

July 9, 2019

Re: Harmful chemicals – endocrine disruptors, review of EU rules

Dear Members of the Joint Research Centre Directorate on Health, Consumers and Reference Materials,

The Endocrine Society appreciates the opportunity to comment on the Roadmap for the Fitness Check on Endocrine Disruptors. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. Our membership of over 18,000 includes researchers who are making significant contributions to the advancement of knowledge in toxicology, especially in the field of endocrine-disrupting chemicals (EDCs). Our comments were developed in consultation with the Endocrine Society's EU Task Force, comprising a select group of 11 members of the Society based in 7 EU member states.

Endocrine Society welcomes EU EDC Fitness Check

We share the concern expressed by many stakeholders that the current legal framework governing various sources of exposure to EDCs is not sufficiently coherent, and legal gaps exist that may increase exposure to harmful EDCs through multiple sources. The Endocrine Society particularly welcomes the stated aim of the Fitness Check to minimize exposure to EDCs as well as the horizontal approach to the identification of endocrine disruptors. We look forward to engaging with the Commission on the development of comprehensive regulatory strategies for cosmetics, toys, food contact materials, construction materials, textiles (including interior trim and upholsteries) and other sectors of the economy. In our comments, we share several recommendations aimed at ensuring that the Fitness Check properly assesses the existing regulatory framework based on the latest scientific knowledge of EDCs and endocrinology.

The Latest Scientific Studies Should Inform the Fitness Check

Upon review of the section on data collection and methodology, we are concerned that many important scientific references will not be taken into consideration using the listed sources. Our knowledge of chemical interference with the endocrine system has advanced substantially since the point of comparison in 1999, and there is a scientific consensus among endocrinologists and other researchers in the field that EDCs pose health risks. The regulatory consequences will need to account for technical features of endocrinology such as non-monotonic dose responses, timing of exposure, as well as chemical mixtures and combination effects. We urge the Commission to conduct a systematic review of published literature; in particular we recommend the inclusion of the following consensus documents in the Fitness Check:



- The Endocrine Society's Second Scientific Statement on EDCs¹
- Supporting the organization of a workshop on thyroid disruption 2017 – Final Report²
- State of the Art Assessment of Endocrine Disrupters (Rev 29 Jan, 2012)³

These reports included the perspectives of many expert scientists and a variety of stakeholders. We also maintain that the report and conclusions of the recent study on Endocrine Disruptors, commissioned by the European Parliament's Petitions Committee and presented to MEPs in April, are highly relevant to the Fitness Check⁴.

Potential Regulatory Actions Should be Clarified

Following from the science cited above, we now have more detailed and extensive knowledge about exposures to humans and wildlife, and consequent harms, than we did when the first Strategy on endocrine disruptors was adopted in 1999. Accordingly, we assert that the Commission's stated goal of minimizing exposures to EDCs⁵ across sectors should be consistent with the regulatory approach in the Biocidal Products Regulation and Plant Protection Products Regulation. Specifically, endocrine disruptors should not be authorized unless exposures are negligible. This would be in alignment with the approach for carcinogenic, mutagenic, and reprotoxic chemicals (CMRs) and consistent with the inherent hazards associated with EDCs.

The level of detail in the Roadmap and Fitness Check should reflect current scientific knowledge and we therefore urge the Commission to:

- Clarify the scope of regulatory approaches under consideration, including hazard-based controls, and the specific measures for how legal gaps will be closed;
- Set ambitious targets for identifying EDCs (consistent with some national strategies in EU);

¹ Gore, AC et al., EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, *Endocrine Reviews*, Volume 36, Issue 6, 1 December 2015, Pages E1–E150, <https://doi.org/10.1210/er.2015-1010>

² Brunel University London and DTU National Food Institute Denmark. ISBN 978-92-79-73427-4 doi: 10.2779/921523 KH-01-17-981-EN-N. European Union, 2017

³ Kortenkamp, A et al., "State of the Art Assessment of Endocrine Disrupters" Project Contract Number 070307/2009/550687/SER/D3. Annex 1 – Summary of the State of the Science.

⁴ Demeneix, B and Slama, R., "Endocrine Disruptors: from Scientific Evidence to Human Health Protection" 2019. Accessed at [http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU\(2019\)608866_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2019/608866/IPOL_STU(2019)608866_EN.pdf) July 1, 2019.

⁵ European Commission. "Towards a comprehensive European Union framework on endocrine disruptors." Brussels, 7.11.2018 COM (2018) 734 final. Accessed at <http://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-734-F1-EN-MAIN-PART-1.PDF> on July 1, 2019.



- Design regulations to account for unique features of EDCs, for example the potential for harm at extremely low doses, potentially indicating no safe threshold for such chemicals, and with consideration for developmental effects, mixture and combination effects;
- Clarify the level of data requirements to inform regulatory decisions where we emphasize the importance of a category-based approach to regulation according to the level of evidence for the chemical in question, i.e., known, presumed, or suspected EDCs. This approach would also allow for the incorporation of new evidence as it becomes available;
- Promote better test methods - including testing requirements for sensitive endpoints that capture interference with endocrine systems and allow regulators to make informed decisions;
- Recognize the need to evaluate groups of chemicals with similar properties for potential regulation to prevent regrettable substitutions, without which regulators will always remain a step behind.
- Consider/Implement regulatory methods for assessment of exposure to mixtures.

Detailed Actions and Concrete Steps Are Needed

We encourage the Commission to take note of the Conclusions on EDCs adopted by the Environment Council on 26 June and the European Parliament resolution on EDCs adopted on 18 April. We share their view that a high level of protection of human health and the environment is necessary and can only be achieved by minimizing exposure to endocrine disruptors through regulatory controls of identified EDCs, including further assessment of suspected EDCs prior to authorization, and stimulating substitution by safer chemicals. We support the call for providing without undue delay an action plan with clear and concrete measures to regulate EDCs and an ambitious timeline for EU action. In the current context, we ask the Commission to proceed expeditiously with the Fitness Check and other proposed actions, such as the stakeholder meeting, towards the development of an effective EU strategy towards consistent regulatory approaches to EDCs.

Sincerely,

Angel Nadal, Ph.D.
Chair, Endocrine Society EDC Advisory Group