CHEMTrust
Protecting humans and wildlife from harmful chemicals

Submission

CHEM Trust written comments to the public consultation on:

'Commission delegated Regulation, incl. Annexes, amending the CLP Regulation'

New CLP hazard classes for EDs, PBT/vPvBs and PMT/vPvMs

17 October 2022

CHEM Trust welcomes the opportunity to comment on the European Commission´s draft Delegated Regulation amending the CLP Regulation as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures.

CHEM Trust fully supports the introduction of new hazard classes for endocrine disrupting properties, PBT or vPvB properties, and PMT or vPvM properties, as this will contribute to an improved protection of human health and the environment. Moreover, it will ensure transparency in supply chains and promote a global effort to increase the level of protection by introducing these hazard classes into the GHS.

CHEM Trust particularly welcomes the ED hazard classes with 2 categories reflecting the different level of evidence for substances' ED properties, as well as the introduction of new hazard classes for (very) persistent and (very) mobile substances.

In our view some important clarifications for consistency are still needed. Please find below our specific suggestions for text changes and respective justifications.

ED hazard classes: Suggestions for specific changes to the legal text (marked in red):

3.11.1.1 and 4.2.2.1 – Definition of `biologically plausible link´
The definition of the biologically plausible link should be phrased in line with the ECHA-EFSA guidance document. The current wording does not capture the meaning of biological plausibility. Proposed text change:

- (*f) biologically plausible link means a plausible correlation between ~~one or a series of biological processes leading to~~ an adverse effect and an endocrine activity, where the correlation is consistent with existing knowledge*

Table 3.11.1/4.2.1 Criteria Category 1:
i)Amend wording to ensure that a decision on Cat 1 identification can be made using information from structural analogues and read-across, as well as other alternative approaches/NAMs.

Proposed text change:
- The classification in Category 1 should be largely but not exclusively based on evidence from human or animal data, or from both human and animal data, possibly supplemented with other information.
ii)Proposed text change:
- (b) an adverse effect in an intact organism or its offspring or future generations.
-iii) The last sentence is superfluous and rather adds confusion and uncertainty re the categories.
Proposed text change: *3.11.1. Delete last sentence*

Table 3.11.1 and 4.2.1 Criteria Category 2.:
i)Amend wording to be in consistency with Cat 2 for reproductive toxicity (`some´ evidence), and to ensure that a decision on Cat 2 identification can be made using information from structural analogues and read-across, as well as other alternative approaches/NAMs. Proposed text change:
- The classification in Category 2 shall be largely but not exclusively based on some evidence from human or animal data, or from both human and animal data, possibly supplemented with other information.
ii)Proposed text change:
- (a) *there is some evidence of an endocrine activity and an adverse effect in an intact organism or its offspring or future generations.*
iii) Proposed text change:
[- (c) *there is some evidence of a biologically plausible link between the endocrine activity and the adverse effect.*

3.11.2.2 and 4.2.2.2 Basis of classification
The current text proposal for ED hazard classes (human health and environment) misses an overall weight of evidence determination. This is not in line with current practice (section 1.1.1.) and the ECHA/EFSA ED guidance document (see e.g. section 3.5).
Proposal for text change:

- *Classification (…) and a weight of evidence determination of each of the criteria (see section 3.11.2.3) and an overall weight of evidence determination (see section 1.1.1.3).*

3.11.2.3.1 and 4.2.2.3.1 Weight of evidence and expert judgement
As laid down in section 1.1.1.3 (already existing text in CLP Annex 1), it should be specifically stated in the text that read across and grouping of analogue substances can be used for ED identification. Moreover, it should be specifically stated in the text that group identifications can be performed.
Proposal for text change:

- *3.11.2.3.1. In applying the weight of evidence determination as referred to in section 1.1.1.3 using expert judgment, all available relevant scientific data …..*
- *a) in vivo studies, studies performed with adequately validated alternative test systems) in vitro, in silico studies) predictive of adverse effects or endocrine activity in humans or animals*
- *b) data from analogue substances using structure-activity relationships (SAR) and read across, informing about endocrine modes of actions or adverse effects in humans or animals*
- d) *any additional acceptable data, including from application of the category approach (grouping considerations)*

***3.11.2.5, 4.2.2.5 and 3.11.4.2, 4.2.4.2* Transition times**
Transition times should be shortened for ED classification and labelling to provide the necessary information to the supply chains for the benefit of workers and the public.
- application times should be changed to 12 and 18 months for substances' classification and labelling, respectively.

