended. Therefore a specific risk assessment is in general more appropriate to define the most effective risk mitigation measure whilst preserving societal benefits. Without considering the uses we may restrict use of certain chemicals that overall benefit the society and pose very little risk, which may lead to adoption of other less effective alternatives. Ex: while active substances in rodenticides may be inherently hazardous, an in-depth risk assessment is necessary to safeguard the benefits of rat control for society. In some areas, decisions are in practice more driven by hazard than risk, even when risk assessments are carried out. Ex: selection of priority substances under the Water Framework Directive and setting EQS; evaluation by POP Review Committee.

Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.	No, If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to. Impacts on competitiveness of EU industry are generally not considered in the context of regulatory decision making on risk management. At best, these impacts are estimated before the main legislative act is proposed by the Commission to Parliament and Council – but not necessarily considered when the rules are finally adopted and become law or when they are implemented. Example: The Biocidal Product Regulation introduced an outright ban on the use of biocidal products by the general public where the said products meet certain hazard criteria. The legislation does not allow potential benefits for society to be considered for these products (e.g. need to control a serious danger), let alone any type of economic or social impact (e.g. lost business, reduced innovation capacity)

Q16: In your view, to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

Transparency of procedures	5
Speed with which hazards/risks are identified	5
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	2
Predictability of the outcomes	1
Stability of the legal framework	2
Clarity of the legal texts	3
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	4
International collaboration and harmonisation	3
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	Predictability/Stability: Under biocides legislation, rules in the form of technical/regulatory guidelines or agreements on interpretation between competent authorities are constantly changing and their applicability can be immediate – with companies having to react within very tight deadlines. Interpretations have been unpredicted and sometimes contradict with the regulation text. Application dossiers for substance approval submitted more than 10 years ago are still under evaluation, within a legal framework that has changed extensively. Also active substances earlier evaluated are again questioned when product authorizations are due and undermining the previous work forcing companies to rush to adapt to new interpretations that may have major impacts on the business. Levels of enforcement are very variable among Member States. This is true for environmental protection legislation, biocides legislation as well as for food contact materials legislation. Interpretations on the regulations vary and may have surprising outcomes depending on the member state in question.

Q17: In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

Hazard identification criteria	3
Risk assessment and characterisation	4
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	4
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	5
Risk management measures restricting or banning the use of chemicals	4
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	4
If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	The transition from DSD to CLP brought along complexity, which resulted in general tightening of classification and significant difference in notified classifications. The direct application of CLP in downstream legislation (waste, Seveso, TDG) has caused more confusion than added safety. The rigid format for labels for consumers often lead to repetition and lengthy text without further info, which is acting against good hazard communication principle.

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?

Yes,

If you answered no, please explain your answer with exception of physico-chemical information

PAGE 6: Efficiency

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)

Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.

,

Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.

Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)

Costs for small and medium sized enterprises,

Costs for large enterprises

Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Classification requirements for substances and mixtures , Chemical labelling and packaging requirements , Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	Yes, If you answered yes, please indicate what these are. The implementation of chemicals control legislation is resource-intensive, also for authorities. Even when the legislation foresees a system of mutual recognition between Member States (cf. Biocides), we often see Member States re-evaluating the first evaluation performed by the lead Member States. These costs are charged back to industry through a system of fees. Chemical data needs to be reported to numerous authorities because of numerous regulatory requirements (Echa, Commission, National Authorities for chemicals, worker safety, Seveso, environment, VOC, GHG …) This leads to costs both for companies and authorities. The Proposal for Poison Information annex VII in CLP (article 45) with extra- SDS-information contains significant new information system needs with significant new costs for all players.

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	4

Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

Novel areas of concern sufficiently addressed by framework	4

PAGE 8: Coherence

Q25: Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

The EU chemicals legislation framework contains gaps and missing links	Disagree
The EU chemicals legislation framework has overlaps	Agree
The EU chemicals legislation framework is internally inconsistent	Agree

Q26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

Overlaps	In occupational health legislation (CAD/CMD)
Inconsistencies	Labelling requirements under BPR and CLP are sometimes contradictory (cf treaded articles) Labelling requirements in TDG and CLP are sometimes contradictory. Seveso-requirements for labelling containers are further different from these. The application of CLP as such leads to unnecessary burden for waste management and unexpected consequenses for Seveso-installations. o Application of CLP leads to unnecessary burden for waste management

Q27: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

Overlapping requirements between REACH and occupational health legislation, between REACH and IED-directive and BREFS as well as between REACH and RoHs. Many legislative instruments contain restrictions for chemicals (REACH, RoHS, IED, POP, Toys, F-gases, CLP, food contact….) not to mention ecolabels.

The interface between REACH and End-of-Waste (and ILUC) is not clear. Same recycled or by-product substance can be registered under REACH, meeting all product requirements marketed accordingly, but under Waste directive considered as waste.

PAGE 9: Part IV: Specific questions on the CLP Regulation

Q28: CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

To what extent are CLP labels effective in communicating hazards to workers?	4
To what extent are CLP labels effective in communicating hazards to consumers?	3

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	Yes
Physical	Yes
Human health	Yes

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)

Guidance documents	4
Helpdesks	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	4
Please add further details as necessary	the issue is not about finding guidance material, but rather the rapid change of interpretations and guidances which puts significant burden on companies to try to follow all the changes all the time

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is not harmonised across most Member States

Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)

Ease of implementation for duty holders	3
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	4
International harmonisation through the Globally Harmonised System (GHS)	3
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	The transition from DSD to CLP brought along complexity, which resulted in general tightening of classification and significant difference in notified classifications. The direct application of CLP in downstream legislation has caused more confusion than added safety. C&L notifications existing without the visibility for the basis, difficult to evaluate which classification is correct when there is e.g. classification based on the REACH registration and more severe classifications. C&L notification database should be completely removed and something more reliable set up in return e.g. based on existing REACH registration data.

Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?	Transition period is sufficient

Q34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)

Transparency of the procedures	4
Involvement of stakeholders	3
Quality of scientific data and related information	4
Speed of the procedure	3

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
There are difficulties in matching the different timelines under CLP and BPR

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	It would have been good to evaluate the fitness including REACH as well, as REACH regulation is so tightly connected to the other regualtions as well. Hopefully this input is also used as reference for the next REACH review.