Open Public Consultation on the Targeted Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP)

Fields marked with * are mandatory.

Introduction

The Regulation on the classification, labelling and packaging of substances and mixtures (in short the CLP Regulation) covers almost all chemicals and products containing them, from industrial chemicals to house-hold ones, from fuels to pens, from solvents to detergents. For the purpose of this questionnaire, substances and mixtures are referred to as chemicals. The CLP Regulation aims to identify **hazards of chemicals**, such as causing cancer, disrupting aquatic life or causing allergy. Hazard identification relies on **scientific facts**. When hazards are identified for a chemical, products containing this chemical should be **labelled and/or packaged** before they are placed on the market. In addition to the hazard, labels also provide **advice on how to avoid and/or reduce exposure** to the hazardous chemical and how to deal with accidental exposure. Finally, the CLP regulation requires that **poison centres** receive information on the composition and hazards of chemicals to give the appropriate advice in case of poisoning accidents.

In other words, the first aim of the CLP Regulation is to **protect citizens and workers and the environment from dangerous substances and mixtures**. The second aim is to facilitate the **intra-EU exchange of chemicals** which can circulate freely within the European Internal Market when properly labelled and packaged according to the CLP criteria. This public consultation will feed into the work of the European Commission in updating and improving the CLP Regulation, as pledged by the Commission in its <u>'Chemicals Strategy for</u> <u>Sustainability'</u>.

This questionnaire consists of **two sections**. This first section contains **general questions** to which all respondents are kindly invited to provide feedback. The second section focuses on **m ore technical points** of the CLP Regulation that requires prior knowledge and expertise.

About you

*Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish
- * I am giving my contribution as
 - Academic/research institution
 - Business association
 - Company/business organisation
 - Consumer organisation
 - EU citizen
 - Environmental organisation
 - Non-EU citizen
 - Non-governmental organisation (NGO)
 - Public authority

Trade union

Other

* First name

Marko

*Surname

Leist

* Email (this won't be published)

leist@vci.de

*Organisation name

255 character(s) maximum

Verband der Chemischen Industrie e.V. (German Chemical Industry Association)

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the <u>transparency register</u>. It's a voluntary database for organisations seeking to influence EU decision-making.

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* Country of origin

Please add your country of origin, or that of your organisation.

Libya Afghanistan Djibouti Saint Martin Åland Islands Liechtenstein Dominica Saint Pierre and Miquelon ۲ Saint Vincent Albania Dominican Lithuania Republic and the Grenadines

		– .				0
Algeria	0	Ecuador		Luxembourg		Samoa
American Samoa		Egypt	0	Macau	0	San Marino
Andorra	0	El Salvador	0	Madagascar	0	São Tomé and Príncipe
Angola	0	Equatorial Guinea	a	Malawi	\bigcirc	Saudi Arabia
Anguilla	0	Eritrea	0	Malaysia	0	Senegal
Antarctica	0	Estonia	۲	Maldives	۲	Serbia
Antigua and	\bigcirc	Eswatini	\bigcirc	Mali	\bigcirc	Seychelles
Barbuda						
Argentina	\bigcirc	Ethiopia	\bigcirc	Malta	\bigcirc	Sierra Leone
Armenia	0	Falkland Islands	\bigcirc	Marshall Islands	\bigcirc	Singapore
Aruba	\bigcirc	Faroe Islands	\bigcirc	Martinique	\bigcirc	Sint Maarten
Australia	\bigcirc	Fiji	\bigcirc	Mauritania	\bigcirc	Slovakia
Austria	\bigcirc	Finland	\bigcirc	Mauritius	\bigcirc	Slovenia
Azerbaijan	۲	France	\bigcirc	Mayotte	\bigcirc	Solomon Islands
Bahamas	۲	French Guiana	\bigcirc	Mexico	\bigcirc	Somalia
Bahrain	\bigcirc	French Polynesia	\bigcirc	Micronesia	\bigcirc	South Africa
Bangladesh	\bigcirc	French Southern	\bigcirc	Moldova	\bigcirc	South Georgia
		and Antarctic				and the South
		Lands				Sandwich
						Islands
Barbados	0	Gabon	0	Monaco	0	South Korea
Belarus	0	Georgia	\bigcirc	Mongolia	\bigcirc	South Sudan
Belgium	۲	Germany	\bigcirc	Montenegro	\bigcirc	Spain
Belize	0	Ghana	0	Montserrat	0	Sri Lanka
Benin	0	Gibraltar	۲	Morocco	۲	Sudan
Bermuda	0	Greece	۲	Mozambique	۲	Suriname
Bhutan	\bigcirc	Greenland	\bigcirc	Myanmar/Burma	\bigcirc	Svalbard and
						Jan Mayen
Bolivia	0	Grenada	۲	Namibia	۲	Sweden
Bonaire Saint	0	Guadeloupe	0	Nauru	0	Switzerland
Eustatius and						
Saba						
Bosnia and	0	Guam	0	Nepal	0	Syria
Herzegovina						

