

## BRIEFING

# Analysis of the draft European Parliament ENVI report regarding the legal proposal for reform of the CLP legislation

27<sup>th</sup> April 2023

This document sets out the analysis of the Health and Environment Alliance (HEAL) regarding the draft report of the European Parliament (EP) ENVI committee on the legal proposal for reform of the legislation on the classification, labelling, and packaging of chemicals (CLP)<sup>1</sup>.

The draft EP ENVI report was prepared by MEP Maria Spyraiki, rapporteur for the file<sup>2</sup>, and published on 11<sup>th</sup> April. It is opened for amendments until 11<sup>th</sup> May.

The content of our analysis is structured as follows:

## I. General Assessment

- 1) Form of the report
- 2) Content of the report
- 3) Voting recommendations

## II. Health-protective improvements of the European Commission proposal that could still be considered through amendments

### I. General Assessment

HEAL supports the reform of the CLP regulation as proposed by the European Commission through its legal proposal<sup>3</sup>, which we consider a high-quality starting base for the co-decision process. Overall, we are concerned that the draft EP ENVI report undermines important health- and environment-protective improvements proposed by the European Commission in this central chemicals-related piece of legislation.

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## 1) Form of the report

In terms of form, the draft report illustrates significant confusion on the role and purpose of the CLP regulation, on the differences between the CLP and REACH regulations respectively, as well as on the important health and environment stakes of the European Commission's proposed changes.

In HEAL's views, **the most problematic aspects** include the following:

- **The lack of understanding of the current scale of the problems in terms of widespread market access for chemicals, of which hazard properties have not yet been properly characterized** (a slow hazard classification system based on individual substances, common under- rather than over- classifications of the substances' hazards).  
The draft report seems to be mostly concerned with a risk of over-classification of chemical substances rather than the overdue revision of CLP towards more efficient and faster classification in view of meeting the regulation's primary objective of health and environment protection in line with the precautionary principle.
  - o This need is supported by the European Commission fitness check on all the chemicals legislations except REACH:  
*"According to ECHA the number of assessments for harmonised classifications under the CLP Regulation is relatively low compared to the likely number of chemicals which merit a harmonised classification [...] The main consequence of this 'slow' pace is that not all of the potentially hazardous chemicals which would therefore merit a harmonised classification are dealt with thus potentially prolonging exposure of EU citizens to such hazardous chemicals. <sup>4</sup>."*
- **The lack of understanding of issues that are relevant in the context of the CLP revision.** For instance, the report makes suggestions for:
  - o Amendments that pertain to the need for increased resources for the European Chemicals Agency (ECHA). While we support this demand, it is mostly relevant in the context of the upcoming founding regulation for ECHA and should not lead to multiple amendments in the context of this report (8, 9, 20, 23, 31, 40, 44, 46). Those multiple mentions read confusing and counter-productive.
  - o The same goes for the multiple mentions of ECHA's role in developing specific guidance documents pertaining to certain scientific topics, which are outside the remit of the European Parliament and of which multiple mentions are confusing (amendment 39).
  - o Amendments that suggest adding new objectives to the CLP regulation such as the replacement of animal testing (amendment 11). While we support the long-term reduction and replacement of animal testing where possible, this objective is out of scope for the purpose of the CLP revision because CLP is not a regulation leading to test requirements for companies.
- **The lack of understanding of what is within the remit of the European Parliament to provide input on through its report,** versus what is within the remit of scientific agencies to decide.
  - o For instance, the report suggests fantastist additions on technical matters, for which the European Parliament is not competent, such as the interpretation on the weight of evidence approach (amendments 3, 22), the suggested approach to the implementation of grouping in chemical

assessment (amendments 5, 30, 33, 57), the suggested approach to more than one constituent substances (MOCS; amendments 1, 2, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 34, 47, 48).

