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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Kerstin Heitmann
Organisation/company	Selenium and Tellurium REACH Consortium
Country	Germany
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.	*Respondent skipped this question*
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:	Other, Other (please specify) industry consortium
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**	4
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)
,

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) ,

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) ,

Urban Waste Water (Directive 91/271/EEC) ,

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) ,

Batteries (Directive 2006/66/EC),

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

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

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

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

Drinking Water (Directive 98/83/EC) ,

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

Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)
,

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

Test methods (Regulation (EC) No 440/2008) ,

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
If a risk management option would be applied for specific uses, there would be less prolonged discussions and implementation delays as the outcome would overall be more targeted and efficient. There would also be less unintended secondary and tertiary impacts, which are often the obstacles leading to prolonged discussion and implementation difficulties. Having more use-specific or tailored measures would allow a more focused use of risk management option on the basis of its specific objective and methodologies.

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. Because of the generic nature of chemicals legislation today, it tends to “grasp all, or lose all”. The more generalised a regulatory measure, the more difficulties it will have to cover and properly address all “relevant considerations”, such as those in the question (additional ones could be overall EU Policy or objectives like to enhance circular economy, stimulate research and innovation etc.). Again, by working on more use-specific risk management options, a more precise scope of action could be assessed and all relevant, to that use, considerations would be easier to identify, consider, and take into account in regulatory decision making. Moreover, all chemicals legislation should duly consider economic feasibility and socio-economic impacts (similar to what is done under REACH Authorisation) to function properly and in line with better regulation. If this cannot be done as part of the legislation preparation, ex-post evaluations should foreseen to include this when legislation is revised, both in terms of impact assessments during revisions, as well as case-specific socio-economic analysis to be provided by the concerned actor on the market to justify one or other compliance approach towards chemicals.

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	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.	As regards the transparency of procedures, these are generally somewhat satisfactory, especially with the increased opportunity of

public consultations provided by the better regulation agenda. However, improvements could be made in preparing e.g. response to comments documents, better justifications for specific legal acts. Appointing an independent advisory body to accompany RAC's work (similar to SCHER) could be helpful to clarify specific scientific questions, in full transparency, for which expertise is scarcer or has a divided opinion. In some specific legislation, despite the scientific data provided by Industry according to the rules in place, decisions taken by the Commission on e.g. industrial emissions limit values under IED are based on minority or even false cases, ignoring the majority of the data or comments expressed. The "discretionary power" of the Commission is not properly exercised and the method to derive these BAT-AELs is not transparently documented or demonstrated. The Industrial Emissions Alliance and various EU Member States have asked that this is improved. As regards the speed with which hazards/risks are identified and with which risk is addressed, speed is not a proper measure of satisfaction. It depends on the complexity of the case and the availability of information and tools to identify the hazard and address the risk. Speed should not undermine quality. As indicated in one of the previous questions, some 'simpler' cases also undergo prolonged discussions and delayed implementations because of the collateral impact the applicable regulatory decision may have. If these impacts are considered upfront, they can be mitigated, the need for prolonged discussion will be reduced, and speed may even increase. As regards the time to allow duty holders to adapt, because of the number of automatic adoptions and triggers between various pieces of chemicals legislation (and in particular between CLP and so-called downstream legislation), in some cases adaptations require more than just "administrative updates". Again, because of the broad scope of many risk management options, a decision to change the classification of one substance may result in major impacts and business changes, across many other value chains, to comply with chemicals legislation overall. Impact assessments before changes to e.g. CLP rules or classifications are adopted will provide a good estimation of downstream impacts and the associated need for adaptation of downstream legislation and transition periods. From a time perspective, more time needs to be foreseen to build the capacity required to address key scientific challenges (e.g. mixture classification is much more complex than substance classification and may need specific projects, trainings, research, etc.). Some hazard-related questions can simply not

