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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Katia Lacasse
Organisation/company	European Copper Institute
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.	04134171823-87
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]:	Mining and quarrying (B), 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	3
Protecting the environment	3
Ensuring a well-functioning internal market**	4
Stimulating competitiveness and innovation	2

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 adapted to the issues at stake
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	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),

REACH, Annex XIII (Regulation (EC) No 1907/2006)
,

Chemical Agents (Directive 98/24/EC),

Carcinogens and mutagens at work (Directive 2004/37/EC)
,

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

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

Waste shipments (Regulation (EC) No 1013/2006),

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

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),

Persistent organic pollutants (Regulation (EC) 850/2004)
,

EU Ecolabel (Regulation (EC) 66/2010),

Safety of toys (Directive 2009/48/EC),

Drinking Water (Directive 98/83/EC),

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

Good Laboratory Practice (Directives 2004/9/EC and 2004/10/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:	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 Product-specific legislations sometimes use a hazard based approach to restrict the use of substances, without proper consideration of the risk dimension. Several regulations now include provisions, where substances meet the requirements for hazard classification, assuming that the substance creates a risk when used in articles. Examples include: 1) EU Ecolabel (Regulation (EC) 66/2010 states in article 6 that The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR)… 2) Safety of Toys (Directive 2009/48/EC): states in Annex II that substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toy The risk a substance poses when used in an article, or embedded in a mixture, depends on a variety of factors, and not exclusively on its intrinsic hazardous properties. We argue against the use of hazard based criteria to impose limitations on substances or products. A common restriction framework based on risk, including use-specific releases and bioavailability (rather than on hazard), is needed. This could be done using the REACH restriction procedure.
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. Limit values of substances in product regulations often insufficiently consider the socio-economic impacts. Despite allowing in some cases for exemptions based on technical considerations, the setting of the limit is based solely on hazard and or risk characterisation, with socio-economic aspects often not, or insufficiently, considered.

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	3
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	3
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 echo the comments made by Eurometaux, especially for the need for an independent advisory body (cf. SCHER) to oversee, on an occasional basis, the outputs from RAC.

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

Hazard identification criteria	1
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)	2
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 echo the Eurometaux position. Specifically we would like to highlight that hazard correctly addresses the intrinsic properties of a chemical. However, to do proper risk management, hazard needs to be linked to exposure and use. For metals, some of the criteria used to define hazards (and possible resulting classifications) sometimes miss out on the specific aspects of metals, metal compounds and their mixtures (modes of action, bioavailability, or fate). This could be improved by developing and recognising metal-specific, hazard assessment approaches and rules for inorganic substances, and by ensuring that EU hazard assessment experts do apply such approaches whenever applicable. In addition, product-specific regulations, such as the Toys Directive, should not restrict or ban products or compounds purely on hazard based criteria. In addition, there are issues with environmental hazard and risk assessment. New tests mean that the environmental toxicity datasets for metals are continuously increasing. Despite these strengthening datasets, in practice, it typically results in ever decreasing toxicity reference points used for classification. This is partly due to a publication bias - scientists battle to find the most sensitive species, or the most sensitive endpoint, otherwise their work will not be novel and not get published. Therefore, hazard and risk assessment datasets tend to punish data-rich substances and it can become a race to the bottom. This situation could be mitigated by restricting hazard identification to standard species and applying relevant statistical techniques to quality control datasets.

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 The question is biased. Today's quality requirements regarding reliability and reproducibility of safety data on chemicals are largely appropriate, in my view. Relevancy of data is an aspect that is often leading to controversial interpretations. This is not addressed by your question, unfortunately.

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, Costs for large enterprises, Costs for consumers
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	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	I don't know

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	Disagree

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	We echo the Eurometaux position.
Inconsistencies	We would like to highlight inconsistencies in the setting of M-Factors, Specific Concentration Limits (SCL) and Ecotoxicity References Values (ERV) among the following directives: Plant Protection Products (PPP, Regulation (EC) No 1107/2009), Biocidal Products (Regulation (EU) No 528/2012), Classification, Labeling and Packaging (Regulation No (EC) 1272/2008). Active substances used in Biocidal and Plant Protection Products require that classifications are harmonised at European level. In this process, the Risk Assessment Committee (RAC) of the European Chemical Agency issues opinions to the European Commission on the proposed harmonised classification by Members States. RAC assesses the quality of the data and might set SCLs and M-factors for the active substance. However, these opinions, along with the validity and reliability of the data used to derive them, are also valid for any other use of the substance. Therefore, more strict opinions, seeking to protect the environment from uses as biocides or PPP, may overestimate the human health and environment concerns for other uses.

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.

We echo the Eurometaux position

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?	3
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	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	No experience
Industry association guidance and materials	5
Other (training, conferences, etc.)	3
Please add further details as necessary	We echo the Eurometaux position
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	I don't know
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	2
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 echo the position of Eurometaux. In addition, we would like to raise the issue of alloys. Classification criteria and methods for alloys, considered special preparations under REACH, should adequately assess the hazard of the mixture. Alloys are explicitly considered to be mixtures for the purpose of hazard classification under GHS (UN, 2013) and EU REACH. However, alloys may not act as simple mixtures of their constituent elements. Rather, they may have unique physical, mechanical and chemical properties that affect the bioavailability of these constituents. Since current classification rules do not reflect this effect, we promote the concept of bioelution to overcome this.
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. We echo the Eurometaux position.

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	1
Involvement of stakeholders	1
Quality of scientific data and related information	1
Speed of the procedure	1

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers

The CLH procedure is not sufficiently transparent and RAC experts have enormous weight in final classification decisions. Appointing an independent advisory body to accompany RAC's work (similar to SCHER) could be helpful, on occasions, to address/resolve, in full transparency, specific scientific questions where expertise is scarcer, or has a divided opinion. Although stakeholders (industry) are involved, their evidence and arguments are not always given sufficient recognition. While this may prolong the process, these contributions should be used to increase the robustness and acceptance of a CLH proposal. Moreover, industry should also be allowed to submit CLH proposals, as an absence 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, unfortunate precedents for others. The quality of the CLH also depends on the data used to support the proposal, which varies depending on the 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