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## COMPLETE

**Collector:** Web Link 1 (Web Link)

**Started:** Tuesday, May 24, 2016 8:12:10 AM

**Last Modified:** Tuesday, May 24, 2016 9:34:38 AM

**Time Spent:** 01:22:28

**IP Address:**

### PAGE 2: Part I – General Information about Respondents

#### Q1: Address

Contact name	Irantzu Garmendia
Organisation/company	Fecc
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.**

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**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)  
,  
Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)  
,  
Manufacture of other chemical products (C20.5),  
Wholesale and retail trade (G) ,  
Transporting and storage (H),  
Other (please specify)  
Distributors of chemical substances and mixtures.  
This does not include the end products.

**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](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	4
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:**

Protecting human health	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
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
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#### 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),  
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),  
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)

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

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

Detergents (Regulation (EC) No 648/2004),

Explosives (Directive 93/15/EEC),

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

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

Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)

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## PAGE 5: Effectiveness

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**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 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 more appropriate to define the most effective risk management measure whilst preserving societal benefits. The requirement to adequately ensure a high level of protection for human health and the environment should be about demonstrating safe use of the products that are placed on the market. This should be done through a risk assessment considering exposure and risk mitigation measures. Directly triggered Risk Management Measures as a default because some certain hazard should not be the way.

**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.

We support Cefic's comments.

**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
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Speed with which hazards/risks are identified	4
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Speed with which identified risks are addressed	4
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Time to allow duty holders to adapt	4
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Predictability of the outcomes	2
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Stability of the legal framework	2
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Clarity of the legal texts	4
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Guidance documents and implementation support	4
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Effective implementation and enforcement across Member States	3
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Consistent implementation and enforcement across Member States	1
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Public awareness and outreach	4
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International collaboration and harmonisation	4
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Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

We support Cefic's comments

**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	5
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	5
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.

Pictograms are useful and work well in multilingual labels. However, new hazard pictograms are not yet well enough understood by consumers. We think that the authorities' awareness campaigns for consumers should be repeated/continued.

**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  
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 is a reporting standard that only ensures reproducibility of the study but does nothing to do with the quality of the testing. Scientific validity including the relevance and applicability of the methods for the chemistry set need to be considered. There are other standards of high quality that are not GLP and should be valid as well, especially for physico-chemical and analytical data.

**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.

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

,

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

## Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

**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

Mechanisms to tackle emerging issues of potential concern already exist in the current legislative framework.

### 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	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	<p>Labelling requirements under different pieces of legislation are sometimes contradictory for example: BPR and CLP (treaded articles) GHS/CLP vs. classification and labelling for the purpose of transport of dangerous goods is not yet harmonized as much as it could be. At present there is a divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs/vPvBs.</p>

**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 as well as between REACH and RoHs  
Inconsistencies between REACH and Toy's Directive.

**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?	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

**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	3
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

Data requirements and applicability of classification methods are challenging especially for importers of chemical mixtures and private label owners. More flexibility is needed to enable better utilization of all relevant data on mixture properties.

**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	3
Speed of the procedure	3

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers  
We support Cefic's comments

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

Harmonisation of legislation at EU level, including its implementation and interpretation, is important for the protection of human health and the environment as well as the functioning of our internal market. However, our legislation should not become such that the requirements are extremely difficult or even impossible to fully comply by companies. The overall complexity, high costs and keeping up with the constantly changing legislation are challenging and burdensome especially to small enterprises with limited resources. Overlap and discrepancies (e.g. restrictions) between chemical legislation and specific product safety legislation create unclarity among business operators. The lack of harmonization on enforcement among Member States, differences in interpretations and level of requirements compromise the goals of well-functioning internal market.

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