be debated in the current framework: e.g. how can you consider essentiality in the threshold/non-threshold DNEL/DMEL derivation, how can you consider inertness in STOT-RE classification, how to consider degradation of inorganics in classification etc.? In this case time is sometimes too short for regulators and affected stakeholders to fully grasp the scientific challenge. As regards the predictability of the outcomes of the overall EU legislative framework, this is currently far from satisfactory, in particular at the stage which precedes the regulatory decision. Before a decision is made on a given chemical or risk management option, again because of the broad scope and impact of a number of these, businesses have difficulties to prepare for the outcome. After the decision is made, although the impact and needs can be predicted up to some extent, there may be cases where specific requirements in related legislation are overlooked, because of the lack of structured mapping and overview of the various vertical and horizontal interlinkages between regulatory decisions taken under the various legislations. The legal framework is relatively stable, with periodic reviews foreseen in the legal texts. In practice however, some reviews do not take place within the foreseen timeline (e.g. BREF document reviews under IED), which can make (or makes sometimes) the implementation context vaguer. There seems to be an important imbalance between the means of the EU institutions for hazard issues (high) and those to more oriented towards risks/ad-hoc issues. For example, headcounts for industrial emissions directive (IPPCB) and workplace legislations are extremely low compared to the resources available in ECHA. This, coupled with the increasing number of Implementing Acts adopted by the Commission leads to instability of the actual role and weight of individual legislations within the overall chemicals legislation package available in the EU. As regards the clarity of legal texts, this is very much subject to interpretation. Some specific articles indeed pose difficulties (the typical letter of the law vs the spirit of the law), but the generation of Guidance using expert groups is very much appreciated as a practical way forward. Support provided national helpdesks is generally appreciated across EU countries. As regards the implementation and enforcement of EU legislation by Member States, feed-back from our Members shows that there is still much divergence in either transposition of EU law, or actual enforcement on EU law provisions, even when the legislation is a regulation which does not require transposition. This creates internal EU market barriers and competition issues, but above all,

	administrative burdens and the associated waste of human and financial resources. Example of this are the classification of waste or Article 4 of the Seveso Directive. An implementation and enforcement which is not consistent cannot be effective in our viewpoint. Enforcement of regulations is expected to be more consistent across the EU than the enforcement of directives, which first need to be transposed into national law. Assuming transposition is done properly (both in terms of content and timing), uneven enforcement is a common weakness of EU chemicals legislation across its territory. The growing number of chemical legislation requirements and downstream legal consequences for all operators and authorities can trigger a growing number of infringements in case of lack of proper controls. The consequence will be a more acute lack of level playing field within the EU and between EU and non-EU producers, but above all, a lack of proper protection of the human health and the environment. Public awareness about overall EU legislative framework is very much related to the enforcement aspects, and vice-versa. Depending on the geographical situation of, or the human and financial resources available to given market actors, they may be more or less confronted with enforcement authorities and/or information about changes to the EU legislative landscape. International collaboration and harmonisation is not as satisfactory as it could be. One example is GHS, where harmonisation is far from achieved. Where partners hesitate or refuse to implement e.g. specific blocks of GHS, or methodological aspects (e.g.: Annexes 9.7 and 10) the reasons should be further investigated, understood, and considered by the EU.

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	Hazard correctly addresses the intrinsic

further information (in particular on specific pieces of legislation), please explain your answers.