Botswana	Guatemala	Netherlands	Taiwan
Bouvet Island	Guernsey	New Caledonia	Tajikistan
Brazil	Guinea	New Zealand	Tanzania
British Indian	Guinea-Bissau	Nicaragua	Thailand
Ocean Territory			
British Virgin	Guyana	Niger	The Gambia
Islands			
Brunei	Haiti	Nigeria	Timor-Leste
Bulgaria	Heard Island and	d [©] Niue	Togo
	McDonald Island	ls	
Burkina Faso	Honduras	Norfolk Island	Tokelau
Burundi	Hong Kong	Northern	Tonga
		Mariana Islands	5
Cambodia	Hungary	North Korea	Trinidad and
			Tobago
Cameroon	Iceland	North Macedon	ia [©] Tunisia
Canada	India	Norway	Turkey
Cape Verde	Indonesia	Oman	Turkmenistan
Cayman Islands	Iran	Pakistan	Turks and
·			Caicos Islands
Central African	Iraq	Palau	Tuvalu
Republic			
Chad	Ireland	Palestine	Uganda
Chile	Isle of Man	Panama	Ukraine
China	Israel	Papua New	United Arab
		Guinea	Emirates
Christmas Island	Italy	Paraguay	United Kingdom
Clipperton	Jamaica	Peru	United States
Cocos (Keeling)	Japan	Philippines	United States
Islands			Minor Outlying
			Islands
Colombia	Jersey	Pitcairn Islands	Uruguay
Comoros	Jordan	Poland	US Virgin Islands
Congo	Kazakhstan	Portugal	Uzbekistan
Cook Islands	Kenya	Puerto Rico	Vanuatu
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 Costa Rica Côte d'Ivoire Croatia 	 Kiribati Kosovo Kuwait 	 Qatar Réunion Romania 	 Vatican City Venezuela Vietnam
Cuba	Kyrgyzstan	Russia	Wallis and Futuna
Curaçao	Laos	Rwanda	Western Sahara
Cyprus	Latvia	Saint Barthélemy	y [©] Yemen
Czechia	Lebanon	Saint Helena Ascension and Tristan da Cunha	Zambia
Democratic Republic of the Congo	Lesotho	Saint Kitts and Nevis	Zimbabwe
Denmark	Liberia	Saint Lucia	

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. Fo r the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published. Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

Anonymous

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

Part I (general questions)

Question 0 - What is your level of knowledge of the following?

	Excellent knowledge	Good knowledge	Some knowledge	None
* The CLP regulation (legal text) and/or its implementation	۲	0	0	۲
* Chemical hazards	۲	0	0	۲

Section 1 - New Hazard Classes

Following **new scientific evidence**, the Commission is considering introducing **new hazard classes** not currently covered by the CLP Regulation. This is expected to enhance the protection of human health and environment.

The European Commission has pledged to introduce an obligation for chemical producers and retailers to identify and explicitly label the following chemicals:

- **Endocrine disruptors**. Endocrine disruptors are chemicals that cause illness by interfering with the hormonal system of human beings or of wildlife (e.g. obesity of children, infertility, etc.);
- Persistent, bio-accumulative and toxic chemicals. These chemicals are not easily degraded in the environment, accumulate in wild plants and animals and are toxic to humans or plants or animals;
- **Persistent, mobile and toxic chemicals**. These chemicals are not easily degraded in the environment, pass from soil into water bodies and contaminate natural resources used to produce drinking water. They are also toxic to humans or plants or animals.

Those new obligations will complement existing requirements to identify hazards in chemicals.

Question 1 - Please indicate how important it is for you to know a chemical is ...?

(One single answer per row)

	Very important	Important	Not important	No opinion
 An endocrine disruptor with adverse effects on human health 	0	۲	0	0
 An endocrine disruptor with adverse effects on the environment (e.g. wild life) 	0	۲	0	0
* Persistent, bio-accumulative and toxic	0	۲	0	0
* Persistent, mobile and toxic	0	۲	O	0

Question 2 - Imagine you want to buy or use a product which bears a label with one of the following hazards. Would you be ready to pay more for alternative products that have the same performance, but which do not have that hazard?

