Introducing new hazard classes under the CLP regulation
European Commission Public Consultation

13th October 2022

The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on the European Commission's proposal for new hazard classes under the CLP regulation.

HEAL fully supports the proposed introduction of the new hazard classes proposed for endocrine disruption as well as for substances with PBT (Persistent, Bioaccumulative and Toxic), vPvB (very Persistent and very Bioaccumulative), PMT (Persistent, Mobile and Toxic) and vPvM (very Persistent and very Mobile) properties.

A swift introduction of such hazard classes is needed to allow for increased protection of workers and consumers as soon as possible, based on the following transition periods:

- 12 months for substances put on market after entry into force; 18 months for substances already on the market before;
- 24 months for mixtures put on the market after entry into force; 36 months for mixtures already on the market before.

We have specific comments with regards to the proposed hazard classes for endocrine disruption. Overall, we thank the Commission for the significant work done on the proposed criteria since the discussions started in the context of the CASG-ED. We believe that important progress has been made and we are overall satisfied with the text and the drafting of the criteria for endocrine disruption for both categories 1 and 2.

Because the wording of the criteria and the supporting classification approach must be unequivocal in order to allow for a practical implementation by authorities, we however have the following additional comments.

Human Health

- **Definitions:** as regards the biologically plausible link, we are concerned that the proposed text deviates from the EFSA-ECHA guidance document for the identification of EDCs under the existing criteria for pesticides and biocides in a way that is scientifically not accurate and increases the burden of proof. The EFSA-ECHA guidance clarifies that: *"The biological plausibility relies on an **understanding of the fundamental biological processes involved and whether they are consistent with the causal relationship being proposed.** In the context of this guidance, the biological plausibility is considered to be **the level of support for the link between the adverse effect and the endocrine activity**" (emphasis added, p.98).* Establishing a biologically plausible link is indeed about guaranteeing consistency with the general biological knowledge when establishing a link between adversity and endocrine activity. However, the current Commission draft focuses too much on the link itself and not enough on the establishment of the support level needed to determine such consistency, and hence

the plausibility. Please align the text with the wording of the EDC guidance document for pesticides and biocides.

- **Allowing for grouping**: If the ambition of the Commission is to move towards increased assessments of substances by groups in the future, it is not clear from the current proposal that the wording would allow for the assessment and related hazard classification of groups of substances rather than individual ones only.

Criteria for category 1 (p.2):

- We recommend keeping the wording of the criteria in line with existing CLP criteria wording, in particular that of reproductive toxicity criteria, and that it ensures that existing data from independent literature can be used to support identification. Therefore, the first sentence should be clarified as follows: *"The classification in Category 1 shall be largely based on evidence from human or animal data, for from both human and animal data, possibly supplemented by other information."*
- Under criteria 1(b), the current wording "*an adverse effect in an intact organism or its offspring AND future generations"* is too restrictive. The sentence should read: *"an adverse effect in an intact organism or its offspring OR future generations".*
- We do not understand the added-value of the sentence under the criteria, which currently reads: *"However, where there is information that raises doubt about the relevance of the biologically plausible link for humans, classification in Category 2 may be more appropriate."* Since criteria for category 2 classification are listed just under this sentence, it brings unnecessary confusion and opens potential loopholes. Therefore, we recommend deleting this sentence entirely.

Criteria for category 2 (p.2):

- We also recommend keeping consistency with existing CLP text, in particular that of reproductive toxicity criteria, for the wording of category 2 criteria. The criteria should also explicitly allow the use of approaches such as read-across in the assessment in order to complement human and/or animal evidence, or remedy data gaps. Therefore, the first sentence should read: *"The classification is Category 2 is largely based on evidence from human or animal data, or from both human and animal data, possibly supplemented by other information (such as read-across)."*

Paragraph 3.11.2.2. Basis of classification (p.3):

- We are not satisfied with the wording used to describe the weight of evidence. The current proposal mentions *"a weight of evidence determination of each of the criteria"*. This introduces a deviation from the definition of the weight of evidence that is included in annex I of the CLP regulation. Therefore, we recommend that the wording sticks to the latter annex formulation and refers to the determination of a *"single weight of evidence*" (CLP regulation, Annex I, point 1.1.1.3).