properties of a chemical. However, to do proper risk management, hazard should not be considered on its own without consideration of exposure/uses. For metals, some of the criteria used to define hazards (and possible resulting classifications) sometimes miss specific aspects of metals, metal compounds and their mixtures (modes of action, bioavailability, or fate). Examples include: - Water solubility test and WAF test: are still often accepted to assess the solubility of metals and complex materials, while not conforming since they measure nominal values. These methods are not in line with the metals hazard and classification system based on pH classes and the Transformation dissolution test (OECD n° 29). - Environmental classifications: criteria are much stricter for inorganics than for organics in many respects, e.g. the lack of criteria for degradability classifies many metals one category stricter. Also, the absence of data often triggers a default chronic category 4 environmental classification for metals, which is not applied to organics. This is unfair and triggers an inappropriate, uneven playing field between materials. - Skin/eye irritation/corrosion testing: the standard in vitro tests often provide a positive signal while in vivo results do not. The consequence under REACH/CLP is that the testing strategy is stopped after the in vitro test, with the substance being classified, whilst this is not confirmed in vivo. - Classifications for STOT-RE: the very low cut-off values for dusts may lead to classification of poorly soluble particulates of low toxicity, on the basis of effects observed after repeated inhalation exposure in animals. However, it is known that poorly soluble particles will lead to a lung overload-related inflammatory response in rats, which is not expected to take place in humans at equivalent exposure levels. At this stage, there is no possibility to distinguish between chemical-specific and inert particle-induced toxicity. - Physical form: for human health endpoints, there is currently no possibility to classify differently a massive and a powder. Whilst labelling of the massive form is exempted in CLP, classifications trigger further requirements beforehand. For the environment, metals are often assessed in the finest form (e.g. an ultra-micron powder represents the worst case reference or representative for the massive), while for organics the form as manufactured/used is tested. - Bioavailability is considered as a yes/no question in the CLP text (article 12 (b)). However, all substances are bioavailable to some extent and its “relative bioavailability” should be considered in classification through an agreed methodology and classification guidance. 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. Furthermore, there is a need to foresee the possibility to adapt some testing requirements/test methods to the 'realities' of substances and mixtures, provided that there is enough knowledge, science, data and transparency. Indeed, hazard identification is an evolving, living science that needs to be fed with research, experience and capacity-building. However, what is the value of this effort, if there is insufficient time to develop the required regulatory capacity-building? It is not obvious, in the current framework, where and how to debate key strategic, hazard-related questions: e.g. how can you consider essentiality in the threshold/non-threshold DNEL/DMEL derivation, how can you consider inertness in STOT-RE classification, how to consider degradation of inorganics in classification etc.? Environmental ecotox data sets for metals are continuously increasing due to new tests. Despite these strengthening the robustness of datasets, in practice it typically results in ever decreasing toxicity reference points used for classification. Compared to small datasets, the very large ecotox datasets available for metals often include non-standard endpoints. The hazard dataset for data-rich substances therefore becomes more and more about deriving a "PNEC". This anomaly can be prevented by restricting hazard identification to standard species and applying relevant statistical techniques to quality control datasets. As regards risk assessment and characterisation, the same applies. As regards hazard and risk communication measures to consumers, these are overly focused on hazard information and not enough on safe use instructions. Informing consumers about how to use and dispose of substances and mixtures, on the basis of their composition and exposure potential, would be more valuable than 'just' listing all ingredients and related classifications, which will result in an overload of labels. For workers, hazard and risk communication is better because it is done in a more structured context, with appointed experts, trainings, etc. It could however be communicated better if e.g. the information in SDS or extended-SDS would be formatted in a more user-friendly manner. There are two pictograms which appear to be particularly non-instinctive: the one of "gas under pressure" and the one on "serious health hazard". These could be replaced by more instinctive ones. As regards risk management measures restricting or banning the use of chemicals, because some of them are based on

	inadequate methodologies (e.g. RoHS) or applicable despite the unlikelihood of emission or exposure (e.g. Seveso), we do not consider them to be satisfactory.
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

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

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 , Other (please specify) The increasing complexity of the EU chemicals legislation, the many EU regulatory processes, and the constant changes to legislation trigger the need for external consultancy and legal advice for companies and for trade associations. This can bring additional significant costs for businesses, which need to allocate ever more resources to follow regulatory processes and ensure compliance, possibly to the detriment of other priorities beyond compliance (e.g. investment in R&D).
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
Please comment	It is known that scientific and regulatory developments do not operate in tandem, and sometimes science lags behind regulatory priorities, or regulation does not pick up scientific developments quickly enough. The EU legislative framework addresses emerging areas of concern properly, but solutions are often dependent on scientific progress and additional research. Where EU could better steer its involvement is in orienting more of its research funds to those areas, ensuring that the outcomes do respond to regulatory questions, and not merely academic ones, as well as build capacity within the regulatory community to take decisions based on this new information. This can be achieved through partnerships between EU policy institutions, academia and other interested and contributing parties. Where science is still under development, it is important for legislation to work on specific cases rather than on generalised assumptions of risk. For example, nanomaterials are just like any other substance in that some are dangerous and some are not, and yet Commission is developing a definition out of a specific context which creates controversy, increased information requirements under Cosmetics and other legislation, and has asked ECHA to host a EU Nanomaterials Observatory that gives the impression that nanomaterials must be supervised because they are suspicious... A size in the nanorange is not a hazardous endpoint and still some MS and NGOs push for a nanomaterial classification entry under CLP. Emerging areas of concern need to be handled in line with available and developing scientific knowledge and not only in a way which ‘addresses’ unjustified (case-specific) pressure from NGOs and the public. While EU frameworks and funds can be used to promote data generation, this should be done as a stimulus of scientific developments before considering administrative compliance requirements for Industry (which cannot go faster than science!). Emerging areas of concern should ideally, especially in their first stages, be handled by non-legislative frames and tools which are less rigid to implement and allow a more flexible learning curve, to ensure an efficient system overall.

