

30 October, 2015

Commissioner Vytenis Andriukaitis, EU Commissioner for Health and Food Safety European Commission Rue de la Loi / Wetstraat 200 1049 Brussels Belgium Regarding: European Commission Roadmap on Endocrine Disrupters

Dear Commissioner,

We are writing to you today on the topic of the European Commission Roadmap on Endocrine Disrupters (EDs) and the ongoing Impact Assessment. As you know, the Endocrine Society contributed to the DG Sante Conference on the 1st of June on "Endocrine disruptors: criteria for identification and related impacts", and many of our members from the EU and beyond have followed the debates with great interest. Following on this conference, we would very much welcome the opportunity to discuss further the latest science on EDs, the logic of our perspective on the options laid out in the Commission Roadmap, and the public health implications in a personal meeting with you.

The Endocrine Society, founded in 1916, is the the world's oldest and largest scientific society dedicated to the study and treatment of endocrine diseases. We are proud to be able to claim that our membership of over 18,000 includes the world's leading experts on hormones and endocrine disrupting chemicals from over 120 countries. It is important to emphasize that the Endocrine Society has no financial interest in the issue of EDCs. Rather, our members are motivated by our public health concerns.

In particular we would like to bring an important new publication to your attention: the Endocrine Society's Second Scientific Statement on Endocrine Disrupting Chemicals. (Executive Summary published on 28th September 2015).

The Scientific Statement represents a comprehensive review of the literature on several human health disorders where there is strong evidence for endocrine disruption. Based on over1300 peer-reviewed scientific publications, the statement focuses on progress in knowledge made during the past 5 years and identifies both knowledge gaps to be filled and the domains where new or further evidence of endocrine disruption has been obtained. These include male and female reproductive disorders, hormone-sensitive cancers and impaired neurodevelopmental conditions. The Statement also includes studies of developmental exposures to EDs, especially in the fetus and infant. These are particularly critical life stages during which perturbations of hormones can increase the probability of disease or dysfunction later in life. Moreover, recent evidence suggests that some EDs may be capable of inducing transgenerational effects which may last even after exposure has stopped, and can extend to children, grandchildren, and beyond. A copy of the executive summary, which also includes research recommendations, is attached to this letter.

2055 L Street NW Suite 600 Washington, DC 20036 T. 202.971.3636 F. 202.736.9705 endocrine.org



Endocrine Society members who attended the June 1 meeting have discussed the scientific issues relevant to setting regulatory criteria to identify endocrine disrupting substances in the European Union. The scientific relevance of the 4 options proposed by the European Commission to identify EDs deserve some comments. Option 1 does not explicitly define an ED and is therefore not operational. The other three options proposed by the European Commission include the consensual WHO definition. Only option 3 introduces additional categories based on the level of evidence. The Endocrine Society believes that a multi-level classification makes sense for EDs, and we consider option 3 to be preferrable to the other options. Option 4 includes potency as a criterion, and the Society does not support this option. Potency is not relevant for hazard identification and is highly dependent on testing conditions and endpoints. We note that potency is not used as a criterion to define other hazardous substances such as carcinogens.

The Endocrine Society and its members will continue to contribute scientific expertise to the EU's efforts to set criteria for EDs for better public health protection. The cost of inaction is striking; recent studies by Trasande et al., in the Journal of Clinical Endocrinology and Metabolism show that health effects from ED exposures cost the EU over €157 billion each year. It is therefore important to identify new EDs as they emerge and to continue to improve our scientific understanding of EDs.

You have before you an ambitious and essential task; we urge you to draw on knowledge from advances in the field of endocrinology as you make decisions that will have an impact on human and wildlife populations now and for generations to come.

We look forward to hearing from you and we would welcome and appreciate the possibility to discuss our new publications in a personal meeting.

Sincerely,

Jean-Pierre Bourguignon, MD, PhD R. Thomas Zoeller, PhD

On behalf of the Endocrine Society's Endocrine Disrupting Chemicals Task Force

In copy

To Commissioner Karmenu Vella, EU Commissioner for Environment, Maritime Affairs and Fisheries

To Commissioner Carlos Moedas, EU Commissioner for Research, Science and Innovation To Commissioner Věra Jourová, EU Commissioner for Consumers, Justice and Gender equality