Paragraph 3.11.2.3. Weight of evidence and expert judgement (p.3):

- While we welcome the effort to provide details on the relevant scientific data to be taken into account, we again regret the deviation from the CLP Annex I definition of the weight of evidence. In particular, the text must clearly allow for the use of grouping and read-across beyond the analysis of the endocrine mode of action (i.e., also for adversity). We recommend

sticking to the language of CLP Annex I when detailing the relevant scientific data to be taken into account, including re-introducing the explicit mention of *"information from the application of the category approach (grouping, read-across)"* (CLP regulation, Annex I, point 1.1.1.3).

Paragraph 3.11.4. Hazard communication (p.5)

- We still support the introduction of a pictogram as part of the labelling elements of the criteria.
- Regarding the hazard statements, as mentioned in previous comments and discussed in previous CASG-ED meetings, we would like to see the impacts on future generations reflected. We therefore propose to amend the statements as follows:
    - Category 1: *"EUH380: May cause endocrine disruption and harm the unborn child and human health"*
    - Category 2: *"EUH381: Suspected of causing endocrine disruption and harming the unborn child and human health"*

Environment

- **Definitions**: As for the human health section, the definition of the biologically plausible link should be modified to be in line with the EFSA-ECHA EDC Guidance document for pesticides and biocides.
- **Allowing for grouping**: We have the same comment as in the human health section.

Criteria for category 1 (p.7):

- As pointed out for the human health section, we recommend keeping the wording of the criteria in line with existing CLP criteria wording. Therefore, the first sentence should be clarified and read: *"The classification in Category 1 shall be largely based on evidence from animal data, possibly supplemented by other information."*
- We also have a similar comment regarding criteria 1(b) as in the human health section, as the current *wording "an adverse effect in an intact organism or its offspring AND future generations"* is too restrictive. The sentence should read *"an adverse effect in an intact organism or its offspring OR future generations".*

Criteria for category 2 (p.8):

- The basis for classification should be clarified to allow the explicit use of the grouping and read-across approaches in the assessment as well as the use of existing human data, when useful and relevant as per expert judgement. Therefore, the first sentence should read: *"The classification is Category 2 is largely based on evidence from animal species living in the environment and/or on data from animal and human studies, possibly supplemented by other information (such as read-across)."*

Paragraph 4.2.2.2. Basis of classification (p.8):

- As is the case for the human health section, we are not satisfied with the wording used to describe the weight of evidence *("a weight of evidence determination of each of the criteria"*), which introduces a deviation from the definition of the weight of evidence that is included in annex I of the CLP regulation. We recommend that the wording refers to the determination of a *"single weight of evidence"* (CLP regulation, Annex I, point 1.1.1.3).

Paragraph 4.2.2.3.1. Weight of evidence and expert judgement (p.8):

- As in the case of the human health section, while we welcome the effort to provide details on the relevant scientific data to be taken into account, we again regret the deviation from the CLP Annex I definition of the weight of evidence. In particular, the text must clearly allow for the use of grouping and read-across beyond the analysis of the endocrine mode of action (i.e., also for adversity). We recommend sticking to the language of CLP Annex I, when detailing the relevant scientific data to be taken into account, including re-introducing the explicit mention of *"information from the application of the category approach (grouping, read-across)"* (CLP regulation, Annex I, point 1.1.1.3).

Paragraph 4.2.4. Hazard communication (p.11)

- We still support the introduction of a pictogram as part of the labelling elements of the criteria.
- Regarding the hazard statements, as mentioned in previous comments, we would like to see the impacts on future generations reflected. We therefore propose to amend the statements as follows:
    - Category 1: *"EUH340: May cause endocrine disruption and harm the offspring and the environment"*
    - Category 2: *"EUH341: Suspected of causing endocrine disruption and harming the offspring and the environment"*