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	One specific example of gaps, overlap and inconsistency relates to the CLH procedures occurring under CLP/REACH, the BPR, and/or the PPP. These do not follow a similar administrative procedure and, even where similar endpoints are assessed for similar substances (e.g. metal compounds from the same family), there is no mechanism to signal a potential link, overlap or inconsistency. Where different industry sectors are involved in each, this is often missed by Industry as well. Another important factor in the case of metals is the variable knowledge level of dossier submitters on the metals classification rules. Different datasets may be used to support a given CLH proposal under each procedure. This may negatively affect the overall quality of the proposed CLH, but moreover creates incoherence between classifications of similar substances, or even worse, bad precedents. The quality of the CLH depends on the data used to support the proposal, which can vary depending on the procedure, budget and appointed consultants. There should be a common set (applicable to REACH, BPR and PPP) of minimum guidelines to prepare and justify a CLH proposal (e.g. general reviews may not be sufficient and primary data should be considered in evaluating the reliability and relevance of the available information, and metal-specific concepts and methodologies should be applied).

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.

One specific example of gaps, overlap and inconsistency relates to the CLH procedures occurring under CLP/REACH, the BPR, and/or the PPP. These do not follow a similar administrative procedure and, even where similar endpoints are assessed for similar substances (e.g. metal compounds from the same family), there is no mechanism to signal a potential link, overlap or inconsistency. Where different industry sectors are involved in each, this is often missed by Industry as well. Another important factor in the case of metals is the variable knowledge level of dossier submitters on the metals classification rules. Different datasets may be used to support a given CLH proposal under each procedure. This may negatively affect the overall quality of the proposed CLH, but moreover creates incoherence between classifications of similar substances, or even worse, bad precedents. The quality of the CLH depends on the data used to support the proposal, which can vary depending on the procedure, budget and appointed consultants. There should

be a common set (applicable to REACH, BPR and PPP) of minimum guidelines to prepare and justify a CLH proposal (e.g. general reviews may not be sufficient and primary data should be considered in evaluating the reliability and relevance of the available information, and metal-specific concepts and methodologies should be applied).
REFIT could reflect on the best way forward to move from an ad hoc system in which classification proposals are submitted under multiple umbrellas and reviewed by dedicated expert panels, to a common, integrated system.
Overall, what is missing is a visual mapping and overview of the broader architecture and vertical and horizontal interlinkages between the different chemicals legislations, which shows the practical impacts of changes across them.
Another useful tool would be to use e.g. PACT to list all on-going hazard assessment initiatives for a given substance, to avoid overlaps or inconsistent work across authorities and legislative contexts. Such a list should also include e.g. SCOEL OEL discussions (now made available in a complete separate source). Making available the reference studies supporting a hazard assessment would increase the coherence of efforts across the various initiatives.
Generally speaking, when the scope of application of risk management options is defined on the basis of CLP classifications or classification rules, the 'risk' management legislative options and policy-making actually end-up being purely hazard-based. This results in overly conservative legislation (which disregards the actual likelihood of exposure, and hence, of risk), as well as in a domino effect of regulatory impacts. It also makes it difficult to determine whether legislation has actually achieved better environmental or human health protection (since the actual occurrence of exposure and risk are not considered in the first place).
Hazard should be a starting point only to assess the need to implement risk management measures. Depending on the context and objective of each measure, the scope should be focused through additional parameters, ensuring a risk-based assessment and decision-making. After a classification is derived, follow-up legislation should make use of information beyond hazard, with decisions based on the need to tackle a demonstrated risk. For example, when the hazard classification of a substance for a given endpoint is driven by only one route of exposure, e.g. inhalation, there is no need to limit its use when such an exposure route is not realistic (e.g. substance is fully contained, or is in a physical form which does not form and/or release dust). Restriction of the use of a given substance must be proportionate to the risk it realistically poses.
A purely hazard-based legislation can restrict scientific and technical advances leading to defensive research, obliging companies to find alternatives for incorrectly stigmatised substances, rather than enabling them to invest in R&D. This hampers innovation and the growth in jobs and leads to companies investing in R&D outside of the EU. Let's not measure CLP's and other chemicals legislation's success

