U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Ensuring the safety of chemicals

EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides

Report No. 21-E-0186 **July 28, 2021**

Report Contributors:

Natasha Henry
Lauretta Joseph
Michael Wilson
Erin Barnes-Weaver

Abbreviations

C.F.R.	Code of Federal Regulations
CMP	Comprehensive Management Plan
EDSP	Endocrine Disruptor Screening Program
EPA	U.S. Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OPP	Office of Pesticide Programs
WoE	Weight-of-Evidence

Cover Photo: Green frogs collected for evaluation on potential effects of endocrine-disrupting chemicals. (U.S. Geological Survey image)

Are you aware of fraud, waste, or abuse in an EPA program?

EPA Inspector General Hotline
1200 Pennsylvania Avenue, NW (2431T)
Washington, D.C. 20460
(888) 546-8740
(202) 566-2599 (fax)
OIG_Hotline@epa.gov

Learn more about our OIG Hotline.

EPA Office of Inspector General
1200 Pennsylvania Avenue, NW (2410T)
Washington, D.C. 20460
(202) 566-2391
www.epa.gov/oig

Subscribe to our Email Updates
Follow us on Twitter @EPAoig
Send us your Project Suggestions

U.S. Environmental Protection Agency
Office of Inspector General

21-E-0186
July 28, 2021

At a Glance

EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides

Why We Did This Evaluation

We performed this evaluation to determine the progress of the U.S. Environmental Protection Agency's implementation of Section 408(p)(3)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act, which requires the EPA to test all pesticide chemicals for human endocrine-disruption activity. We also sought to determine compliance with Section 408(p)(6), which requires the EPA to take action if it finds, after testing and evaluation, that a substance disrupts the human endocrine system.

Endocrine systems regulate biological processes in humans and animals. Endocrine disruptors are chemicals found in many products that mimic, block, or disrupt the normal function of hormones. The EPA developed its Endocrine Disruptor Screening Program in 1998.

This evaluation addresses the following:

- *Ensuring the safety of chemicals.*

This evaluation addresses these top EPA management challenges:

- *Communicating risks.*
- *Complying with key internal control requirements (risk assessments).*

Address inquiries to our public affairs office at (202) 566-2391 or OIG_WEBCOMMENTS@epa.gov.

List of OIG reports.

What We Found

Without the required testing and an effective system of internal controls, the EPA cannot make measurable progress toward complying with statutory requirements or safeguarding human health and the environment against risks from endocrine-disrupting chemicals.

Twenty-four years after the Food Quality Protection Act of 1996 amendments were passed, the Office of Chemical Safety and Pollution Prevention has not implemented Section 408(p)(3)(A) of the Federal Food, Drug, and Cosmetic Act to test all pesticide chemicals for endocrine-disruption activity. In addition, the OCSPP's Office of Pesticide Programs recommended in 2015 that 17 pesticides needed additional testing for endocrine disruption in wildlife in order to provide the data needed to conduct an ecological risk assessment, but that recommendation has not been implemented. Endocrine Disruptor Screening Program testing delays are inconsistent with the Federal Food, Drug, and Cosmetic Act, which directs the EPA to take appropriate action to protect public health if a substance is found to have an effect on the human endocrine system.

We also found that the EPA does not have controls in place to effectively implement the EDSP, such as strategic guidance documents or performance measures. Additionally, the EDSP has not conducted annual internal program reviews to monitor or assess progress in fulfilling regulatory requirements, and the EDSP has not effectively communicated with internal and external stakeholders. Moreover, previous OCSPP leadership provided acceptable corrective actions to meet the recommendations in a 2011 EPA Office of Inspector General report regarding the EDSP yet failed to actually implement those corrective actions beyond an initial period of compliance with them. Lastly, some EPA staff indicated that they were instructed to function as if the EDSP was eliminated from the EPA's budget.

Because the EDSP has not had effective internal controls in place since 2015, it cannot have reasonable assurance that the objectives of the program will be accomplished and that resources will be allocated efficiently and effectively. Moreover, an established system of management controls would provide mechanisms for consistent program operations.

Recommendations and Planned Agency Corrective Actions

We make ten recommendations to the assistant administrator for Chemical Safety and Pollution Prevention related to testing, strategic planning, performance measurement, annual reviews, and internal and external communications. The recommendations are resolved with corrective actions pending.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

July 28, 2021

MEMORANDUM

SUBJECT: EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides
Report No. 21-E-0186

FROM: Sean W. O'Donnell

TO: Michal Ilana Freedhoff, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this evaluation was OA&E-FY20-0379. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Chemical Safety and Pollution Prevention is responsible for the issues discussed in this report.

In accordance with EPA Manual 2750, your office provided acceptable planned corrective actions and estimated milestone dates in response to OIG recommendations. All recommendations are resolved, and no final response to this report is required. If you submit a response, however, it will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

Table of Contents

Appendices

Purpose

The U.S. Environmental Protection Agency's Office of Inspector General conducted this evaluation to determine the EPA's progress in implementing Section 408(p)(3)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act, which requires the EPA to test all pesticide chemicals for human endocrine-disruption activity. We also sought to determine compliance with Section 408(p)(6) of the FFDCA, as amended by the FQPA, which requires the EPA to take action if it finds, after testing and evaluation, that a substance disrupts the human endocrine system.

Top Management Challenges

This evaluation addresses the following top management challenges for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Top Management Challenges*, issued July 21, 2020:

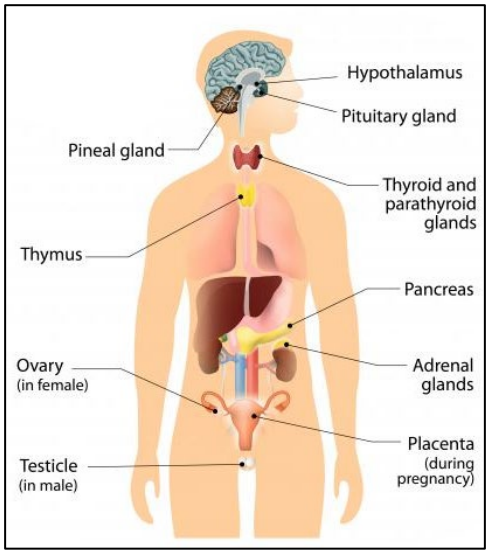
- Communicating risks.
- Complying with key internal control requirements (risk assessments).

Background

Endocrine Systems and Endocrine Disruptors

Endocrine systems, also referred to as hormone systems, are found in all mammals, birds, fish, and many other organisms. The endocrine system regulates biological processes in the body from conception through adulthood, including the development of the brain and nervous system, the growth and function of the reproductive system, and the metabolism and blood-sugar levels. The female ovaries, male testes, hypothalamus, pituitary gland, and thyroid glands are major constituents of the endocrine system (see Figure 1). Some hormones in the endocrine system include estrogens, androgens, and thyroid hormones. Endocrine disruptors are chemicals that mimic, block, or otherwise disrupt the normal function of hormones.

Figure 1: Human endocrine system



Source: EPA website. (EPA image)

Small disturbances in endocrine function, particularly during certain highly sensitive stages of the life cycle, such as pregnancy and lactation, can lead to profound and lasting effects. Adverse endocrine-related effects in humans may include breast cancer, diabetes, obesity, infertility, and learning disabilities.

