#1

COMPLETE

Collector: Web Link 1 (Web Link)
Started: Wednesday, March 30, 2016 1:16:17 PM
Last Modified: Wednesday, May 25, 2016 9:35:02 AM
Time Spent: Over a month
IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address	
Contact name	Jurgen van Belle
Organisation/company	Ministry of Health, Welfare and Sport
Country	The 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.	*Respondent skipped this question*
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.	My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q5: Please indicate whether you are replying to this questionnaire as:	A government or public authority
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	4
Protecting the environment	3
Ensuring a well-functioning internal market	4
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 the environment	The legislation is not adapted to the issues at stake
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	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	Classification, labelling and packaging (Regulation No (EC) 1272/2008) , Plant protection products (Regulation (EC) No

familiar with.

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),

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),

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

Marine Strategy Framework (Directive 2008/56/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)

,

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

,

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

,

Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)

,

Residues of pesticides (Regulation (EC) No 396/2005)

,

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

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

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

Detergents (Regulation (EC) No 648/2004),

Drinking Water (Directive 98/83/EC),

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

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

,

Aerosol dispensers (Directive 75/324/EEC),

Explosives (Directive 93/15/EEC),

Pressure equipment (Directive 2014/68/EU),

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:	c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)
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. It depends on the specific directive or regulation, but in some legislation the attention for specific vulnerable groups is lacking. To refer to question 14, this gives some difficult situations since some compounds are restricted in one regulation because it leads to effects on young children, while there is no restriction in the other piece of legislation, although the exposure route and the exposed group is more or less the same. In general, the coherence between different parts of the chemical legislation is lacking, for example in the approval of plant protection products no consideration is given to the priority list in the water framework directive. Also missing is information on the effect of combination of chemicals. As already identified in Commission Communication COM/2012/0252, the current EU legislation lacks an integrated approach to address cumulative effect of different chemicals that also takes into account the different exposure routes. As a consequence, the cumulative risk might exceed the assessed safe level, both for health and for the environment. Therefore, appropriate regulatory approaches to address combination effects of chemicals need to be developed. Another relevant consideration is the technical and economical feasibility of proposed measures. The legislation with very low concentration limits for chemicals (e.g. POP's) result in situations where at least half of the EU member states are not compliant with such regulations for at least the next decades. The consequences of proposed measures should be scrutinized in an impact assessment.

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	1
Time to allow duty holders to adapt	5
Predictability of the outcomes	3
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	1
Consistent implementation and enforcement across Member States	1
Public awareness and outreach	3
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.	The framework seems solid but implementation is rather slow. The procedures are more or less transparent. There is an overlap and/or ambiguity between the several legislations. Postponing decisions is delaying clarity which regulation is applicable and who is in charge. The outcome of negotiations is often difficult to predict. Sometimes political involvement in decision making interferes with the scientific/legal approach of those preparing decisions. This may lead to decisions which are legally correct but difficult to explain. Implementation and enforcement across member states needs a more streamlined approach.

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	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	4
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.	Communication to consumers and workers turns out to be rather difficult. It is doubtful whether this can be solved by legislation. More and better information on exposure is necessary to assess risks. Legislation tends to be slow to adapt to technology (e.g. nanomaterials) or scientific advancement (e.g. endocrine disruptors). This can lead to underestimation of hazards and risks. Risk management measures are not obliged in all parts of the legislation (like (veterinary)medicines). The risk assessment methodology in transport is implicit and not very transparent.

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
Reliability and reproducibility does not depend on GLP-testing. This is a common misunderstanding. Reliability should be assessed case by case, for GLP-studies as well for studies from public literature. Also data from public literature can be reliable and very relevant to use for risk assessment and should not be disregarded.

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. , Stimulating competition and trade within the EU single market , Stimulating international trade between the EU and other countries
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
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 , Risk management measures under the different legislation , Understanding and keeping up-to-date with changes in legal 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. Understanding and keeping up to date with changes in legal requirements, preparation of national dossiers on chemicals (if needed to initiate EU-wide action).

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	4

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
Please comment	Emerging areas are always sensitive for discussion about the framework that is most appropriate for coping with new risks. For instance, Member States stated that they were in favor of stand-alone legislation for tattoos. Before a start could be made the process in the EU took several years to decide how to deal with this emerging area. Also, a comprehensive approach to nanomaterials turned out to be difficult with lengthy discussions on a definition in several legal frameworks.

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	Mixture toxicity en cumulative effects of chemicals are not sufficiently taken into account between the different legislative frameworks. The relation between sectoral and horizontal legislation should be strengthened. E.g. substances that are banned in new products can still be placed on the market in recycled material.
Overlaps	For instance the line between biocidal products and cosmetics is thin and often there is overlap leading to difficulties. Products have to fit in both frameworks at the same time.
Inconsistencies	The above described overlap might lead to inconsistencies. A possible problem is the ban on animal testing for cosmetics while the biocide regulation specifically asks for animal testing. Other examples are the PBT assessment which is not consistent within different parts of the legislation and the difference in classification of substances between transport and supply and use.

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.

27. The Construction Product Regulation should be added to the list, as well as legislation on (veterinary) medicines and pharmaceuticals (especially assessment on environmental effects).

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?	3

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	For hazard class on PBT substances is not covered this would be very helpful and was intended by the introduction of CLP (art. 53.2) Endocrine disruption is not a hazard class in CLP. This might be a gap.

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	5
Industry association guidance and materials	5
Other (training, conferences, etc.)	3
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	3
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	5
Involvement of stakeholders	5
Quality of scientific data and related information	3
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.	*Respondent skipped this question*