(One single answer per row)

	Yes	Probably	No	No opinion
* Endocrine disruptors (human health)	0	0	0	۲
* Endocrine disruptors (wild life)	0	0	۲	۲
* Substances that are persistent, bio-accumulative and toxic	0	0	۲	۲
* Substances that are persistent, mobile and toxic	0	0	0	۲

Section 2 - Testing chemicals on animals

The foreseen introduction of new classes of hazards in CLP (such as endocrine disruptors) is likely to **incre ase testing, including on animals**, to assess if a chemical is safe or not for human health or the environment. Despite efforts made, there are **not yet full alternatives to animal testing of chemicals** for certain hazard classes.

This means that to know if a chemical is harmful, and hence to be able to take the appropriate protective measures, **tests will have to be done on some species of animals** (mainly rats, mice, fishes and invertebrates).

Question 3 - In order to balance the increased protection of human health and of the environment with animal welfare, do you think?

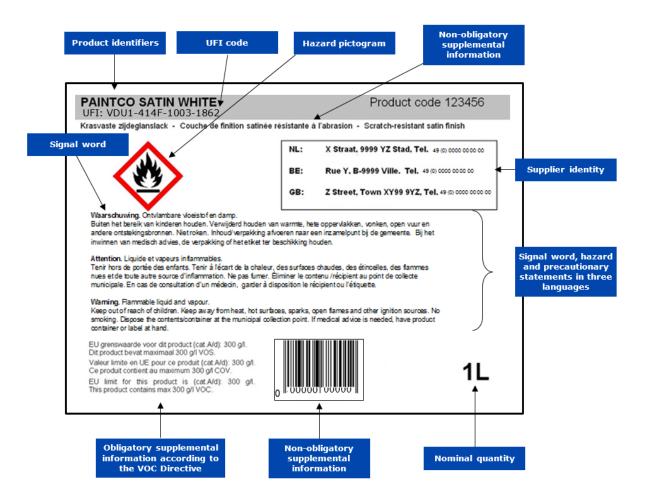
(One single answer)

- Animal testing is unacceptable for chemicals safety purposes and should stop now
- Animal testing should be the last resort and used only when alternative tests are not available

No opinion

Section 3 - Labelling

Chemicals labels are often full of information. See the example below.



Question 4 - In your view, how clear and easy to understand are labels of chemicals in general (think for instance of products you often use, such as detergents, glues, paints, etc.)

(Only one answer possible)

- Very clear and easy to understand
- Clear/ understandable
- Unclear and hard to understand
- Unclear and very hard to understand
- No opinion

Question 5 - Considering the example above, if you would like to improve this label, what would you prefer?

(Only one answer possible)

- Less information but clearer information on the label
- As much information as possible. This may make reading the label more difficult in some cases.

Question 5a - Considering the example above, which pieces of the label would you like to keep?

(Select as many options as needed)

- Pictogram showing the risk (e.g., flame symbol for flammable chemical)
- Hazard statement and signal word (e.g., Danger It can cause cancer)
- Instructions of use
- Precautionary statements on how to store, dispose, prevent accidents etc.
- The name of the chemicals causing the hazard
- Additional specific labelling information (e.g. in case of chemicals containing lead, 'Warning! contains lead')
- Identification code for poison centres (so called UFI code and allows poison centres to know the composition of a chemical)
- Other piece(s) of the label
- None of the provided options

Question 6 - Would you like to be able to consult labels of chemicals digitally in the future (e.g. on your computer or smartphone?)?

It might be a digital consultation of the whole label or just part of it.

(Only one answer possible)

- Useful
- Not very useful
- Useless
- No opinion

Question 7 - Imagine you buy a detergent in bulk in a grocery. You have brought your own bottle which does not bear a label for this detergent. What would be the best option to inform you on the hazards and safety instructions?

(Only one answer possible)

- You do not need any information
- Information is displayed at the point of sale only
- Information is provided in the form of a document provided by the seller (leaflet or on the counter ticket)
- You can access the information digitally (scanning of a QR code for example)
- Other option(s)
- No opinion

Question 7a - Please detail your additional option(s)

Products must be labelled with safety-relevant information. The label must be permanently attached to the packaging. Substances and mixtures classified as dangerous must not be filled or stored in typical food-containers (like bottles for beverages or food storage jars)

Question 8 - Individual pens are very small items, with little room for a label and information about hazards. What would be the best option for you to inform on the hazardous substances they may contain and the safety instructions?

