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IP Address:

PAGE 2: Part I – General Information about Respondents

Q1: Address

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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:

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),
Other (please specify)
Manufacture of chemical substances and mixtures. This does not always include the end product.

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	5
Protecting the environment	5
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	5
Ensuring a well-functioning internal market	3
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 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	5
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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),
Pregnant workers (Directive 1992/85/EEC),

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

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)

,

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

,

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

,

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

,

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

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

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

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)

,

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)

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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

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, as well as the conditions for use (e.g. amount, containment, personal protection measures, packaging, and awareness of user). Therefore a specific risk assessment is in general more appropriate to define the most effective risk management measure whilst preserving societal benefits. 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. Also, assessment processes under BPR focus on worst case scenarios and conservative assumptions that do not reflect reality. Moreover, it is not uncommon that 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. Areas where decisions are in practice more driven by hazard than risk, even when risk assessments are carried out include: the selection of priority substances under the Water Framework Directive and setting Environmental Quality Standards; the evaluations by the POP Review Committee; and the consideration of environmental properties under the Seveso III Directive. Risk assessments should be based on the weight of all available evidence and consider the specific characteristics of each individual substances. There are situations such as for PBT/vPvB substances where default criteria do not adequately predict the behavior of a substance and consideration should be given to the full range of scientific studies, including environmental measurement.

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.

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. Societal benefits of products are insufficiently considered under the Biocidal Product Regulation. The Regulation has introduced an outright ban on the use of biocidal products by the general public when meeting certain hazard criteria. Thus, the legislation does not allow potential benefits for society to be considered for these products (e.g. need to control a serious danger), let alone any type of economic or social impact (e.g. lost business; movement of business outside of the EU or reduced innovation capacity). More generally speaking, detailed cost-benefit analyses are not conducted during the approval process of active substances. This prevents societal benefits of substances to be considered and may lead to unintended effects for society (e.g. lack of appropriate and effective pest control and antimicrobial solutions, increased potential for resistance to biocides due to restricted number of chemistries and modes of action). Finally, 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 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	5
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

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

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 the EU 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. 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 and the outcomes of the scientific evaluations linked to the data submitted are not easy to predict. Application dossiers for active substance approval submitted more than 10 years ago are still under evaluation, within a legal framework that has changed extensively. The same applies for the Harmonized Classification and Labelling (CLH) processes under the CLP Regulation. Implementation support: in the space of the notifications to the C&L Inventory, solutions supporting bulk notifications are not very efficient. This leads to significant burden in complying with the C&L Inventory notification obligations. In addition there is no possibility for obsoleting notifications and no clarity on the obligations related to substances no longer present in a company's portfolio. Guidance documents: guidance should be provided on a more scientifically robust weight-of-evidence approach, including an objective scoring methodology that allows selecting the most reliable, relevant and highest quality data at different levels including environmental measurements. At present there is a divergence between the commitment to weight-of-evidence consideration and how substances are being identified in practice. Existing guidance explicitly refers to the need to “use all available data for assessing bio-accumulation” but it unfortunately is always followed by “the weight-of-evidence and all the available data need to be compared back to the criteria defined in the legal text” which for bio-accumulation is only Bioconcentration Factor. Consistent implementation & enforcement: implementation and enforcement across Member States varies across many chemicals and chemical-related legislation, particularly under environmental protection legislation and, biocides and food contact materials legislation. Under the BPR, there is a requirement linked to all suppliers of active substances in Europe to

be part of the review programme and the Article 95 list. Products containing actives from suppliers not on the Article 95 list should have been removed from the market as of 1st September 2015. It has to be understood that this requirement is also a way to manage the risk of active substances supplied by a non-compliant source, where the risks associated with them cannot be assessed. To this date, only a few Member States have taken specific and concrete measures for the enforcement of this requirement. In general, the lack of enforcement in biocides (in the Biocidal Products Regulation and its predecessor, the Biocidal Product Directive) is unsatisfactory. Strikingly, the level of enforcement on non-compliant actors is disproportionate to the level of scrutiny on and regulatory burden for compliant companies. This may lead to uncontrolled risks and market distortion situations. International harmonisation: the regional differences in GHS implementation add complexity to supply chain communication. In this context what is often mentioned is lack of harmonization in the applied hazard classes and categories. It cannot be however forgotten that some of the major differences in C&L under various GHS implementations stem from the differences in the implemented generic concentration limits.

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.

