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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 'Chemicals Strategy for Sustainability'.
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.

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- ( ) Trade union
- ( ) Other

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* Surname

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CHEM Trust

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- Bosnia and Herzegovina
- Ecuador
- Egypt
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- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
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- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Luxembourg
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- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria

- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
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- New Zealand
- Nicaragua
- Niger
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- Papua New Guinea
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- Tonga
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- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu

- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
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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	○	◉	○	○
* Chemical hazards	○	◉	○	○

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	◉	○	○	○
* An endocrine disruptor with adverse effects on the environment (e.g. wild life)	◉	○	○	○
* Persistent, bio-accumulative and toxic	◉	○	○	○
* Persistent, mobile and toxic	◉	○	○	○

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)	○	○	○	◉
* Endocrine disruptors (wild life)	○	○	○	◉
* Substances that are persistent, bio-accumulative and toxic	○	○	○	◉
* Substances that are persistent, mobile and toxic	○	○	○	◉

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).

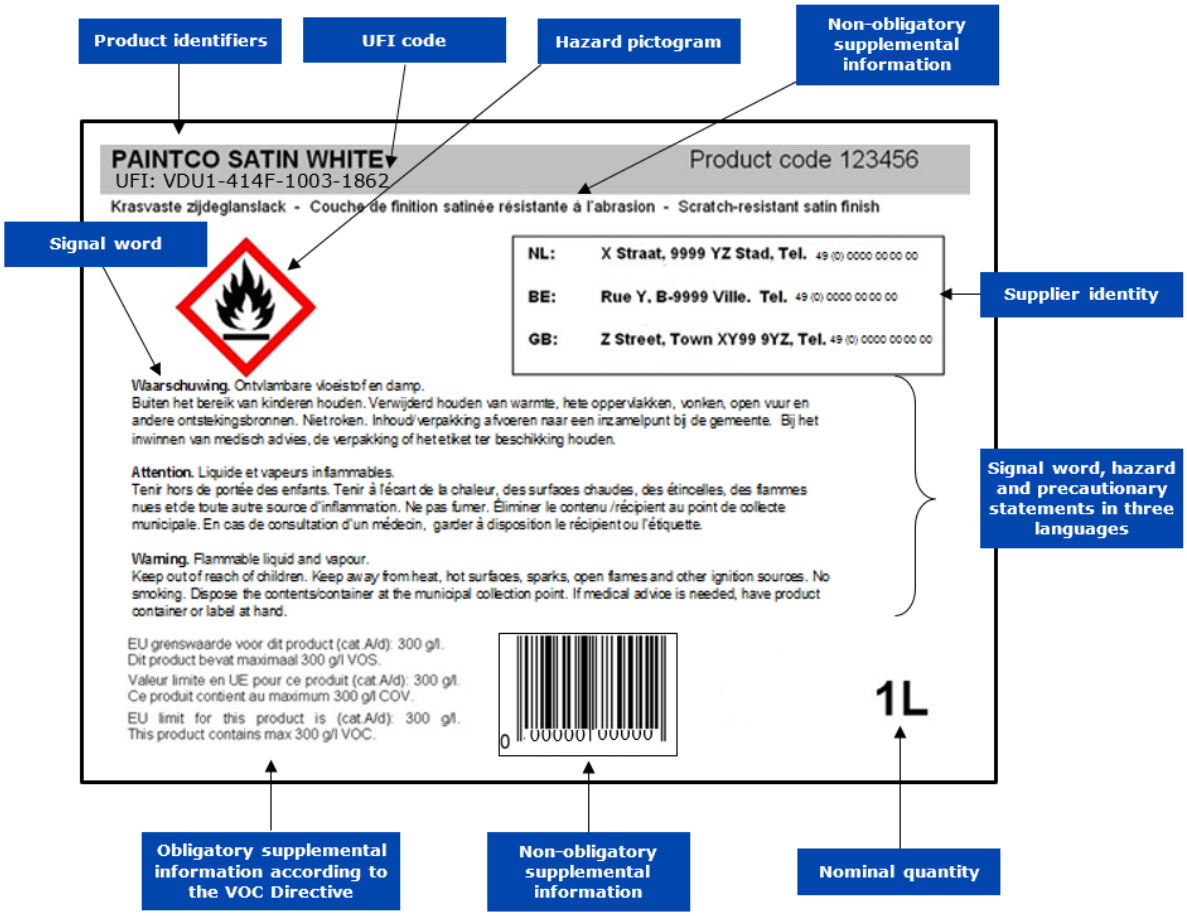
Question 3 - In order to balance the increased protection of human health and of the environment with animal welfare, do you think?