- You don't need any information
- Information displayed in the shop
- Information in the form of a document provided by the seller (leaflet or on the receipt)
- Information on the outer packaging, overwrapping a set of 10 pens
- Access the information digitally (scanning of a QR code for example)
- Other option(s)
- No opinion

Question 8a - Please detail your additional option(s)

- Information on the outer packaging must be in accordance with the GHS system

- Determination of container size, if necessary also for individual products

Section 4 - Online sales

Question 9 - Online shopping of chemicals is becoming more and more common. Do you think it is important to receive the same safety information when you buy chemicals in a shop or online?

- Yes
- No
- No opinion

Question 9a - When should you receive such information on hazards?

- Before ordering the chemical online
- When the chemical is delivered to you
- In both cases
- No opinion

Question 9a.i - Which information would you like to receive before ordering?

- Most important information (type of hazards, presence of hazardous components)
- All pieces of information which are on the label
- No opinion

Section 5 - Scope of the CLP regulation

Currently the product categories listed below are exempted from the CLP Regulation on classification and labelling.

- Medicines
- Veterinary medicines
- Cosmetics
- Medical devices (e.g. lens cleaning solutions)
- Food such as food additives, flavouring foodstuffs, or feed such as animal nutrition complement.

This is because hazards to human health are generally identified and dealt with by specific pieces of legislation. However, information on environmental hazards (such as "substance toxic to aquatic life") are not identified and information is not provided to the users of the above products.

Question 10 - When buying or using the product categories listed below, you might not be informed that they could be hazardous to the environment. What is your opinion?

	An issue which should be immediately solved	An issue where future improvement would be welcomed	Not an issue	No opinion
Medicines	0	0	۲	0
Veterinary medicines	0	0	۲	0
Medical devices (e.g. lens cleaning solutions)	0	0	۲	۲
Cosmetics	0	0	۲	0
Food or feed, such as additives	0	0	۲	۲

Question 11 - in case you you would like to share anything else in addition to the previous questions and in the view of the targeted revision of the CLP regulation (optional):

The choice of answers to some questions suggests that the authors want a particular answer. A truly objective survey would have been desirable. Regardless of this, we would like to emphasise here that the introduction of new hazard classes, which are not foreseen in the GHS, is contrary to the objectives of the GHS to which the CLP Regulation is committed. Furthermore, some of the questions require further comment, such as question 10:

Medicines

An environmental risk assessment for medicines is mandatory for many years and must be submitted with the application for authorisation. If necessary, a specific disposal notice is added into the package leaflet; this makes it possible to inform patients without confusing them with a label according to the CLP Regulation on the medicinal product package.

Veterinary Medicines

The statement that information on environmental hazards is not identified in specific regulation is not correct for veterinary medicinal products (VMPs). Within the framework of the authorisation of veterinary medicinal products an environmental risk assessment is mandatory for many years. In case potentially harmful effects are identified risk management measures are defined to reduce those risks. These are also addressed in the package leaflet as well as instructions for disposal. If the risks for the environment are considered unacceptable and outweigh the therapeutic benefit the veterinary medicinal product cannot be authorised.

Cosmetics:

To guide use/disposal, information on products must be meaningful and understandable for consumers. Indicating the damage that a mixture could cause under unrealistic conditions (i.e. hazard) should be reserved to situations where the real life use/disposal cannot be foreseen by the manufacturer. When use /disposal are strictly pre-determined, then targeted information and warnings are more easily understood by consumers. This principle has been successfully implemented for many years in the Cosmetics Product Regulation (CPR) for human safety. The upcoming revision of the CPR and the Sustainable Products initiative provide an opportunity to introduce relevant information on the environmental impact of cosmetic products, going beyond hazard information. Simple extension of CLP labelling to cosmetics would not add any useful consumer information and would often contradict the intended use/disposal.

Medical Devices

As there is already adequate legislative control in place, we do not see a reason why the current exemption from the hazard communication requirements under CLP for such products might be adapted/revoked. If these exemptions were nonetheless withdrawn, sufficiently long transitional periods would be required, as any change of labelling of medicines and medical devices is strictly regulated by the MDR and requires significant efforts, time and approval. For more details see VCI document.

Food additives

Food additives are foodstuffs. In our view, hazard labelling of foods, e.g. food additives, which are supplied to end consumers is unsuitable and does not lead to the desired results. On the contrary, an additional labelling of food or food additives with GHS pictograms would mislead the consumer. In our view, this would lead to a deterioration of hazard communication and consumer information, as well as to considerable consumer uncertainty without any benefit in terms of protecting human health and the environment. This is because food additives are safe substances and foods within their approved conditions of use.

Feed additives

There is also an environmental risk assessment in place in the authorisation process for feed additives. Feed additives (unless those that are on the market as finished products for the end user) do fall under CLP legislation and are therefore labelled according to CLP. Feed additives that are used in compound feed as well as feed and compound feed in general have also detailed labelling rules laid down in regulation 1831 /2003 and 767/2009. This does cover all necessary information for users and consumers to ensure a high level of safety.