-In the case of PBTs, there is language in REACH guidance documents indicating that other evidence cannot be used to override a valid Bioconcentration Factor (BCF). However, by using the BCF only, a highly lipophilic substance could be deemed bioaccumulative even if it is broken down and never increases in concentration in the food chain. Hazard identification criteria must consider as well the use of a weight-of-evidence approach (including various lines of evidence) and professional judgment prior to concluding on B/vB or not B/vB status. Lines of evidence include but are not restricted to: in silico and/or in vitro biotransformation rate data, read-across from existing toxicity (ADME/TK) testing, field data, etc. -Hazard identification and methodologies for risk assessments should be aligned as much as possible across different legislations, taking into account the specificities and objectives of each piece of legislation. -Cooperation between regulatory bodies responsible for risk assessments under several pieces of legislation should be improved to maximize the effectiveness of different risk assessments - Risk Management: when general bans for certain hazard classes and categories are foreseen in the legislative framework, without allowing for further consideration of other factors to select the most appropriate risk management option, there is a risk that political considerations interfere with the scientific analysis underpinning the hazard identification.

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. But GLP is not always sufficient to decide on the most relevant study/safety data (data-rich substances): relevance, robustness are criteria that should be equally considered. GLP only ensures reproducibility of the study. Scientific validity including the relevance and applicability of the methods for the chemistry set need to be considered.

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.

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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

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. For the EU biocides legislation, due to the over-burdensome BPR requirements and the in-depth evaluation of dossiers, Member States need significant resources and expertise - although this is often lacking. Since the legislation foresees a system of mutual recognition between Member States, a better use of resources could be ensured if Competent Authorities would not re-evaluate the first evaluation performed by the lead Member State, which is often happening in practice. Costs incurred by authorities 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 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 4

Please comment

The current EU legislative framework is appropriate 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 Agree

The EU chemicals legislation framework has overlaps Neutral

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

-Biocides: additional steps in the risk management of active substances are needed allowing for a cost-benefit analysis to be carried out. -Seveso: With the inclusion of tighter hazard categories in 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. Automatic legal consequences in downstream legislation without risk assessment should be avoided. - Food contact: full harmonization of the legislation on food contact materials is needed, as mutual recognition is not working effectively in practice. -Labelling requirements under the different pieces of legislation (cf. F-gas Regulation, REACH Annex XVII, BPR, PPPR), could be better integrated to facilitate compliance.

Inconsistencies

-Labelling requirements under BPR and CLP are sometimes contradictory (cf. treated articles). -At present there is a divergence between the commitment to weight-of-evidence considerations and how substances are being identified as PBTs/vPvBs.

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

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 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	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	4
Please add further details as necessary	However, we are observing cases where the guidance documents are not consistently implemented by authorities. For example, the revised interpretation form ECHA guidance on the application of classification as H318 for substances classified as H314 has not been reflected in the ATPs to the CLP for a prolonged period of time – creating uncertainty for operators.

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

Enforcement is not harmonised across most Member States

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Please add further details as necessary
Not uncommon are cases where the same chemical is requested to have different sets of C&L information between different Member States. This is particularly the case for plant protection products and biocidal products. Active substances for use in biocidal products are subject to harmonised classification and labelling under CLP. Hazard classification involves the assignment of a standardised description of the substance's hazards in accordance with CLP classification criteria. For biocidal products however, the CLP legislation is quite complicated and requires 'experts' in classification. The process also requires up to date information on all co-formulants. Moreover, the biocidal product's classification is determined by the evaluating Competent Authority which in certain cases leads to non- harmonised classification for the same product.

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) 3

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

The fact that various non-EU countries selected to implement different building blocks of GHS is not sufficiently addressed in the legislation and in practice, in particular in the labelling space. The related consequences for communication in the supply chain lead to significant costs.

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,

Please elaborate if you answered that the transition period is too short or too long.
For editorial changes to the text of H and P statements stemming from revisions of the UN GHS Model Regulation longer transitional periods would be beneficial for the industry.

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 3

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

There are some inefficiencies in the CLH process with respect the changes that affect the existing elements of harmonized C&L from Annex VI. Such changes can be brought by industry only to the attention of a Member State Competent Authority but not directly to ECHA. Unlike for the CLH Intentions that are submitted to ECHA for these intentions there is no publicly available registry of intentions. This means that if a given intention for a change of an existing Annex VI element for a substance was reviewed by a MSCA and was not found justified (thus it is not in the ECHA registry of intentions) this decision/conclusion cannot be readily accessed by e.g. downstream users. Also, for the « older » Annex VI entries there are sometimes difficulties in identifying the data which were the basis of the original classification decisions leading to the current harmonized classification in Annex VI. If it would be possible to make these historical records available this would be of great assistance for companies when determining their classification globally but also when identifying if they hold actual new data that challenges existing Annex VI elements. Finally, problems of coordination have been experienced between CLP classification procedures and the procedures for adjustment of the Ecolabel criteria, requiring sometimes fast-track derogations for which no established process is currently in place.

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

Respondent skipped this question