NGO comments following the 5th CASG-ED meeting

7th October 2021

The Health and Environment Alliance (HEAL), CHEM Trust, and the European Environmental Bureau (EEB) thank the European Commission for the opportunity to provide written comments in follow-up to the 5th CASG-ED meeting, which took place on 13th September 2021.

General comments

We were surprised about format of the meeting and the narrow scope of the agenda and questions discussed. Many comments were sent by the subgroup members following the 4th meeting, and it is currently very hard to understand how these are being processed. Overall, this situation makes the response to the specific questions that are now being raised difficult due to a lack of important context.

Therefore, we would recommend that the Commission prepares a document that compiles all the comments from stakeholders proposing amendments in order to make the process more transparent.

Comments in response to the four questions discussed during the meeting

Question 1 – What is the view of the experts regarding the alternate option for the drafting of the hazard categories?

The European Commission recently proposed new wording for the drafting of the hazard category 1, which integrates the criteria for an endocrine disrupting chemical in the definition of the hazard category and reads as follows:

> *"Known or presumed endocrine disruptors for human health*
>
> *The classification in Category 1 is based on evidence from human and/or on data from animal studies. Such data shall provide clear evidence of endocrine disruption, i.e.,*
>
> *a) it shows an adverse effect in an intact organism or its progeny; and*
>
> *b) it shows endocrine activity; and*
>
> *c) the substance has an endocrine disrupting mode of action, i.e. there is a biologically plausible link between the endocrine activity and the adverse effect.*
>
> *However, when there is information that raises doubt about the relevance of the endocrine disrupting mode of action for humans, classification in Category 2 may be more appropriate."*

Our organisations can fully support the text changes and the proposal to move the text from section 3.11.1.2 to section 3.11.2.1, and the integration of the criteria for endocrine disruptors (ED) into the table 3.11.1 with the hazard categories for human health. This will ensure coherence with the existing approach for carcinogens, mutagens and reprotoxicants (CMR). In addition, it is important to stress that this text is not per se a definition. It rather outlines elements of the criteria that clarify

the level of evidence required to identify a substance as an ED, when implementing the WHO definition in the CLP Regulation.

We support a similar text change and related section move of the criteria text for the ED hazard class for the environment.

As we have highlighted in previous written HEAL-CHEM Trust[1] comments, we would, however, like to see the following aspects reflected:

- **The distinction between Category 1A and 1B,** which we believe is important to reflect the level of available scientific evidence supporting the categorisation;
- The specification that classification as a Category 1 substance **is largely, <u>but not exclusively</u>, based on evidence from humans and/or on data from animal studies, <u>possibly supplemented with other information (such as read-across data)</u>**.

Science is constantly advancing, leading to the development of new methods for ED identification, and the REACH legislation stipulates that animal testing should only be used as a last resort. Therefore, in the course of ED identification, it should also be possible to use other information than animal studies that might be available, e.g. information that increases the level of evidence to conclude that it is plausible that the observed adverse effects are endocrine-mediated, or that it is plausible that the substance will have endocrine disrupting properties *in vivo.*

Question 2 – What is the opinion of the experts of the CASG-ED regarding this alternate proposal for Category 2?

The European Commission recently proposed the following reworked wording for Category 2:

> *"Suspected endocrine disruptors for human health*
>
> *A substance is classified in Category 2 for endocrine disrupting properties, if:*
>
> - *The evidence is sufficient to presume that the substance meets 2 of the 3 criteria below; and*
> - *For the remaining criteria not covered by the previous point, some evidence is available, but not sufficiently convincing to place the substance in Category 1.*
>
> *The 3 criteria to be assessed are:*
>
> *a) the substance shows an adverse effect in an intact organism or its progeny;*
> *b) the substance shows endocrine activity;*
> *c) the substance has an endocrine disrupting mode of action, i.e. there is a biologically plausible link between the endocrine activity and the adverse effect.*
>
> *If the criteria cannot be applied directly, a substance can be classified as Category 2 by a weight of evidence determination using expert judgment used in accordance with Art. 9(3) and 9(4) with the same level of evidence as mentioned in the first paragraph."*

[1] See Joint Health and Environment Alliance and CHEM Trust comments on EC proposal for CLP hazard class for EDCs, https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_draft-final_1.pdf ; April 2021

Our organisations strongly disagree with the above proposal, which requires a very high level of evidence to allow for the identification of suspected EDs and will make such identification extremely difficult in practice.

First of all, it is important to keep in mind that it is difficult to fully separate the three elements of the criteria for the identification of an ED and assess them completely independently from each other. As experts involved in ED identifications know well, the identification process is a weight of evidence evaluation requiring expert judgements on these three different elements in parallel. In real-life, there is often some evidence for adverse effects and for ED activity; and then a plausible link between these two is assumed, unless authorities have information that would suggest the opposite. In this context, suggesting that two elements of the criteria should be fully met and a third one partly evidenced to identify a suspected ED makes no sense from a scientific point of view.

