

Jeffery T. Morris,
Acting Director, Office of Pollution Prevention and Toxics.
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: EPA-HQ-OPPT-2016-0399-0001

August 22, 2016

Dear Acting Director Morris,

On behalf of the Endocrine Society, I appreciate the opportunity to provide comments to EPA as it develops its guidance on processes for risk evaluation and chemical prioritization under the amended toxic substances control act (TSCA). 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. The Society's membership of over 18,000 includes researchers who are making significant contributions to our understanding of the effects of exposures to manufactured chemicals that interfere with hormone systems – an area of science investigating endocrine-disrupting chemicals (EDCs). The Society has been involved in the development of TSCA reform legislation and we appreciate EPA's interest in quickly and effectively implementing the Frank R. Lautenberg Chemical Safety in the 21st Century Act.

To ensure that the new law achieves meaningful public health protections through TSCA modernization, we recommend EPA include the following points as it develops its guidance on risk evaluation and chemical prioritization:

- EPA should develop a consistent approach and criteria that are applied in the same way to all studies in the risk assessment and chemical prioritization processes. This includes peer-reviewed academic literature.
- The term "Weight of Evidence" (WOE) should explicitly refer to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based on strengths, limitations, and relevance.
- WOE approaches should also ensure that the EPA consider academic studies fully along with any other category of evidence.
- The default approach for evaluating risks from chemicals should be that there are risks at low doses and that a dose at which there is no effect must be proven.

Incorporating the recommendations above in the guidance will help address a deficiency in the existing regulatory approach. We have found that federal agencies responsible for conducting risk assessments and protecting the public from harms due to exposure to EDCs often fail to consider the latest scientific studies from the world's top researchers into the mechanisms of EDC actions and



impacts in humans. In addition, academic scientists are frequently unable to participate in public meetings or deliver public comments due to short timeframes and travel requirements. The expertise of academic scientists is imperative to ensure that assessments incorporate the latest peer-reviewed scientific studies.

Therefore, we request that EPA's guidance for chemical prioritization and risk assessment include an explanation of how academic studies will be incorporated in these processes. Such studies are frequently published in recognized scientific journals that require conflict of interest disclosures, have undergone rigorous peer-review, and have been corroborated through subsequent research by independent groups. Moreover, the design of these studies has been evaluated by an additional rigorous and competitive peer review system to qualify for federal funding. To maximize the efficiency of the government's investment in biomedical research, we believe that these state-of-the-art scientific studies that form the basis for improving clinical care of endocrine diseases should also be used for chemical risk assessments and prioritization in order to reduce the prevalence or severity of those same diseases.

Thank you for considering our comments. If we can be of any assistance, please do not hesitate to contact Joseph Laakso, PhD., Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

Henry Kronenberg, MD
President
Endocrine Society