

BRIEFING

Response to the public consultation on the revision of the legislation on the classification, labelling, and packaging of chemicals (CLP)

March 2023

The Health and Environment Alliance (HEAL) welcomes the draft proposal for a revision of the CLP legislation and overall shares a positive assessment of the set of measures put forward by the European Commission in order to modernise the legislation and make it more protective, efficient, and coherent. Below are our detailed observations and recommendations.

Scope of the CLP legislation

We particularly welcome **the addition of new hazard classes for important health and environmental endpoints** that are currently not taken into account in the CLP text, namely for endocrine disrupting chemicals (EDC); persistent, bioaccumulative, toxic chemicals (PBT); chemicals that are very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic chemicals (PMT); chemicals that are very persistent, very mobile (vPvM). The hazard classes are detailed in the delegated act accompanying the main text reform proposal, which we have strongly welcomed ¹ and which will be referenced in article 36 of the main text.

We are however surprised that not all references to hazard classes that currently exist in the CLP text have been adapted to the addition of these new classes. For instance, article 18.3(b), which relates to the identification of substances in mixtures lacks an inclusion of the new hazard classes. We would like the European Commission to fix this omission as soon as possible.

We positively regard the **specific provisions to ensure consistency between the introduction of such new hazard classes in the text and other legislations**, through which the identification of the above-mentioned hazards has taken place until the creation of the new hazard classes (REACH, Plant Product Protection Regulation or PPPR, Biocides Products Regulation or BPR). The proposed **update of CLP Annex VI part 3 (table of harmonised classifications and labelling)** is therefore very welcome, notably through the addition of:

- Substances identified as substances of very high concern (SVHCs) under REACH;
- Substances already identified as endocrine disrupting chemicals (EDCs) under the PPPR and BPR under the new category 1 (known EDCs);
- Substances identified as PBT/vPvB under PPPR and BPR under the new PBT/vPvB category.

Based on the Chemicals Strategy for Sustainability's commitment to assess the need for the addition of specific hazard criteria for immunotoxicity and neurotoxicity, we are surprised not to find any proposed initiatives regarding the future inclusion of these important health endpoints in the Commission's proposal. We would recommend the addition of a target date by which such endpoints will be appropriately included in the CLP legislation.

For more information:

Natacha Cingotti

natacha@env-health.org+32 (0)2 329 00 81 · env-health.org

We are positive about efforts to adapt CLP to recent societal changes and efforts to promote more circular consumption patterns, by introducing provisions to cover new means of sale of chemical products:

- By explicitly including **the sale of products in bulk, or the use of refill stations** (Annex II), as these are increasingly used and promoted in the context of the transition towards more circularity;
- By **explicitly including online sales of chemicals and the role of distributors**, which are currently not accounted for, in the legislation and which represent an important channel for chemicals' trade.

Procedural aspects of CLP implementation

Initiating CLP classifications

In terms of procedural changes in the classification process, we welcome the following proposals in order to make the system faster and more efficient:

- Article 37: **The extension of the mandate to propose classification to the European Commission** (it is currently only granted to industry players and Member States);
- Article 37: **The possibility to introduce classification proposals for groups of chemicals rather than for individual substances only**, as is currently the case.

In order to truly encourage the uptake of the grouping approach for classification purposes in the future, we would however suggest to strengthen the legal text through a mention of the need to prioritise grouping for classification, whenever deemed scientifically justified and possible by regulatory authorities. The mention of the authorities' expert judgment is important to ensure that proposed grouping approaches are scientifically sound and not misused to lower classification proposals. This could be done by adding a sentence to the proposed reformulation of article 37, paragraph 1, such as: *"Whenever considered scientifically justified and possible by a competent authority or the European Commission, proposals for classification should prioritise groups of substances rather than individual substances."*

