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Collector: Web Link 1 (Web Link)

Started: Friday, May 27, 2016 1:56:54 PM

Last Modified: Friday, May 27, 2016 2:29:24 PM

Time Spent: 00:32:30

IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address

| | |
|----------------------|------------------|
| Contact name | Leah Charpentier |
| Organisation/company | Albemarle |
| 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.

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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 business

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 other chemical products (C20.5)

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

Large company (250 employees or more)

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 | 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 | 4 |
| Ensuring a well-functioning internal market | 2 |
| Stimulating competitiveness and innovation | 1 |

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 adapted to the issues at stake |
| Stimulating competitiveness and innovation | The legislation is unclear, 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

Consultation on the regulatory fitness of chemicals legislation (excluding REACH)

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)
,
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),
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)
,

EU Ecolabel (Regulation (EC) 66/2010),
Safety of toys (Directive 2009/48/EC),
Drinking Water (Directive 98/83/EC),
Pressure equipment (Directive 2014/68/EU),
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)
,
Other (please specify) the ATEX Directive

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 has been successfully applied to chemicals with widely differing toxicity profiles and human exposures over the last 30 years. Unfortunately, many EU policies are driven by hazard rather than risk, and this even when risk assessments are carried out. Examples include: the Water Framework Directive, PBT assessments, BPR, PPPR, the nanomaterials debate, and the work done by the POPs 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.

Yes,

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.
Economic impact and technical feasibility are in some cases barely taken into in the processes which set risk management measures for some of the laws in scope of this consultation. We would like to see these taken into account more thoroughly going forward. The fact that the impact assessment on the endocrine disrupter criteria, which sought to assess this economic impact, was cut short for political reasons is indicative of how little focus is given to these considerations in current EU chemicals legislation.

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 | 2 |
| Speed with which hazards/risks are identified | 3 |
| Speed with which identified risks are addressed | 3 |
| Time to allow duty holders to adapt | 2 |
| Predictability of the outcomes | 1 |
| Stability of the legal framework | 2 |
| Clarity of the legal texts | 3 |
| Guidance documents and implementation support | 3 |
| Effective implementation and enforcement across Member States | 2 |
| Consistent implementation and enforcement across Member States | 1 |
| Public awareness and outreach | 3 |
| International collaboration and harmonisation | 2 |

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.

Chemicals legislation is complex, any simplification efforts are always welcome. Such simplification/ streamlining efforts are especially valid for EU chemicals legislation which has not been transposed in a uniform manner across member states. The greatest shortcoming of this body of legislation is the inability to predict what substance will be addressed by which legislative tool. This is especially confusing in cases when the same substance is being targeted by multiple laws. Albemarle also believes there is room for improvement on international collaboration. Common principles for information sharing, prioritising chemicals for review and evaluation and increasing the coherence in hazard and risk assessment, would dramatically improve the international regulatory environment on chemical policy.

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 | 2 |
| Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.) | 4 |
| 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.

Hazard identification criteria are clear but often subject to overly precautionous interpretations by authorities. Risk characterization is based on standard worst case assumptions, this can be very removed from realities on the ground, and difficult to understand for practitioners. At the moment, we see many substances being targeted for bans multiple times via different EU legislation: REACH and ROHS, REACH and OSH, REACH and POPs...We hope that as the Risk Management Option Analysis process, as it gains maturity, will prevent such developments in the future, as they send mixed messages to the market, and create a climate of uncertainty which is not conducive to attracting investment in Europe.

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

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 ecosystems 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

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)

• Supply chain management communications & IT costs • Data Sharing and SIEF management costs • Costs of external consultants • Additional data generation

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?

I don't know

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 3

Please comment

New and emerging scientific issues present the EU with opportunities to align regulations with other major international partners and prevent divergence prior to their enactment. Albemarle favours extensive international alignment to ensure that new science is taken into account in as consistent a manner as possible. We also believe these 'emerging areas of concern' should not be regulated in an overly precautionary fashion, as this would impact innovation and technological progress.

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 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

Please refer to previous answers.

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.

REACH/RoHS: ensuring coherence

If analysis shows that key environmental and health concerns are related to the use of the substance in EEE, RoHS should be considered as a possible appropriate regulatory tool to address these concerns, as it addresses both environmental and health while considering industry specific needs for the continued use of a substance. This is particularly important for EEE, where new technologies and applications are constantly developed.

Clearly defined scopes are also critical to a coherent system. For instance, when substances are being assessed under REACH but have already been addressed under RoHS, the scope of uses/applications under REACH should clearly exclude EEE products already regulated by RoHS. This is aligned with the common understanding paper.