Despite being exhaustive and expensive hazard assessments, without real precedent, REACH datasets (sometimes even validated at OECD under the Mutual Acceptance of Data scheme) are often disregarded in Member State and EU policies, such as the Water Framework Directive (for the derivation of Environmental Quality Standards) or IED (for the identification of priority pollutants that require emission control). In these policies and various others, REACH datasets are not yet fully recognised as reliable references. As an example, the IED BREF/Self Standing Document on Refractory Metals refers to the hazardousness of certain metals, inspired from the classifications available in the C&L Inventory only, and disregarding the substantiated evidence available in the REACH dossiers for these metals and their compounds. The same happens with the recently generated InfoCards and Brief Profiles, which display classifications submitted via unjustified CLP notifications on the same level as classification information documented in REACH dossiers. The USETox database used in Life-Cycle Assessments also disregards REACH datasets (although we are working to improve this).
Industry has the impression that due to this focus on regulating chemicals through ECHA (where resources are) and REACH and CLP-related implementing acts, the trend is to use REACH as a patch cover to address weaknesses of other chemicals legislation. This in time will lead to duplication of requirements and obsoleting of tailored and use-specific legislation. Instead, REACH should be used to inform on weaknesses of other chemicals legislation, helping to prioritise the reviews and improvements of these other legislation, in line with better regulation. A REACH one-fits-all legislative solution will miss specifics and will not work.
The reference DNELs derived by RAC under REACH cause confusion in the OSH context, where OELs prevail, because of differences in interpretation (e.g. Point of Departure, Assessment Factors) and methodologies (threshold vs. non-threshold). We look forward to the outcomes of the ongoing work of RAC and SCOEL in the context of REACH Article 95(3) (at least a Memorandum of Understanding such as the one prepared by CARACAL for RoHS and REACH?).
We encourage the Commission to continue its work to better align OSH legislation and REACH to create synergies and avoid possible overlaps and inconsistencies (e.g. OELs vs. DNELs, identification of OSH as risk management option (RMO) in RMO Analyses). We are a member of a cross industry initiative (CII) which seeks to promote better regulation in chemicals management by encouraging synergies and consistency between workplace legislation and REACH, as well as the application of risk management option analysis to identify the best risk management measure and avoid overlaps. Where workplace legislation, including the setting of EU-wide OELs, can address an identified risk which is limited to the workplace, the additional application of e.g. "Candidate Listing and Authorisation" under REACH, should be avoided. Further information about the CII is available at: http://www.cii-reach-osh.eu/positions.html.
On a more general note, we consider that the wealth of data generated under REACH could be taken more into account and used under other legislative frameworks