Endocrine disruptors are in many products, including pesticides. A 2016 study published in *The Lancet*, a medical journal, found that annual costs associated with endocrine-disrupting pesticides in the United States was $42 billion.

Examples of common endocrine disruptors include:

- Bisphenol A.
- Perfluoroalkyl and Polyfluoroalkyl substances.
- Dioxins.
- Phthalates.

Source: National Institute of Environmental Health Sciences.

Endocrine Disruptor Screening Program

Based on evidence that certain chemicals may disrupt the endocrine system, Congress passed amendments to the Safe Drinking Water Act and the FQPA, which amended the FFDCA, in 1996. The FFDCA, as amended, contains provisions regarding estrogenic substances, including requirements for the EPA to evaluate those chemicals for their potential to produce effects similar to those produced by estrogen in humans or other endocrine effects designated by the EPA.

The EPA's Office of Chemical Safety and Pollution Prevention, referred to as the OCSPP, implements the FQPA, and related portions of the FFDCA, as well as the Federal Insecticide, Fungicide, and Rodenticide Act. We evaluated the EPA's progress in implementing and complying with two sections of the FFDCA:

- Section 408(p)(3)(A) on testing of all pesticide chemicals for human endocrine-disruption activity.

- Section 408(p)(6) on taking appropriate action to protect public health when finding, through testing and evaluation, that a substance has human endocrine effects.

In order to meet these statutory mandates, the EPA established the Endocrine Disruptor Screening and Testing Advisory Committee in October 1996 to recommend how the EPA's Endocrine Disruptor Screening Program would work. The committee was composed of representatives from industry, government, environmental and public health groups, worker safety groups, and academia. The committee's task was to recommend a screening and testing program that would provide the Agency with the information needed to make regulatory decisions about chemicals that disrupt the endocrine system. In August 1998, the committee issued a final report establishing the framework for the EDSP.

The committee's key recommendations, which the EPA adopted, were that EDSP screening should:

- Evaluate both human and ecological effects.
- Test for disruption of the estrogen, androgen, and thyroid hormone systems.

- Evaluate both pesticide and nonpesticide chemicals.
- Implement a tiered approach.

The EDSP, which the EPA created in August 1998, is not the only mechanism available to the Agency to regulate endocrine-disrupting chemicals. According to the EPA's August 2010 *Report to Congress on Pesticide Licensing and Endocrine Disruptor Screening Activities*, from August 3, 1999, through September 30, 2009, the EPA regulated 79 of the 1,095 pesticides subjected to Federal Insecticide, Fungicide, and Rodenticide Act regulatory review on the basis of endocrine effects.

EDSP Prioritization Lists

The EPA's "List of the EDSP Universe of Chemicals" encompasses approximately 10,000 chemicals, as defined under the 1996 FFDCA and Safe Drinking Water Act amendments, and as of December 2020, EPA senior staff reported that 1,315 of those chemicals were pesticides. Since available resources and laboratory capacity limit the number of chemicals that can be tested simultaneously, the EPA created lists to prioritize which chemicals to evaluate first. The EPA published EDSP List 1 in April 2009, which contained 67 pesticides and High Production Volume chemicals used as pesticide inert ingredients. The EPA later revised this list to 52 chemicals because 15 chemicals were subsequently canceled or discontinued.

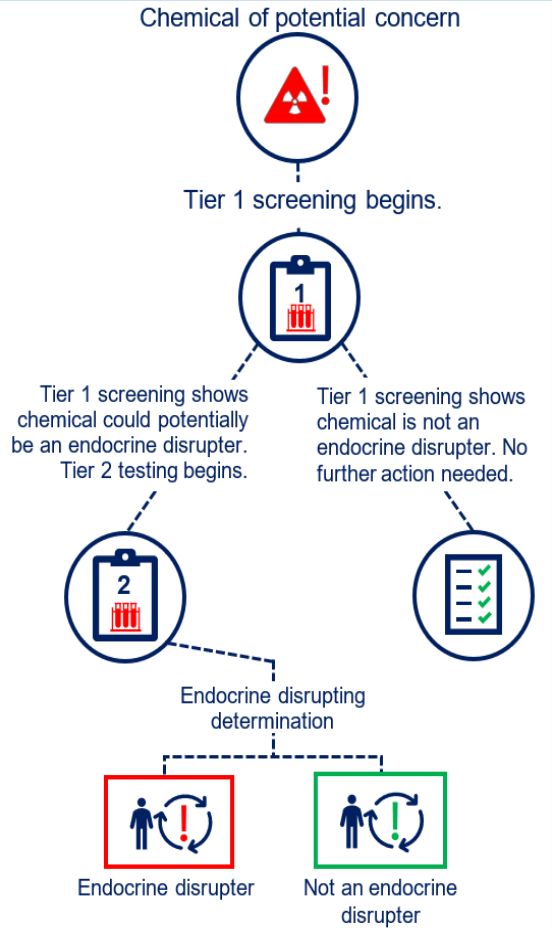
In its fiscal year 2010 House Appropriations Committee report, Congress directed the EPA to publish an additional EDSP list by October 30, 2010. The Agency published EDSP List 2 in June 14, 2013. List 2 consisted of 109 chemicals—41 pesticides and 68 other chemicals that were identified under the Safe Drinking Water Act amendments. Congress also directed the EPA to issue 25 test orders per year from List 2, starting in fiscal year 2011. A test order requires a pesticide manufacturer to conduct one or more specified tests and submit the results to the EPA for review. As of this evaluation, the Agency has not issued any test orders from List 2.

EDSP Tiers 1 and 2

The EPA uses a multistep process to determine a chemical's potential as an endocrine disruptor. The EPA implemented a two-tiered approach as a result

of a recommendation from the Endocrine Disruptor Screening and Testing Advisory Committee. The purpose of the Tier 1 screening is to identify substances that have the potential to interact with estrogen, androgen, or thyroid hormone systems. The purpose of the Tier 2 testing is to determine whether the substance causes adverse effects and to establish a quantitative relationship between the dose and the adverse effect. Figure 2 illustrates the tiered testing process.

Figure 2: EPA tiered testing process



Source: OIG summary of the EPA's EDSP information. (EPA OIG image)

EDSP Progress

After going through public review and comment, the EPA published a guidance document titled *Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing* in 2011. This WoE guidance document sets forth general principles, criteria, and considerations for evaluating data submitted as part of the EPA's two-tiered paradigm for screening and testing chemicals for endocrine-disrupting activity—that is, estrogen, androgen, and thyroid hormonal systems. The EPA applied the WoE guidance to EDSP List 1–Tier 1 data in 2015 and made recommendations for Tier 2 testing. Table 1 describes the prioritization of chemicals for tiered testing.

Table 1: Prioritization of chemicals for tiered testing

	TIER 1 Identifies substances and chemicals that may interact with the endocrine system.	TIER 2 Determines whether a substance or chemical adversely affects the endocrine system, if warranted by the Tier 1 screening results.
LIST 1	The first group of 52 chemicals identified for testing. The EPA issued Tier 1 test orders. ✓	The EPA recommended additional testing, known as Tier 2 testing, for 18 out of the 52 chemicals from List 1–Tier 1. *The EPA has not issued any Tier 2 test orders. ✗
LIST 2	The second group of 109 chemicals identified for testing. *The EPA has not issued any Tier 1 test orders. ✗	*The EPA has not identified nor issued any Tier 2 test orders. ✗

Source: OIG summary of EPA tier testing information. (EPA OIG table)

*As of this evaluation.