- **Confusion between hazard and risk assessment and about the fact that CLP is solely intended to identify substances' hazard** and to allow for their appropriate classification, labelling, and packaging information but **not to regulate them**. Therefore, attempts to bring in socio economic considerations (through amendments 1, 10, 30, 35) in the hazard classification process are out of scope.
  - o Again, the focus of the CLP regulation on hazard assessment is an important cornerstone of the EU chemicals legislative acquis, which was highlighted in the EU Commission's chemicals fitness check and should not be modified through this revision:  
*"The CLP Regulation was identified as one of the most efficient aspects of the functioning of the EU chemicals legislative framework, as it allows hazard classification of a wide range of chemicals without creating a disproportionate administrative burden for public authorities while focusing their resources on the most relevant substances for human health and environmental protection. **The clear separation of hazard assessment and hazard classification from the risk assessment and risk management decision making steps is an important cornerstone of the framework's effectiveness and should be safeguarded.**"<sup>5</sup>*
  
- **Attempts to extend stakeholders' commenting opportunities that risk threatening the possibility to reach agreement on classification process** and will only benefit industry stakeholders with significant resources to comment at the behest of health-protective information for workers and consumers. This is all the more concerning, as the process can already be slow and it already caters for public consultation opportunities (on the proposed classification dossier at ECHA, but even at the very end of the process before the Commission takes a decision on amending CLP Annex VI through the CARACAL expert group's discussions, which are routinely used by industry to present their arguments<sup>6</sup> (amendment 6)).
  - o The already slow pace of the system was also highlighted in the European Commission's chemicals fitness check:  
*"In many cases, the process is slowed down and there is some reticence because of the consequences that the harmonised classification may trigger in downstream legislation e.g. ban of CMRs under the Cosmetic Products Regulation or cut-off criteria under the Plant Protection Products Regulation<sup>7</sup>."*
  - o The proposal for industry actors to directly reach out to ECHA's RAC to submit new information that may lead to a change in the classification instead of the relevant competent authority (amendment 36) risks adding confusion in the process and further extending industry's access to the process at the expense of other stakeholders.
  
- **Overall, the drafting style and format of the report is that of a European Parliament resolution rather than that of proposed amendments to a piece of legislation**, which raises concerns about creating confusion rather than clarifying the legal text. The draft report urgently needs a review by the European Parliament legal services.

## 2) Content of the report

In terms of content, the following aspects – partly related to the formal aspects mentioned above – are problematic:

### - Proposals regarding more than one constituent substances (MOCS)

The European Commission proposals regarding the assessment from MOCS stem from the current lack of legal clarity in the CLP text, which hampers the adequate hazard identification of these substances. Only focusing on the toxicity of the overall MOCS is not sufficient to apprehend their full hazard potential and the EC proposal to use information on individual constituents is therefore a practical and science-based approach to do so.

In this regard, it is important to highlight that the EC proposed approach:

- o Is in line with existing provisions regarding the identification of carcinogens, mutagens, and reprotoxicants in mixtures.
- o Would mostly consist of making a better use of existing information and would not lead to new data production requirements for industry representatives (the CLP regulation does not include testing obligations for companies).
- o Would contribute to the better identification of properties such as endocrine disruption supported by the European Parliament, in a context of lack of sensitive validated tests. On this specific aspect, the optimum use of information available on individual constituents when data on the entire MOCS is either absent or insufficient to conclude in the context of CLP is also coherent to the European goal of reduced animal testing in other legislations such as REACH or the cosmetics legislations.
- o Therefore, the provisions proposed on MOCS contribute to increased coherence between chemicals legislations as well as increased health and environment protection, and should therefore be supported.

**In contrast, changes proposed in the draft report (amendments 1, 2, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 34, 47, 48) introduce confusion and run counter health- and environment-protective objectives:**

- o Through the use of new terms that have no scientific or legal relevance (e.g. 'natural complex substance') and do not adequately reflect the issue at stake, i.e. substances with more than one constituents, whether natural or not.
- o Reflect the demands of specific industry sectors against the use of the information on individual constituents, which would make the adequate hazard identification of MOCS impossible. This would be in contrast to the CLP objectives as well as earlier demands for better identification of harmful chemicals from the European Parliament itself.

### - Grouping of chemical substances

The European Parliament has consistently supported the use of grouping to accelerate hazard assessment for increased health and environment protection – for instance through its resolution on the Chemicals Strategy for Sustainability<sup>8</sup>) and grouping is an important driver of the future health- and environment-delivery of the Chemicals Strategy for Sustainability. In contrast, the draft report

suggests amendments (5, 30, 33, 57) that would make its implementation very difficult, ignore that the grouping approach already requires thorough scientific justifications to be used today across chemicals legislations, and introduce suggestions beyond the remit of the European Parliament without adequate scientific justifications.