(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)

- [x] Pictogram showing the risk (e.g., flame symbol for flammable chemical)
- [x] Hazard statement and signal word (e.g., Danger It can cause cancer)
- [x] Instructions of use
- [x] Precautionary statements on how to store, dispose, prevent accidents etc.
- [x] The name of the chemicals causing the hazard
- [x] Additional specific labelling information (e.g. in case of chemicals containing lead, 'Warning! contains lead')
- [x] 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 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

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	◉	○	○	○
Veterinary medicines	◉	○	○	○
Medical devices (e.g. lens cleaning solutions)	◉	○	○	○
Cosmetics	◉	○	○	○
Food or feed, such as additives	◉	○	○	○

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):

In CHEM Trust`s view it is very important to provide clear and detailed information on the chemicals used in consumer products and other items to the public. This information should be easily accessible. In question 5 we would therefore have preferred to answer: ´More information but clearer presentation on the label´ and regret that this option was not available.
Regarding Question 6 on digital labels: In CHEM Trust`s view digital information could be made available in addition, but not instead of the information on the label. We also refer to the arguments presented in the

position paper by the EU consumer voice BEUC:
https://www.beuc.eu/publications/beuc-x-2021-016_why_moving_essential_product_information_online_is_a_no-go.pdf

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 criteria 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 plant protection products or for biocide products, 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 13a - Please describe how the existing criteria at EU and international level should be further refined. Please indicate whether there should be differences between human health and the environment.

The WHO`s established definition for EDs is the basis for the criteria for endocrine disrupting properties adopted under the EU Biocides & Pesticides regulations. At the time of the adoption of these criteria in 2017, several Member States, environmental and health NGOs, the scientific community, the European Parliament and the wider public expressed strong concerns about the high burden of proof needed for the identification of ED properties.

CHEM Trust has since then actively contributed to the discussions about establishing horizontal ED criteria under the CLP as part of the CASG ED group (see links below).

In general, we recommend

- to establish horizontal ED criteria in line with the approach for the CMR criteria under CLP.
- To sufficiently take into account the specific characteristics of endocrine disruption when establishing horizontal ED criteria under CLP.
- to build on the text from the WHO-definition/existing ED criteria under BPR/PPPR, clarifying that the link between adverse effects and the endocrine activity should be biologically plausible in line with the ECHA /EFSA Guidance Document, to avoid an unrealistic high burden of proof for ED properties.
- to supplement the WHO-definition/existing criteria with additional text defining the level of evidence required for legally binding identification as ED, to clearly state what is needed to identify a substance as an ED ('real' ED criteria).
- to implement the full WHO-definition, which also includes potential EDs, allocating EDs to several hazard categories, thereby reflecting the varying degrees of available data and the current scientific level of evidence.
- to establish ED categories which integrate the assessment for human health and environment to ensure full utilization and integration of all available data.
- To ensure that the ED assessment includes a comprehensive literature search with a focus on all aspects of endocrine disruption and endocrine related endpoints.

Based on the recent discussions in the CASG ED, CHEM Trust recommends the following refined version of the criteria for a CATEGORY 1: Endocrine Disruptor

"A substance shall be considered as having endocrine disrupting properties, i.e. causing endocrine-mediated adverse effects, if:

a) it shows an adverse effect in an intact organism or its progeny;
b) it shows endocrine activity;
c) there is a biologically plausible link between the endocrine activity and the adverse effect.

Substances are classified in Category 1 for endocrine disruption when they are known or presumed to have produced endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects in animal species living in the environment, or when there is evidence from experimental studies (in vivo), possibly supported with other information (e.g. (Q)SAR, AOPs, analogue and category approaches), to provide a strong presumption that the substance has the capacity to cause endocrine-mediated adverse effects in humans or population-relevant endocrine-mediated adverse effects on animal species living in the environment.