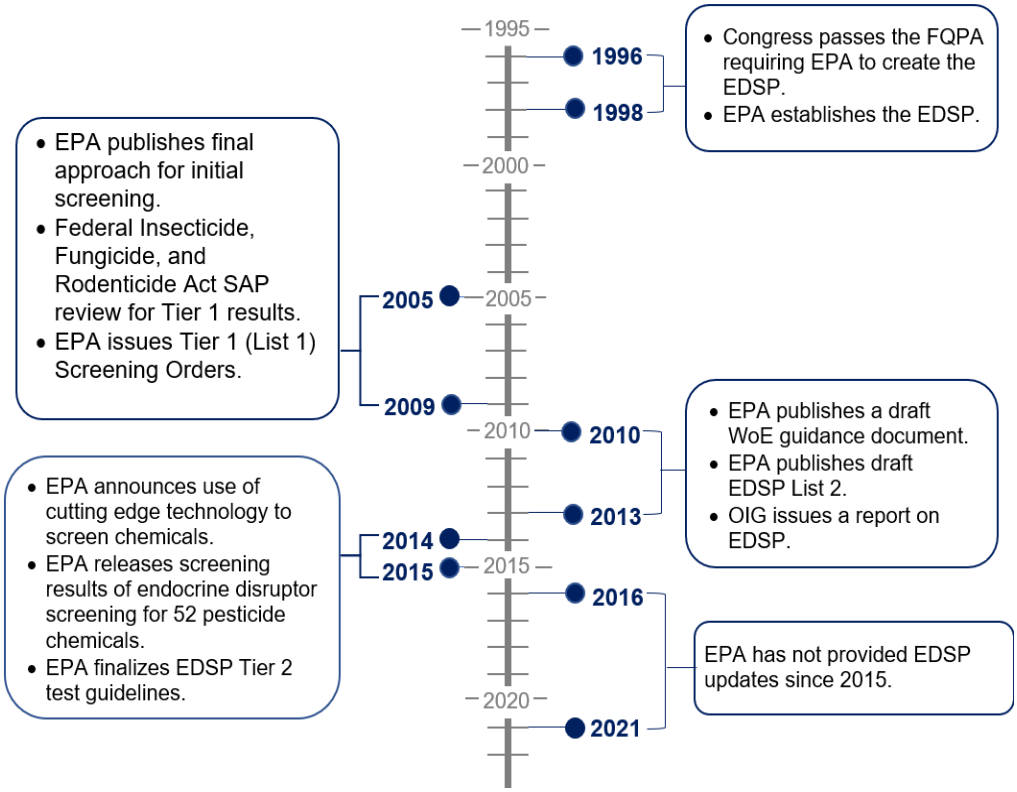
In 2015, the EPA published a *Federal Register* notice describing how the Agency planned to incorporate an alternative scientific approach to screen chemicals for their ability to interact with the endocrine system. The approach would incorporate validated high-throughput assays and a computational model and would serve as a faster, more cost-effective, and less animal-intensive testing alternative for some of the assays in the EDSP Tier 1 battery.[1]

That same year, the EPA released the Tier 1 screening assay results for 52 pesticide chemicals. For each chemical, the EPA decided whether additional Tier 2 testing was necessary based on whether the evidence from the assay results, as well as other scientifically relevant data, showed potential for endocrine activity. Based on its 2015 findings, the EPA recommended that 18 of the 52 chemicals undergo Tier 2 testing. In 2021, the OCSPP is still evaluating whether these chemicals need Tier 2 wildlife testing to conduct the chemical's ecological risk assessment. Wildlife testing are EDSP tests that the EPA uses to characterize the endocrine-disruptor activity of the chemical and to assess the chemical's risk to wildlife. The OCSPP has subsequently decided that three of these chemicals no longer need Tier 2 human health studies for the chemical's human health risk assessment. For the two chemicals that the OCSPP decided still needed Tier 2 human health studies, the OCSPP has yet

[1] High-throughput assays are automated methods that allow for a large number of chemicals to be rapidly evaluated for a specific type of bioactivity at the molecular or cellular level.

to receive the Tier 2 human health data from the chemicals' manufacturers. Figure 3 describes a general timeline of EDSP progress.

Figure 3: Timeline on EDSP progress

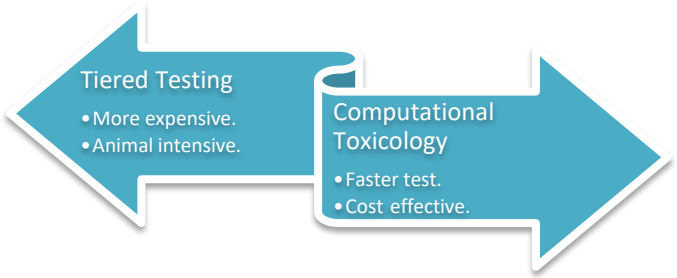


Source: OIG timeline based on the EPA's EDSP materials. (EPA OIG image)

Computational Toxicology

Computational toxicology is the application of mathematical and computer models to help assess chemical hazards and risks to human health and the environment. In 2012, the EDSP began a multiyear transition to use computational toxicology methods and high-throughput screens to quickly and cost-effectively assess potential chemical toxicity (Figure 4).

Figure 4: Tiered testing versus computational toxicology



Source: OIG summary of EPA information. (EPA OIG image)

The initiative, referred to as EDSP21—or EDSP in the 21st century—aimed to use computational or high-throughput screening assays to prioritize and screen chemicals to determine their potential to interact with estrogen, androgen, or thyroid bioactivity.

Internal Controls

Every federal program is required to have internal controls, and federal managers are responsible for maintaining an effective internal control system. Internal controls comprise the plans, policies, and procedures used to implement the regular operation of the program, as well as to achieve the program's goals and objectives. The U.S. Government Accountability Office's *Standards for Internal Control in the Federal Government*, known as the Green Book,[2] contains standards to implement management control requirements, including program operations, data collection and reporting, and consistent implementation. It also notes that programs should use relevant data from reliable sources to support decisions and federal managers should use performance measures to evaluate performance in achieving objectives. The Green Book also states that information should be communicated at all levels within and outside an organization.

Per the Government Accountability Office, to assist performance monitoring, federal managers should promptly resolve the findings of audits and other reviews and complete and document corrective actions to remediate internal control deficiencies on a timely basis. The Office of Management and Budget's Circular No. A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, issued on July 15, 2016, requires federal managers to implement Government Accountability Office guidance and defines management's responsibilities for assessing and managing programmatic risks.

EPA OIG's Prior Review of the Endocrine Disruptor Screening Program

The OIG evaluated the EDSP in Report No. 11-P-0215, *EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results*, issued May 3, 2011. The OIG sought to determine whether the EPA had planned and conducted the requisite research and testing to evaluate and regulate endocrine-disrupting chemicals.