- **Animal testing**

While all actors involved in European chemicals policy processes, the draft report suggests amendments pertaining to the full replacement of animal testing that are problematic for several reasons (amendments 11, 45):

- o Firstly, the CLP regulation does not include test requirements for chemicals companies and CLP classification proposals are based on existing data, mostly REACH registration data and independent scientific literature. Therefore, an objective on the replacement of animal testing is technically and legally outside of its scope.
- o Furthermore, the primary way to limit animal testing is the better use of all existing data in a weight of evidence approach. We therefore regret that the draft report contains contradictory demands and undermine the weight of evidence approach by proposing amendments about technical aspects that are in the remit of scientific agencies and are not in line with currently accepted scientific language and guidelines (through its proposed amendments 3, 21).
- o Finally, the draft report makes proposals that are disconnected from the reality of the international scientific discussions on advancing non-animal test methods and their validation (for instance through amendment 45).

- **Labelling provisions**

Throughout the draft report, a distinction is introduced regarding labels through the systematic mention of 'a label or a fold-out label', which suggests that a fold-out label is therefore different from a label, while it is one specific variation of it. No concrete definitions are offered to explain such distinction, therefore introducing legal uncertainties throughout the text (amendments 24, 26).

We are further concerned at the draft report suggestions to:

- o Reduce the fonts of the labels, making them unreadable for consumers and workers (amendments 52, 53, 54, 55, 56).
- o Move important label information (e.g. signal words, hazard statements) to the inner pages of fold-out labels (amendment 24, 27, 28).
- o Delay the adaptation deadline of labelling information for a substance or a mixture from 6 to 18 months once a classification has been updated (amendments 4, 26), which would go against the protection interests of consumers and workers.
- o Discharge industries from their responsibilities' regarding the hazard of the substance(s) they put on the market and pass it on to the consumers and workers by suggestions that a user should 'always read and follow product label information' (amendments 41, 42).
- o Limit labelling obligations for distance sales directed at consumers only, but not to other users (e.g. workers and other professional users such as transporters; through amendment 43).

- **Provisions regarding addressing multiple entries for the same substance**

The European Commission proposal rightly suggests that notifiers with divergent entries for the hazard classification of a substance have to provide justification for such divergences (article 40).

- o We are concerned about the proposed amendments (7, 37, 38) in the draft report, which propose conditions for the application of this obligation which are not well defined and do not reflect the regulatory reality (under which it is not possible to request new data) and read as follows: “where applicable and practically achievable, without acquiring new data or studies being necessary”. Therefore, amendment 7 should be rejected.

- **Proposed extension of transition delays for the entry into force of the obligations stemming from the introduction of new hazard classes**

We are concerned by the proposals made in the draft report to extend those transition periods, which will keep consumers and workers uninformed about the hazards of the substances they are exposed to up to four years in the case of mixtures (amendments 47,48, 50, 51). We are also concerned at the suggested separation of provisions pertaining to substances and mixtures respectively in the legal text, while they are always referenced together in the CLP regulation.

### 3) Voting recommendations regarding proposed amendments

**On the basis of the above analysis, we recommend to:**

- **Fully reject** amendments: 1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 24, 26, 27, 28, 30, 33, 34, 35, 36, 37, 38, 39, 41, 42, 43, 45, 47, 48, 50, 51, 52, 53, 54, 55, 56, 57
- **Merge amendments** 8, 9, 20, 21, 23, 31, 40, 44, 46 regarding the need for increased resources for ECHA and transfer the merged reference to recitals linking the issue to the ECHA Founding Regulation currently under development.

## II. Health-protective improvements of the European Commission proposal that could still be considered through amendments

In HEAL's view, aspects that could still be improved and clarified in the European Commission's proposal through the European Parliament scrutiny include the following:

- **The addition of a reference to the newly created hazard classes in article 18.3(b)**, which relates to the identification of substances in mixtures, and currently lacks such a reference.
  - This addition is important to keep consistency throughout the text and promote the implementation of the new hazard classes not only to substances on their own but also in mixtures.
- **The addition of an amendment requesting a target date, by which the Commission should make a legal proposal for the development of hazard criteria for immunotoxicity and neurotoxicity, no later than 2025**
  - This is based on the Chemicals Strategy for Sustainability's commitment to assess the need for the addition of **specific hazard criteria for immunotoxicity and neurotoxicity in the CLP legislation**, since those health endpoints are not fully and appropriately covered in existing hazard classes.
- **The clarification on the priority use of grouping in view of speeding up hazard classification proposals**

