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Collector: Web Link 1 (Web Link)
Started: Friday, May 27, 2016 11:18:31 AM
Last Modified: Friday, May 27, 2016 12:23:15 PM
Time Spent: 01:04:43
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	J Hynes
Organisation/company	Humane Society International
Country	BE
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.**	05097472836-90
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:**	A non-governmental organisation (NGO)
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]:**	*Respondent skipped this question*
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**	*Respondent skipped this question*

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**	I don't know
Stimulating competitiveness and innovation	I don't know

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	3
Protecting the environment	3
Ensuring a well-functioning internal market	I don't know
Stimulating competitiveness and innovation	I don't know

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:

Protecting human health	The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Protecting the environment	The legislation is not adapted to the issues at stake, The legislation is not effectively implemented
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

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) ,

Cosmetic products (Regulation (EC) No 1223/2009) ,

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

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
We believe that new hazard and risk assessment paradigms (OECD IATA, AOPs, EDSP, Tox21, Risk21) have the potential to provide superior data for risk assessment, for cheaper, and faster than existing cumbersome and substance-focussed regimes. We envision the development of high-throughput systems for hazard assessment that will, critically, allow the meaningful assessment of mixtures/formulations, with the added benefits of improved early-stage product design and thus more confident product innovation. As example, we point to the developments in the USEPA Endocrine Screening Program (EDSP), where high-throughput AOP-based systems have been developed and accepted.

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. Because of the fragmented nature of chemical regulations, the risks presented of exposures from multiple sources are inadequately addressed. We point as an example to the recent SCCS opinion on phenoxyethanol, where only cosmetics uses were assessed. Phenoxyethanol has a very wide range of consumer uses, which is evident from inspection of the REACH dossier. Yet these combined exposures are not assessed, and this can lead to public harm (as with the case of MIT which, despite all the evidence, is still allowed to cause public harm today). http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf

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	2
Speed with which hazards/risks are identified	2
Speed with which identified risks are addressed	2
Time to allow duty holders to adapt	I don't know
Predictability of the outcomes	I don't know
Stability of the legal framework	I don't know
Clarity of the legal texts	2
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	2
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	3
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.	

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

Hazard identification criteria	4
Risk assessment and characterisation	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	3
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	3
Risk management measures restricting or banning the use of chemicals	2
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	3
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.	Risk assessments must consider all exposure sources. It is difficult to assess the adequacy of RMMs, as this is the responsibility of national enforcement, and there are clearly variations here. From a consumer perspective, the case of MIT shows that labeling has been inadequate. From experience, a significant proportion of SDS are insufficient and/or out of date.

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 GLP Yes, however this is again an issue of enforcement, which is unevenly applied across Members States. In a recent report published by ECHA, the capacity of laboratories to conduct EOGRTS was determined through questionnaire. This report raises real concerns, for example the 200% price differences between laboratories, some of which are outside of the EU, and thus beyond EU animal welfare law. Also, it fails to address the lack of expertise which was identified in 2012. The concerns of one respondent re: the quality offered by some CROs and absence of historical control data should ring alarm bells. We have asked ECHA if they intend to follow-up with audits of the facilities, and they say no. Further to this, from experience of reviewing many many tox reports, there is a clear decline in study and report quality since REACH has been implemented. We believe that market forces are leading to corners being cut in test laboratories, and that GLP is not effectively implemented or reported. In many cases, the raw study data are not provided / available, yet it is here that the real problems of a study become evident, and not from an executive summary.

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. , 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. , 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
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 authorities at national level, Costs for small and medium sized enterprises, Costs for consumers, Costs for society in general
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Other (please specify) Many companies do not provide sufficient SHE resources, and indeed much of this work is outsourced to consultants. Product managers can wash their hands of responsibility in this way. Too much trust is placed in consultants, without critical internal review.
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. It is clear that Authorities are under huge administrative burden. They openly state this (MSC, BPC).

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	I don't know

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	3
Please comment	Emerging risks are identified, but it takes far too long to arrive at decisions, even agreeing on definitions (e.g. nanomaterials). The USEPA Endocrine screening program started in 1999. In Europe, 17 years later we are still arguing over the criteria for identification. A global approach is required.

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	Agree
The EU chemicals legislation framework has overlaps	Strongly Agree
The EU chemicals legislation framework is internally inconsistent	Strongly 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.

Gaps or missing links	Mixtures!
Overlaps	Hazard and risk assessments are not harminised, and they need to be.
Inconsistencies	Some MS are very vocal, whislt others say nothing and block vote.

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.	*Respondent skipped this question*

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	I don't know
Physical	I don't know
Human health	I don't know
Please list any hazard classes that are not covered	It's a difficult question. Of course we could expand the hazard classes, but then it would be too complex/unmanageable. Best to keep alignment with GLP!

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)	
Guidance documents	3
Helpdesks	3
Industry association guidance and materials	3
Other (training, conferences, etc.)	3
Please add further details as necessary	Hard to say as there is variation between sectors.

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	I don't know
Appropriateness of classification criteria and methods for substances	I don't know
Appropriateness of classification criteria and methods for mixtures	2
International harmonisation through the Globally Harmonised System (GHS)	I don't know
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	GHS/CLP trigger concentrations are inadequate, e.g. for skin sensitisers.

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?	I don't know or have no opinion

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	I don't know
Involvement of stakeholders	4
Quality of scientific data and related information	I don't know
Speed of the procedure	I don't know

PAGE 10: Part V: Additional comments

Q35: **In case you have any additional comments with relevance for this public consultation, please insert them here.**	Thank you. We will be happy to answer any questions or contribute further from our perspective, by means of an interview/other.