The OIG concluded, in part, that the EDSP had not:

- Determined whether any chemical is an endocrine disruptor since the FQPA and Safe Drinking Water Act amendments were passed.
- Developed a management plan laying out the program's goals and priorities or established outcome performance measures to track program results.
- Conducted annual internal program reviews of the EDSP.

The OIG made six recommendations to strengthen the EDSP, including that the EPA finalize Tier 1 and Tier 2 criteria to evaluate testing data, develop performance measures and a *Comprehensive Management Plan*, and hold annual program reviews. The Agency agreed with the findings and conclusions and provided acceptable corrective actions.

[2] U.S. Government Accountability Office, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 10, 2014.

Responsible Offices

The OCSPP is responsible for the issues in this report. Within the OCSPP, the Office of Pesticide Programs oversees the EDSP.

Scope and Methodology

We conducted this evaluation from December 2020 to June 2021 in accordance with the *Quality Standards for Inspection and Evaluation*, published in January 2012 by the Council of the Inspectors General on Integrity and Efficiency. Those standards require that we perform the evaluation to obtain sufficient, competent, and relevant evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations.

We reviewed statutory and regulatory language, the EPA's strategic plan titled *Working Together: FY 2018–2022 U.S. EPA Strategic Plan*, relevant guidance, and procedure documents. We also reviewed materials provided by the EDSP, including the WoE guidance document; the EDSP's 2018 draft *Comprehensive Management Plan,* or *CMP*; and other relevant internal documents. We interviewed OCSPP staff and managers to gather their perspectives on the program and its progress.

Results

Twenty-four years after passage of the FQPA and Safe Drinking Water Act amendments in 1996, the EPA's EDSP has made limited progress in implementing Section 408(p)(3)(A) of the FFDCA as amended by the FQPA, which requires the EPA to test all pesticide chemicals for endocrine-disruption activity. In addition, the OPP's Human Effects Division and Environmental Fate and Effects Division recommended on June 29, 2015, that 17 of 18 pesticides from List 1 needed additional EDSP Tier 2 testing for endocrine disruption in wildlife in order to provide the data needed to conduct an ecological risk assessment.[3] However, the OPP management has not acted on that recommendation.

EDSP testing delays are inconsistent with Section 408(p)(6) of the FFDCA, which directs the EPA to take appropriate action to protect public health if a substance is found, as a result of testing and evaluation, to have an effect on the human endocrine system. We also found that previous OCSPP leadership did not ensure continued implementation of corrective actions related to the OIG's 2011 report recommendations. The EDSP has not had effective internal controls in place since 2015.

[3] The 18th pesticide needed only Tier 2 human health testing.

Without the required testing, the EPA cannot make measurable progress toward compliance with statutory requirements or safeguard human health and the environment against risk from endocrine-disrupting chemicals. Without internal controls, the EDSP cannot have reasonable assurance that the goals and objectives of the program will be accomplished and that resources will be allocated efficiently and effectively. Moreover, an established system of management controls would provide mechanisms for consistent program operation.

Endocrine Disruptor Testing Has Stalled

The OCSPP has not implemented Section 408(p)(3) of the FFDCA to test all pesticide chemicals for endocrine-disruption activity. In June 2015, the EPA recommended that 18 pesticides from List 1 needed additional Tier 2 testing. As of early 2021, the OCSPP has not issued any List 1–Tier 2 test orders for wildlife studies and has only issued test orders for two pesticides for human health studies. Likewise, although the EPA developed and published List 2 with 109 chemicals, the EPA did not issue any List 2–Tier 1 test orders. As a result, the EPA has not made meaningful progress in meeting its statutory obligation to test all pesticide chemicals for endocrine-disruption activity.

We also found that the EPA did not meet a congressional direction from the fiscal year 2010 House Appropriations Committee report to publish EDSP List 2 by October 30, 2010. Instead, the EPA published List 2 on June 14, 2013, more than two-and-a-half years after the deadline. Furthermore, Congress directed the EPA to issue 25 test orders per year from List 2 starting in fiscal year 2011. As of February 2021, the Agency still had not issued any List 2–Tier 1 test orders.

OPP staff and managers stated that a lack of overall support and direction for the EDSP from previous OCSPP leadership resulted in no testing progress. We found that previous OCSPP leaders did not make the necessary decisions to issue List 1–Tier 2 and List 2–Tier 1 test orders. When asked why testing decisions were not made, one EDSP staff person reported that previous leaders instructed them to treat the EDSP as if the program had been eliminated from the EPA's budget even though Congress funded the program.[4] Without EDSP testing progress, the EPA cannot adequately characterize or assess whether pesticides, chemicals, and other environmental contaminants pose a endocrine-disruptor risk to estrogen, androgen, and thyroid hormone systems.

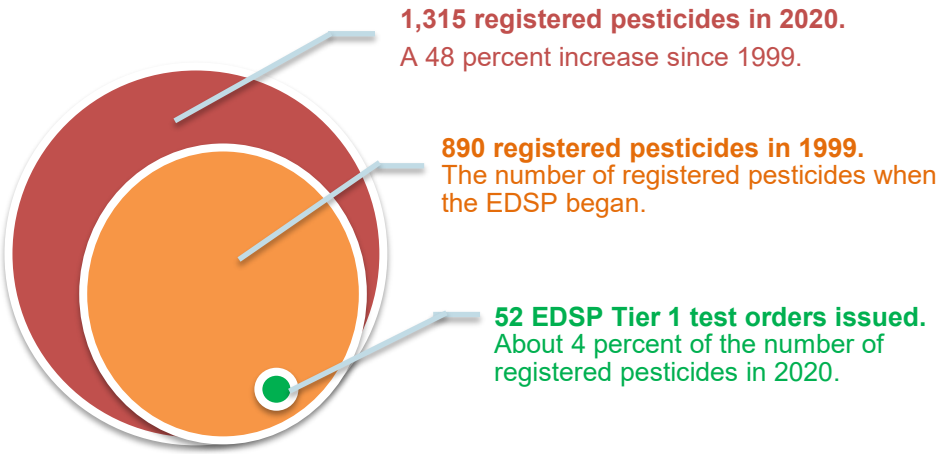
Opportunity Exists to Incorporate EDSP Tier 1 Testing into Pesticide Registration Application

The OCSPP's pace of testing pesticides for endocrine-disruption activity is insufficient to keep up with the growth in pesticide registrations. Since the EPA established the EDSP in 1998, the number of active pesticide

[4] OIG Notification Memorandum, *Performance Measures for Eliminated EPA Programs Later Funded by Congressional Appropriation*, Project No. OE-FY21-0135, March 8, 2021.

registrations has increased at a much faster pace than the EPA's pesticide testing. Figure 5 depicts the increase in the number of pesticide registrations from 1999 through 2020 and the number of EDSP Tier 1 test orders issued by the EPA.

Figure 5: Approximate number of registered pesticides in 1999 and 2020 versus EDSP Tier 1 test orders



Source: OIG analysis of EPA information. (EPA OIG image)

In order to mitigate the ever-growing backlog, the EPA needs to consider other processes to generate the necessary EDSP evaluation data. For example, the OPP's pesticide registration program could incorporate EDSP testing as a registration data requirement. Under 40 C.F.R. § 158, the EPA's pesticide registration process has mandatory data requirements that are needed during the application process. If the EDSP testing is a pesticide registration data requirement, all new pesticide registration applications would include EDSP Tier 1 data. Absent this, the EPA will continue to issue registrations for new pesticides without obtaining additional information on the pesticides' potential endocrine-disruptor activity.

