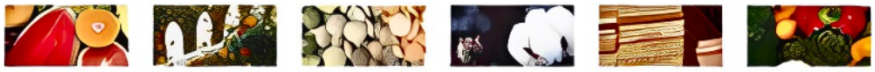


PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

February 26, 2024

Catherine Aubee
Endocrine Disruptor Screening Program
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 204600-0001

RE: Endocrine Policy Forum Comments on the US EPA's "Endocrine Disruptor Screening Program (EDSP); Near-Term Strategies for Implementation" [88 FR 73841/Published October 27, 2023/ EPA-HQ-OPP-2023-0474]

*Submitted via regulations.gov*

Dear Ms. Aubee:

The Pesticide Policy Coalition (PPC) respectfully submits comments on the Environmental Protection Agency's (EPA or the Agency) Endocrine Disruptor Screening Program (EDSP); Near-Term Strategies for Implementation for Public Comment.

The PPC represents agriculture, food, fiber, public health, pest management, landscape, environmental, and related industries, including small businesses/entities, which are dependent on the availability of pesticides. Our coalition supports the development and implementation of public policies and laws that utilize the best available science and technology to ensure protection of human health and the environment.

PPC members include national and regional trade associations; commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators, and distributors; pest and vector-control applicators and operators; research organizations; state departments of agriculture; equipment manufacturers, and other interested stakeholders. The PPC serves as the unifying voice for the review, discussion, development and advocacy on pest management regulation and policy that is based on the best available science.

The public is confronted with increasing pest pressure, resistance management concerns, and disease threats introduced into the United States via trade, weather, and other factors. It is through pest control products, used by farmers, ranchers, public health officials, and other

pesticide applicators; and produced by pesticide manufacturers, that we can address and mitigate these threats. These products are essential tools for users to protect not only America's food, fiber, and biofuel; but also, to protect public health from vector-borne disease, safeguard our infrastructure from the damage caused by pests, and mitigate the increasing threat to the environment from invasive species.

The PPC appreciates this opportunity to submit comments on the document entitled **Endocrine Disruptor Screening Program (EDSP); Near-Term Strategies for Implementation.** The PPC acknowledges the long history of research, method development, and validation that EPA has undertaken to develop and implement the two-tiered EDSP to assess endocrine disruption in response to the Congressional mandate set forth in the Federal Food, Drug, and Cosmetic Act (FFDCA) §408(p). This has included considerable work over many years to develop, validate and implement appropriate endocrine screening and testing methods.

We appreciate the Agency's continued dedication to advancing the EDSP and for the support extended towards the inclusion of Other Scientifically Relevant Information (OSRI) in the regulatory process. EPA's commitment to enhancing the quality and depth of data considered in endocrine assessments is commendable and reflects a proactive approach to safeguarding public health and the environment.

Specific Comments on the document:

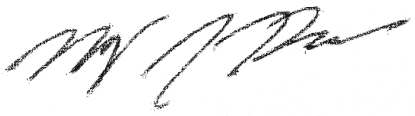
1. It is important to emphasize that the extensive data packages submitted currently in support of pesticide registrations serve to address EPA's obligations and commitments under FFDCA. Decisions can be reached without the explicit conduct of every screen and test in the EDSP toolbox. As science has progressed, endocrine endpoints are often not the most sensitive or the basis for regulatory action. This is clearly illustrated by the outcome of the weight-of-evidence assessments EPA completed earlier for its 52 "List 1" chemicals.
2. The PPC would recommend that the Agency continue engagement with relevant stakeholders to implement a consistent framework designed to meet the evolving needs of an endocrine assessment. A standardized approach to assessment methodologies can provide several benefits, including consistency and transparency; efficiency in resources; incentivized acceptance of new, non-animal methods; and increased regulatory confidence in agency decisions.
3. EPA should be sensitive to the need for data call ins (DCI) to factor in time for registrants to assess laboratory and contract research organization (CRO) competence. Large, blanket DCI's can overwhelm the available competent testing contractors which also will need to establish a sufficient historical control database to ensure the validity of study results.
4. The PPC has been told by registrants that there are errors in the grouping of pesticides – these should be addressed before any DCI is imposed to avoid unnecessary testing or the possibility of misleading the public about the profile of a particular pesticide.

5. For some classes of compounds endocrine testing may not be necessary. EPA should avoid blanket DCI's and consider categories where the likelihood of identifying evidence of endocrine activity in vivo is improbable due to the non-endocrine toxicity of the molecule -- including compounds like rodenticides, organophosphates, those with high systemic toxicity, and compounds of negligible toxicity.
6. In the document, the terms "positive" and "negative" are used to describe results of the testing tiers. Such terms are too simplistic, can be confusing, and undermine the Weight of Evidence (WoE) interpretations that the document advocates.
7. Similarly, to avoid possible confusion about the tested pesticide, the document should include an explanation of the importance of considering the potency by which a chemical can operate via an endocrine mode of action, especially given the necessity of sufficient potency to produce a functionally significant physiological effect via endocrine pathways.
8. Lastly, the PPC supports the Agency's commitment to reducing the use of animal testing and would encourage efforts to minimize vertebrate testing. Adoption of new non-animal approach methodologies can exemplify EPA's dedication to integrating relevant mechanistic alternative data streams to help prioritize chemicals that may have endocrine disrupting potential.

The PPC appreciates the Agency's transparency and willingness to not only work with and solicit suggestions from stakeholders, but to thoughtfully consider suggestions to improve and advance the scientific basis of the EDSP. We hope our comments will assist the Agency as it continues to screen and evaluate chemicals for endocrine activity/disruption more efficiently.

Thank you for your consideration of these comments. If PPC members can be of assistance in any way, or if you have questions, please do not hesitate to contact us at shensley@cotton.org or (703) 475-7716 and Megan Provost at mprovost@pestfacts.org or (202) 570-3551.

Sincerely,



Steve Hensley
Chair, Pesticide Policy Coalition

Megan J. Provost
Vice Chair, Pesticide Policy Coalition