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Collector: Web Link 1 (Web Link)
Started: Thursday, March 31, 2016 1:17:38 PM
Last Modified: Friday, May 27, 2016 12:57:11 PM
Time Spent: Over a month
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Hannele Tonteri
Organisation/company	The Federation of Finnish Technology Industries
Country	Finland
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.	39705603497-38
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) , Manufacture of computer, electronic and optical products (C26) , Manufacture of electrical equipment (C27), Manufacture of machinery and equipment (C28), Manufacture of motor vehicles, trailers and semi-trailers (C29)
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	Medium-sized enterprise (under 250 employees)
Q8: Please indicate the level at which your organisation is active:	National

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)
,

Biocidal products (Regulation (EU) No 528/2012),

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

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),

Batteries (Directive 2006/66/EC),

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

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

Drinking Water (Directive 98/83/EC),

General Product Safety (Directive 2001/95/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. Today, chemicals legislation has a generic nature. Developing the chemicals legislation having 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.

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	2
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.

The time to allow duty holders to adapt is short, because connections between various pieces of chemicals legislation and in particular between CLP and so-called downstream legislation) adaptations require practical actions not just “administrative updates”. Because of the broad scope of many risk management options, a decision to change the classification of one substance may result in major business changes, across many other value chains, to comply with chemicals legislation overall. 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.). 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. As regards the implementation and enforcement of EU legislation by Member States, 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. 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 harmonization is not as satisfactory as it could be. One example is GHS, where harmonization is far from achieved. We very much support the fact that EU agencies and representatives are actively involved in a number of international fora, but would expect the EU to be stronger in

	influencing international partner's legislation before forcing EU nationals to do so in a resulting isolated manner.

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.	Hazard correctly addresses the intrinsic 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 (e.g. bioavailability). Examples include: - 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. - 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. - 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. 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.

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 , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	I don't know

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	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	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.

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	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.
Overlaps	An 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.
Inconsistencies	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).

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.

Commission should standardize the basic requirements of the different regulations and directives concerning chemicals. This would enable prompter and better quality inforcement activities both for authorities and companies. Many companies have to report of the requirements of both REACH and RoHS. One example of the differences between REACH and RoHS, is that some substances of concern are communicated differently e.g Chromium 6+ is communicated in REACH Cr2O3 and in RoHS Cr6+. This leads to confusion and is time consuming for companies.

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	5
Industry association guidance and materials	5
Other (training, conferences, etc.)	3
Please add further details as necessary	ECHA has very good set of guidance in general level, but these should be reviewed by national expert groups to make them more practical to companies. In Finland the national helpdesk works very well and gives important information to the companies.

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	4
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	3
International harmonisation through the Globally Harmonised System (GHS)	2
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Regulations linking to EU Chemical regulation (CLP directive) with content criteria, Content criteria comes from toxicology / ecotoxicology developed for organic compounds and liquids (not for inert articles or metal alloys). Hard metallic alloys: Me1+Me2+Me3 • Not liquids, acids, salts or organic compounds! • Health or environmental effect only if there is a metal ion release => Bioavailable metal • Massive, hard, no metal release ▭ The metals are not bioavailable ▭ No risk Metal content cannot alone be used to assess health or environmental effects.

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.
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	I don't know
Speed of the procedure	3

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

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	REACH regulation has good processes to both foresee and verify substances of very high concern. These processes should developed more visible in public and taken in use in higher level in other more industry sector focused directives like RoHS, ELV, battery directive. Chemical legislation should not be obstacle to prolong the life cycle or use of products or materials. A balance should be created between restrictive and permissive regulation in substances. A well-functioning circular economy can only work efficiently by using a risk-based approach instead of completely categorised regulation where only non-toxic substances are allowed. There is a need to define possible non-risky reusing or recovery for materials containing small quantities risky substances, for example circulated metals including Pb or Cd. Chemical legislation should allow repair as produced for products. Toxic free economy needs enough overlapping time to be able to develop new substances and technology to develop new kind of products in the same time when existing materials (including toxic elements) flows are in use. Waste legislation should be assessed into mode of resource recovery legislation: reassess waste hierarchy to respect new products (fuels, product gas) and industrial co-generated products, expand criteria on by-products to prevent them from becoming waste, and facilitate exchange among industries and use in infrastructure building. Create quality standards for (waste) material flows and end of waste criteria to promote market-driven development of secondary materials.