EDSP Tier 2 Testing Delayed by Additional Evaluation of Tier 1 Data

We found that the OCSPP did not act in a timely manner on the 2015 recommendations from its own Health Effects Division and Environmental Fate and Effects Division that 18 List 1 pesticides should undergo additional Tier 2 testing. When the OCSPP conducted its 2015 evaluation of the List 1–Tier 1 data, it followed its established 2011 WoE guidance. The Environmental Fate and Effects Division recommended that the OCSPP conduct 23 Tier 2 studies across 18 List 1 pesticides. As stated earlier, the OCSPP is still evaluating whether these pesticides need Tier 2 wildlife testing to conduct the pesticide's ecological risk assessment. The OCSPP has subsequently decided that three of these pesticides no longer need Tier 2 human health studies for the pesticide's human health risk assessments. For

the two pesticides that the OCSPP decided still needed Tier 2 human health studies, the OCSPP has yet to receive the Tier 2 human health data from the manufacturers. Without EDSP Tier 2 data, the EPA cannot fully characterize or assess whether these pesticides pose an endocrine-disruptor risk to the estrogen, androgen, and thyroid hormone systems.

We found that previous OCSPP leadership decided to forgo the office's established WoE approach for evaluating EDSP Tier 1 data and, instead, undertook and reevaluated the List 1–Tier 1 data using a different approach. Unlike the OCSPP's established WoE guidance, an EDSP manager stated that the OCSPP's new approach has not yet undergone public review and comment or been reviewed by the Federal Insecticide, Fungicide, and Rodenticide Act Science Advisory Panel. As of June 2021, the OCSPP's reevaluation of the List 1–Tier 1 data is still pending. In its draft reevaluation of the List 1–Tier 1 data, the OCSPP proposed that no additional List 1–Tier 2 wildlife studies were needed. By not communicating this change in its evaluation approach for EDSP Tier 1 data—and by continuing to delay this reevaluation—the EPA risks public confidence in its commitment to test and evaluate pesticides for endocrine-disruptor activity.

Changing Evaluation Approach After Receiving Data Can Lead to Appearance of Bias

Since the OCSPP changed its evaluation approach after it received the Tier 1 data and after it recommended additional Tier 2 testing, the OCSPP's new evaluation approach of the Tier 1 data can appear biased. The OIG's 2011 EDSP report recommended that the OCSPP "finalize specific criteria for evaluating the Tier 1 screening data received." The OIG report stated that the EPA needed to have this evaluation criteria in place *before* receiving the Tier 1 data in order to avoid an appearance of bias. The OCSPP issued the final WoE guidance in 2011 and implemented the EPA's WoE guidance in its 2015 recommendations. The OCSPP's decision to later reevaluate the same List 1-Tier 1 data using a different set of evaluation criteria after it already received the data could lead to an appearance of bias.

Potential bias also stems from the OCSPP not reevaluating all 52 pesticides' List 1–Tier 1 data, but only evaluating List 1–Tier 1 data for the 17 pesticides in which the EPA had previously recommended additional Tier 2 wildlife testing in 2015. The OCSPP can appear biased by not using its new approach to reevaluate the 35 pesticides for which no additional Tier 2 testing was recommended. By not implementing the 2015 WoE recommendations for additional Tier 2 testing, the EPA risks losing credibility with the public that its decisions are impartial.

EDSP Has Not Fully Implemented Effective Internal Controls

The EPA does not have internal controls in place to provide reasonable assurance of effective program implementation of the EDSP. The EDSP has not finalized strategic guidance documents or performance measures on achieving its statutory requirements. Additionally, the EDSP has not conducted any internal program reviews to monitor or assess progress in fulfilling the requirements of the FFDCA, as amended by the FQPA. The OIG's 2011 report found that internal controls were missing and recommended that, among other actions, that the EPA develop a strategic planning document known as the *CMP*, and annually review EDSP results, progress toward milestones, and achievement of performance measures. The EPA agreed to corrective actions that address these recommendations, but we could not confirm that the Agency conducted or implemented any of this work beyond an initial period of compliance with them.

Complying with key internal control requirements concerning risk assessment is a top management challenge for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Top Management Challenges*, issued July 21, 2020. The EPA faces overarching challenges in implementing and operating internal controls that establish and maintain an effective work environment.

Internal controls help ensure accountability and enhance transparency of the steps needed to implement a program and achieve results. Without internal controls, the EDSP cannot have reasonable assurance that program goals and objectives will be accomplished and that resources will be allocated efficiently and effectively. Moreover, an established system of internal controls would provide mechanisms for consistent program operations that would outlast changes in leadership and increase programmatic progress.

EDSP Does Not Have Strategic Plan

The EDSP does not have a strategic or annual planning document that clarifies priorities or guides the program's activities. In response to the OIG's 2011 report recommendations, the EDSP agreed to develop and publish a *CMP*. The 2014 *CMP* provided strategic guidance and included estimates of the EDSP's budget requirements, priorities, goals, and key activities. It also discussed performance measures and annual review planning. However, the OCSPP has not finalized and published a *CMP* since 2014. A draft 2018 *CMP* was provided to OCSPP leadership in 2019, but it was never finalized. As a result, the EDSP has not had strategic guidance since the 2014 *CMP*. As of this evaluation, no other consistent or standardized system of planning for the EDSP has been implemented.

The absence of a strategic plan also impacts the OCSPP's EDSP resource allocations. In fiscal year 2021, the program was allocated $7.5 million but had only approximately four full-time equivalent staff members, according to OCSPP budget staff. OCSPP budget staff indicated that, based on the actual

budget allocation, the program could support at least seven full-time equivalent staff members. Several staff and managers shared their belief that the program is understaffed, which may impact the program's ability to make measurable progress.

EDSP Does Not Have Performance Measures

The EDSP has not developed performance measures to determine the effectiveness of the program. The Government Accountability Office's Green Book states that management should evaluate performance in achieving objectives. The 2011 OIG report recommended that the EDSP develop short-term, intermediate, and long-term outcome performance measures and additional output performance measures, with appropriate targets and time frames, to measure program progress and results. In response, performance measures were developed and included in the 2014 *CMP*. We found that, after the 2014 *CMP*, the EDSP has not documented performance measures and has not identified short-term, intermediate, and long-term targets to clarify expectations and guide work prioritization. In fact, some program staff stated that the program lacked support and some staff were specifically instructed to function as if the program was not funded. Absent performance measures, the EPA cannot appropriately track the EDSP's progress toward meeting statutory requirements on identifying and testing endocrine-disrupting chemicals.

EDSP Has Not Conducted Internal Monitoring Reviews

The EDSP has not conducted any internal monitoring, such as annual reviews, to determine whether the program is achieving its goals. Monitoring is an important component of internal control and encompasses activities that management establishes and operates to assess the quality of performance over time and to promptly resolve the findings of audits and other reviews. According to the Office of Management and Budget's Circular No. A-123, continuous monitoring and other periodic assessments should provide the basis for the Agency's annual assessment of and report on internal controls. The EDSP agreed to conduct annual reviews in response to the OIG's 2011 report recommendations, but none of the staff and managers we interviewed could produce any documents from previous annual reviews. Absent management establishing program accountability through consistent monitoring and annual reviews, the EDSP will not be able to establish an effective screening and testing program.

