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Collector: Web Link 1 (Web Link)
Started: Wednesday, March 09, 2016 7:26:33 AM
Last Modified: Friday, April 08, 2016 3:57:25 PM
Time Spent: Over a week
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Rocky Rowe
Organisation/company	ECPA
Country	Belgium
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.	0711626572-26
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:	An industry association
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 pesticides and other agrochemical products (C20.2)
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:	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	3

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	2
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)
,

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)
,

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

Water Framework (Directive 2000/60/EC),

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)
,

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

Drinking Water (Directive 98/83/EC),

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 In any chemicals management risk management shouldn't just be about the hazard of a chemical but part of the process to applying good risk management based on exposure. With PPP substances the application of cut off criteria for CMRs is not scientifically justified and is just an arbitrary way of identifying potentially problematic substances. The use of cut off criteria is leading to the loss of important PPP substances for no valid scientific reason and thus jeopardises the PPP sector across Europe regarding jobs, investment and competitiveness in a global market.
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. Depending on what areas are investigated the answer to this question is both yes and no as certain areas are more than adequately covered and other not so. For the PPP sector vulnerable groups are dealt with adequately and on the question of mixtures there is no scientific justification to assume that the use of two or more PPPs produce anything more than additive effects. One the other side greater socio-economic input should be applied when assessing PPPs to ensure that goals on sustainable agriculture are achieved and to ensure that Europe stays at the competitive edge of PPP R&D in a global market.

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	3
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	4
Predictability of the outcomes	4
Stability of the legal framework	3
Clarity of the legal texts	5
Guidance documents and implementation support	5
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	2
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.	Transparency within ECHA is high however the same level should be achieved by Efsa. Hazard identification with PPPs is becoming very problematic with the duel roles of ECHA and Efsa and leads to confusion and frustration and delays. CLP implementation at a national level has caused numerous problems owing to the disconnect between 1107/2009 and 1272/2008 and the responsibility to classify mixtures. I.e. industry of the national CA. This leads to the same mixture being classified differently in adjoining MSs. Enforcement is still seemingly at an early stage so its difficult to comment however many enforcement officers are not conversant with PPP regulations. Public awareness and outreach seems minimal so one wonders whether the general public are any the wiser to all these measures that are being put in place to protect them.

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	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.)	4
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.	The application of the PIC regulation defines a chemical as banned when usually a full risk management assessment is incomplete or could not be completed. PPPs are notified as being banned following regulatory action as being banned when Annex 1 inclusion to 1107/2009 or previously 919/414 was not achieved. Annex 1 inclusion is often not achieved owing to an incomplete data set or the manufacturer withdrawing the substance for commercial reasons. The inclusion in the PIC regulation leads for greater export restriction and places European manufacturers at a global disadvantage.

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?	No, If you answered no, please explain your answer The obsession with GLP is excessive e.g. GLP for physical properties is inappropriate. The focus should be "is the data good quality" rather than on is all the relevant paperwork in place. GLP has its uses and is important in many areas of data generation but for SDS it seems burdensome and inappropriate.

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.
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 society in general
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 , Training staff to ensure compliance with legal requirements , Other (please specify) The implementation of CLP applied a cost burden on both industry and authorities and is arguably doing nothing the help protect human health and the environment. For the PPP sector the confusion between 1107/2009 and 1272/2008 as to whether who had responsibility for classification and labelling was expensive ad time consuming and non productive for all parties. The clear message that 1272/2008 should be applied was never given and left to MSCAs to decide.
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. As mentioned in Q.21 the burden placed on CAs to implement 1272/2008 for PPPs caused numerous problems on resources and thus costs.

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	3

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
Please comment	Emerging areas of concern are addressed by the EU legislative framework however it can focus on being over protective and precautionary without any real evidence. A balanced approach is always necessary and rational scientific opinion sought.

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	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.

Gaps or missing links	!!07/2009 and 1272/2008
Overlaps	Labelling under CLP and labelling under 1107/2009
Inconsistencies	Responsibilitity for classification i.e manufacturer or CA

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.

REACH vs. 1107 for substances between R&D and EU registration

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	5
Helpdesks	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	3
Please add further details as necessary	ECPA is impressed with the guidance on CLP developed and provided by ECHA and the involvement of stakeholders in its on-going development. DG Sante and Efsa should be encouraged to follow a similar pathway.
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is harmonised across most Member States , Please add further details as necessary In the PPP sector, enforcement is complicated by the national pesticide authorities determining, often incorrect, classifications, and the lack of linkage between the CA doing the enforcement and the CA managing PPP.

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)	4
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Subject is inherently complex and difficult to implement. EU specific (e.g. EUH066) should continue to be reduced. Mandatory classifications in EU and other regions pose difficulties

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,

Please elaborate if you answered that the transition period is too short or too long.
The transitional periods allow sufficient time for implementation of new or revised criteria however there is still the open question on the use of RAC opinions as best scientific knowledge and their use when classifications are changed rather than waiting for the legal application of the classification through an ATP.

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	5
Involvement of stakeholders	3
Quality of scientific data and related information	4
Speed of the procedure	4

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
ECPA is encouraged by the arrangements for harmonised classification and has worked hard to ensure that our input is based an the highest scientific knowledge. The involvement of stakeholders at RAC is applauded and is only marked down owing to the wider issue of the PPP and BP sector not being allowed to submit a CLH similar to the general chemical industry and must work though a MSCA who are not always cooperative. This seems a gross unfairness to the PPP and BP sectors and should be rectified thus relieving some of the alignment issues between PPP approval and CLH.

PAGE 10: Part V: Additional comments

Q35: **In case you have any additional comments with relevance for this public consultation, please insert them here.**	Key issues asrise from the many disconnects between the PPPR and CLP and the responsibiliies for classification and labelling. 2. The alignment of substances under going approval and CLH. The tendency to classify on a precautionary basis and the need to look at bringing a potency element into CMP classification