

Jean-Claude Juncker
President, European Commission
Rue de la Loi / Wetstraat 200
1049 1049 Brussels
Belgium

Frans Timmermans,
First Vice-President, European Commission
Rue de la Loi / Wetstraat 200
1049 1049 Brussels
Belgium

April 02, 2017

Dear President Juncker and First Vice-President Timmermans,

On behalf of the Endocrine Society, I am writing to express our serious concern with the Commission's proposed criteria on Endocrine Disruptors (EDs). The criteria, as currently constructed, will likely fail to identify many ED and won't secure a high level of health and environment protection as required per EU Treaty on the European Union (EU). Furthermore, the criteria contain exemptions for chemicals specifically designed to disrupt the endocrine system. 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.

Founded in 1916, the Endocrine Society is the world's oldest and largest scientific society dedicated to the study of endocrine systems and treatment of endocrine disorders. Our membership of over 18,000 from over 120 countries includes the world's leading experts on hormones and endocrine disrupting chemicals. Our researchers and clinicians are motivated by the desire to advance biomedical research and improve public health.

While the 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 may not be identified as such via the criteria as currently written. The pace of scientific knowledge on potential EDs is increasing rapidly. The Endocrine Society's second scientific statement on EDCs, released in 2015, contains over 1300 references to peer-reviewed scientific literature, most of which were published in the last decade.

We also strenuously object to the addition of loopholes in the criteria. As currently written, the criteria contain an exemption designed to exclude certain biocides and pesticides that act by interfering with endocrine systems. This exemption is arbitrary in the context of an identification



process that is supposed to be science-based. **The criteria therefore lack coherence** by creating divergent frameworks wherein certain chemicals that are designed to be EDCs cannot be defined as EDCs in the context of applicable laws.

The Endocrine Society is disappointed that the criteria do not align with Option 3 as originally presented in the EDC 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. Taking into account the current proposal, we ask the Commission to improve the criteria for the identification of EDCs by:

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. Maintain 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 member of the Endocrine Society, please contact Joseph Laakso, PhD, Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

A handwritten signature in black ink that reads "Henry Kronenberg".

Henry Kronenberg, MD
President
Endocrine Society