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Collector: Web Link 1 (Web Link)
Started: Friday, May 27, 2016 9:26:35 AM
Last Modified: Friday, May 27, 2016 11:01:32 AM
Time Spent: 01:34:57
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Leondina Della Pietra
Organisation/company	Fertilizers Europe
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.	Ferti397326704 - ID: 80788715017-29
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 basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)
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	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	2

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	No opinion or not applicable
Protecting the environment	No opinion or not applicable
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)
,

Inland transport of dangerous goods (Directive 2008/68/EC)
,

Chemical Agents (Directive 98/24/EC),

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

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

Water Framework (Directive 2000/60/EC),

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

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

Fertilisers (Regulation (EC) No 2003/2003),

Pressure equipment (Directive 2014/68/EU),

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 Risk assessment is central to industry's chemicals management approach in order to determine how and under what conditions a chemical can be safely used. The risk associated with each chemical is dependent on the specific use for which it is intended, as well as the conditions for use (e.g. amount, containment, personal protection measures, packaging, and awareness of user). Therefore a specific risk assessment is in general more appropriate to define the most effective risk management measure whilst preserving societal benefits. Risk assessments should be based on the weight of all available evidences and consider the specific characteristics of each individual substance. There are situations where default criteria do not adequately predict the behavior of a substance and consideration should be given to the full range of scientific studies, including environmental measurement.
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. Where a cost-benefit analysis has taken place these are not always considered during the final voting stage of new legislation. For example in the case of CLP Regulation Article 45, several outputs of the cost benefit study as well as the discussions amongst various stakeholders on the draft proposal now seem to be disregarded during the final REACH Committee process.

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	3
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	3
Predictability of the outcomes	2

Stability of the legal framework	2
Clarity of the legal texts	4
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.	Under the under the CLP Regulation, 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. Implementation support: in the space of the notifications to the C&L Inventory, solutions supporting bulk notifications are not very efficient. This leads to significant burden in complying with the C&L Inventory notification obligations. In addition there is no possibility for obsoleting notifications and no clarity on the obligations related to substances no longer present in a company's portfolio. Guidance documents: guidance should be provided on a more scientifically robust weight-of-evidence approach, including an objective scoring methodology that allows selecting the most reliable, relevant and highest quality data at different levels including environmental measurements. At present there is a divergence between the commitment to weight-of-evidence consideration and how substances are being identified in practice. International harmonisation: the regional differences in GHS implementation add complexity to supply chain communication. In this context what is often mentioned is lack of harmonization in the applied hazard classes and categories. It cannot be however forgotten that some of the major differences in C&L under various GHS implementations stem from the differences in the implemented generic concentration limits.

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.)	5
Risk management measures restricting or banning the use of chemicals	3
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5
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.	-Hazard identification and methodologies for risk assessments should be aligned as much as possible across different legislations, taking into account the specificities and objectives of each piece of legislation. -Cooperation between regulatory bodies responsible for risk assessments under several pieces of legislation should be improved to maximize the effectiveness of different risk assessments - Risk Management: it is good to have different options for risk management available in the framework, however general bans for certain hazard classes and categories may well hamper the risk identification as no exposure or societal benefit is taken into account for the identification of the most appropriate risk management measure.
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 Except for physico-chemical data. For physico-chemical data we believe that appropriate quality systems are in place.But GLP is not always sufficient to decide on the most relevant study/safety data (data-rich substances): relevance, robustness are criteria that should be equally considered. GLP only ensures reproducibility of the study. Scientific validity including the relevance and applicability of the methods for the chemistry set need to be considered.

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 , Stimulating competition and trade within the EU single market , Stimulating international trade between the EU and other countries
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?	I don't know

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
Please comment	The current EU legislative framework is appropriate to address emerging areas of concern. The framework should however consider the latest scientific advances with regards to new test methods, new methodologies, and ensure required testing is linked to clear human health or environment emerging concerns.

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	Neutral
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	Seveso: With the inclusion of tighter hazard categories in the Seveso Directive from CLP, the expectation is that many more substances will fall under the Seveso requirements resulting in additional obligations and compliance costs. Automatic legal consequences in downstream legislation without risk assessment should be avoided.Labelling requirements under the different pieces of legislation could be better integrated to facilitate compliance.
Inconsistencies	-Labelling requirements under BPR and CLP are sometimes contradictory .

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

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	5
Industry association guidance and materials	4
Other (training, conferences, etc.)	4
Please add further details as necessary	However, we are observing cases where the guidance documents are not consistently implemented by Authorities.

Q31: To what extent is CLP enforced in a harmonised manner across Member States?	Enforcement is not harmonised across most Member States , Please add further details as necessary Not uncommon are cases where the same chemical is requested to have different sets of C&L information between different 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 fact that various non-EU countries selected to implement different building blocks of GHS is not sufficiently addressed in the legislation and in practice, in particular in the labelling space. The related consequences for communication in the supply chain lead to significant costs

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.
For editorial changes to the text of H and P statements stemming from revisions of the UN GHS Model Regulation longer transitional periods would be beneficial for the industry.

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	2

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
There are some inefficiences in the CLH process with respect the changes that affect the existing elements of harmonized C&L from Annex VI. Such changes can be brought by industry only to the attention of a Member State Competent Authority but not directly to ECHA. Unlike for the CLH Intentions that are submitted to ECHA for these intentions there is no publicly available registry of intentions. This means that if a given intention for a change of an existing Annex VI element for a substance was reviewed by a MSCA and was not found justified (thus it is not in the ECHA registry of intentions) this decision/conclusion cannot be readily accessed by e.g. downstream users. Also, for the « older » Annex VI entries there are sometimes difficulties in identifying the data which were the basis of the original classification decisions leading to the current harmonized classification in Annex VI. If it would be possible to make these historical records available this would be of great assistance for companies when determining their classification globally but also when identifying if they hold actual new data that challenges existing Annex VI elements. Finally, problems of coordination have been experienced between CLP classification procedures and the procedures for adjustment of the Ecolabel criteria, requiring sometimes fast-track derogations for which no established process is currently in place.

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*