and used under other legislative frameworks.
Moreover more attention should be paid to the potential impacts which risk management options such as classification based Candidate Listing, Authorisation, restrictions and substance bans can have across different policy areas. This is to avoid taking regulatory decisions which would hamper the achievement of public policy objectives set under different policy areas (e.g. industrial policy, climate and energy policy).
There are, in CLP Annex VI, some group entries for metals ("metal X with the exception of Y and of compounds specified elsewhere in this Annex"), which were defined under the DSD for a series of reasons including data availability. The REACH registration process has generated more data, including specific metal compound data, on a number of endpoints including physico-chemical, human health and environmental ones not necessarily addressed in harmonised classifications. REACH also developed additional data sets and read-across evidence for substances with existing classifications in Annex VI. Depending on the endpoint, these data can be used for re-classification. However, many companies refrain from doing so due to the high burden required to change a harmonised hazard identification even for a "simple endpoint" like acute toxicity. This triggers inconsistency between REACH and CLP classifications.
A further example is illustrated by the >100 Ni compounds, classified under the DSD based on read-across and water solubility, which resulted in a significant number of entries for Ni compounds in Annex I (now Annex VI). It was stressed by industry at that time that most were not available on the EU market (will be confirmed after the REACH 2018 deadline - most are not/will not be registered). Although it is acknowledged that a REACH Registration is not a condition sine qua non to keep a classification in Annex VI, one may wonder if the scientific basis behind these classifications is actually robust enough.
In order to reduce such inconsistencies, a process should be set up to allow refinements of the Annex VI classifications, based on REACH data, as those may be very relevant for hazard communication. While it is clear that such a process should take into consideration the workload of authorities, in particular of ECHA and RAC experts, we should avoid situations where the burden prevents hazard identification and communication becoming more accurate. Industry should also be encouraged to continue to take its responsibility on hazard identification and communication.
A final example is the difference in requirements for physical hazards. This has been progressively addressed by presentations of "experts in the physical hazard classification" field over the last years but has required repeated communication sessions. Also, the CLP text is sometimes vaguer than REACH on the conditions to be met for information to be considered reliable (e.g. debate on the quality requirements for labs performing physico-chemical tests, which lasted for > 1 year in CARACAL). This also applies to the water solubility test, which has an equivalent specifically designed for metals, namely the Transformation Dissolution test (OECD 29). While the latter should be conducted to achieve a correct classification, most companies are unaware of this and conduct the water solubility test, leading to more severe, default classifications based on the surrogate approach, while ecotoxicity evidence on the metal ion is often readily available. Guidance and IUCLID software should perhaps guide companies to implement the proper test method when assessing metals.
Under REACH, justification for a given classification must be provided in the REACH Registration Dossier submitted to ECHA. So-called 'self-classifications' notified to the C&L Inventory under CLP, do not require supporting evidence. This is one of the key reasons for the number of different classifications notified for the same substance. If evidence and justification had to be provided, the notification exercise would be more robust and its outcome more trustworthy and useful. As mentioned above, currently there is a trend to use the worst classification reported in the C&L Inventory for a given substance, because there is easy way to validate the various classifications that are displayed in the Inventory. A second reason is the lack of an agreed interpretation of what an "agreed entry" could mean in the context of Article 41 of the CLP regulation.
Finally, REACH is a substance-driven Regulation, meaning that industry has registered substances, also as components of mixtures, and provided data focusing on the substances to be registered. However, the CLP classification of mixtures requires additional data and thinking, due e.g. to the different tonnages requirements, data in case of very low tonnages not covered by REACH registrations, non-classified components or components for which there is no REACH data, e.g. in the acute toxicity mixtures formula. Also, aspects like CLP article 12 (c) may require additional data, e.g. on synergistic effects, not required under REACH.
Despite the Memorandum of Understanding on RoHS and REACH recognised by CARACAL, the approach towards selecting substances to be restricted in EEE or under REACH does not seem to be consistent, e.g. the need to consider available alternatives.
Overall, what is missing is a visual mapping and overview of the broader architecture and vertical and horizontal interlinkages between chemicals and other EU legislation.
As already mentioned, a useful tool would be to use, e.g. PACT, to list all on-going hazard assessment initiatives for a given substance, to avoid overlaps or inconsistent work across authorities and legislative contexts. Such a list should also include e.g. RAC reference DNEL discussions, and SCOEL OEL discussions (now made available in a completely separate source). Making available the reference studies supporting a hazard assessment would increase the overall consistency of efforts made across the various initiatives.
All legislations leading to the generation of data which may support the classification of substances and mixtures, should ideally work in full synergy rather than in isolation. In addition to CLP, legislations such as Biocides or REACH offer good opportunities to validate methodologies and generate data to derive well-founded classifications. However, it is not obvious how regulators are using these to improve the efficiency of the overall classification process (as mentioned

earlier, metal-specific methodologies are not applied in a consistent manner especially under CLH).
There is some level of inconsistency and overlap between the CLP and the REACH Regulations, especially for substances which are already listed on Annex VI of the CLP Regulation. The inconsistency is two-fold: a) several substances do not exist on the EU market (e.g.: some nickel compounds), b) for some of the substances, the information generated for REACH indicates that the harmonised classification is either correct, but needs to be completed for some endpoints, or is incorrect on the basis of the most recent dataset. This situation is challenging for companies to implement with inconsistencies present in the information provided to end-users.

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	4
Industry association guidance and materials	5
Other (training, conferences, etc.)	3
Please add further details as necessary	In the case of the metals industry, Eurometaux provides additional guidance to that of the authorities. This is mainly in linking the guidance to the specificities of carrying out hazard assessments for metals and metal compounds. Sometimes this guidance is integrated into authorities' guidance, like in ECHA Guidance on application criteria of the CLP and the metals annex (and we appreciate this opportunity, which increases awareness on metal-specific aspects and approaches), and in other cases it remains internal.

Q31: To what extent is CLP enforced in a harmonised manner across Member States?