In cases where the review of a substance has already taken place under REACH or RoHS, it is critical to use the knowledge already generated and draw the conclusions from the regulatory decisions made. For example, information generated under REACH on substances, their classification, uses, exposure and best risk management options, should be fully taken into consideration in the context of RoHS. To maximise the necessary synergies with REACH, we recommend that all relevant opinions from the Risk Analysis Committee (RAC) and Socio-Economic Analysis Committee (SEAC), as well as the regulatory decision of the European Commission, are taken into account. At the same time, RoHS should be recognised as a possible legal basis for exemption from REACH authorisation obligations.

REACH/ OSH: avoid overlap and select the best risk management measure

While REACH is rightly established as the regulatory pillar of EU chemicals management and has contributed to unrivalled data collection about the use and effects of substances, our organisations believe that REACH Candidate Listing and Authorisation should not be considered as the preferred option when potential risks from a substance have found to be limited to the workplace and can be more effectively addressed by workplace-specific legislation. Referring to the Commission's Roadmap on Substances of Very High Concern (SVHC Roadmap), we would like to stress that Risk Management Option Assessments (RMOAs) are rightly aimed at identifying the best regulatory option to manage the risk 'either in REACH [...] or outside of REACH'.

REACH/Water framework directive: potential overlap and inconsistencies

Substances proposed for inclusion as priority substances, or priority hazardous substances, under the Environmental Quality Standard (EQS) Directive have already been subject to other pieces of EU legislation that introduced specific risk management measures. For example, substances that have been included in REACH Authorisation Annex XIV cannot be produced, imported or used by companies unless a 'use specific' authorisation is granted. Prioritising one of these substances as priority hazardous substance (PHS) under the EQS Directive can therefore be perceived as incoherent with the REACH Authorisation process. Indeed the PHS status under EQS Directive means that the substance needs to be eliminated from surface waters, while REACH Authorisation allows companies to continue using the substance.

Nanomaterials in cosmetics/ REACH/medical devices/novel foods

There are different definitions of nanomaterials in specific/sectoral pieces of legislation.

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 | 3 |
| Industry association guidance and materials | 3 |
| Other (training, conferences, etc.) | 3 |
| Please add further details as necessary | The CLP helpdesk should be able to provide more information than it currently does when industry encounters a classification problem. |

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 |
| If you answered 1, 2 or 3 and would like to provide further information, please explain your answer | <p>CLP is a complex legislation (as data is to be interpreted by experts) and regular changes with different ATPs are difficult to cope with for some formulators. Classification in annex VI can also lead to confusion as not all endpoints are concerned and therefore not all require self-classification. It would be easier to understand if the relevant endpoints were listed.</p> <p>International harmonization / GHS is not easy to implement: different cut-offs values, different lists (eg CLP annex VI, Japan 'recommended' substance list (NITE), IARC classifications..)</p> <p>Greater coordination at Global level would be welcome.</p> |

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.
This depends. The transition period may be sufficient in the case of some substances, but it is often too short in the case of mixtures. Additional time may also be needed because of the specificity of certain supply chains.

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 | 3 |
| Speed of the procedure | 2 |

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

There is uncertainty about when classifications may be reviewed by member states. This is un-transparent. The fact that RAC members are hard to approach, is also an obstacle to the transparency of the process. Concretely, we also believe that if discussions on a specific substance conclude that no classification is needed, it should be made public. At the moment that information is not easily available. We believe that such substances should also be visible on Annex VI to help all actors within the supply chain.

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.

1. Even though REACH is excluded from the scope of this consultation, we believe it is an integral part of the 'gaps and overlaps' discussion which is necessary to assessing the effectiveness of the rest of the body of EU chemicals policy. 2. Regarding the repeated questions on whether EU chemicals policy has helped innovation, we believe it is important to stress that EU regulation, like all regulations, are necessary and a license to operate. They may impact business decisions, but they are not a driver of R&D or innovation in the chemicals industry. Substitution is not in itself innovation. 3. Each decision to substitute is dependent on a specific context. Regulatory developments are one of many factors (including performance, availability of substitutes, health and environmental impact, customer demand and expectations...) that weigh in the decision to phase out a substance. 4. EU chemicals regulation is not happening in a vacuum, greater coordination with global initiatives is to be welcomed, especially as it comes to new and emerging issues where there is the possibility to proceed in a concerted fashion. 5. Finally on EU chemicals policy being a driver for the single market, we believe this is true in theory, but that unfortunately, there are still too many national initiatives targeting specific substances at the moment to say that there is a truly a single market for chemicals in Europe today. This situation is made worse by the fact that many of the laws assessed in this consultation are not enforced by member states in practice, or if so, enforced inconsistently.
