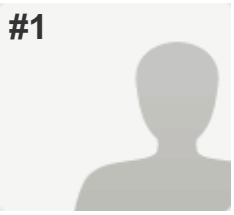

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Collector: Web Link 1 (Web Link)
Started: Thursday, March 10, 2016 6:53:18 AM
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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Sten Öhman
Organisation/company	Elfins Development AB
Country	Sweden
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.	*Respondent skipped this question*
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 under the name indicated; 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:	Other, Other (please specify) Consultant about these issues
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]:	Other, Other (please specify) Not specialised with respect to branch

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	Self-employed
Q8: Please indicate the level at which your organisation is active:	EU

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	5

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	4
Protecting the environment	4
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	3

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 effectively implemented

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	4

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)
,

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)
,

Carcinogens and mutagens at work (Directive 2004/37/EC)
,

Young people at work (Directive 1994/33/EC),

Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
,

Waste framework (Directive 2008/98/EC) and List of Waste
,

Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
,

Water Framework (Directive 2000/60/EC),

Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
,

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

Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
,

Residues of pesticides (Regulation (EC) No 396/2005)
,

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) , 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), 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)

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 research should focus on the limits for no effect (DNEL, PNEC) and to educate the public about the scientific basis of these limits.
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. This is a very big field for research, and probably it will never be fully established. Nevertheless, this research must be prioritised by EU, and be given sufficient economic support, preferently on federal basis. The EU commission should stimulate cooperation between the European universities in order to strengthen the knowledge in toxicology, ecotoxicology and risk management.

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	4
Speed with which hazards/risks are identified	4
Speed with which identified risks are addressed	3
Time to allow duty holders to adapt	4
Predictability of the outcomes	I don't know
Stability of the legal framework	5
Clarity of the legal texts	5
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	3
Public awareness and outreach	1
International collaboration and harmonisation	5
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	Media seldomly cite these issues, and hence the public is not well informed. The biocide and plant protection regulations are in force, but still a lot of differences between member states remain.

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	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	5
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 copyright of ISO 31 000 should be buyed by the EU commission and made public in all member states languages. Also other standards, cited in the EU legislation should be made public, i.e. the standards for safety gloves. Also note my petition 0781/2015 to the EU parliament, about the copyright of primary references in dossiers sent to ECHA. This copyright seriously impairs the possibility to compile data from several original references in order to achieve more reliable information. There is an urgent need for a change of Article 16 in the ATD regulation (EC 1049/2001).
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?	I don't know

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 consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy , Stimulating competition and trade within the EU single market
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
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal requirements , Other (please specify) Evaluating of the primary references about toxicity and ecotoxicity and, in case these studies are not sufficient, to do complementary tests by any OECD method or similar. This especially applies to the STOT short- and longtime effects, where primary references too often are lacking. It also applies to acute toxicity by inhalation, where a great deal of the classifications are not based on experiment, but analogy to studies of acute toxicity in other routes.
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	No

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	2

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	Neutral
The EU chemicals legislation framework has overlaps	Neutral
The EU chemicals legislation framework is internally inconsistent	Neutral

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.

Gaps or missing links	Radiotoxic effects. Should be implemented in REACH
Inconsistencies	Standards and primary scientific data should be public

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.

The ATD regulation, see above

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?	5
To what extent are CLP labels effective in communicating hazards to consumers?	5

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

Environmental	No
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	Environmental: The former risk phrases R54-58. The GHS classifications Aquatic Acute 2 and 3 For human health: The GHS classification Acute tox 4. Also the STOT classification should be divided into more classes, depending on the kind of effect. Many well-known hormonal effects have not been considered at all, e.g. the anti-thyroid effect of thiocyanate.

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	No experience
Other (training, conferences, etc.)	No experience
Please add further details as necessary	It is not easy to find the appropriate guidance document. Not all personnell in the helpdeskt is sufficiently skilled.

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is 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	4
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	3
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	Primary data for classification of mixtures can be found in the ECHA database, but these data are associated to each REACH dossier and it needs a lot of skil and time to find relevant data. The use of these data are also seriously hampered by the copyright of primary data, as stated in Article 16 in the ATD regulation.

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	4
Quality of scientific data and related information	2
Speed of the procedure	3

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
Evaluating of primary references is very important, but it is time-consuming and expensive, and therefore important studies too often has been missing.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.

Respondent skipped this question