Enforcement is not harmonised across most Member States

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Please add further details as necessary
Our Members report differences in the levels of enforcement, e.g. control over labelling, classification of mixtures, etc. The acceptance of bioavailability also varies from one Member State to another. This is explicitly discussed in the context of using bioelution information to derive the classification of complex inorganic materials and alloys. Article 41 of CLP is not enforced (and there is not yet an agreed interpretation of what an “agreed entry” could mean in the context of and considering the limitations (e.g. unavailability of notifiers’ contact details) of the C&L Inventory, which is a second reason why the C&L Inventory is populated by multiple classifications for the same substance (in addition to the fact the classifications notified outside a REACH dossier do not need to substantiated/justified).

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	4
Appropriateness of classification criteria and methods for substances	3
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 find the STOT RE criteria incorrect/confusing. The flexibility embedded in a number of criteria and methods to classify substances allows expert judgement to be applied when relevant. This flexibility may be seen as facilitating the implementation by some and as complicating it, for others wishing to have more systematic rules. But overall, the criteria ruling the classification of substances are not the most difficult ones to implement. The classification criteria and methods for mixtures seem to be challenging, because the rules are difficult to understand and implement, because the classification of the components of the mixtures is not always readily available (or multiple classifications are available in the C&L Inventory), and several calculation approaches can be followed. Some Member States recommend using the classification submitted under REACH, while others recommend using the worst case available. This could be corrected by harmonising the rules (follow GHS?) and improving the accuracy of the C&L Inventory. The use of CLP classification criteria for the classification of waste (following the mixtures rules) is not at all straightforward because the heterogeneous nature of waste makes it difficult to check its composition, and because the impact of having a hazardous classification of waste has more far-reaching consequences for e.g. transport (Basel Convention) than the consequences triggered by the hazardous classification of a substance or mixture. As mentioned previously, harmonisation of the classification criteria of GHS is not yet achieved, especially for the environmental endpoints.

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.
The new or revised classifications or classification criteria trigger changes in the classification of substances and mixtures with hazard classes which then trigger automatic requirements under other legislation. As an example, a change in a classification of a substance can, from one day to the next, change the status of a site into Seveso. If Article 4 of Seveso wanted to be invoked, e.g. to obtain an exemption on the basis of the unlikelihood of exposure, the time for the site to comply with the change in CLP and its impact on Seveso is shorter than the time the full Article 4 notification takes (5-7 years). If the secondary and tertiary impacts of the changes to CLP would be mapped before adopting the decision to change CLP, it would identify the number and extent of impacts, consider the relevance of the change, as well as the implementation timeframe. The exercise would also serve the interests of those having to comply with legislation, as it would guide their attention towards those areas where the change requires adjustments for duty holders. Still 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	4
Involvement of stakeholders	3
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 (similar to SCHER) 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. Data used are often of good quality but can be considered/interpreted in different ways because of the context surrounding their "generation": e.g. source (industry data vs. peer-reviewed data), purpose for data generation, positive vs. negative result, and type of data (animal, epi, in vitro, in silico). To illustrate the latter, epidemiological data are often more difficult to interpret and animal data/in vitro are usually preferred by regulators as considered to include less uncertainty. However, just as much uncertainty lies in the extrapolation of such data to the workplace (relevance of exposure route, test material, particle size etc. in addition to the intrinsic experimental uncertainty). On exposure routes, we had a debate in RAC on the relevance of the intraperitoneal (i.p.) route to draw a conclusion on genotoxicity and the existence of a threshold for carcinogenicity. Several studies conducted using worker-relevant exposure route (inhalation, oral) were negative, but did not outweigh the positive i.p. results. Having a checklist allowing CLH experts to assess more easily epidemiological studies for completeness and reliability may help to make better use of the existing human data and observations. Having a quality checklist or streamlined format for reporting/assessing would also be a valid support. Templates should be prepared to help authorities/industry to assess easily quality, completeness and reliability of data. This would help to overcome the hurdle of the unknown, which results often in 'discarding' or 'overprecaution'. There should be a common set of minimum guidelines to prepare and justify a CLH proposal (e.g. general reviews may not be sufficient and primary data should be considered in evaluating the reliability and relevance of the available information). As indicated above, the speed of the procedure does not infer the quality of the outcome. It is a case-specific element of the procedure that we consider to be generally satisfactory. Still from a time perspective, more time needs to be foreseen for capacity building by regulators (see Q33).

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