Article 37 of the Commission's legal proposal introduces the possibility to initiate classification proposals for groups of chemicals rather than for individual substances only, which is a positive step forward. However, in order to truly encourage the uptake of the grouping approach for classification purposes in the future, we would suggest strengthening 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 can be done through an amendment of article 37 paragraph 1**, adding the following sentence: *"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."*
- **The addition of a guarantee in favour of the most protective classification whenever multiple entries about the same substance(s) differ without appropriate justification or when entries are obsolete**

In the Commission's proposal, article 40 provides that whenever different notifiers have divergent classification information for the same substance(s), this needs to be duly justified and that any updates following changes in entries to address divergences between recent and obsolete classifications need to take place within 6 months. This is a positive addition. However, the proposal does not clarify that in case of debate about the level of classification needed between notifiers, of remaining scientific uncertainties

of lack of evidence, the most protective classification should always be used. It also does not concretely grant ECHA the power to delete obsolete entries in the inventory. **This can be fixed by amending article 40 through:**

- The addition of a sentence, which will **provide guarantees against the misuse of this provision to lower proposals for classifications;**
- The addition of a sentence that clarifies that **ECHA is being granted the power to delete obsolete entries in the classification inventory.**

- **The addition of a deadline for Commission's decisions on hazard classification(s) to make the CLP classification process more efficient.**

It can currently take a very long time between the moment when an opinion of the ECHA Risk Assessment Committee (RAC) on a classification proposal is agreed upon and when the European Commission takes a decision to update Annex VI of CLP.

- **We suggest introducing an amendment to add 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.**

- **Clarifications to ensure minimum labelling obligations towards consumers and workers.**

In the Commission's proposal, articles 34(a) and 34(b) propose to add digital options in order to access parts of the labelling information. However, we 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.

- **We suggest introducing an amendment to article 34** to clarify that the decision about what part of the information is *'not instrumental for the safety of the user or the protection of the environment'* needs to be transparently documented and that hazard labels will always remain excluded from this option.

- **Clarifications about the health- and environment-protective referencing of the use of NAMs for hazard classification purposes**

In the Commission's proposal, article 53 rightly proposes to adapt CLP to new developments regarding test methods and the possibility to include hazard classification criteria based on NAMs in the future. However, considering that only few NAMs are currently available (especially for sensitive health endpoints such as endocrine disruption, or carcinogenicity) in a context of overall data scarcity for numerous chemicals, it is important that this positive inclusion cannot be misused to block classification proposals from moving forward.

- **This can be avoided by amending article 53**, through the addition of a sentence 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.**



NOTES:

<sup>1</sup> Draft report on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (COM(2022)0748 - C9-0433/2022 - 2022/0432(COD)), Committee on the Environment, Public Health and Food Safety, [https://www.europarl.europa.eu/doceo/document/ENVI-PR-745493\\_EN.html](https://www.europarl.europa.eu/doceo/document/ENVI-PR-745493_EN.html)

<sup>2</sup> See European Parliament procedure page:

[https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2022/0432\(COD\)&l=en](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2022/0432(COD)&l=en)

<sup>3</sup> See HEAL response to public consultation the revision of the legislation on the classification, labelling, and packaging of chemicals (CLP), March 2023: [https://www.env-health.org/wp-content/uploads/2023/03/2023.03.28.HEAL-CLP\\_Revision\\_Public\\_Consultation.pdf](https://www.env-health.org/wp-content/uploads/2023/03/2023.03.28.HEAL-CLP_Revision_Public_Consultation.pdf)

<sup>4</sup> European Commission, Fitness Check of the most relevant chemical legislation (excluding REACH),

[https://commission.europa.eu/system/files/2020-04/swd\\_2019\\_0199\\_en.pdf](https://commission.europa.eu/system/files/2020-04/swd_2019_0199_en.pdf), p.49

<sup>5</sup> Ibid , p.108

<sup>6</sup> Long delays about recent hazard classification proposals, notably for substances such as titanium dioxide, or lithium salts, perfectly illustrate the industry ability to provide input throughout the process and delay decisions from the European Commission.

<sup>7</sup> European Commission, Fitness Check of the most relevant chemical legislation (excluding REACH),

[https://commission.europa.eu/system/files/2020-04/swd\\_2019\\_0199\\_en.pdf](https://commission.europa.eu/system/files/2020-04/swd_2019_0199_en.pdf), p.49

<sup>8</sup> European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)),

[https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.pdf)

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*HEAL gratefully acknowledges the financial support of the European Union (EU), Global Greengrants 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