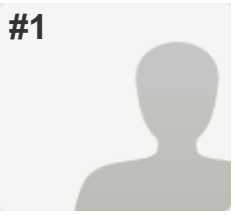

#1

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Collector: Web Link 1 (Web Link)
Started: Wednesday, March 09, 2016 2:31:19 PM
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Time Spent: Over a month
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PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Nishma Patel
Organisation/company	Chemical Industries Association
Country	UK
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.	33067463234-52
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 chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1) , Manufacture of pesticides and other agrochemical products (C20.2) , Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3) , Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4) , Manufacture of other chemical products (C20.5) , Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21) , Manufacture of rubber and plastic products (C22)
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	Small enterprise (under 50 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	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	4

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	5
Protecting the environment	5
Ensuring a well-functioning internal market	3
Stimulating competitiveness and innovation	3

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	The legislation is not effectively implemented
Stimulating competitiveness and innovation	The legislation is not adapted to the issues at stake

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

EU-level legislation adds value to national level action	4

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.

Classification, labelling and packaging (Regulation No (EC) 1272/2008)
,

Plant protection products (Regulation (EC) No 1107/2009)
,

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

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

Inland transport of dangerous goods (Directive 2008/68/EC)
,

Chemical Agents (Directive 98/24/EC),

Asbestos (Directive 2009/148/EC),

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

Young people at work (Directive 1994/33/EC),

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)
,

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

Export and import of hazardous chemicals (Regulation No 649/2012)
,

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

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

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

Drinking Water (Directive 98/83/EC) ,

Explosives (Directive 93/15/EEC),

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

General Product Safety (Directive 2001/95/EC) ,

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

Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
,

Protection of animals used for scientific purposes (Directive 2010/63/EU)

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
Risk assessment is central to industry's chemicals management approach in order to determine how and under what conditions a chemical can be safely used. The risk associated with each chemical is dependent on the specific use for which it is intended. Therefore a specific risk assessment is more appropriate to define the most effective risk management measure whilst preserving societal benefits. For example in the area of biocides, the legislation has very prominent elements of hazard-based decision-making with a number of automatic risk management responses based on CLP. Exclusion criteria under BPR are purely hazard based and assessment processes under BPR focus on worst case scenarios and conservative assumptions that do not reflect reality. In addition studies which are 'outliers' are used instead of the weight of evidence provided by extensive data packages. While active substances used in biocides may be inherently hazardous, an in-depth risk assessment is necessary to safeguard their benefits for society while minimizing emissions and exposure. The requirement to adequately ensure a high level of protection for human health and the environment should be about demonstrating safe use of the products that are placed on the market. This should be done through a risk assessment considering exposure and risk mitigation measures. In some areas, decisions are in practice more driven by hazard than risk, even when risk assessments are carried out. The concept of 'weight of evidence' should be better utilized, particularly where the criteria alone does not predict the behaviors of the substance with a need to consider relevant scientific studies and substance behavior (e.g. the PBT, vPvB criteria is a good example). Examples of hazard based decisions can also be found in the selection of priority substances under the Water Framework Directive and setting EQS; evaluation undertaken by POP Review Committee.

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.
In CIA's opinion the wording of this question is ambiguous. For effective regulatory decision making on risk assessment, we agree both the science and socio-economic aspects need to be considered. However, we question the choice of wording in the question since this implies that the combined effects of substances are not currently considered. This is not the case, as by addressing the toxicity of single substances through risk management measures we are also controlling any risks when they are present in combination with other substances. The evidence to date indicates that even when combined chemical exposures are found to potentially pose a risk, these are more often than not found to be driven by only one or just a few of the chemicals within the combination. In most of these cases, existing risk assessment processes and regulations are considered to be sufficient to identify and address the risk posed."
Beyond this, CIA view on regulatory decision making are as follows: Impacts on competitiveness of EU industry are generally not considered in the context of regulatory decision making on risk management. At best, these impacts are estimated before the main legislative act is proposed by the Commission to Parliament and Council – but not necessarily considered when the rules are finally adopted and become law or when they are implemented. The poor quality impact assessment produced for new regulations is more often than not a common problem undermining EU legislation. In many cases the potential economic impact is not well considered which results in legislation that hampering EU's priority on stimulating growth, innovation as well as job creation. Going forward we strongly urge that impact assessment for EU regulation to be based on sound science and evidence taking into account that it could impact on all sectors i.e. any resulting legislation should be balanced and proportional to ensure perspective is built into the process. Finally, in addition where a cost benefit analysis has taken place these are not always considered during the final voting stage of new legislation. For example in the case of CLP Regulation Article 45, several outputs of the cost benefit study as well as the discussions/agreements amongst various stakeholders on the draft proposal now seem to be disregarded during the final REACH Committee process.

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	4
Speed with which hazards/risks are identified	3

Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	3
Predictability of the outcomes	2
Stability of the legal framework	2
Clarity of the legal texts	4
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	4
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.	Predictability/Stability: Under biocides legislation, rules in the form of technical/regulatory guidelines or agreements on interpretation between competent authorities are constantly changing and their applicability can be immediate – with companies having to react within very tight deadlines. Application dossiers for substance approval submitted more than 10 years ago are still under evaluation, within a legal framework that has changed extensively. As a whole, the level of legal certainty and predictability is very low for biocides. The timelines for the approval of active substances and the authorization of biocidal products in the BPR are not predictable. The same applies for the Harmonized Classification and Labelling (CLH) processes under the CLP Regulation. Levels of enforcement EU legislation has encouraged a level playing field within Europe, as same requirements apply for all European based companies and as a consequence there is a reduction in national bans/restrictions on chemicals compared to previous regimes. However enforcement across Member States varies across many chemicals legislation, particularly under environmental protection legislation and for biocides legislation. International collaboration and harmonization: Beyond CLP Regulations the EU chemicals legislation has been known to offer a high level of protection to human health and the environment. Several other parts of the world have now adopted similar approaches to chemicals in their national regulatory regime. However in some cases this has led to businesses having to duplicate procedures to satisfy national requirements. For example, although K-REACH is comparable to EU REACH Regulation, the data gathered under EU REACH is unsatisfactory for submission to Korean authorities. As a consequence we believe further efforts are necessary to ensure existing work done by businesses is recognised in other global emerging regulation.

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

Hazard identification criteria	4
Risk assessment and characterisation	4
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.)	5
Risk management measures restricting or banning the use of chemicals	3
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5
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 and risk communication to consumers: The increased labelling requirements stemming from CLP, BPR and others is considered to weaken the intended effect of a hazard warning to end users, particularly consumers. This is also supported by the Commissions Eurobarometer report on consumer understanding of labels and the safe use of chemicals.

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?

Yes,

If you answered no, please explain your answer
Except for physico-chemical data. For physico-chemical data we believe that appropriate quality systems are in place which would include: - Tests performed according to a standard method and therefore comparable - Tests are properly documents - Tests are performed by a competent person.

PAGE 6: Efficiency

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)

Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.
,

Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.
,

Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.

Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)	Costs for small and medium sized enterprises, Costs for large enterprises, Costs for consumers
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Classification requirements for substances and mixtures , Chemical labelling and packaging requirements , Risk management measures under the different legislation , Inspections and administrative requirements
Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	Yes, If you answered yes, please indicate what these are. The implementation of chemicals control legislation is resource-intensive, also for authorities. Even when the legislation foresees a system of mutual recognition between Member States (cf. Biocides), we often see Member States re-evaluating the first evaluation performed by the lead Member States. These costs are charged back to industry through a system of fees.

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 current EU legislative framework for chemicals is sufficient to address emerging areas of concern. The framework should however consider the latest scientific advances with regards to new test methods, new methodologies, and ensure required testing is linked to clear human health or environment emerging concerns.

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	Neutral
The EU chemicals legislation framework has overlaps	Agree
The EU chemicals legislation framework is internally inconsistent	Agree

Q26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

Gaps or missing links	Interface between CLP Regulation and Seveso Directive – with the inclusion of tighter hazard categories included into the Seveso directive from CLP, the expectation is that many more substances will fall under the Seveso requirements resulting in additional obligations and compliance costs. One example is the case of Nitric acid where the Risk Assessment Committee proposed classification would have resulted in a number of non/lower tier COMAH sites now being captured under the Directive. In these cases we believe that automatic legal provisions in downstream regulations without risk assessment should be avoided. We believe similar implications are foreseen for waste classification although it is still early to identify specific examples at this stage.
Overlaps	In occupational health legislation (CAD/CMD)
Inconsistencies	Labelling requirements under BPR and CLP are sometimes contradictory (cf treated articles)

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.

Overlapping requirements between REACH and occupational health legislation as well as between REACH and RoHs Definition of ‘placing on the market’ within various chemicals legislation. This has multiple consequences for CLP, BPR, POPs and REACH.

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?	5
To what extent are CLP labels effective in communicating hazards to consumers?	3

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	4
Other (training, conferences, etc.)	4

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	3
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	4
International harmonisation through the Globally Harmonised System (GHS)	4

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 sufficient

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	4
Speed of the procedure	2

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	Question 23: The EU legislative framework may have ld to reduced number of hazardous chemicals but not always replaced with safer alternative. For example our engagement with the retail sector highlights the replacement of phthalate lining in door mats has led to consumers slipping. Whilst chemical properties of phthalate may be a concern consumers are now exposed to an even bigger risk to harm that is more likely to occur compared to the low levels of exposure to phthalate lining under the article. We once again emphasis the need for legislative framework that considers risk during intended use and exposure whilst maintaining both societal and economic benefits.