The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily based on human data (Category 1A) or on animal data (Category 1B).

CHEM Trust`s proposed criteria text for Suspected EDs (Category 2), and in addition for Substances showing endocrine activity (Category 3), including the text on the required level of evidence for ED properties for all categories is specified in responses to question 14 and 15.

The text defining the level of evidence required should especially reflect the consensus statement from various ED experts that ´the adverse effect not necessarily has to be demonstrated in an intact organism, but may be shown in adequately validated alternative test systems predictive of adverse effects in humans and/or wildlife´, see: Scientific principles for the identification of endocrine-disrupting chemicals: a consensus statement (springer.com).

Further, it is absolutely necessary to update standard information requirements for REACH, BPR and PPPR

and other relevant pieces of legislation to cover ED endpoints, see also our comments as follow-up to CASG-ED4 (2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_final.pdf) and to the public consultation on the update of REACH standard information requirements in October 2021.

CHEM Trust briefings and papers:
Comments on new ED hazard classes discussed in CASG ED (April 2021 and October 2021: https://chemtrust.org/wp-content/uploads/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_final.pdf.

https://chemtrust.org/wp-content/uploads/CHEM-Trust-and-HEAL-comments.pdf

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 14a - Please detail why and how a subcategorisation should be provided. Please indicate whether there should differences between human health and the environment.

Sub-categorisation
CHEM Trust strongly supports that the ED hazard class/es include sub-categories for EDs. Only very few substances have been officially identified as ED until now. This is partly due to the existing strict ED criteria that require a high burden of proof for ED properties, but also because there is a lack of data on ED properties and especially on relevant ED endpoints, even from the legally required tests.
As regards sub-categorisation, it is important to align the horizontal ED criteria with the CLP criteria for CMR-substances to ensure consistency in legislation. We made detailed comments on the subcategorization in our joint paper with HEAL and ClientEarth, see (Microsoft Word - Joint CT_HEAL_CE proposal on CLP ED criteria March 2021 final with date (chemtrust.org)).

We recommend:
- ED Category 1, including the two subcategories 1A and 1B, reflecting the level of evidence and making it transparent on what kind of data (human/wildlife or animal experimental) the assessment is based.
- a Category 2 for Suspected EDs to identify substances with endocrine disrupting properties that do not fully meet the criteria for ED category 1, fully in line with the current approach for CMR classification. (see also answer to question 15)
- A Category 3 for Substances showing endocrine activity to identify those substances that show endocrine activity in specified in vitro tests. This is important to ensure transparency, and to reflect that endocrine activity is a part of the definition of an ED.

Although the regulatory consequences may be the same for Category 1A and 1B, it is still important to make it transparent whether evidence comes from human/wildlife data or from animal experiments. Therefore, this information should be clearly indicated, as it may be of relevance for other regulatory purposes.

Endocrine activity is a strong indicator of a potential for ED properties and is part of the WHO-definition and

thus the elements of the ED criteria. Therefore, substances showing endocrine activity should be classified in a category for endocrine activity. (such a 'special' hazard category is also established under CLP for reproduction toxicity for lactation effects).

Integration or separate classes for HH and the ENV
We prefer to have an integrated approach for human health and environment, acknowledging that the hormonal system is well-conserved across vertebrate species with little variation, and to take a precautionary approach as regards invertebrate species for which there is a huge gap of knowledge. In case ED properties for human health and environment will be identified in two separate hazard classes, it is still relevant to have subcategories under the two hazard classes. The subcategories should reflect the current level of evidence considering all relevant data including both human and animal data for both hazard classes, as effects in one vertebrate species is predictive for endocrine disrupting effects in other vertebrate species, as well as they may be indicative for effects in invertebrate species, unless appropriate scientific evidence clearly demonstrate the opposite.
An integrated ED criteria (see response to question 13) with subcategorization for Category 1 EDs could look like the following (can be adapted for separate hazard classes for HH and ENV):
"Category 1A: Known endocrine disruptor
• The classification of a substances in Category 1A is largely based on evidence from humans /animal species living in the environment. This could e.g. be epidemiological studies, case-reports, or environmental field studies, possibly supplemented with other information. Note: as for CMR-substances, for the vast majority of substances there will not be sufficient data for classification in Category 1A .

