**#253**

**COMPLETE**

**Collector:** Web Link 1 (Web Link)
**Started:** Friday, May 27, 2016 10:23:41 PM
**Last Modified:** Friday, May 27, 2016 10:57:08 PM
**Time Spent:** 00:33:27
**IP Address:**

**PAGE 2: Part I – General Information about Respondents**

| | |
|---|---|
| **Q1: Address** | |
| Contact name | Ian Dewhurst |
| Organisation/company | HSE Chemicals Regulation Directorate |
| 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.** | *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:** | EU |

**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** | 5 |
| Stimulating competitiveness and innovation | 3 |

**Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.**

| | |
|---|---|
| Protecting human health | 5 |
| Protecting the environment | I don't know |
| Ensuring a well-functioning internal market | I don't know |
| 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:**

| | |
|---|---|
| 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 | 3 |

**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)
,

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

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

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

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

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)
,

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
This varies with the specific legislation. For pesticides and biocides specific risk assessments are available but these can be overridden by hazard based exclusion criteria. The hazard criteria take no account of the dose that triggers the hazard e.g. 5 mg/kg bw/day or 500 mg/kg bw/day and the estimated human exposure e.g. 0.5ug or 50ug.

| | |
|---|---|
| **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.** | I don't know,<br><br>If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.<br>My expertise is in human health risk assessments, I cannot comment on environmental or socio-economic aspects. On the human health side I believe relevant considerations are taken into account. |

**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 | 2 |
| Speed with which identified risks are addressed | 4 |
| Time to allow duty holders to adapt | I don't know |
| Predictability of the outcomes | 2 |
| Stability of the legal framework | 4 |
| Clarity of the legal texts | 2 |
| Guidance documents and implementation support | 2 |
| Effective implementation and enforcement across Member States | I don't know |
| Consistent implementation and enforcement across Member States | 3 |
| Public awareness and outreach | I don't know |
| International collaboration and harmonisation | I don't know |
| Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it. | The responses are an overall score for the legislation with which I am familiar. The answers vary within and across the different schemes and relate primarily to aspects related to human health hazard and risk assessments. In terms of legislation clarity, one of the problems is that different sections of legislation are contradictory or inconsistent. For example in 1107/2009 several paragraphs relate to human data but are worded differently and can be interpreted in markedly different ways. The quality and relevance of guidance documents varies, as does the time taken to produce them. |

**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.) | 2 |
| 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 | 2 |
| Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment) | 4 |
| 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. | For consumers, I believe most do not have the background to discriminate effectively between different categories of warning. For risk management measures banning or restricting chemicals, there is inconistency between different legislation. For example for plant protection products and biocides the legislation places restrictions on availability to the general public of products classified as skin sensitizing. Similarly classified products can be purchased as general 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
I did not find the question to have an easy answer as a 'yes' / 'no' option. GLP in association with agreed test guidelines gives confidence in the reported results of a specific study report. They do not guarantee good science, which can be important for more complex investigative studies. In addition, for a number of aspects of EU chemicals legislation reliance is placed on reports in the published literature - these do not normally comply with GLP.

## 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.

| | |
|---|---|
| **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)** | I don't know |
| **Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?** | I don't know |
| **Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?** | I don't know |

**PAGE 7: Relevance**

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

| | |
|---|---|
| Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives | 3 |

**Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)**

| | |
|---|---|
| Novel areas of concern sufficiently addressed by framework | 2 |
| Please comment | Q23 is too complex for a single answer. The framework has contributed to a number of chemicals being removed from the market for a variety of reasons. The alternatives might offer a reduced risk in certain areas related to human exposures, but an increased risk (but still acceptable) in environmental areas; and vice versa. Q24. The legislation I am familiar with is generally slow to respond to emerging concerns and scientific developments. It can take several years to modify data requirements or agree revised guidance documents. Not all developments are a concern, for example the incorporation of new tests that minimise animal usage into data requirements is slow and in the interim can lead to variable acceptance across member states. |

**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 | Disagree |
| 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.**

| | |
|---|---|
| Overlaps | The same chemical can be covered by CLP, biocides and plant protection products legislationand on occasions different outcomes are reached even with the same dataset. |
| Inconsistencies | controls on biocides and plant protection products are more restrictive than on general chemoicals due to classification based exclusion criteria. |

| | |
|---|---|
| **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? | 2 |

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

| | |
|---|---|
| Environmental | I don't know |
| Physical | I don't know |
| 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 | No experience |
| Helpdesks | No experience |
| Industry association guidance and materials | No experience |
| Other (training, conferences, etc.) | No experience |

| | |
|---|---|
| **Q31: To what extent is CLP enforced in a harmonised manner across Member States?** | I don't know,<br><br>Please add further details as necessary<br>I cannot comment on enforcement specifically, but have experience of differences in implementation in terms of requirements for (self classification) prior to formal implementation dates. |

**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 | I don't know |
| Appropriateness of classification criteria and methods for substances | 3 |
| Appropriateness of classification criteria and methods for mixtures | 3 |
| International harmonisation through the Globally Harmonised System (GHS) | 4 |
| If you answered 1, 2 or 3 and would like to provide further information, please explain your answer | Some elements of the classification scheme appear to have little grounding in the real world. Substances and mixtures of low volatility and with no uses that can generate fine particles can still be classified for acute inhalation toxicity based on the results of an atmosphere of artificially generated fine particles. The EU does not implement some of the lower categories of hazard in the GHS system. Although this can create some difficulties I believe the EU approach is more suited to a hazard based warning scheme. Some of the EU specific phrases can cause difficulties for companies based outside the EU. However, I believe a number of the EU phrases (e.g. EUH208) are soundly based. |

| | |
|---|---|
| **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,<br><br>Please elaborate if you answered that the transition period is too short or too long.<br>As a regulator dealing mainly with pesticides and biocides, I believe the CLP implementation periods are a reasonable match for timescales in the related legislation. |

| 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 | I don't know |
| Quality of scientific data and related information | 4 |
| Speed of the procedure | 4 |

**PAGE 10: Part V: Additional comments**

| | |
|---|---|
| Q35: **In case you have any additional comments with relevance for this public consultation, please insert them here.** | My comments relate primarily to human health assessments, not environmental assessments. |