Justifications for hazard classifications

- Article 40: We welcome **the proposal to grant ECHA the power to delete incomplete and/or obsolete industry self-classifications entries in the CLP repository**, which currently is ridden with outdated entries, hindering the usefulness of the repository as a reliable tool to access hazard information about chemicals that already are on the market.
- Article 40: **We find the proposal to request different notifiers to provide a justification when their respective classification information differs to be a good addition**. We also welcome the obligation for notifiers to update their notifications within 6 months after a decision to change the entry to address divergences between recent and obsolete classifications.
- However, we would like guarantees that the notifiers' obligation to justify the divergences in their entries always leads to the use of the most protective classification, in case of ongoing debate, remaining scientific uncertainties, or lack of evidence. This is to avoid that this provision is misused to lower proposals for classifications. **These details for implementation can be added either directly in the legal article or in a guidance document.**
- Article 53: **Adapting CLP to new developments regarding test methods and the possibility to include hazard classification criteria based on NAMs in the future is positive**. However, we would like guarantees that such a provision cannot be used as an excuse to block current classification proposals from moving forward, when data is lacking and no validated NAMs are yet available to assess the endpoint at play. **The text needs to clarify that the expert judgment of regulatory authorities to assess**

whether the level of evidence necessary to proceed with a hazard classification is met or not remains central to the testing approach and is protected.

Considerations regarding assessment of mixtures and MOCS

- Articles 5 and 6: **We welcome the practical approaches proposed regarding the assessment of more than one constituent substances (MOCS) and mixtures.** We believe that requesting data on individual constituents, when available, is an improvement when it comes to assess critical properties such as endocrine disruption for health and the environment – in a context when data on such properties is missing and currently available test methods lack sensitivity.

Transparency

- **Overall, we welcome the efforts to make the CLP implementation more transparent** through the introduction of specific provisions for the different stakeholders involved. In particular, the following are positive:
 - Article 37.2(a): Transparency about the initiation of the process for the development of a classification proposal process;
 - Article 42(1): Transparency obligation regarding the notifier's identity;
 - Article 45: Extension of obligation to submit emergency health response information to distributors, which is very important for online sales;
 - Article 48: Extension of transparency obligations regarding advertising.

Definitions

- Annex I: **We particularly welcome clarifications added in CLP Annex I regarding the definition of the Weight of Evidence,** specifically regarding what information can be considered for its implementation. Such a clarification is crucial for the protective implementation of the entire regulation.

Aspects that could still be improved in the current draft

Efficiency of the process

- It can currently take a very long time between the moment when a RAC opinion on a classification proposal is agreed upon and when the European Commission takes a decision to update Annex VI of CLP. **We suggest adding a formal deadline for the Commission to issue a final decision on hazard classification(s) within 6 months once a RAC opinion is agreed upon.**

Labelling obligations

- Articles 34(a) and 34(b): **In general, we can understand the rationale for adding digital options in order to access parts of the labelling information. We however would like to see guarantees that this will not lead to reduced consumer and worker information about the properties of the substances that they enter in contact with.** The current text proposal mentions that information that is considered to be '*not instrumental for the safety of the user or the protection of the environment*' (as per recital 12 of the proposal) can be moved to a digital labelling, without clarifying how this condition will be decided. An inclusive and transparent discussion process should precede such conclusions and the Commission should clarify in the text that hazard labels will remain excluded from this option.

- Article 29 and Annex I, section 1.5: **As regards the labelling of small items**, it is important that consumers and workers can have access to the relevant information whatever the size of the item. We believe that further clarifications are needed in the text to do so.

NOTES:

For more information regarding HEAL's work on the CLP revision, please visit: env-health.org/campaigns/clp-reform/

¹ HEAL has contributed to the discussions regarding the development of the hazard classes over the last years and welcomed the proposal in December 2022: <http://www.env-health.org/environmental-health-groups-welcome-introduction-of-european-harmonized-hazard-classes-for-endocrine-disruptors/>

Natacha Cingotti

Health and Chemicals Programme Lead

Health and Environment Alliance (HEAL)

E-mail: natacha@env-health.org

Tel: +32 (0)2 329 00 81

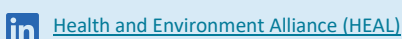
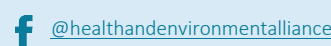
Health and Environment Alliance (HEAL)

Avenue des Arts 7/8

1210 Brussels, Belgium

Tel: +32 (0)2 329 00 80

E-mail: info@env-health.org



The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 90 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.



HEAL gratefully acknowledges the financial support of the European Union (EU), European Environment and Health Initiative (EEHI) and Adessium Foundation for the production of this publication. The responsibility for the content lies with the authors and the views expressed in this publication do not necessarily reflect the views of the EU institutions and funders. The European Climate, Infrastructure and Environment Executive Agency (CINEA) and the funders are not responsible for any use that may be made of the information contained in this publication.

HEAL's EU Transparency Register Number: 00723343929-96