EDSP Needs to Improve Communication with Stakeholders

The EDSP needs to improve its communication with both internal and external stakeholders. The Government Accountability Office's Green Book states that management should communicate both internally and externally to maintain accountability and transparency. In *Working Together: FY 2018–*

2022 U.S. EPA Strategic Plan, one of the Agency's strategic objectives is to "increase transparency and public participation," which includes coordination across the EPA's programs to ensure alignment of mutual efforts. The strategic objective also included platforms to ensure that the public can meaningfully participate in all of the EPA's work—including policy making, regulatory development, outreach, education, and community engagement. Additionally, EPA Administrator Michael Regan emphasized the importance of transparency and earning public trust in an April 12, 2021 agencywide email that stated that the "EPA will provide for the fullest possible public participation in decision-making."

Internally, the EDSP lacks an effective procedure for coordinating with other EPA program offices that are responsible for potential endocrine-disrupting chemicals. For example, the Office of Water conducts Safe Drinking Water Act-related work on endocrine disruptors, and the Office of Research and Development oversees the EPA's overall research planning. EDSP management expressed concern on how to better engage other program offices since everyone is strained for resources. The OCSPP's October 2020 reorganization gives the EDSP an opportunity to develop needed procedures for internal communication and coordination with other relevant program offices.

Despite public interest in the health effects from endocrine-disrupting chemicals, we found that the EDSP has not published any technical documents for public review and comment since 2015. EDSP staff stated that they have been working on a summary of the comments the EPA received for its 2015 *Federal Register* notice regarding its plan to incorporate an alternative scientific approach to screen potential endocrine-disrupting chemicals and the Agency's responses to those comments. The EDSP still needs to complete and publish its comment responses to the *Federal Register* notice.

EDSP staff said that they are working on a white paper that summarizes the scientific progress for using new approach methodologies for prioritizing and screening chemicals. Staff added that the white paper lists which new approach methodologies are considered as alternatives to some of the 11 assays in the Tier 1 screening battery and could be considered as "other scientifically relevant information" toward fulfilling certain Tier 1 screening requirements. In reviewing the EDSP's website, we found that most of the website has not been updated since 2017. Absent transparent internal and external communication regarding the EDSP, the public cannot make necessary decisions on endocrine disruptors and their potential health effects.

Conclusions

In 1996, Congress directed the EPA to establish the EDSP, and the program received approximately $7.5 million in funding in fiscal year 2021. Yet, the EDSP can show only limited results. Without the required testing and an effective system of internal controls, the EPA cannot make measurable progress toward compliance with statutory requirements or safeguard human health and the environment against risk from endocrine-disrupting chemicals.

Recommendations

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention:

1. Issue Tier 1 test orders for each List 2 chemical or publish an explanation for public comment on why Tier 1 data are no longer needed to characterize a List 2 chemical's endocrine-disruption activity.

2. Determine whether the EPA should incorporate the Endocrine Disruptor Screening Program Tier 1 tests (or approved new approach methodologies) into the pesticide registration process as mandatory data requirements under 40 C.F.R. § 158 for all pesticide use patterns.

3. Issue List 1–Tier 2 test orders for the 18 pesticides in which additional Tier 2 testing was recommended or publish an explanation for public comment on why Tier 2 data are no longer needed to characterize the endocrine-disruption activity for each of these 18 pesticides.

4. Issue for public review and comment both the Environmental Fate and Effects Division's approach for the reevaluation of List 1–Tier 1 data and the revised List 1–Tier 2 wildlife recommendations.

5. Develop and implement an updated formal strategic planning document, such as the *Comprehensive Management Plan*.

6. Develop performance measures, with reasonable time frames, to document progress toward and achievement of milestones or targets. Specifically, the Endocrine Disruptor Screening Program should consider at least one performance measure that tracks progress in testing pesticides for human endocrine disruptor activity.

7. Conduct annual internal program reviews of the Endocrine Disruptor Screening Program.

8. Complete and publish the Endocrine Disruptor Screening Program's response(s) to 2015 *Federal Register* notice comments and its related white paper.

9. Establish a procedure for Endocrine Disruptor Screening Program communications and coordination with relevant Agency program offices with testing responsibilities.

10. To increase external communication and transparency, update the Endocrine Disruptor Screening Program website, including the program timeline, and publish any relevant program documents.

Agency Response and OIG Assessment

The EPA generally agreed with our recommendations and provided acceptable corrective actions and estimated completion dates for all ten recommendations. The recommendations are considered resolved with corrective actions pending. We also revised our report where appropriate based on technical comments provided by the Agency.

The Agency's full response to our draft report is in Appendix A.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	15	Issue Tier 1 test orders for each List 2 chemical or publish an explanation for public comment on why Tier 1 data are no longer needed to characterize a List 2 chemical's endocrine-disruption activity.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/25	
2	15	Determine whether the EPA should incorporate the Endocrine Disruptor Screening Program Tier 1 tests (or approved new approach methodologies) into the pesticide registration process as mandatory data requirements under 40 C.F.R. § 158 for all pesticide use patterns.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/24	
3	15	Issue List 1–Tier 2 test orders for the 18 pesticides in which additional Tier 2 testing was recommended or publish an explanation for public comment on why Tier 2 data are no longer needed to characterize the endocrine-disruption activity for each of these 18 pesticides.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/24	
4	15	Issue for public review and comment both the Environmental Fate and Effects Division's approach for the reevaluation of List 1–Tier 1 data and the revised List 1–Tier 2 wildlife recommendations.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/23	
5	15	Develop and implement an updated formal strategic planning document, such as the *Comprehensive Management Plan*.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/22	
6	15	Develop performance measures, with reasonable time frames, to document progress toward and achievement of milestones or targets. Specifically, the Endocrine Disruptor Screening Program should consider at least one performance measure that tracks progress in testing pesticides for human endocrine disruptor activity.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	10/1/24	
7	15	Conduct annual internal program reviews of the Endocrine Disruptor Screening Program.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/22	
8	16	Complete and publish the Endocrine Disruptor Screening Program's response(s) to 2015 *Federal Register* notice comments and its related white paper.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/21	
9	16	Establish a procedure for Endocrine Disruptor Screening Program communications and coordination with relevant Agency program offices with testing responsibilities.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/21	
10	16	To increase external communication and transparency, update the Endocrine Disruptor Screening Program website, including the program timeline, and publish any relevant program documents.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/30/21	

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: OCSPP Response to Draft Report entitled, "EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides," Report No. OE-FY20-379.

FROM: Michal Freedhoff, Ph.D.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2021.06.28 14:32:24 -04'00'

TO: Sean W. O'Donnell
Inspector General

This memorandum responds to the OIG's Draft Report entitled "EPA's Endocrine Disruptor Screening Program Has Made Limited Progress in Assessing Pesticides," Report No. OE-FY20-379, June 8, 2021.

I. General Comments:

The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating the following two objectives:

1. Progress in implementing Section 408(p)(3)(A) of the Food Quality Protection Act, which requires the EPA to test all pesticide chemicals for human endocrine disruption activity.

