#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Friday, May 27, 2016 8:54:29 AM
Last Modified: Friday, May 27, 2016 10:40:36 AM
Time Spent: 01:46:07
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Daniela Vigilante
Organisation/company	BeST - The Beryllium Science and Technology Association
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.	40023137761-50
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 metals (C24), Manufacture of fabricated metal products, except machinery and equipment (C25)

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	4
Protecting the environment	4
Ensuring a well-functioning internal market**	3
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	3
Protecting the environment	3
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:

Protecting human health	The legislation is not adapted to the issues at stake
Protecting the environment	The legislation is not adapted to the issues at stake
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) , REACH, Annex XIII (Regulation (EC) No 1907/2006) , Chemical Agents (Directive 98/24/EC), Carcinogens and mutagens at work (Directive 2004/37/EC) , Waste framework (Directive 2008/98/EC) and List of Waste , Waste shipments (Regulation (EC) No 1013/2006) , Water Framework (Directive 2000/60/EC) , Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU) , End of life vehicles (Directive 2000/53/EC)

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:	c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)

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. The impacts on jobs and competitiveness do not seem to be taken under considerations. Regarding beryllium, there is an ongoing decision for a European Occupational Exposure Limit (OEL). If this European limit is too low compared to the current national limits (which are however efficient to protect workers according statistic and scientific data), there can be an impact on economic activities, employments, competitiveness and innovation. Beryllium has unique properties and is cannot be substituted in many applications, that is why beryllium is a Critical Raw Material for the EU. The Scientific Committee for Occupational Exposure Limits SCOEL, which is going to propose a value, does not seem to be taking into account this aspect. That said, a Socio Economic Analysis should be conducted by the European Commission. It seems that the SCOEL proposition could be 10 to 100 times lower than the current national values, and the impacts would be obviously important.

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	3
Speed with which identified risks are addressed	2
Time to allow duty holders to adapt	2
Predictability of the outcomes	1
Stability of the legal framework	3
Clarity of the legal texts	3
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	2
Consistent implementation and enforcement across Member States	3
Public awareness and outreach	3
International collaboration and harmonisation	2
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	We are not very satisfied with the transparency of procedures, even if there is undeniably a progress that we appreciate. We just had indeed a positive experience regarding Beryllium (Risk Management Option Analysis RMOA conducted by the BAuA in Germany involving stakeholders). International harmonization: for certain substances, the regulatory situation (Occupational Exposure Limit in our case) could be much more severe in Europe than USA or Asia. That could cause trade barriers and directly threat our activities and those of our customers at different levels of the value chain in Europe

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	3
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)	I don't know
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.	We believe that, when the risk is limited to the workplace, an Occupational Exposure Limit (OEL) is the best risk management measure, compared to REACH procedures of restriction and/or authorization. It is the case for beryllium: further to the RMOA, decision (presented in last February) not to put it on the REACH candidate list and to manage the risk with an European OEL and good safety practices in the industry. This is a good decision which enables the best balance between health, environment, trade and innovation

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 beryllium industry believes that there is a necessity of harmonization of measurements methods and units for OEL. In the case of beryllium, there are large difference factors between Respirable/Total/inhalable OEL: - there is a six-fold difference between respirable and Inhalable (Proctor study) - there is a three-fold difference between Total and inhalable (Fraunhofer study)

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 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?	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 , 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	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

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.

Inconsistencies	between REACH and RoHS ; between CLP and CMD

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.

Example of lead: inconsistency between REACH (0,3% lead for massive form) and RoHS (0,1% - Exemption up to 4% for copper alloys). This is therefore not always clear to know if we are in compliance or not with the European regulations.

What concerns beryllium, an Occupational Exposure Limit could be based on sensitization instead of chronic Beryllium Disease (which is the critical health effect for beryllium), while beryllium is not classified as respiratory sensitizer in the CLP regulation : that would be an inconsistency between the Carcinogens directive and the CLP regulation.

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?	2
To what extent are CLP labels effective in communicating hazards to consumers?	2

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

Environmental	No
Physical	No
Human health	No

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	No experience
Industry association guidance and materials	4
Other (training, conferences, etc.)	3

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	2
Appropriateness of classification criteria and methods for substances	1
Appropriateness of classification criteria and methods for mixtures	2
International harmonisation through the Globally Harmonised System (GHS)	2
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	We think that the classification criteria are not always appropriated. They should systematically take into account the physical and chemical forms of the substance. Example of beryllium: common classification (Carcinogen 1B) for beryllium metal and beryllium soluble salts while the bio availability and therefore the toxicity of the 2 forms are obviously different. Like for other substances, metal should be classified separately and differently from soluble compounds." "Moreover, we believe that a metallic alloy containing a metal as an additive should be not classified like the pure metal. Beryllium is for example mostly used in copper alloys (typically less than 2% beryllium in copper). The toxicological proprieties of an alloy are not the simple sum of the proprieties of its different constituents. There is a lack in the current regulations on this specific issue of mixtures classification.

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 too short, Please elaborate if you answered that the transition period is too short or too long. From a time perspective, but earlier in the process, more time needs to be foreseen for the capacity building required to build consensus on key scientific challenges (e.g. mixture classification is not as straightforward as substance classification and may need specific projects, trainings, research, etc.). Time is sometimes too short for regulators and affected stakeholders to fully grasp the scientific challenge. As a result, a given CLP rule or classification is adopted and adapted in a hurry, with insufficient supporting information and without a better understanding of the secondary and tertiary consequences.

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	2
Involvement of stakeholders	2
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

The procedures are seen as generally transparent, although written procedures followed by RAC and decision-making in the Commission are generally less transparent than other segments of the overall procedure for CLH. Appointing an independent advisory body to accompany RAC's work could be helpful to address/resolve, in full transparency, specific scientific questions where expertise is scarcer or has a divided opinion. Although stakeholders (Industry) are involved in the procedure, their evidence and arguments are not always given sufficient recognition. While this may prolong the process, their contributions should be used to increase the robustness and acceptance of a CLH proposal. Moreover, Industry should also be allowed to submit CLH proposals or changes to existing CLH, as the absence of a correct CLH (meanwhile a Member State frees up resources to take ownership for the applicable CLH (amendment) proposal) may cause market distortions which penalise EU actors. As regards the quality of the data supporting CLH, the selection of key studies can be subject to differences in opinion. More importantly, decisions around methodologies and assessment factors do not always recognise metal-specificities, despite them being part of authorities' Guidance documents. This negatively affects the overall quality of the proposed CLH and creates inconsistencies between the classifications of similar substances, or even worse, bad precedents for others. The quality of the CLH also depends on the data used to support the proposal, which varies depending on the procedure, budget and appointed consultants.

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*