

June 15, 2017

Dear Minister,

On behalf of The Endocrine Society, the European Society of Endocrinology and the European Society for Paediatric Endocrinology, representing the world's leaders in endocrinology and endocrine science, we express our serious concern with the European Commission's proposed criteria on Endocrine Disruptors (EDs). As scientific and medical professional societies devoted to the study of hormone-related diseases and disorders, we recognize that EDs contribute to serious health problems such as diabetes, obesity, and neurodevelopmental and reproductive disorders. These diseases affect the health and quality of life for people around the world and scientific criteria to effectively identify and regulate EDs are critical to ensure the health and well-being of the public, for this and next generations.

The criteria, as currently constructed, will likely fail to identify EDs that are currently causing human harm, and will not secure a high level of health and environment protection as required per the Treaty on the European Union (EU). Furthermore, the criteria contain arbitrary exemptions for chemicals specifically designed to disrupt target insect endocrine systems that have similarities to systems in wildlife and humans. Consequently, the criteria cannot be called science-based, nor can they be considered as "fit for purpose" according to the better regulation strategy, as they lack coherence and will not be effective or efficient. We strenuously object to the addition of loopholes in the criteria. This creates divergent frameworks wherein certain chemicals that are designed to be EDs cannot be defined as EDs in the context of applicable laws.

While the Commission's current proposal is largely based on the World Health Organization's definition of an ED, **the criteria will not be effective** in protecting public health because they do not integrate a process to address those chemicals where additional scientific evidence may be needed to arrive at a suitable level of confidence for a determination. Consequently, many EDs will not be identified as such via the criteria as currently written. The pace of scientific knowledge on potential EDs is increasing rapidly, as demonstrated by recent reviews of the peer-reviewed scientific literature wherein many studies were published in the last decade.

Our societies are disappointed that the criteria do not align with Option 3 as originally presented in the European Commission Roadmap. This option would have created an efficient, effective, and coherent system for the identification of EDCs that would be synergistic with the identification scheme for carcinogens. We appreciate that representatives and government officials from the EU Member States will have an important role in improving the criteria, and that further input will be critical. Taking into account the current proposal, we urge Member States to work towards improved criteria for the identification of EDCs by incorporating the following recommendations:

1. Removing the exemption for biocides and pesticides designed to act on endocrine systems;

2. Adhering to a science-based definition of EDCs that includes categories for known EDCs and chemicals for which more information is needed to make a determination; and
3. Maintains a hazard-based identification system, without derogations based on risk.

Thank you for considering our comments. If you have any questions, or would like to connect with an expert endocrine scientist, please contact Joseph Laakso, PhD, Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

A handwritten signature in blue ink that reads "Angel Nadal". The signature is fluid and cursive.

Prof. Angel Nadal, PhD
Chair, Endocrine Society EDC Advisory Group

A handwritten signature in blue ink that reads "A.J. van der Lely". The signature is stylized and somewhat abstract.

Prof. A.J. van der Lely, MD PhD
President of the European Society of Endocrinology

A handwritten signature in black ink that reads "Peter Clayton". The signature is written in a cursive style with a horizontal line underneath.

Prof. Peter Clayton, MD, MRCP, FRCPCH
Secretary-General, European Society of Paediatric Endocrinology