***3.11.3.4, 4.2.3.4 and 3.11.4.3, 4.2.4.3* Transition times**
- application times should be changed to 24 and 36 months for mixtures' classification and labelling, respectively.

Table 3.11.2 and 4.2.2
As previously commented, setting generic concentration limits is a method widely used but has severe limitations when it comes to non-threshold substances, and especially to EDs. The usual principles for toxicology cannot always be applied due to ED specificities (non-threshold substances, low dose effects and NMDRs). If generic concentration limits are included, the text should at least foresee a review of the relevance of using the approach in the next 4 years.

Table 3.11.3 Label elements
The hazard phrase should specifically mention the harm to the unborn child/offspring and a pictogram should be introduced.
-EUH380: May cause endocrine disruption in humans and harm the unborn child/future generations
- EUH381: Suspected of causing endocrine disruption in humans and harm the unborn child/future generations

Table 4.2.3 Label elements
-EUH430: May cause endocrine disruption in the environment and harm the offspring/future generations
- EUH431: Suspected of causing endocrine disruption in the environment and harm the offspring/future generations

PBT/vPvB hazard classes: Suggestions for specific changes to the legal text (in red):

4.3.2.1.2 Bioaccumulation
The current bioaccumulation criterion is too limited and moreover, usually only available for chemicals above 100 tpa. Therefore it should be expanded with the logKow, which is used for CLP classification for aquatic tox chronic 1 and 2 and can be obtained without the use of animal testing.
Proposal for text change:
A substance shall be considered to fulfil the bioaccumulation criterion (B) where the bioconcentration factor in aquatic species is higher than 2000 or the log Kow>4.5

4.3.2.1.3 Toxicity
The current T criterion should be expanded to include consideration of category 2 for C and M substances as well as ED as is already the case for reprotoxic substances.
Proposal for text change:
b) *the substance meets the criteria for classification as carcinogenic (category 1 A, 1B or 2), germ cell mutagenic (category 1 A, 1B or 2) or toxic for reproduction (category 1 A, 1 B or 2) according to sections 3.5., 3.6. or 3.7*

d) *the substance meets the criteria for classification as endocrine disrupter (Category 1 or 2) for humans or the environment according to sections 3.11. or 4.2.*

4.3.2.3.2. Assessment of B or vB properties
The purpose of this section is to specify which information can be used in the assessment of B or vB properties. We propose to add the word `subpopulations` to clarify that information from field studies at certain regional scale cannot be dismissed in the assessment.
Proposal for text change:
b) (iii) detection of elevated levels in biota, in particular in endangered species or (sub)populations, compared to levels in their surrounding environment

Table 4.3.1 Label elements
In order to communicate the particular properties of these substances the hazard statement should mention persistence as well as the potential for transfer from the mother to the baby.

Transition times
The transition times are too long and should be shortened in line with the suggestions made for the ED hazard classes above.

PBT/PMT hazard classes: Suggestions for specific changes to the legal text (in red):

4.4.2.1.2. Mobility (M)
In CHEM Trust view the criteria used for the new hazard classes must be protective to avoid persistent water contaminants falling through the net. In the present case, the size of the net is defined by the log Koc threshold. Therefore we propose a log Koc cut-off of <4 for M. Several very persistent and toxic substances identified in drinking water resources be missed if the highest cut-off value for log Koc was 3. (For details see our previous comments.)
Proposal for text change:
A substance shall be considered to fulfil the mobility criterion (M) when the log Koc is less than 4.

4.4.2.1.3 Toxicity
As for PBT substances: The current T criterion should be expanded to include consideration of category 2 for C and M substances as well as ED as is already the case for reprotoxic substances.
Proposal for text change:
b) *the substance meets the criteria for classification as carcinogenic (category 1 A, 1B or 2), germ cell mutagenic (category 1 A, 1B or 2) or toxic for reproduction (category 1 A, 1 B or 2) according to sections 3.5., 3.6. or 3.7*
d) *the substance meets the criteria for classification as endocrine disrupter (Category 1 or 2) for humans or the environment according to sections 3.11. or 4.2.*

4.4.2.2.2. Mobility (vM)
A substance shall be considered to fulfil the ´very mobile´criterion (vM) when the log Koc is less than 3.

Transition times

The transition times are too long and should be shortened in line with the suggestions made for the ED hazard classes above.