Category 1B: Presumed endocrine disruptor
• The classification of a substance in Category 1B is largely based on data from experimental studies in vivo. This could e.g. be animal experimental studies, possibly supplemented with other information.

Substances can be allocated to Category 1 based on:
• Reliable evidence from humans or from animal species living in the environment where it is plausible that the observed adverse effects are endocrine-mediated, or

• Experimental studies where it is plausible that the observed adverse effects are endocrine-mediated, or

• Experimental studies showing endocrine activity in vivo predicted to have a biological plausible link (e.g. through (Q)SAR, AOPs, analogue and category approaches) to adverse effects in vivo."

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?

See also our response to question 14. CHEM Trust has made detailed proposals for a second category in our joint comments with HEAL in April 2021as follow-up to CASG-ED4. See: https://chemtrust.org/wp-content/uploads/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_final.pdf

A Category 2 for Suspected EDs reflecting the current level of evidence for ED properties is crucial for increasing the protection of human health and environment from exposure to endocrine disruptors. The inclusion of Category 2 will also ensure consistency in legislation and be logic, as several ED substances are already classified as Rep2 or Carc2 under CLP. In addition, a Category 2 will be very useful for downstream and sector legislation to be able to protect health and the environment from Suspected EDs.

We recommend:

- that a Category 2 for Suspected EDs is used to identify substances for which there is some evidence for ED properties but not sufficient to meet the ED Category 1 criteria.
- that the criteria for Category 2 ED is based on similar wording and are in line with the current approach for CMR classification under CLP.
- That the identification in Category 2 ED is reflecting the varying degrees of available data and the current scientific level of evidence for both endocrine activity and adversity.

CHEM Trust proposal for integrated ED criteria with subcategorization for Category 2: (can also be adapted for separate hazard classes for HH and ENV):

"CATEGORY 2: Suspected Endocrine Disruptor
Substances are classified in Category 2 for endocrine disruption, when there is some evidence for endocrine-mediated adverse effects, i.e. relating to adverse effects, endocrine activity or to a plausible link - from humans, animal species living in the environment or from experimental studies, possibly supplemented with other information - and where the evidence is not sufficiently convincing to place the substance in Category 1.
If deficiencies in the study (or studies), or in demonstrating a biologically plausible link, make the quality of evidence less convincing, Category 2 could be the more appropriate classification.

Substances can be allocated to Category 2 based on:

- Evidence from humans or from animal species living in the environment where it is suspected that the observed adverse effect is endocrine-mediated, or
- Experimental studies where there is a biologically plausible link that the observed adverse effects are endocrine-mediated but where, for example, specific weaknesses in study design (e.g. limitations in relevant ED endpoints), or execution weaken this conclusion, or
- Experimental studies in vivo where it is suspected that the observed adverse effects are endocrine-mediated.
- Experimental studies showing endocrine activity in vivo which is suspected to be linked to adverse effects in vivo (e.g. through (Q)SAR, AOPs, analogue or category approaches), or
- Experimental studies in vivo showing endocrine activity but for which the link to an adverse effect is uncertain, or
- Experimental studies in vitro showing endocrine activity, combined with toxicokinetic in vivo data, linked to adverse effects in vivo (e.g. through Q(SAR), AOPs, analogue and category approaches) but for which the link is suspected."

CHEM Trust proposal for integrated ED criteria with subcategorization for Category 3 – endocrine active substances: (can also be adapted for separate hazard classes for HH and ENV):

"CATEGORY 3: Substance showing endocrine activity

Substances are classified in the Category 3 for endocrine activity, if they have shown endocrine activity in vitro, and are not placed in Category 1 or 2.

- Substances can be allocated to the Category 3 for endocrine activity based on:
- Evidence from in vitro experimental studies showing endocrine-active properties. The evidence should come from the in vitro tests specified for ED modalities or similar tests in the information/data requirements (recently updated or under update)."

