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## Pesticide Update

EPA's Office of Chemical Safety and Pollution Prevention

## **EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides**

WASHINGTON - Today, the U.S. Environmental Protection Agency (EPA) is announcing a strategic plan to ensure that its assessments of pesticides more closely, quickly, and effectively evaluate the potential for endocrine effects in humans. These strategies will also improve EPA's ability to protect against those effects as part of its pesticide decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and to implement the Endocrine Disruptor Screening Program (EDSP) under section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

"This plan is a major milestone in our efforts to ensure that pesticide decisions continue to protect human health," said Deputy Assistant Administrator for Pesticide Programs for the Office of Chemical Safety and Pollution Prevention Jake Li. "Starting with our highest priority chemicals, EPA will communicate more transparently our endocrine findings for humans, pulling from existing data when possible, and requesting new data when necessary to evaluate potential estrogen, androgen, and thyroid effects."

Endocrine systems, also referred to as hormone systems, are found in all mammals, birds, fish, and many other living organisms. The systems regulate many biological processes in the body from conception through adulthood and into old age, including the development of the brain and nervous system, the growth and function of the reproductive system, and metabolism and blood sugar levels.

Endocrine disruptors are chemicals that mimic, block, or disrupt the normal function of hormones. Following the 1996 amendment of FFDCA, EPA established EDSP to evaluate how pesticides and other chemicals may affect estrogen, androgen, and

thyroid systems. Since then, EPA has encountered several challenges with implementing EDSP. For example, the Agency has historically lacked scientific methods to rapidly and cost-effectively test thousands of chemicals for endocrine-disrupting effects. Further, EPA's FIFRA decisions rarely explained whether or how they fully obtained all needed endocrine data or complied with FFDCA by protecting humans from potential endocrine effects. EPA staff also received minimal support and direction from leadership in the last Administration to implement EDSP. Because of these and other issues, the Office of Inspector General issued a report in 2021 concluding that the Agency had made limited progress in implementing EDSP and recommending, among other things, that the Agency develop an EDSP strategic plan.

The strategic plan and supporting documents released today advance EDSP in several unprecedented ways.

**EPA will use its FIFRA process to obtain endocrine data and make endocrine decisions for human health**. Going forward, EPA will use its existing FIFRA data collection authorities to obtain the data it needs to make both FIFRA and EDSP decisions on whether the pesticide impacts the human estrogen, androgen, and thyroid systems, and will require any needed protections. Given the large number of pesticides awaiting these decisions, EPA is prioritizing the approximately 400 conventional pesticide active ingredients that are being registered for the first time or undergoing registration review.

**EPA will make endocrine decisions related to human health more expeditiously by using existing data when possible.** EPA routinely obtains data under FIFRA that are identical or comparable to data that EPA would have obtained through EDSP. Additionally, other existing studies may also inform EDSP findings. Where these data are sufficient to support EDSP findings under FFDCA, EPA will make those findings without seeking additional data. This minimizes duplicative and expensive animal testing and expedites EPA's ability to make those findings without waiting for new studies. To support the strategic plan, EPA is releasing a science paper that addresses longstanding questions about which types of existing data can inform endocrine findings under FIFRA and FFDCA.

After evaluating available data for 403 conventional pesticides, EPA has determined it has adequate estrogen and androgen data for 86 of these chemicals. Thus, as part of registration review, after assessing for potential thyroid effects, EPA can make final EDSP decisions on the potential for these chemicals to impact the human estrogen, androgen, and thyroid systems. Similarly, EPA has determined it has sufficient data for 52 pesticide chemicals (50 conventional active ingredients and two inert ingredients) it prioritized in 2009 to assess the potential for these chemicals to impact the human estrogen, androgen, and thyroid systems. Now, as a supplement to the strategic plan, the Agency is communicating its final EDSP decisions relating to impacts on the human estrogen, androgen, and thyroid pathways for these 52 chemicals.

Because the science on the human endocrine system evolves constantly, especially for thyroid, EPA anticipates seeking in 2025 scientific peer review on scientific advancements and on its current approach to thyroid assessments. The Agency will then determine whether to update its approach.

In the near-term, EPA will require additional endocrine data for human health for 30 pesticides. EPA has identified 30 high-priority pesticides that require additional data on potential human estrogen and/or androgen effects. These pesticides are considered high priority because preliminary data indicate the chemicals may cause activity in the endocrine system. EPA is seeking available data or information on these chemicals for 60 days as part of a public comment period. Additionally, to fill any remaining data gaps, the Agency intends to issue FIFRA human health data requests for these chemicals in the spring of 2024. EPA is also seeking available data or other information to evaluate endocrine data needs for a second group of 126 conventional pesticides for which the Agency's initial analysis has found limited endocrine data. For 161 additional conventional pesticides, the Agency will determine which ones it needs to obtain updated endocrine data for in the coming years as part of registration review.

The comment period for this action will open Friday, October 27. Once available, interested parties can submit data or a comment in docket <u>EPA-HQ-OPP-2023-0474</u> at www.regulations.gov.

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