ENDOCRINE SOCIETY
Hormone Science to Health

July 18, 2025

The Endocrine Society appreciates the opportunity to comment on the FDA's proposed tool for the prioritization of food chemicals for post-market assessment. The Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. Our membership consists of over 18,000 scientists, physicians, educators, nurses, and students in more than 100 countries. We represent all basic, applied, and clinical interests in endocrinology, including many of world's leading experts on the health effects of endocrine-disrupting chemicals (EDCs), many of which are found in food and in food contact materials.

We welcome the development of a robust, systematic process for post-market assessment of chemicals in food. Such assessments are desperately needed, as exposure to EDCs often used in food contact materials, including bisphenols and phthalates, is widespread, often with cumulative and mixture effects. Unfortunately, the tool as described is inadequate and will not appropriately prioritize chemicals with effects on the endocrine system. Furthermore, key details about the tool and the underlying information used to establish the scoring methodology remain vague or are not sufficiently disclosed, making it difficult to rigorously evaluate the tool. Below, we offer several recommendations to ensure that the tool meets the public's expectations and assesses EDCs.

Address endocrine disruption – As described, the tool does not explicitly include an approach to identify endocrine disruptors or chemicals that interfere with hormone systems, and it is not clear if this would be captured in the section on other organ-specific toxicity. We urge FDA to explicitly describe how endocrine effects, such as estrogenicity or altered thyroid hormone levels, would be evaluated in the tool to ensure EDCs in food are prioritized for review and action appropriately.

Broaden the evaluation process to include chronic effects – The tool includes a section on evaluating acute toxic effects but lacks a similar emphasis on chronic effects and/or chronic disease. FDA should ensure that the tool can evaluate chemicals for metabolic effects and other endpoints that may lead to chronic diseases such as diabetes and obesity.

Establish separate offices for prioritization – In our response to FDA's notice announcing the enhanced systematic process for the FDA's postmarket assessment of chemicals in food we urged FDA to establish a separate office of reassessments so that risk assessments are conducted by individuals who have not been involved in the approvals process. We reiterate that it would be inappropriate for individuals involved in approvals to also participate in reassessment.

Evaluate chemicals currently on the market – Scientific evidence developed in recent decades has identified numerous hazardous chemicals that are used in food contact materials. Widespread exposures to bisphenols, phthalates, PFAS, and other EDCs occur

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routinely through food and are implicated in the development of endocrine diseases. FDA should include existing chemicals in the prioritization process for review.

Finally, we note that several elements of the tool are highly subjective and inadequately explained. We worry that without clear guidelines these aspects could inappropriately establish priority over other chemicals with significant evidence of harm. To further evaluate the tool, we urge the FDA To extend the existing comment period and allow for additional public comment.

Thank you for considering our comments.