



Health and Environment Alliance (HEAL)

August 2020

Comments in response to the European Commission paper on “Options to include criteria for endocrine disruption in the CLP Regulation” presented at the second CASG-ED meeting on 2nd July 2020 (CASG-ED/2020/06)

Sent by email to: ENV-CARACAL@ec.europa.eu and GROW-CARACAL@ec.europa.eu

The Health and Environment Alliance (HEAL) thanks the European Commission for the work invested in the preparation of the paper on “Options to include criteria for endocrine disruption in the CLP Regulation” and of the second CASG-ED meeting on 2nd July 2020, in which the paper was presented and discussed. We welcome the opportunity to comment on the above mentioned paper.

Hereby HEAL would like to express its support for proposed option (i): (introduce new hazard class(es) in CLP).

- As we have expressed on numerous occasions, including in our [response](#) to the recent public consultation on the EU fitness check on endocrine disruptors, the current lack of provisions allowing for harmonised hazard assessment of endocrine disruptors is a major issue, which is at the source of major inconsistencies across regulations and most importantly inadequate protection measures for people and the environment.
- In HEAL’s view, EDC identification should be based on the hazard profile of the substance, in line with the latest scientific knowledge and the different levels of evidence. Because of EDCs’ specificities (low-dose effects, non-monotonic dose response, varying windows of human vulnerability, possible delays between exposure and effects, cocktail effect) every effort should be made to facilitate identification of EDCs across sectors.

On the basis of our analysis of the different options presented, **we are of the opinion that creating specific hazard class(es) under the CLP regulation is possible and currently the best presented option in order to reach the objectives mentioned above.**

- Option (i) would help recognize that EDC hazard is at least equivalent to that of substances with carcinogenic, mutagenic or reprotoxic properties (CMRs) and provide for consistency in the hazard identification step of substances, as different regulations derive risk management measures based on the CLP classification. This would also increase clarity the EU assessment of known and suspected ED substances, likely boost public confidence in it, and contribute to a more effective use of the EU resources devoted to assessment.
- Importantly, CLP hazard class(es) for EDCs would work towards an improved information flow throughout supply chains and towards workers.
- We are thankful for the example provided that illustrates clearly that the EU moving forward with on the CLP front is possible without first going to the UN GHS system and that a successful precedent indeed exists. All the conditions are therefore met for the Commission and Member States to move forward in developing proposals for such hazard class(es).
- We also note that the EU regularly boasts about having the most advanced chemical regulatory system in the world. The creation of a hazard class(es) for endocrine disruptors is

a prime opportunity to match words with action and demonstrate that the EU is indeed leading by example. In this regard, we noticed several references to the US screening system for EDCs during the last CARACAL meeting. While it is good for the EU to stay aware of what is happening in the rest of the world, we need to highlight that to date this screening programme has not led to ED identification, and therefore we do not find such reference very useful in the present discussion.

Recommendations for next steps in the process

For Member States:

- **Support the option (i)** presented by the European Commission and constructively contribute knowledge in further developing this option.
- **Mobilise work currently undertaken at national level** (e.g. to develop various ED lists, including lists of suspected EDCs), and join forces to help operationalise the categorisation of ED hazard under CLP. For instance, Member States could share past or ongoing examples of analysis of individual substances in order to compare the different levels of evidence and initiate the thinking on where to draw the line between known, presumed and suspected EDCs based on concrete cases.

For the European Commission and Member States:

- Seize the important opportunity of this hazard class(es) proposal development to:
 - o **Include different levels of EDC characterisation** according to the available levels of scientific knowledge and evidence in the CLP class(es) under development, differentiating between know (1A), presumed (1B) and suspected (2) EDCs. This would be in line with the WHO definitions, which cover known and potential endocrine disruptors.
 - o **Operationalise the definition of ‘suspected’ EDCs**, based on concrete examples (as mentioned above), existing testing requirements under the OECD GD 150, and useful scientific concepts, such as the key characteristics (for instance by using the recent “Consensus statement on key characteristics of endocrine disrupting chemicals as a basis for hazard identification” (Michele A. La Merrill et al., Nature Reviews, Endocrinology, Vol 16, Jan 2020) in order to clarify crucial ED characteristics that might not fully be captured by standard test methods - such as the alteration of hormone receptors, of signal transduction in hormone-responsive cells, of hormone metabolism or clearance, of fate of hormone producing or hormone responsive cells, of hormone synthesis, of hormone distribution or circulating hormone levels; induction of epigenetic modifications in hormone-producing or hormone responsive cells... In HEAL’s view, the mobilisation of all of the tools mentioned above can be helpful to fully define a suspected EDC, for which evidence will typically only allow concluding on one but not all of the following three parameters: the substance adverse effect, its endocrine mode of action, or the plausible link between the two.



- **In developing the above mentioned proposals, guarantee the involvement of leading independent scientists specialised in endocrine disruption**, including the Endocrine Society and the scientists involved in the EURION cluster for the development of new test methods for EDCs.
- **Clarify the timeline and next steps** for the current process to move forward, including on the related and important aspect of the update of the information requirements for endocrine disruptors that is also covered by the mandate of this subgroup.

Contact:

Natacha Cingotti, Senior Policy Officer, Health and Environment Alliance, natacha@env-health.org