2. Compliance with Section 408(p)(6) of the Food Quality Protection Act, which requires the EPA to take action when finding, through testing and evaluation, that a substance has an endocrine effect on humans.

OCSPP is in general agreement with the 10 recommendations in the Draft Report regarding the Endocrine Disruptor Screening Program (EDSP). OCSPP is proposing to broadly address the recommendations with an iterative EDSP Strategic Plan, which we anticipate will be developed and updated to reflect new data and findings. This EDSP Strategic Plan is described in more detail in our response to the specific recommendations, below.

As an important first step, OCSPP has already put into place a new organizational structure to ensure management accountability for the EDSP. With the OCSPP reorganization in October 2020, the Office of Pesticide Programs (OPP) now has responsibility for the EDSP, which was previously effectively divided between OPP and the former Office of Science Coordination and Policy (OSCP). OPP has already begun the process of aligning the human and technical infrastructure to accelerate the implementation of EDSP testing and decisions. OCSPP is optimistic that through these efforts, the pace of evaluations for endocrine disruption will accelerate, become more transparent, and be more clearly communicated.

While OCSPP acknowledges the challenges faced by the EDSP in the past, including efforts from previous OCSPP leadership to not fully implement the EDSP and its funding, OCSPP disagrees with the Draft Report's finding that the Agency "has not made meaningful progress in meeting its statutory obligation to test all pesticides for endocrine-disruption activity." By developing and enacting a screening and testing program, EPA has fulfilled numerous goals associated with the legal mandate. Notably, test orders were issued for Tier 1 data for 67 List 1 chemicals in 2009, and reviews of the submitted data and conclusions were published in 2015. Furthermore, in addition to the Tier 1 data on the List 1 chemicals, EPA has:

- Generated in vitro estrogen and androgen receptor pathway data for approximately 500 pesticide chemicals;
- Compiled some human health Tier 2 data for hundreds of conventional, food-use pesticides;
- Identified EDSP assays from the scientific literature on a wide range of EDSP chemicals for the uterotrophic, Hershberger, steroidogenesis, amphibian metamorphosis, male and female pubertal assays;
- Developed cancer and/or non-cancer human health risk assessments using endocrine related endpoints for over 100 conventional pesticides; and
- Initiated collaborative work with the Office of Research and Development (ORD) to collect additional in vitro data on estrogen and androgen for approximately 250-750 additional pesticide active ingredients.

In assessing the EDSP's accomplishments, it is important to note that in the last decade, EPA focused its efforts on developing new approach methods (NAMs).[5] This investment was made because of the extensive resources (time, cost, and use of laboratory animals) required to develop and evaluate the Tier 1-List 1 data. These new approach methods are faster, more efficient, and provide more human-relevant and mechanistically-driven data for use in the evaluation of estrogen, androgen, and thyroid bioactivity. In collaboration with ORD and the National Institutes of Environmental Health Science (NIEHS) - NTP Interagency Center for the Evaluation of Alternative Toxicology Methods (NICEATM), the EDSP has made substantial progress in this area. OCSPP's announcement of the acceptance and use of in vitro and computational approaches will be described in a NAMs White Paper, which will be published for public comment in 2021, and is expected to be finalized in 2022.

OPP leadership met with me on June 22, 2021 to discuss their vision for an EDSP transition. As part of this vision, an internal council of staff across OPP will be created to address the science policy issues associated with the EDSP data needs. This OPP/EDSP Council will begin meeting in September 2021. One of its first duties will be to develop 3 - 6 case studies for the different types of pesticide chemicals (e.g., conventional, antimicrobial, biopesticides, etc) regulated by OCSPP. These case studies will evaluate the approaches for using NAM data, in combination with existing Tier 1 or Tier 2 studies submitted for pesticide registration in the 40 CFR part 158 and other scientifically relevant information. The evaluations of these case studies will be used to inform short, intermediate, and long-term activities for the EDSP, including the development of the ESDP Strategic Plan, additional research needed by ORD or NIEHS, and possible test order needs.

Even with the expected efficiencies from this approach, prioritization of the workload is critical because of the large number of substances identified as being within the EDSP universe. EPA's first priority will be on the statutorily-required testing of pesticide chemicals (i.e., active ingredients and inerts). This work will occur prior to the evaluation of the discretionary Safe Drinking Water Act (SDWA) chemicals. Moreover, the ordering (i.e., prioritization) of chemical testing for EDSP is currently being reevaluated to better align with pesticide registration review and registration schedules. Accordingly, while the Draft Report in some cases recommends a binary choice of actions, OCSPP's proposed Corrective Action Plan in some instances explains why it is necessary to propose additional, alternative corrective actions to address the recommendations.

In addition to this memo, OCSPP has prepared Technical Comments on the Draft Report, which we will transmit under separate cover. These Technical Comments in redline/strikeout (1) corrections, (2) proposed language changes and (3) lesser issues of concern in the Draft Report itself.

II. OCSPP's Response to the Recommendations:

[5] NAMs refer to any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment to avoid the use of animal testing.

Recommendation 1: Issue Tier 1 test orders for each List 2 chemical or publish an explanation for public comment on why Tier 1 data is no longer needed to characterize a List 2 chemical's endocrine-disruption activity.

OCSPP acknowledges that Tier 1 test orders have not been issued for List 2 chemicals and agrees that action on List 2 is needed. OCSPP agrees with two possible outcomes that the OIG proposes: that List 2 test orders need to be issued, or that an explanation should be published articulating why test orders are not needed for List 2 (including that EPA expects to acquire the needed data from other sources). OCSPP proposes, as an additional action, that some decisions on some List 2 chemicals may be delayed due to test chemical reprioritization consistent with the needed refocus to address mandatory elements under the statute first, namely estrogen effects on pesticide chemicals.

- **Proposed Corrective Action 1a**: OCSPP, with input from the Office of Research and Development and the Office of Water, will publish for comment a List 2 Action Plan, which may include a combination of test orders, explanations as to why test orders are not needed, or a reprioritization of the order of EDSP evaluations.

- **Proposed Corrective Action 1b**: Following notice and comment as described in Corrective Action 1a, OCSPP will initiate the process to issue test orders for List 2 substances, as appropriate.

- **Target Completion Dates**: September 30, 2024 for Action 1a. September 30, 2025 for 1b.

Recommendation 2: Determine whether the EPA should incorporate the EDSP Tier 1 tests (or approved new approach methodologies) into the pesticide registration process as mandatory data requirements under 40 C.F.R. § 158 for all pesticide use patterns.

OCSPP agrees that a determination should be made and shared with the public on whether the EPA will incorporate the EDSP Tier 1 tests (or appropriate NAMs/new approach methodologies) into the pesticide registration process as mandatory data requirements under 40 C.F.R. part 158 for all pesticide use patterns. OCSPP is not developing new EDSP test guidelines for NAMs, but instead is accepting NAMs as other scientifically relevant information for alternatives to Tier 1 guideline studies on a case-by-case basis.

- **Proposed Corrective Action 2**: OCSPP will make a determination on the inclusion of the EDSP Tier 1 tests into the pesticide registration process as mandatory data requirement under 40 C.F.R. part 158 for all pesticide use patterns.

- **Target Completion Date**: September 30, 2024.

