European Society of Endocrinology

The voice for endocrinology

18 October 2022

Re: Public consultation on the amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging (CLP) of substances and mixtures

The European Society of Endocrinology (ESE) welcomes the ambition of the Commission to create a non-toxic and safe EU environment as laid out in the Chemical Strategy for Sustainability. ESE has continuously pointed to the growing importance of appropriate legislation and guidance on classifying and identifying Endocrine Disrupting Chemicals (EDCs) within the European and wider international community. Being able to label and classify EDCs as such is an important first step towards a phaseout that will protect human health and the environment.

Strict regulation of EDCs is pivotal to address the many adverse health outcomes associated or linked with exposure to EDCs including altered reproductive function in men and women, abnormalities in sex organs, endometriosis, early puberty, altered nervous system development and function, immune function disorders, cancers, neuroendocrine tumours, respiratory problems, diabetes, obesity, cardiovascular conditions, neurological issues and learning disabilities. These effects have been described extensively in peer reviewed literature.

We are pleased to see that the current proposal establishes legally binding hazard identification of EDCs by adding hazard classes. Clear classification makes it easier to restrict EDCs once the criteria are met. Adding a "category 2" of suspected endocrine disruptors will enable the classification of substances for which there is substantial evidence to be categorised as a known or assumed EDC and exempts only those substances where evidence conclusively demonstrates that adverse effects are not relevant to humans. This will provide workers and the general public with crucial information for their health and safety and improve supply chain transparency.

We also support the fact that a chemical will be regarded as fulfilling the toxicity criterion (T) in any of the cases where it satisfies the requirements for being classified as an EDC. ESE further applauds hazard classes and criteria for the classification, labelling and packaging of substances and mixtures.

We only have a few suggested changes that may be considered:

- **3.11.1.1 (a):** The definition presented here does not align with the WHO definition. To ensure consistency we suggest to change the text to "'endocrine disruptor' means a substance or a mixture that alters the functioning of the endocrine system …"

- **3.11.1.1 (f):** this should be reworded to better reflect that a correlation between a chemical and the endocrine system can also be theoretical. The sentence "where the correlation is consistent with existing knowledge" can be deleted.

- **Table 3.11.1:** For category I and category II, in the sentence "an adverse effect in an intact organism or its offspring and future generations", "and" should be replaced with "or".

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- **Table 3.11.2**: In our view there is no safe threshold for exposure to EDCs and hence we recommended that for category I not to allow any concentration of an EDC as a component of a mixture

The surmised administrative burden from revisiting the criteria of classification should not distract from the efforts put towards ensuring a high level of protection for human health and the environment. We invite policy makers to keep relying on experience and increased peer reviewed scientific knowledge, as there is decisive evidence showing that EDCs pose a significant concern for human and animal health as well as our general environment.

ESE will continue to support the Commission's goal to create a more resilient EU society and as such is available to provide more detailed scientific input where requested in a formal or more informal manner.

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