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EPN Comments on Proposed Partial Settlement Agreement and Consent Decree, Claim Regarding Implementation of Endocrine Disruptor Screening Program Under the Section 408(p) of the Federal Food, Drug, and Cosmetic Act

Docket No.: EPA-HQ-OGC-2024-0391

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The Environmental Protection Network (EPN) harnesses the expertise of more than 650 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

EPN is gratified that EPA has entered into this Partial Settlement Agreement committing to meeting its statutory obligations under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) by implementing its Endocrine Disruptor Screening Program (EDSP) following the agency's Near-Term Strategies document[1]. EPA initially conceived the EDSP as a broad and ambitious two-tiered screening and testing program separate from the agency's general obligation to evaluate the safety of pesticide chemicals. The resources required to implement the original EDSP and its separation from EPA's pesticide registration program resulted in under-investment and delay in implementing the EDSP. The Near-Term Strategies limits and focuses the EDSP on those pesticide chemicals undergoing registration and registration review.

EPN believes the approach described in the Near-Term Strategies document will result in major progress toward meeting EPA's obligations under the FFDCA regarding screening, testing, and regulation of pesticide chemicals for their potential to disrupt endocrine systems. The Partial Settlement Agreement articulating EPA's commitment to implementing this strategy represents a significant step forward.
We offer the following comments to improve the clarity of the Agreement and implementation of the EDSP.

General Comments

The estrogen and androgen systems are recognized to be less complicated to evaluate in the EDSP than the thyroid system. Although the screening assays for estrogen and androgen are not yet fully converted to the implementation of non-whole animal study designs, there are a number of *in vitro* screens and *in silico* models that are already being used to identify potential endocrine disruptors. However, the complexity of the thyroid system has led to its being further behind in the development of useful screening tools. We therefore strongly agree that EPA needs to hold a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) meeting to obtain the SAP's guidance relative to these challenging thyroid screening issues.

The term "conventional active ingredient" pesticide needs to be more clearly defined. It could be understood to refer only to pesticides handled in the Registration Division of the Office of Pesticide

[1] https://www.federalregister.gov/documents/2023/10/27/2023-23721/endocrine-disruptor-screening-program-edsp-near-term-strategies-for-implementation-notice-of

Programs (OPP) but could also refer to active ingredients in antimicrobial pesticides that are handled in OPP's Antimicrobials Division. OPP needs to clearly communicate whether it means only the chemicals covered by the Registration Division or by both divisions.

Three scenarios are set forth in the Near-Term Strategy Document and listed in paragraph 6(b)(i) of the draft Agreement. One states EPA may find that the pesticide is exempt from FFDCA section 408(p)(6) requirements because the pesticide "is anticipated not to produce any effect in humans similar to an effect produced by naturally occurring estrogen." This follows the statutory language which lays out the minimum required of EPA; however, it neglects androgen and thyroid. EPA should either amend the strategy document or explain this statement.

It is unclear whether EPA is committing to continue to issue notices concerning the status of its registration review actions (paragraph 6(c)). We recommend making it clear: that EPA will issue such notices every three months for at least five years from the date of entry of the settlement agreement, to whom the notices will be sent, and what information the quarterly notices will contain.

If a force majeure event were to occur (paragraph 14), 20 days would probably not be sufficient time for OPP to figure out what, if anything, could bring resolution. OPP may need as much as 90 days to assess the situation. In addition, a shortfall in appropriated funds is identified as one possible circumstance, but there could also be a shortfall in collected fees. Both, separately or together, could have a significant impact.

Additional comment:

In the past, EPA has poorly tracked responses to Data Call-In notices (DCIs), especially when respondents asked for a waiver or submitted public literature to satisfy a DCI. To meet such a reporting obligation, OPP should implement a system with better tracking if one doesn't exist already.

Minor comments:

1. The draft Agreement should be updated to capture the timing of certain actions (see paragraphs 4(a) and 8). For instance, did the actions promised by September 30, 2024, actually happen, or should there be a new date once the Agreement is finalized?
2. Paragraph 9 – the correct term is "FIFRA Scientific Advisory Panel," not "Science Advisory Panel."

These comments were prepared by William Jordan, Gary Timm, and Penelope Fenner-Crisp on behalf of EPN.