ENDOCRINE SOCIETY
Hormone Science to Health

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CRITERIA FOR IDENTIFICATION OF ENDOCRINE DISRUPTING CHEMICALS: AN ENDOCRINE SOCIETY PERSPECTIVE

The Endocrine Society expresses disappointment and concern that the European Commission's regulatory criteria published on June 15, 2016 are too narrow to effectively protect the public from endocrine-disrupting chemicals.

The Endocrine Society includes over 18,000 physicians, scientists, and health care professionals devoted to the study of hormone-related diseases and disorders that affect health and quality of life for large numbers of people. Ten of our members have received Nobel Prizes for their contributions to science and medicine. We have contributed to the European Commission process of setting criteria for the definition of EDC since 2013; our detailed comments can be found at http://press.endocrine.org/edc.

Our concerns have been matched by the United Nations/World Health Organization State of the Science 2012 (9) and consensus statements made by a variety of experts and expert societies (1,2,3) related to neuro-development (4), obesity (5), metabolic disorders including diabetes (6), as well as reproductive disorders and aiming at chemicals such as flame retardants (7, 8). The economic costs of these chemical-related diseases and disorders have been conservatively estimated to be in the billions of euros per year (10), but the human costs are incalculable.

Despite this, the Commission has proposed criteria to identify EDCs requiring a level of certainty that are nearly unachievable scientifically. For instance, changing the WHO/IPCS definition from a chemical "altering the function of the endocrine system" to a chemical with a specific "mode of action" represents a fundamental misunderstanding of how endocrine signaling works by connecting different organ systems within the body. The criteria will inappropriately exclude chemicals that interfere with hormone actions through secondary effects on e.g., the liver. Moreover, with a single category approach, regulatory agencies will be unable to rank chemicals of concern based on the strength of the scientific evidence. Because health effects can take years or even generations to become apparent, this proposal will not protect public health; mandating that a chemical be "known" to cause

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adverse effects in humans suggests that a chemical would already have caused severe and obvious harms to populations, irrespective of strong preexisting scientific evidence in animals or in vitro systems. We therefore have strong concerns about the scientific validity of the Commission's proposal.

A second point of concern is the introduction of negligible risk in the derogation of the EU pesticide law. This is de facto opening the door for potency considerations, which was criticized as a problematic concept elsewhere (11).

Finally, the proposed criteria exclude precautionary action on such chemicals, putting the criteria at odds with the provisions of Article 191 of the Treaty on the Functioning of the European Union which requires protecting the environment and human health.

It is obvious that endocrine-related diseases and disorders are multicausal; therefore, evidence from biochemical and animal studies must be employed and prioritized to interpret human epidemiological information. Further, guideline studies should not have precedence over other reliable sources of information. A consistent approach and criteria should be applied in the same way to all studies in the regulatory process, including peer-reviewed academic literature. This manner of integration for categorization of chemicals has been well developed by IARC as we have pointed out previously (12, 13). Thus, identification based on the original WHO/IPCS definition and categorization based on the Commission's Option 3 are the most logical and scientifically relevant approach. For a list of references used in the current statement, please see https://www.endocrine.org/advocacy-and-outreach/letters-and-alerts/society-letters

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