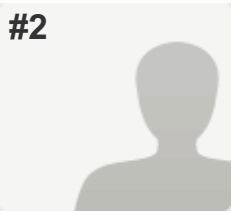

#2

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Tuesday, May 24, 2016 2:01:22 PM
Last Modified: Tuesday, May 24, 2016 2:58:10 PM
Time Spent: 00:56:48
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	
Organisation/company	
Country	Netherlands
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.**	
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 but should be kept anonymous; 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 do not want to be contacted
Q5: **Please indicate whether you are replying to this questionnaire as:**	A non-governmental organisation (NGO)
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]:**	*Respondent skipped this question*
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:	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	5

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	5
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	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

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	5

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.	Water Framework (Directive 2000/60/EC), Marine Strategy Framework (Directive 2008/56/EC), Drinking Water (Directive 98/83/EC), Fertilisers (Regulation (EC) No 2003/2003), Other (please specify) Birds- and Habitatdirectives

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:	b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted), If you answered a or b, please explain It is not possible to achieve a high level of protection of the environment through a risk-based approach. Risk assessments are notoriously slow processes and a systematic lack of exposure data frequently leads to high levels of uncertainties meaning that the establishment of acceptable exposure levels are ultimately political, rather than scientific, decisions. Furthermore, a safe threshold can not be established for several groups of substances such as EDC, PBT, CMR, sensitizers. This means that if risk based aproaches are used, people and the environment are left exposed to toxic chemicals for much longer than would be possible under a hazard-based approach. Hazard based approaches are incorporated to several pieces of EU legislation since more than 20 years and cmpanies have switched to alternatives chemicals, materials or technologies in order to comply with them, so they significantly triggered innovation.
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. Uncertainties or not dealt with adequately, decisions are not based on the precautionary prinicple. Other relevant considerations that are not taken into account include added exposure from different sources, combined effects, lack of adequate exposure information (including environmental monitoring and human biomonitoring data, vulnerable timing of exposure, vulnerable groups); lack of information on hazardous properties of most chemicals, for example, only 5% of chemiclas have been examined on neurological effects; costs to society underestimated and costs to industry overestimated.

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	1
Speed with which hazards/risks are identified	1
Speed with which identified risks are addressed	1
Time to allow duty holders to adapt	5
Predictability of the outcomes	5
Stability of the legal framework	5
Clarity of the legal texts	3
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	1
International collaboration and harmonisation	4
Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	an example of the lack of transparency is EFSA refusal to publish industry studies on which it has based its opinions. Speed: the candidate and authorisation listing process is an example of how slow the identification of hazards is happening. Although thousands of substances have been identified as SVHC only 168 and 31 are included in the candidate and authorisation lists respectively. The Water Framework Directive priority substances should have been tackled by Member States by 2010. However, the data on how this was done has just been published at the end of 2015, with still around half of the Member States delaying adoption of the river basin management plans. Also the lack of regulations on nano and the limited regulations on EDC are examples of how the regulation of hazardous substances is delayed for years. The EU strategic approach on pharmaceuticals in water is also seriously delayed. Examples of wide differences among MS in compliance and surveillance of the legislative framework include, among many others waste management, water protection and worker protection regulations. Concerning water, the reporting of chemicals data in the first river basin management plans in 2009 was so incoherent among Member States that the European Commission could not make a meaningful assessment of it. Better results can be expected in the 2nd cycle but we still do not have the necessary data in 2016.

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

Hazard identification criteria	I don't know
Risk assessment and characterisation	2
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	2
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	3
Risk management measures restricting or banning the use of chemicals	2
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	2
If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	Risk management is not at all satisfactory. Risk characterisations are inadequate as appropriate information on hazardous properties of chemiclas in the market is still widely lacking, in particular fo endpoints such as endocrine disruption or neurotoxicity. Exposure characterisations do not take in account exposures to mixtures, low dose effects, vulberable periods of exposure, etc. Exposure characterisations are based on models which are irrelevant to real life exposures. Both consumers and workers lack information on the susbtances that are present in articles and lack information on the substances of very hgh concern in all types of goods and packaging. The risk management measures restricting or banning the use of chemicals are insufficient to protect the population and the environment. The process is extremely slow (since 2007 only 18 substances have been restricted in the EU). Measures need to be implemented to speed up the procees to restrict SVHC in all consumer products.
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?	No, If you answered no, please explain your answer GLP should not be used to judge the quality of research studies. GLP is a measure of good laboratory practice, not good study design, execution or interpretation . Systematic review criteria should be applied impartially to both GLP and non-GLP studies in order to arrive at accurate conclusions about a body of evidence.