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

Question 16a - Please provide alternative labelling options

In our comments as follow-up to CASG-ED5 in September 2021 we have proposed the following wording:
“May cause endocrine disruption and harm the unborn child and human health”, and
“May cause endocrine disruption and harm the offspring and the environment”.
See:
https://chemtrust.org/wp-content/uploads/CHEM-Trust-and-HEAL-comments.pdf

We emphasize that the statement on a label is easy to understand for the public and therefore, we have proposed also to mention the consequences of endocrine disruption.

However, if a shorter text is preferred, we would strongly recommend that the specificity of the hazard class is clearly stated in the text so it reads:
“EUHXXX: May cause endocrine disruption on human beings.”
“EUHXXX: May cause endocrine disruption on the environment.”

(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 the REACH regulation.

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 18a - Please provide suggestions for criteria for category 2 for PBT and vPvB

In CHEM Trust view, a category for suspected PBT (and one for suspected vPvB) would be needed and bring the following advantages, among others:

• Including a category 2 would make the CLP regulation more efficient by facilitating hazard identification of harmful PBT/vPvB properties, leading to more transparency and communication in the supply chain.
• It would ensure coherence with the current CMR classification (categories for 'known and resumed' CMRs and 'suspected CMRs').
• It would promote innovation aiming at chemical substitution in order to reduce the accumulation of persistent and potentially harmful substances in humans and wildlife.

For criteria for category 2 we propose a weight of evidence determination which could include
- a combination of positive results from the REACH Annex XIII screening criteria
- with additional supporting information for (v)P, (v)B and T properties based on other available evidence, e.g. from human and environmental monitoring studies.

Some scientists have proposed that consideration of long-range transport potential should be given more weight in the assessments (Zarfl, C. and Matthies, M., 2013. PBT borderline chemicals under REACH. Environmental Sciences Europe, 25(1), pp.1-11. https://enveurope.springeropen.com/articles/10.1186/2190-4715-25-11). A strong emphasis should be placed on findings from human biomonitoring data in the general population.

See also CHEM Trust comments on Commission document 'Ad-hoc CA/02//2021 Discussion on PBT/vPvB possible criteria in CLP' https://chemtrust.org/wp-content/uploads/CHEM-Trust-comments_PBT-vPvBcriteriaCLP_Oct2021_final.pdf

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

CHEM Trust recommends that the hazard statements should reflect the specificity of these new hazard classes. This includes persistence, bioaccumulation in animals and humans, irreversibility, and human health toxicity. We also recommend the language to be easily understandable, which means replacing words such as persistent and bio-accumulative with more intuitive/descriptive words.
Example of our proposal: If a chemical is identified as PBT and carcinogen category 1, in addition to “May cause cancer” the label could display one of the following statements: ex 1: Accumulate in living organisms including in humans with long lasting effects; ex 2: Accumulate in breastmilk; ex 3: Accumulate in humans and can be transferred from the mother to the baby.

(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 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

CHEM Trust recommends that the hazard statements should reflect the specificity of these new hazard classes. Which includes persistence, mobility in the aquatic/water environment, irreversibility, threat to the quality of drinking water, threat to natural water resources. We also recommend the language to be easily understandable, which means replacing words such as persistent and mobile with more intuitive/descriptive words.
Example of our proposal: If a chemical is identified as PMT and carcinogen category 1, in addition to “May cause cancer” the label could display one of the following statements: ex 1: Accumulate in water environment including drinking water sources; ex 2 Contaminant of drinking water sources with long lasting effects;

AND HERE OUR ANSWER to QUESTION 21 a (there was a bug: the text field only appeared when `no` was ticked).

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

In CHEM Trust view, a category for suspected PMT (and one for suspected vPvM) would be needed and bring the following advantages, among others:

- Including a category 2 would make the CLP regulation more efficient by facilitating hazard identification of harmful PMT/vPvM properties, leading to more transparency and communication in the supply chain.
- It would ensure coherence with the current CMR classification (categories for ‘known and resumed’ CMRs and ‘suspected CMRs’).
- It would promote innovation aiming at chemical substitution in order to reduce the accumulation of persistent and potentially harmful substances in humans and wildlife.

For criteria for category 2 we propose a weight of evidence determination which could include
- a combination of positive results from the REACH Annex XIII screening criteria
- with additional supporting information for (v)P, (v)M and T properties based on other available evidence. A strong emphasis should be placed on monitoring data, in particular findings in groundwater.

See also CHEM Trust comments on Commission document Ad-hoc CA/03/2021 ‘Discussion on PMT/vPvM possible criteria in CLP’ https://chemtrust.org/wp-content/uploads/CHEM-Trust-comments_PMT-vPvMcriteriaCLP_Oct2021_final.pdf

Other hazard classes

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)

10

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)

10

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)

10

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)	○	○	◉	○	○
Endocrine disruptors (environment)	○	○	◉	○	○
PBT/vPvB	○	○	◉	○	○
PMT/vPvM	○	○	◉	○	○

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)	○	○	○	○	◉
Endocrine disruptors (environment)	○	○	○	○	◉
PBT/vPvB	○	○	○	○	◉
PMT/vPvM	○	○	○	○	◉

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

5

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

5

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	◉	○	○	○
Harmonising DMELs (Derived Minimum-Effect Limits) in CLP	○	○	◉	○
Harmonising PNECs (Predicted No-Effect Concentrations) in CLP	◉	○	○	○

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	◉	○	○	○
Ensure level playing field across sectors	◉	○	○	○
Increase workload of the Risk Assessment Committee	○	◉	○	○
Increase of burden and regulatory requirements	○	◉	○	○

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)

4

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

0

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

0

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 positive, to classify (your) chemicals accordingly:

  (●) Yes
  ( ) No

- In the case the result of a test performed with an alternative method is negative, 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.	○	◉	○
The obligation to come to an agreed entry should be strengthened.	◉	○	○
ECHA should be able to remove/refuse notifications that seem incorrect after having informed the notifier.	◉	○	○

Section 3 - Labelling

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

- ○ Yes
- ○ No

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	○	○	○
Exempt bulk chemicals (fuels) from certain labelling requirements	○	○	○
Allow a wide use of multilanguage labels / fold-out labels	○	○	○
Provide certain obligatory labelling information digitally instead of on the label	○	○	○
Provide additional information digitally	○	○	○

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	○	○	○	○
Exempt bulk chemicals (fuels) from certain labelling requirements	○	○	○	○
Allow a wide use of multilanguage labels / fold-out labels	○	○	○	○
Provide certain obligatory labelling information digitally instead of on the label	○	○	○	○
Provide additional information digitally	○	○	○	○

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)?

0

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?

0

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 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

Section 5 - Scope of the CLP regulation

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	☐	☐	☐	☐	☐
Veterinary medicines as defined in Directive 2001/82/EC	☐	☐	☐	☐	☐
Medical devices as defined in Regulation (EU) 2017/745 and Directive 98/79/EC	☐	☐	☐	☐	☐

Cosmetics as defined in Regulation (EC) No 1223/2009	☐	☐	☐	☐	☐
Food and feeding stuffs as defined in Regulation (EC) No 178/2002, 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	◉	○	○	○
Veterinary medicines	◉	○	○	○
Medical devices	◉	○	○	○
Cosmetics	◉	○	○	○
Food and feeding stuffs, including flavouring of 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	◉	○	○	○	○	○
Harmonised DNEL, PNEL, PNEC	○	◉	○	○	○	○
Improvements to CLH process (prioritisation mechanism, ECHA dossier submitter)	○	◉	○	○	○	○
Improve self-classifications	○	◉	○	○	○	○
Remove certain exemptions from CLP (medical devices, medicines, cosmetics etc.)	○	◉	○	○	○	○
Simplify labelling	○	○	○	○	○	◉
Tackle online sales lack of compliance	○	◉	○	○	○	○
Improve notification to poison centres	○	◉	○	○	○	○

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

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):

The CLP Regulation is a key piece of EU law which helps to identify and communicate chemical hazards. The inclusion of new legally binding hazard classes to improve the efficiency of identifying harmful

substances in the CLP Regulation was one of the Commission commitments set out by new European Chemicals Strategy for Sustainability.