Second, it is important to highlight that the added-value of introducing a Category 2 is precisely to allow authorities to make a decision in a context of difficult cases, for which we have some evidence, (even moderate) on at least one of the elements, yet without being able to confidently draw a conclusion to place the substance in Category 1. The latest proposal runs counter to this aim by requesting a level of evidence that is as high, if not even higher, as that necessary for Category 1 substances because it requires that the elements of the criteria should be evidenced separately. Furthermore, the development of a hazard class for ED should be fully in line with those existing for CMR substances. For the latter hazard classes, substances are placed in Category 2 when the evidence is not sufficient to place them in Category 1, regardless of the cause for the lower level of evidence. Therefore, it makes no sense to raise the level of evidence necessary for a classification in Category 2 specifically for endocrine disrupting substances.

To conclude, we would like to draw the Commission's attention to:

- Text comments we provided in response to the original Commission's proposal, and whereby we suggested that Category 2 could read as follows: ***"A substance is classified in Category 2 for endocrine disruption for human health when there is evidence of endocrine disruption, and where the evidence is not sufficiently convincing to place the substance in Category 1."***[2]
- The recent joint CHEM Trust paper-HEAL-ClientEarth, in which we suggested detailed wording regarding the necessary level of evidence to define a Category 2 substance: ***"the overall level of evidence for endocrine-mediated adverse effects should be at least moderate for at least ONE of the elements: 1) adverse effects, 2) ED MoA (in vitro or in vivo) or for 3) a biologically plausible link."***[3]

We believe that the combination of these two proposals would offer a good alternative to the current wording suggested by the Commission and would best serve the identification of suspected EDs.

Lastly, it should be emphasized that the purpose of hazard classification is to contribute to the protection of human health and the environment against hazardous substances, by providing information about hazards and precautionary measures. The ED Category 2 is important for the identification of all those substances, for which there is a substantial amount of data to suspect that they are endocrine disruptors but for which the evidence does not meet the criteria for ED Category

[2] Ibid, pp. 5-6

[3] CHEM Trust, HEAL, ClientEarth, "Identification of Eds under CLP – Criteria for hazard classification of Eds and allocation to hazard categories, incl. for Suspected EDs", https://www.env-health.org/wp-content/uploads/2021/03/Joint-CT_HEAL_CE-proposal-on-CLP-ED-criteria-March-2021-final-with-date.pdf ; p.15

1. Therefore, the level of evidence required should not be as high as for the ED Category 1 and certainly not higher than what is requested for Category 2 CMRs. An ED Category 2 is crucial for increasing protection levels (e.g. ensuring better consumer protection under the cosmetics, toys and food contact materials regulations). It would also contribute to increased transparency and the implementation of 'the right to know' through clarifying which substances need to be substituted in the future and enabling companies and the public to make informed choices.

Question 3 – Do the experts support the modification of "(sub-)population" with "population"?

Our organisations are <u>fully opposed</u> to this proposal. The word '(sub)-population' is a part of the WHO definition of an endocrine disruptor, and we see no justification for it to be excluded from the text. Such an exclusion would limit the assessment. Information about subpopulation is needed, in particular in the context of the integration of the data on human health and environment, respectively.

Question 4 – What are the views of the experts regarding the pictograms, Pstatements and signal words proposed?

In general, our organisations <u>can agree</u> to the proposals that are presented. We are missing a precautionary statement about the potential harm to the unborn child, which we remember had gathered support during the last meeting. Please bring back the P263 statement in the text: *'Avoid contact during pregnancy/while nursing'.*

Question 5 – Which options do the experts support?

On the hazard phrase, we acknowledge that it is not easy to reach the right balance, also keeping in mind possible translation issues. We hereby would like to express our **<u>support for the first option</u>** proposed:

> *"EUHXXX: May cause endocrine disruption on human beings."*
> *"EUHXXX: May cause endocrine disruption on the environment."*

Alternatively, we a**lso refer to the options our organisations had proposed in our previous written comments**[4]:

> *"May cause endocrine disruption and harm the unborn child and human health".*
> *"May cause endocrine disruption and harm the offspring and the environment".*

After considering the comments discussed at the 5th CASG ED, **we would further suggest that the wording *'the environment'* in both of the above sentences is replaced by *'species in the environment'***.

Question 6 - Should we give the possibility to precise specific effect of concern or primary target organ?

Our organisations are <u>not in favour</u> of this possibility, which we believe presents practical challenges and might turn very resource intensive to implement.

[4] Joint Health and Environment Alliance and CHEM Trust comments on EC proposal for CLP hazard class for EDCs, April 2021; https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26.HEAL_CT_comments_CLP_proposal_EDCs_draft-final_1.pdf ; p. 13 and p. 23

First of all, the hormonal system is very complex and intercommunicative, and the very challenge of endocrine disruption is inherently related to potential impacts on various organs. For instance, when it comes to disruption of the functioning of the thyroid hormone system, it is precisely the potential adverse effects of such disruption for other organs - such as the developing brain - that are of concern and often more difficult to capture.

Second, the development of hazard categories for ED must serve the swiftest possible identification as soon as the requested level of evidence is met for the criteria. In practice, the possibility mentioned here above might be used to challenge available evidence regarding certain types of adverse effects (e.g. on fertility) because other effects are less documented in the identification dossier. This should be avoided at all costs. We also fear that such possibility might lead to requests for further unnecessary animal testing to investigate some of the concerns when the aim of the exercise should really be to use all the data more efficiently.

This said, we are in favour of transparent information and therefore, we find it highly recommendable that the P-statement includes the wording *'may harm the unborn child or the offspring'* for human health or the environment, respectively.