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. , Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy
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
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Other (please specify) It depends on how you define costs. For most of the companies environmental legislation costs are not significant compared to energy or labour costs or compared to sales and profits. Also, the costs for companies are not significant if we consider the avoided pollution that would be much more expensive to remediate after it had happened. The Commission, national authorities and different stakeholders conducted several studies on cost and benefits of regulating chemicals in the frame of the REACH regulation development that hihlightedthe overal benefits for society are way over the costs for certain industry sectors. For example: - Pearce- Koundouri, 2003. The social cost of chemicals. WWF - University of Sheffield, 2005 The Impact of REACH on occupational helath.ETUC. - RPA, 2003. Assessment of the Impact of the New Chemicals Policy on Occupational Health.Commisioned by DG Environment. - DHI, 2004. The impact of REACH on the environment and human health. Commisioned by DG Environment. - KPMG, 2005. REACH- further work on impact assessment A case study approach. - European Comission, 2003. REACH Extended Impact Assessment.COM(2003)644final

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. Preparation of CLH, SVHC, evaluation, restriction, etc dossiers as well as enforcement activities lead to significant costs to authorities. A better implementation of the polluters pay principle is needed.A good example to follow is the Toxics Use Reduction Act from Massachussets, wich obliges users of SVHC to pay a fee which is used by authorities to help reducing the use of SVHC. This act has succesfully reduced the emmission of hazardous substances to the environment as well as the generation of hazardous waste while supporting local companies. http://www.mass.gov/eea/agencies/massdep/toxics/tur/

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	2
Please comment	The existing EU legislative framework has shown to be clearly insufficiently to adress address emerging areas of concern such as nantomaterials, endocrine disrupters, mixture toxicity, low dose exposure, combined risks, pharmaceuticals etc.

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	Disagree
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	Different chemicals are regulated in different points of their supply chain but there is no overall approach. The precautionary principle should be used before applying them.
Inconsistencies	Lists of substances limited in different pieces of legislations should be harmonized.

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.

Respondent skipped this question

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?	4

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	No
Physical	Yes
Human health	No
Please list any hazard classes that are not covered	Environmental: no hazard classes for PBT or EDC. Also several environmental haz class were lost when adapting to GHS.

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)

Respondent skipped this question

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

Please add further details as necessary
ECLIPS project report shows very high deficiencies in quality of MSDS sheets throughout the EU, including wrong classification of substances and mixtures. ECLIPS Working Group. European Classification and Labelling Inspections of Preparations, including Safety Data Sheets. FINAL REPORT. CLEEN, 2004. http://www.cleeneurope.eu/projects/ECLIPS.html

Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)

Appropriateness of classification criteria and methods for substances	3
Appropriateness of classification criteria and methods for mixtures	3
If you answered 1, 2 or 3 and would like to provide further information, please explain your answer	The current criteria provide a scientific base for identifying hazardous properties of substances, thus establishing a clear, predictable and systematic base for identification. However, a more precautionary approach is needed when applying the criteria, as well as better use of the available epidemiological data. Many relevant hazard categories are included in the CLP Regulation. We believe that no existing hazard classes should be removed, and that hazard categories for endocrine disruption, neurotoxicity, allergenic properties, nanoforms/nanomaterials, biodegradationand PBTs/vPvBs should be added.There is a need to update existing test methods,. Most of the existing test methods are decades old and therefore fail to take into consideration many new scientific insights such as vulnerable windows in development or epigenetics. Available tests should be introduced for additional endpoints such as immunotoxicity, neurotoxicity, endocrine disruption, persistence, etc. There is also a need to update testing methods to avoid non-genotoxic carcinogens being undetected.

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?	Transtion period is too long,
	Please elaborate if you answered that the transition period is too short or too long. We believe that the time for companies to adapt to technical progress is more than sufficient taking in account it takes several years since a substance is proposed for a harmonised classification, it is included in the CLP Regulation and then transition periods are considered. Perhaps better information for companiesin early stages is required, instead of considering giving longer periods to adpat to changes.

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	1

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

The lack of capacity and resources within CSO and SMEs hinder their capacity to participate in the CLH process. By contrast chemical manufacturers have the capacity to follow and influence the outcome of each classification dossier. This situation is affecting the consistency and objectiveness of the process and should be tackled. Independent academic data is given a lower value than industry data that conforms GLP procedures. Also, the Risk Assessment Committee is reluctant to use results from non-animal testing methods and epidemiological studies for example, for classifying carcinogens. The CLH process is extremely slow, for example only 13 substances have been classified (harmonised) as carcinogens in the last five years. It took over 30 years to classify asbestos as a carcinogen! A good indicator of the problems with CLH procedures is the fact that industry is self-classifying more substances as carcinogens than the authorities (ECHA's Classification and Labelling inventory shows that 1017 substances have a CLH classification as Category 1 carcinogens, however, industry has notified this classification for over 2400 substances.

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	The public consultation and the refit exercise, instead of aiming to justify industry complaints on the high cost burdens of environmental and chemicals legislation should be seeking to answer if the chemicals related legislation is protecting people and the environment from hazardous substances, if it is covering all issues, if citizenss, workers, downstream companies and authorities are sufficiently informed on the risks, and if the underlying principles of EU legislation are being implemented adequately, such as the precautionary principle or the polluter pays principle.