In CHEM Trust's view the focus of the CLP revision should be placed on these key points:

- Introduction of new hazard classes for endocrine disruptors (EDs) with different sub-categories.
- Introduction of new hazard classes relating to persistent, bioaccumulative and toxic properties (PBT, as well as vPvB properties) and persistent, mobile and toxic properties (PMT, as well as vPvM properties).
- Introduction of new hazard classes for the identification of substances with developmental neurotoxic and immunotoxic properties.

This will lay the basis for identifying harmful substances and speeding up the measures to reduce human and environmental exposure to toxic chemicals. If the EU Green Deal is supposed to live up to its aims to result in more prevention and precaution, this will require a more efficient identification of the harmful properties of substances and subsequent control measures that provide for long-term benefits.

Need for adequate data:
It is important to underline that an increased protection level can only be obtained, and substances with these hazardous properties can only be identified, if data are available. Therefore, it is crucial to improve the information requirements under all relevant pieces of EU legislation. REACH requires companies to ensure safe uses of their chemicals. Yet, the REACH review 2018 has shown that companies often failed to fulfil their obligations. Current information requirements do not allow a sufficiently thorough hazard assessment, including for endocrine disruption The Commission Communication on the REACH review in 2018 stated: that "incentives are lacking for companies to update their registration dossiers and work is still needed to rectify important data gaps or inappropriate adaptations to testing". (…) This failure to fulfil obligations from the companies' side should be addressed and the legal text should be clarified and options for enforcement improved.
We also encourage a greater emphasis for grouping and read-across approaches in the CLP legislation, for example for carcinogens, as these would be approaches to increase speed of action and the level of protection, while reducing animal testing.

Problematic design of questionnaire:
We find that several questions and possibilities for responses in the questionnaire are formulated in a way that makes them ambiguous or the answers are too simplistic/insufficient to provide the necessary more nuanced answer. In several cases, we have therefore, not answered the questions.

For example, in CHEM Trust's view question 34 is badly designed as it can be interpreted in different ways. Current EU regulation partly requires animal tests as part of a broader testing and assessment strategy for identification of endocrine disruptors. It is concerning that discussions in CASG ED on the update of the REACH Annexes in relation to ED properties have highlighted the risk of false negatives from alternative methods, which could lead to an incorrect assessment of safety. (see our comments in https://chemtrust.org /wp-content/uploads/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_final.pdf).
In conclusion, in order to make identification future proof and less reliant on animal data: Identification should be based on all available data, including peer-reviewed academic studies and read-across, in a weight-of-evidence approach.

A more precautionary approach to chemicals assessment and regulation is needed for better protection of environment and human health. This can be achieved by regulating based on more predictive methods and earlier decision points, using grouping of substances, and reducing the burden of evidence, for example by regulating chemicals based on the evidence of adverse effects that are provided by in vitro testing, QSAR and read across.

These approaches will improve protection whilst also minimising animal testing.

For details see:
CHEM Trust response to the public consultation on the Commission's Inception Impact Assessment on the CLP revision (May 2021)
https://chemtrust.org/wp-content/uploads/Final-CHEMTrust-CLP-IIA-Response-May-2021.pdf

CHEM Trust Comments on European Commission proposal for update of the REACH Annexes in relation to endocrine disruption properties
https://chemtrust.org/wp-content/uploads/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_final.pdf

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

01dc4c85-a2c6-43e0-b6c7-7587e0c5ddb8/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_final.pdf
ed49dd99-2acb-4eef-b94d-77d2072916e6/CHEM-Trust-and-HEAL-comments_October_2021.pdf
5d69cb6c-baaf-47a4-859d-cba80b162706/CHEM_Trust_comments_PBT-vPvBcriteriaCLP_Oct2021_final.pdf
afb9d4d2-6c05-455f-962c-776bf1a6666f/CHEM_Trust_comments_PMT-vPvMcriteriaCLP_Oct2021_final.pdf
a71e4739-9f33-4a54-8175-8c7c0ef17276/Final-CHEMTrust-CLP-IIA-Response-May-2021.pdf

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