Question 12 - in case you would like to share a document in the view of the targeted revision of the CLP regulation, please upload it below (optional):

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Part II - Questions for experts

This section should be answered by people having an excellent or good understanding of the CLP, from a legal or implementation perspective, or of chemical hazards.

Section 1 - New hazard classes

Endocrine disruptors

The World Health Organisation (WHO) has defined <u>criteria</u> for endocrine disruptors which are the basis for the existing criteria for endocrine disruptors in plant protection and biocide products.

Question 13 - For known endocrine disruptors, do you think ...?

- The WHO's definition and criteria should be taken over, word for word, in the foreseen EU CLP criteria.
- The foreseen CLP criteria should be the criteria in place for <u>plant protection</u> <u>products</u> or for <u>biocide products</u>, which are based on the WHO definition and criteria.
- It is necessary to further refine WHO's definition and criteria and/or existing criteria for plant protection and biocide products to develop the foreseen CLP criteria.

Question 14 - Are you in favour of a sub-categorisation for chemicals with a high level of certainty on their endocrine disrupting properties, as for mutagenic chemicals (e.g. Categories 1A and 1B)?

- Yes
- No
- No opinion

Question 15 - What would you suggest as criteria for a second category for chemicals with a lower level of certainty on their endocrine disrupting properties (human health and environment), as for mutagenic chemicals?

- Endocrine disruption is not a separate toxicologically defined endpoint. For this reason, a separate hazard class is not justified and does not serve the purpose. Furthermore, adverse effects triggered by endocrine disruptors, such as carcinogenic or reproductive toxic effects are already covered by existing CLP hazard classes.

- In case new hazard classes are introduced in CLP, the evidence of an adverse effect must be a prerequisite for the classification of substances for endocrine disrupting properties for human health or the environment.

- For classification in Category 2 for Endocrine disrupting properties at least some evidence of an adverse effect, which is a consequence of the endocrine activity, is needed.

- The introduction of a category of "Suspected Endocrine Disruptors" based solely on in vitro data is not scientifically justified.

Question 16 - According to you, what would be the best statement on a label for chemicals identified as toxic to reproduction and as an ED according to the foreseen ED criteria?

- May cause infertility or damage to the unborn child
- May cause infertility or damage to the unborn child via an endocrine mode of action
- May cause infertility or damage to the unborn child
 - May cause endocrine-related adverse effects on human health
- Other option(s)
- No opinion

(Very) persistent, (very) bio-accumulative and toxic substances

The introduction of criteria for persistent, bio-accumulative and toxic (PBT) or very persistent and very bi-accumulative (vPvB) substance in the CLP Regulation is expected, based on the criteria laid down in Annex XIII of <u>the REACH regulation</u>. **Question 17 - Do such criteria as provided in Annex XIII of REACH need to be**

updated before their foreseen introduction into the CLP Regulation?

- Yes
- No
- No opinion

Question 18 - Do you think a category for suspected PBT (and one for suspected vPvB) would be needed?

- Yes
- No
- No opinion

Question 19 - According to you, what is the best statement on a label for chemicals on the foreseen PBT, vPvB hazard classes?

If a chemical is identified as PBT and carcinogen category 1, its label should display:

(Only one answer possible)

- May cause cancer
 - Persistent, bio-accumulative and toxic (PBT)
- May cause cancer
 - Persistent (P)
 - Bio-accumulative (B)
- Other option(s)
- No opinion

Question 19a - Please provide alternative labelling options

Symbol/pictogram	None, alternatively GHS07
Signal word	None, alternatively 'warning'
Hazard Statement	EUHxxx
Precautionary Statements	P203, P273, P391, P501

(Very) persistent, (very) mobile and toxic substances

The foreseen introduction of criteria for **persistent**, **mobile and toxic (PMT) or very persistent and very mobile (vPvM) substances** aims at improving protection, from chemical contamination, of water bodies when **used for drinking water purposes** (to protect human health).

Question 20 - Do you think environmental toxicity should be part of the toxicity criterion?

Yes

No

No opinion

Question 21 - do you think a category for suspected PMT (and one for vPvM) would be needed?

Yes

No

No opinion

Question 21a - Please provide suggestions for criteria for category 2 for PMT and vPvM

Question 22 - According to you, what is the best statement on a label for chemicals on the foreseen PMT, vPvM hazard classes?

If a chemical is identified as PMT and carcinogen category 1, its label should display:

(Only one answer possible)

• May cause cancer

- Persistent, mobile and toxic (PMT)
- May cause cancer
 - Persistent (P)
 - Mobile (M)
- Other option(s)

No opinion

Question 22a - Please provide alternative labelling options

Symbol/pictogramNone, alternatively GHS07Signal wordNone, alternatively 'warning'Hazard StatementEUHxxx:Precautionary StatementsP203, P273, P391, P501

Question 23 - In the environmental classification of chemicals, do you consider it relevant to use toxicity data obtained on terrestrial organisms to complement the information on toxicity for aquatic organisms?

(Please rate from 0 - not relevant to 10 - very relevant)



Question 24 - Immunotoxicity effects are currently covered under the hazard classes 'Specific target organ toxicity' and 'Reproductive toxicity' (in case of developmental immunotoxicity). Do you consider relevant to develop a separate specific hazard class/criteria for Immunotoxicity?

(Please rate from 0 - not relevant to 10 - very relevant)

0

Question 25 - Neurotoxicity effects are currently covered under the hazard classes 'Specific target organ toxicity' and 'Reproductive toxicity' (in case of developmental neurotoxicity). Do you consider relevant to develop a separate specific hazard class/criteria for neurotoxicity ?

(Please rate from 0 - not relevant to 10 - very relevant)

0

Possible impacts of the new hazard classes

Question 26 - The CLP regulation requires to use all available data to identify hazards in chemicals. Data may come from REACH registration(s) or public scientific litterature. To what extent do you think that the data currently available on chemicals are sufficient to perform an assessment for the foreseen hazard classes mentioned above?

	Totally sufficient (with specific data on all substances)	Sufficient (incl. read- across and bridging)	Only partially sufficient covered (incl. read-across and bridging)	Not sufficient at all	No opinion/Not relevant to me or my organisation
Endocrine disruptors (human heatlh)	©	۲	\odot	0	0
Endocrine disruptors (environment)	0	0	۲	0	0
PBT/vPvB	0	۲	0	0	0
PMT/vPvM	0	0	۲	0	0

Question 27 - Considering the suggested new criteria for additional hazard classes, do you foresee a need to invest significant resources to get the expertise to assess the hazards of chemicals?

	Need to invest in significant additional resources	Need to invest in some additional resources	Need to invest in little additional resources	No investment needed at all	No opinion or not relevant to me or my organisation
Endocrine disruptors (human heatlh)		۲	0	0	0
Endocrine disruptors (environment)	0	۲	۲	0	0
PBT/vPvB	0	۲	0	0	0
PMT/vPvM	۲	0	0	0	0

Question 28 - Do you or your organisation/company already have an estimate of the number of impacted chemicals due to the potential new hazard classes?

- Yes (it will unfold a series of more detailed questions)
- No information or no opinion

Section 2 - Classification

Question 29 - In order to increase the number of substances with harmonised classification, to what extent do you agree to the following statements?

The European Commission should also have the right to initiate European classification for some substances

-3

The European Commission should help Member States to submit more dossiers.

0

Question 30 - Setting toxicological/ecotoxicological values such as DNEL /DMEL, PNEC is part of the hazard assessment. These values are currently

derived in accordance with REACH or specific sectorial regulations (e.g. food contact materials, cosmetics, biocidal products, workers protection). As part of the 'One substance, one assessment' concept, the Commission intends to include a procedure to harmonise values for some toxicological /ecotoxicological parameters in CLP. Such harmonised values could be then used for risk assessment in the different EU chemicals legislations. How important would you rate the harmonisation of toxicological /ecotoxicological values?

	Important	Neutral	Not important	No opinion
Harmonising DNELs (Derived No-Effect Limits) in CLP	0	0	۲	۲
Harmonising DMELs (Derived Minimum-Effect Limits) in CLP	0	O	۲	٥
Harmonising PNECs (Predicted No-Effect Concentrations) in CLP	0	0	۲	O

Question 31 - How would you assess the possible impact of the harmonisation of toxicological/ecotoxicological parameters (e.g. DNELs or PNECs)?

	Important	Neutral	Not important	No opinion
Increase the level of protection of human health and the environment	O	O	۲	0
Ensure level playing field across sectors	0	0	۲	0
Increase workload of the Risk Assessment Committee	۲	0	0	0
Increase of burden and regulatory requirements	۲	O	O	۲

Question 32 - Currently CLH dossiers can be submitted by national competent authorities and in some cases by companies. Once received, the dossiers are checked for accordance.

What is your opinion about the three following statements?

The system should allow prioritisation of substances for which serious concerns are raised (e.g. priority given to substances highly suspected of being an endocrine disruptor, once the criteria are adopted)

-5

The system should allow low prioritisation of substances of lower concerns.

-5

No need to modify the current approach as the system already contained a prioritisation mechanism (National Authorities' priorities, ECHA screening)

5

Question 33 - Currently economic operators (manufacturers, importers, downstream users, distributors) are not allowed to submit a proposal to ECHA to revise an existing harmonised classification for an Annex VI entry. Only Member states can submit such a proposal.

Please select the preferred option amongst the following ones:

- The system should not change to avoid a proliferation of CLH revision requests by stakeholders
- The CLH revision request by a stakeholder should be addressed first at the EU Commission for decision on the need of an action at Community level. If accepted by Commission, the request will be provided to ECHA against the payment of a fee covering all expected costs.
- The revision request by a stakeholder should be allowed and be provided to ECHA against the payment of a fee covering all expected costs.

Question 34 - To derive the correct classification of certain chemicals, the use of animal testing is still necessary.

Would you be confident to classify (your) products on the basis of alternative methods only?

- In the case the result of a test performed with an alternative method is <u>positive</u>, to classify (your) chemicals accordingly:
 - Yes
 - No
- In the case the result of a test performed with an alternative method is <u>negativ</u> <u>e</u>, not to classify (your) chemicals for that hazard class:
- Yes
- No

Question 35 - Currently, where the notification to the classification and labelling inventory (C&L inventory) results in different entries for the same substance, manufacturers and importers shall make every effort to come to an agreed entry in the inventory. Despite this obligation, different entries for the same substances are very frequent and significantly reduce the usefulness of the inventory.

Please provide your views on the potential following options below.

	Agree	Disagree	No opinion
The system should not change.	۲	0	0
The obligation to come to an agreed entry should be strengthened.	0	۲	0
ECHA should be able to remove/refuse notifications that seem incorrect after having informed the notifier.	۲	0	0

Section 3 - Labelling

Question 36 - Did you experience issues with double or contradicting labelling obligations (CLP v. other legislation)?

- Yes
- No

Question 36a - Please describe the situations of double or contradicting labelling obligations.

The main aim of the simplification of labels should be removal of duplicate information from the label originating from different regulations. In this way, the relevant information will be easier to find by the user and will also result in the reduction of administrative cost and regulatory burden for companies and facilitate the competitiveness for EU chemicals industry.

Question 37 - How do you rate the economic impact (cost savings) of the following five policy options?

	Significant savings	No significant savings	No opinion
Exempt small products (pens, lighters) from certain labelling requirements	۲	0	O
Exempt bulk chemicals (fuels) from certain labelling requirements	0	0	۲
Allow a wide use of multilanguage labels / fold-out labels	۲	0	0

Provide certain obligatory labelling information digitally instead of on the label	۲	0	0	
Provide additional information digitally	0	۲	0	

Question 38 - How do you rate the health, safety and environmental impacts of the following policy options? Please justify your choice in box below

	Significant positive impacts	No significant impacts (neutral)	Significant negative impacts	No opinion
Exempt small products (pens, lighters) from certain labelling requirements	O	۲	0	0
Exempt bulk chemicals (fuels) from certain labelling requirements	0	0	0	۲
Allow a wide use of multilanguage labels / fold-out labels	0	۲	0	0
Provide certain obligatory labelling information digitally instead of on the label	O	۲	O	O
Provide additional information digitally	0	۲	0	0

Section 4 - Online sales

Question 39 - Some chemicals purchased online from non-EU countries often do not comply with EU law (e.g. are not providing obligatory safety information). In those cases, it is very difficult to identify the responsible company and take corrective measures.

In such a case, do you think the online service providers, platforms should be considered responsible?

- Yes
- No
- No opinion

Question 40 - How would you rate the need to apply the same CLP obligations (e.g. labelling, classification and notifications to poison centres) also to hazardous chemicals purchased online (compared to traditional purchase)?

5

Question 41 - How would you rate the need to have a responsible actor for compliance with CLP located in the EU also for chemicals purchased online?

5

Question 42 - What in your view are the major problems with online sales to ensure a level-playing field between companies?

(Please select as many answers as needed)

- Wrong or incomplete advertising
- Wrong or incomplete information on the webpage where the order is placed
- Wrong or incomplete labelling/packaging of chemicals
- Other problems than listed above
- No problem
- No opinion

Question 42a - Please add any additional issue related to on-line sales of chemicals

Safety data sheets: Non-compliance REACH restriction: Non-compliance

Question 43 - What in your view are the major problems with online sales to ensure the same level of health, safety and environmental protection?

(Please select as many answers as needed)

- Wrong or incomplete advertising
- Wrong or incomplete information on the webpage where the order can be placed
- Wrong or incomplete labelling/packaging of products
- No poison centre notifications
- None of the options above

Question 44 - Do you think that the CLP regulation should address problematic issues arising from on-line sales of hazardous substances and mixtures?

- Yes
- No
- No opinion

Question 45 - Do you consider that there are gaps or overlaps between Article 1(5) of the CLP regulation and provisions in other legislations or that the wording is unclear?

	Overlaps	Gaps	Lack of clarity	Everything is clear	No opinion
Medicines as defined in Directive 2001/83/EC				V	
Veterinary medicines as defined in <u>Directive</u> 2001/82/EC					
Medical devices as defined in <u>Regulation (EU)</u> 2017/745 and Directive <u>98/79/EC</u>					
Cosmetics as defined in <u>Regulation (EC) No</u> <u>1223/2009</u>					
Food and feeding stuffs as defined in <u>Regulation (EC) No 178/2002,</u> including flavouring of foodstuffs, animal nutrition and feed additives					

Question 46 - Currently neither the CLP nor the specific ('sectorial') legislation applying to the products listed in the table below require that information on classification and labelling of environmental hazards is provided to the users.

In your view, what would be the best option to make users aware of these environmental hazards?

	Add an obligation to classify and label according to CLP for environmental hazards.	Add an obligation to assess and label according to sectorial legislation	Promote voluntary use of CLP classification and labelling for environmental hazards	No opinion
Medicines	0	0	0	0
Veterinary medicines	0	0	0	0
Medical devices	0	0	0	0
Cosmetics	0	0	0	0
Food and feeding stuffs, including				

flavouring of	\odot	\odot	\odot	0
foodstuffs, animal nutrition and feed additives				

Section 6 - Notifications to poison centres

Question 47 - CLP states that mixtures classified on the basis of their health and physical effects shall be submitted to appointed bodies (poison centres) in the Member States to provide emergency health response. CLP also provides that hazardous substances shall be notified to ECHA's classification and labelling inventory (C&L inventory) which is publicly accessible.

For poison centre purposes, is it useful to submit information also on substances?

- Yes
- No
- No opinion

Question 48 - What are in your view the most suitable transitional periods until the new rules become applicable for the different aspects amended under CLP?

	As soon as possible	18 months	24 months	36 months	48 months	No opinion
Introduction of new hazard classes	0	0	0	0	۲	0
Harmonised DNEL, PNEL, PNEC	0	0	0	0	۲	0
Improvements to CLH process (prioritisation mechanism, ECHA dossier submitter)	0	0	0	0	0	۲
Improve self-classifications	0	0	0	0	0	۲
Remove certain exemptions from CLP (medical devices, medicines, cosmetics etc.)	0	0	0	O	۲	O
Simplify labelling	0	0	0	0	۲	0
Tackle online sales lack of compliance	۲	0	0	0	0	۲
Improve notification to poison centres	0	0	0	0	0	۲

Question 48a - Please provide the reasons for the above proposed timelines for the applicability period.

Introduction of new hazard classes

No guidance available, studies need to be performed and in the end, the new hazard classes are not needed.

Harmonised DNEL, PNEL, PNEC

Harmonised limit values will be available via time consuming processes only. The scope of these values is defined in the REACH Regulation. An extension of the scope to the CLP Regulation is not supported.

Improvements to CLH process (prioritisation mechanism, ECHA dossier submitter) not important for companies

Improve self-classifications

If this aspect targets the C&L inventory, the C&L inventory has no value for anyone (regradless if the C&L information would be improved or not). Just take the C&L of the lead dossier.

Remove certain exemptions from CLP (medical devices, medicines, cosmetics, etc.)

VCI does not see any need to amend Article 1 paragraph 5 which includes exemptions from labelling requirements for certain products which are regulated by specific sectoral legislation. A detailed explanation can be found in the VCI document under question 46. If these exemptions would nonetheless be withdrawn, long transitional periods would be required because any change of labelling of medicinal products, veterinary medicinal products, cosmetic products, and medical devices is strictly regulated by sectoral legislation and requires significant efforts and time.

Simplfy labelling Might be of benefit for the actors in the supply chain

Tackle online sales lack of compliance Level playing field

Improve notification to poison centres not relevant

Section 7 - final (additional) feedback

Question 49 - in case you you would like to share anything else in addition to the previous questions to experts and in the view of the targeted revision of the CLP regulation (optional):

We would like to point out at this point that a number of the questions require detailed commentary. They can be found in the attached PDF document.

Question 50 - in case you would like to share a document in the view of the targeted revision of the CLP regulation, please upload it below (optional):

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Contact

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