

A. Context and Problem

The Endocrine Society welcomes the proposal to revise the European Union (EU) legislation on Classification, Labeling and Packaging of chemicals (CLP) to align legislation with the objectives described in the Chemicals Strategy for Sustainability (CSS). As the world's leading experts on the subject of chemical interference with endocrine systems, our comments propose several recommendations that would allow EU regulators to more effectively minimize exposure to endocrine-disrupting chemicals (EDCs) and thereby reduce the incidence of chronic diseases associated with EDC exposure such as cancer, diabetes, neurodevelopmental disease and infertility.

B. Objectives and Policy Options

EDCs should be included as a critical hazard class: There are several features of EDCs that require special consideration by regulatory agencies when evaluating these chemicals for health effects¹. For example, the effects of EDCs can be seen at extremely low levels, often display non-monotonic dose responses (NMDR)², and may act on multiple generations through epigenetic effects³. In addition to a special hazard class for known EDCs, a separate class of suspected EDCs should be included with regulatory consequences to allow protective actions to apply to many more EDCs. The suspected category is necessary because despite abundant information generated about individual and classes of chemicals, only 20 chemicals have met regulatory thresholds for identification as EDCs.

Improved data requirements for EDCs are necessary: For revisions to the CLP regulation to have the desired effect, these changes must be coupled to updates to REACH requirements to improve and update data provisions for effects on endocrine systems and other particularly concerning hazards such as neurodevelopment and immune systems in order to provide sufficient data for accurate identification. Newer testing and screening methods should be developed and implemented that take advantage of the latest science to make use of more sensitive, clinically relevant endpoints within these hazard domains, such as mammary gland and brain development.

C. Assessment and Impacts

Our members were extremely encouraged by important commitments in the CSS to improve public health by minimizing exposures to EDCs. Revisions to CLP should advance these commitments and prioritize protections from EDCs. In doing so, regulations will be better able to advance the social benefits of the CSS and achieve more equitable public health outcomes in particular for susceptible

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¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3423612/

² https://academic.oup.com/jes/article/4/10/bvaa085/5869417

³ <u>https://onlinelibrary.wiley.com/doi/10.1111/bcpt.12878</u>



populations such as infants, pregnant women, and adolescents; and also low-income communities and other marginalized groups who may face disproportionate EDC exposures and effects. In conclusion, we believe that by addressing the recommendations above the revision to CLP legislation will better protect public health and reduce the impact of disease on EU citizens. Any forthcoming impact assessment studies need to adequately consider these significant benefits.

We thank the Commission for considering our comments and look forward to engaging further during the open public consultation.