

# Consultation on the regulatory fitness of chemicals legislation (excl. REACH)

## Part I – General Information about Respondents

### 1. Address

Contact name: Oliver Loebel  
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### 2. If you have a Transparency Register ID number, please provide it below.

27993486325-38

### 3. 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.

- My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication.

### 4. We might need to contact you to clarify some of your answers. Please state your preference below:

- I am available to be contacted.

### 5. Please indicate whether you are replying to this questionnaire as:

- An industry association

### 6. 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 rubber and plastic products (C22)

### 7. For businesses, please indicate the size of your business:

Not relevant.

### 8. Please indicate the level at which your organisation is active:

- EU

## Part II – General Questions

**9. 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)**

	1	2	3	4	5	I don't know
Protecting human health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Protecting the environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ensuring a well-functioning internal market**	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Stimulating competitiveness and innovation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**\*10. Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective).**

	1	2	3	4	5	I don't know
Protecting human health	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Protecting the environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ensuring a well-functioning internal market	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stimulating competitiveness and innovation	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**\*11. 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:**

	The legislation is unclear	The legislation is not adapted to the issues at stake	The legislation is not effectively implemented	No opinion or not applicable
Protecting human health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Protecting the environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ensuring a well-functioning internal market	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Stimulating competitiveness and innovation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**\*12. 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)**

	1	2	3	4	5	I don't know
EU-level legislation adds value to national level action	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Part III - Specific Questions

**13. Please select the legislation that regulates or otherwise affects your sector's or your company's activities.**

- Classification, labelling and packaging (Regulation No (EC) 1272/2008)
- Inland transport of dangerous goods (Directive 2008/68/EC)
- Chemical Agents (Directive 98/24/EC)
- 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)
- Packaging and Packaging Waste (Directive 94/62/EC)
- Export and import of hazardous chemicals (Regulation No 649/2012)
- 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)

Other (please specify)

X Regulation 517/2014 on fluorinated greenhouse gases

## Effectiveness

**14. In the EU legislative framework, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations, 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. 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)
- b. Be more oriented towards generic risk considerations (i.e. take more cautious approaches, despite the possibility that certain uses of a chemical that are in the interest of society might be restricted )
- 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)
- d. I don't know

If you answered a or b, please explain

The risk associated with a chemical substance largely depends on its specific use conditions and the related exposure / release to the environment.  
For example, an eco-toxic substance might be used in an application without any risk of release to waste water. Alternatively, it might be used in a way that involves risks of release to the environment, e.g. in the case of washing agents. The first use is safe, while the second is not.  
Hence a specific risk assessment is in general more appropriate to assess impacts and define the most effective risk mitigation measures.

**15. 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  
 No  
 I don't know

If you answered no, please explain which considerations are not (sufficiently) taken into account and, if relevant, explain which legislation you are referring to.

The "impacts on jobs / competitiveness of EU industry" are not fully taken into account.

Example: European implementation of the Rotterdam Convention/PIC

The EU legislation covers more substances than global PIC. Hence, if chemical manufacturers want to export products containing these substances outside EU, additional administrative efforts and costs occur which chemical manufacturers in other countries (e.g. China, USA) do not have to sustain. The most recent amendment of this directive covers organotin compounds. If the costs for "EU organotin" increase due to this legislation, customers in non-EU countries might switch to organotin compounds that are manufactured under less safe conditions than in the EU.

**16. 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)**

	1	2	3	4	5	I don't know
Transparency of procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speed with which hazards/risks are identified	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speed with which identified risks are addressed	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Time to allow duty holders to adapt	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Predictability of the outcomes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Stability of the legal framework	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clarity of the legal texts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Guidance documents and implementation support	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Effective implementation and enforcement across Member States	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consistent implementation and enforcement across Member States	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Public awareness and outreach	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
International collaboration and harmonisation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

In the case of environmental protection, national levels of enforcement vary significantly between Member States.

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

	1	2	3	4	5	I don't know
Hazard identification criteria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Risk assessment and characterisation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Risk management measures restricting or banning the use of chemicals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**18. 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  
 No  
 I don't know

## Efficiency

**19. What are the most significant benefits generated for EU society by the EU chemical and chemical related legislation?**

- Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.  
 Reducing the exposure of workers to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc.  
 Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc.  
 Encouraging research and innovation, generating new jobs, and improving the competitiveness of the EU chemicals industry by encouraging/supporting a shift towards green, sustainable chemistry and a circular economy  
 Stimulating competition and trade within the EU single market  
 Stimulating international trade between the EU and other countries

**20. What are the most significant costs incurred by EU society due to EU chemical and chemical related legislation?**

- Costs for authorities at EU level  
 Costs for authorities at national level

- Costs for small and medium sized enterprises
- Costs for large enterprises
- Costs for consumers
- Costs for society in general

**21. 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
- We do not view the business costs of meeting EU chemicals legislation to be significant

**22. Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?**

- Yes
- No

## Relevance

**23. 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)**

	1	2	3	4	5	I don't know
Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

**24. 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= they are not sufficiently addressed, 5 = they are sufficiently addressed)**

	1	2	3	4	5	I don't know
Novel areas of concern sufficiently addressed by framework	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please comment

Generally, the current EU legislative framework includes the tools to address emerging areas of concern.

## Coherence

**25. Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall**

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
The EU chemicals legislation framework contains gaps and missing links	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
The EU chemicals legislation framework has overlaps	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The EU chemicals legislation framework is internally inconsistent	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

**26. 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.**

### Gaps or missing links

There is sometimes a poor integration of labelling requirements under the different pieces of legislation (cf. F-gas Regulation, REACH Annex XVII, CPR).

### Inconsistencies

It happens that classification and labelling differs between ADR and CLP. For example, one additive is classified toxic (class 6) for ADR and warning (SGH 07) for CLP.

**27. 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.**

Certain overlapping requirements exist in REACH and the occupational health legislation.

## Part IV: Specific questions on the CLP Regulation

**28. 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)**

	1	2	3	4	5	I don't know
To what extent are CLP labels effective in communicating hazards to workers?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
To what extent are CLP labels effective in communicating hazards to consumers?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

**29. Do the hazard classes in the CLP Regulation cover all relevant hazards?**

	Yes	No	I don't know
Environmental	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Physical	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Human health	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

	1	2	3	4	5	No experience
Guidance documents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Helpdesks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Industry association guidance and materials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (training, conferences, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please add further details as necessary

UIC Guidelines (French chemical industries) are generally very good.

**31. To what extent is CLP enforced in a harmonised manner across Member States?**

- Enforcement is harmonised across all Member States
- Enforcement is harmonised across most Member States
- Enforcement is not harmonised across most Member States
- I don't know

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

	1	2	3	4	5	I don't know
Ease of implementation for duty holders	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Appropriateness of classification criteria and methods for substances	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Appropriateness of classification criteria and methods for mixtures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
International harmonisation through the Globally Harmonised System (GHS)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**33. CLP is revised regularly through adaptations to technical progress. Do transitional periods allow sufficient time to implement new / revised classification criteria?**

- Transition period is sufficient
- Transition period is too short
- Transition period is too long
- I don't know or have no opinion

**34. To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)**

	1	2	3	4	5	I don't know
Transparency of the procedures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Involvement of stakeholders	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quality of scientific data and related information	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Speed of the procedure	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>