Recommendation 3: Issue List 1–Tier 2 test orders for the 18 pesticides in which additional Tier 2 testing was recommended or publish an explanation for public comment why this Tier 2 data is no longer needed to characterize the endocrine-disruption activity for each of these 18 pesticides.

OCSPP agrees the List 1-Tier 2 test orders for the 18 pesticides need to be addressed. Recommendation 4, below, specifically addresses the List 1-Tier 2 ecotoxicology data needs for 17 pesticides. One of the 18 pesticides (Chlorthal Dimethyl (DCPA)), was not recommended for any Tier 2 ecotoxicology data.

- **Proposed Corrective Action 3a**: OCSPP will make a determination on the need for List 1-Tier 2 data. OCSPP will also provide an explanation, which will be published for public comment, for any of the 18 pesticides for which it is determined that Tier 2 data is no longer needed.

- **Proposed Corrective Action 3b**: Following publication and comment as described in Corrective Action 3a, OCSPP will initiate the process to issue any Tier 2 test orders for List 1 determined to be needed.

- **Target Completion Date**: December 31, 2023 for Corrective Action 3a. September 30, 2024 for Corrective Action 3b.

Recommendation 4: Issue for public review and comment both the Environmental Fate and Effects Division's approach for the reevaluation of List 1–Tier 1 data and the revised List 1–Tier 2 wildlife recommendations.

Along with Recommendation 3, OCSPP agrees that any revisions to the final determinations on the List 1–Tier 1 data and any revisions to the List 1–Tier 2 wildlife recommendations need to be issued for public review and comment.

- **Proposed Corrective Action 4**: OCSPP will issue for public review and comment any reevaluation of List 1–Tier 1 data and any revisions to the List 1–Tier 2 wildlife recommendations.

- **Target Completion Date**: Final determinations of the need for List 1-Tier 2 ecotoxicology data will be completed and posted for public comment by December 31, 2023 together with Proposed Corrective Action 3a.

Recommendation 5: Develop and implement an updated formal strategic planning document, such as the *Comprehensive Management Plan*.

OCSPP agrees with the finding that an updated formal strategic planning document should be developed. At the same time, the previous Comprehensive Management Plan took significant time and resources to develop, and such a model will not suit OCSPP's immediate needs. Nevertheless, OCSPP is proposing to develop its EDSP Strategic Plan, which will be an iterative document and will take into account the OCSPP re-organization and the EDSP's transition to a focus on implementation.

- **Proposed Corrective Action 5**: OCSPP, with input from the Office of Research and Development and the Office of Water, will develop an EDSP Strategic Plan. OCSPP expects to update this document on an as needed basis.

- **Target Completion Date**: September 30, 2022.

Recommendation 6: Develop performance measures, with reasonable time frames, to document progress toward and achievement of milestones or targets. Specifically, the Endocrine Disruptor Screening Program should consider at least one performance measure that tracks progress in testing pesticides for human endocrine disruptor activity.

OCSPP agrees that tracking the progress of the EDSP is an important component of the reorganization and that at least one performance measure is needed. Testing and experimentation can take months to years to develop, analyze and finalize conclusions on the data. Although OCSPP has already taken steps to initiate some in vitro testing in collaboration with ORD, a performance measure on testing pesticides for human endocrine disruptor activity cannot be implemented immediately. This activity will incorporate an evaluation of whether testing is needed.

- **Proposed Corrective Action 6a**: OCSPP will develop short-term performance measures, such as scientific publications, number/type of accepted new approach methods, and exemptions granted.

- **Proposed Corrective Action 6b:** OCSPP will develop longer-term performance measures, including at least one measure to track progress in testing pesticides for human endocrine disruptor activity.

- **Target Completion Date**: Short-term performance measures under **Proposed Corrective Action 6a** will be developed by and tracked beginning October 1, 2022. Long-term performance measures under **Proposed Corrective Action 6b** including at

least one that tracks progress in the evaluation and testing of pesticides for human endocrine disruptor activity will be developed and tracked by October 1, 2024.

Recommendation 7: Conduct annual internal program reviews of the Endocrine Disruptor Screening Program.

OCSPP agrees that annual internal program reviews of the EDSP need to be conducted. This review process will be conducted internally, within OCSPP, and will be designed to ensure that proper management controls are in place so that progress and accountability within the EDSP can be determined.

- **Proposed Corrective Action 7a**: OCSPP will conduct the first annual internal program review of the EDSP, and provide a briefing and report out to the OCSPP Assistant Administrator on EDSP progress, especially as it relates to the Corrective Actions in this Report and progress developing the EDSP Strategic Plan.

- **Target Completion Date**: September 30, 2022.

Recommendation 8: Complete and publish the Endocrine Disruptor Screening Program's response(s) to 2015 *Federal Register* notice comments and its related white paper.

OCSPP agrees that the Endocrine Disruptor Screening Program's response to the 2015 *Federal Register* notice comments and the related NAM White Paper need to be completed and published.

- **Proposed Corrective Action 8**: OCSPP will complete and publish the response to 2015 *Federal Register* notice comments and the NAM White Paper.

- **Target Completion Date**: OCSPP will complete and publish these documents by December 2021.

Recommendation 9: Establish a procedure for Endocrine Disruptor Screening Program communications and coordination with relevant Agency program offices with testing responsibilities.

OCSPP agrees that a procedure for better communications and coordination between the Endocrine Disruptor Screening Program and other Agency program offices needs to be established. OCSPP already routinely coordinates with ORD and has already been including EDSP in those discussions.

- **Proposed Corrective Action 9**: OCSPP will establish a procedure for communications and coordination with relevant Agency program offices with EDSP testing responsibilities.

- **Target Completion Date**: OCSPP will establish the procedure by September 30, 2021.

Recommendation 10: To increase external communication and transparency, update the Endocrine Disruptor Screening Program website, including the program timeline, and publish any relevant program documents.

OCSPP agrees that the EDSP website needs updating.

- **Proposed Corrective Action 10**: The EDSP will update the EDSP website to post the response to the 2015 *Federal Register* notice comments and the NAM White Paper on the Endocrine Disruptor Screening Program website. Continuing updates, for example on the OCSPP reorganization, will also be done as needed to increase external communication and transparency.

- **Target Completion Date**: Corrections to the EDSP website, including hyperlinks to documents and other webpages, have already begun. The NAM White Paper and associated documents will be published on the Endocrine Disruptor Screening Program website by December 30, 2021.

cc: All OCSPP DAAs

Program Office OD, DOD
Erin Barnes-Weaver, OIG
Lauretta Joseph, OIG
Michael Wilson, OIG
Natasha Henry, OIG
Janet L. Weiner, OCSPP Audit Liaison
Cameo Smoot, OPS Program Office Audit Liaison

Appendix B

Distribution

The Administrator
Deputy Administrator
Chief of Staff, Office of the Administrator
Deputy Chief of Staff, Office of the Administrator
Assistant Administrator for Chemical Safety and Pollution Prevention
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Deputy Assistant Administrator for Chemical Safety and Pollution Prevention
Director, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention
Director, Office of Continuous Improvement, Office of the Chief Financial Officer
Audit Follow-Up Coordinator, Office of the Administrator
Senior Audit Advisor, Office of Chemical Safety and Pollution Prevention
Audit Liaison, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention