#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Tuesday, May 17, 2016 10:29:48 AM
Last Modified: Friday, May 27, 2016 10:52:25 AM
Time Spent: Over a week
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Marco Vallini
Organisation/company	Nickel 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.**	77947983421-21
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), Other (please specify) The Nickel Institute follows regulatory and non-regulatory issues related to the production and use of nickel and nickel compounds and their applications. Nickel Institute is the global association representing primary nickel producers at EU and international level. Our mission is to support the use of nickel in appropriate applications. Through our science division NiPERA (www.nipera.org), we also undertake leading edge scientific research relevant to human health and the environment and are considered a centre of excellence for information on nickel and nickel-containing materials.
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:	Global

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	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	4
Protecting the environment	4
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	2

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Protecting human health	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	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) ,

Signs at work (Directive 92/58/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) ,

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) ,

Drinking Water (Directive 98/83/EC),

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
EU chemical-related legislation should be risk based rather than hazard-based. A risk-based approach, focused on assessing and managing the potential risks of a substance in a specific context (e.g. at the workplace) and in certain applications/products or uses, is more appropriate and effective, helping regulators and businesses to address real risks where they may be. Taking into consideration the existing hazard classification of a substance, (if it is correct), this can of course be a first, preliminary step. However, it cannot be the only criterion to trigger automatically risk management measures, substances restrictions, bans or other requirements, without a proper risk assessment mechanism, taking into account the substance specificities, its benefits, the intended applications and socio-economic aspects.

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.
Socio-economic aspects as well as the potential impact on competitiveness and innovation are considerations that should be taken more into account in the regulatory decision making process on risk management. On a more general note, more attention should be paid to the potential impacts which risk management measures, such as restrictions and substances bans, can have across different policy areas. This in order to avoid regulatory outcomes whose cumulative effects can hamper the achievement of public policy objectives set under different policy areas (e.g. industrial policy, energy policy). On a more specific note, we take the view that the potential regulatory and non-regulatory impacts of the changes to a harmonised hazard classification of a substances under the CLP Regulation, are not sufficiently taken into consideration. The Commission should carry out some kind of impact assessment when adopting EC Regulations amending the Annexes to the CLP Regulation (so-called Adaptations to Technical Progress, ATPs), which affect the harmonised classification of substances. Impact assessments should be carried out even though the ATPs Regulations are not adopted by the EU ordinary legislative procedure (co-decision) but by EC comitology / implementing acts. Furthermore, the specificities of metals and inorganic substances, as well as of alloys should be better taken into account. Risk management measures for these substances and materials, should be adopted following an evaluation that takes into account metal specific risk assessment methodologies and concepts (e.g. bioavailability). For instance, the effectiveness of the CLP Regulation should be improved with respect to classification of complex materials, such as alloys. Alloys classification is presently based on the hazard profile of its components for all endpoints, while it is well known that alloys have different properties from those that can be predicted based solely on their metal constituents. The CLP Regulation should allow for special guidelines for such cases to ensure that the most scientifically appropriate classification are achieved.

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	4
Speed with which identified risks are addressed	3
Time to allow duty holders to adapt	3

Predictability of the outcomes	2
Stability of the legal framework	2
Clarity of the legal texts	2
Guidance documents and implementation support	3
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	3

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	Lack of predictability of the outcomes: We take the view that there is currently a lack of outcomes predictability, in particular at the stages which precede the regulatory decision making. Moreover, the interlinkages between the CLP Regulation (e.g. harmonized classification) and other EU sectoral legislation (or downstream legislation) can in some cases trigger automatic risk management measure(s) under sectoral / downstream legislation. This can have unintended consequences and create further uncertainty and unpredictability. The fact that the CLP Regulation is constantly amended, with revision to existing harmonised classifications or the introduction of new classifications, has in many cases a direct impact on those sectoral regulations, which refer the CLP classification of a substance to determine their scope (i.e. substances and businesses covered) and the type of applicable requirements (e.g. restrictions of the substances covered). This can create uncertainty and can have unintended consequences which can be difficult to manage and predict for competent authorities and businesses alike. For example, the Seveso Directive refers to the CLP harmonised classification to determine, under some conditions, which substances are covered by the Directive and hence which installations are subject to the stringent Seveso regime. Therefore, a change in the hazard classification of a substance under the CLP Regulation can automatically trigger a change to the scope of the Seveso Directive making an installation subject to Seveso requirements. This has huge implications for the affected businesses and competent authorities, for which it can be difficult to anticipate and foresee changes in the scope of the Seveso Directive following unrelated and uncoordinated amendments to the CLP Regulation. Issue of speed of hazards/identification: As regards the speed with which hazards/risks are identified and with which risk are addressed, we take the view that the speed is not a proper measure of satisfaction. Moreover, it is difficult to make general statements. The speed also 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.

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.)	I don't know
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	4
Risk management measures restricting or banning the use of chemicals	1
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	3
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.	As indicated in previous responses, risk management measures such as restrictions and bans on substances should not be triggered automatically under downstream legislation only on the basis of the hazard classification of a substance. We caution against “automatic linkages” between CLP and downstream legislation with purely hazard based approaches and once-size-fits-all solutions, which can have unintended and unjustified outcomes, e.g. restricting or banning the use of substances when there is no risk to human health and the environment. 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. In addition, for metals some of the criteria used to define hazards (and possible resulting classifications) sometimes miss to take specific aspects of metals and metal compounds and their mixtures (modes of action, bioavailability or fate) into account. This could be improved by developing and recognizing metal-specific hazard assessment approaches and rules for inorganic substances, and by ensuring that hazard assessment experts in the EU do apply such metal-specific approaches whenever applicable.

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 authorities at EU level , Costs for authorities at national level , Costs for small and medium sized enterprises , Costs for large enterprises , Costs for consumers , Costs for society in general
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 , Other (please specify) The increasing complexity of the EU chemical legal framework, the EU many regulatory processes and the constant changes in legislation (e.g. amendments to the CLP Regulation) imply very often the need for external consultancy and legal advice for companies (to understand, implement the legislation and follow its changes) and for trade associations, which have to provide support to companies. 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	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	3

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	Neutral

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 practical impacts of changes across them. Hazard should be a starting point only for deciding to implement risk management measures, and depending on the context and objective of each measure, the scope should be defined by 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, and decisions should be 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 the use of such substance when this use poses no risk of exposure via this route (e.g. substance is fully contained, or is in a physical form which does not result in the formation and release of dust). Restriction of the use of a given substance should be proportionate to the risk it poses. A purely hazard-based legislation can restrict scientific and technical advances leading to defensive research. This can hamper innovation and may lead to companies investing in R&D outside of the EU.
Overlaps	See above.
Inconsistencies	See above.

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 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). In this context, 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 targeted application of risk management options to 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 wealth of data generated under REACH could be taken more into account and used under other legislative frameworks.

Moreover, as noted in earlier replies, more attention should be paid to the potential impacts which risk management measures, such as classification-based Candidate Listing, authorization, restrictions and substance bans, can have across different policy areas. This is to avoid regulatory outcomes, whose cumulative effect, can hamper the achievement of public policy objectives set under different policy areas (e.g. industrial policy, climate and energy policy).

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?	4
To what extent are CLP labels effective in communicating hazards to consumers?	I don't know
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	3
Helpdesks	No experience
Industry association guidance and materials	5
Other (training, conferences, etc.)	3
Please add further details as necessary	One of the problems is that existing guidance (e.g. for the CLP Regulation) does not always include and acknowledge metal specific concepts and is not always suitable for metals and inorganics materials.
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	3
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)	3
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	Lack of guidance and suitable approaches and methods to classify-alloys. Because CLP was crafted with organic substances in mind, when it is applied to inorganic substances, a number of default rules/criteria may trigger over-classification of metals and their compounds. Furthermore, as regards the physical from, for human health endpoints there is currently no possibility to classify differently a massive and a powder. The assumption that a mixture will have the same intrinsic properties of its components does not necessarily apply to complex materials such as alloys. Applying the current CLP rules alloys may therefore result in their under- or over-classification.

Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?

Transition period is too short,

Please elaborate if you answered that the transition period is too short or too long.
Given the significant, potential implications of changes to the CLP Regulation (ATPs, etc.) longer transitional periods could be foreseen.

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	3
Involvement of stakeholders	2
Quality of scientific data and related information	2
Speed of the procedure	2

If you answered 1, 2 or 3 and would like to provide further information, please explain your answers
Some of the problems concern the following aspects: - New scientific developments, approaches or refinement are not always taken into account; - Default assessment factor are often applied strictly as per guidance, independently from the wealth of available scientific information for a substance. This can lead to over conservative and scientifically unjustified outcomes which in turn can raise unjustified concerns and trigger disproportionate and unnecessary risk management measures. - In the context of some processes, the involvement of stakeholders is very limited and the available commenting periods are too short. - Similarly, in some cases (introduction of harmonized classifications), the “speed of the procedure” is too fast and does not allow for sufficient time for stakeholder inputs. It is, however, difficult to make general statements, as the speed of procedure can vary depending on the legislative framework and the committees involved.

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*