



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

NOV 22 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to OIG's August 19, 2011 Memorandum regarding Final Evaluation Report, "EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results"
Report No. 11-P-0215

FROM: Stephen A. Owens, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

TO: Arthur A. Elkins, Jr.
Inspector General

A handwritten signature in blue ink, appearing to read "S. A. Owens", is written over the "FROM:" field.

This memorandum is in response to the Office of Inspector General's (OIG's) August 19, 2011 memo regarding the Office of Chemical Safety and Pollution Prevention's (OCSPP's) Corrective Action Plan for the subject audit. In that memo, the OIG issued a partial acceptance of OCSPP's Corrective Action Plan and closed recommendations 3(a) and 6.¹ The memo also requested additional information regarding OCSPP's planned corrective actions and deadlines for recommendations 1, 2, and 3(b). OCSPP staff have had extensive discussions with OIG staff regarding clarifications and the key deliverables associated with your recommendations. Based on these discussions, attached is a revised Corrective Action Plan. Also attached are the key deliverables: the final EDSP21 Work Plan Summary and EDSP Weight of Evidence documents. These documents contain the substance of the actions we have taken to address recommendations 1, 2, and 3(a).

The OIG's August 19, 2011 memo also asked for clarification that deliverables associated with recommendations 1 and 2 would be completed by September 30, 2011. I am pleased to confirm the OIG's understanding of our schedule for this work and to attach copies of the completed work products.

OCSPP appreciates the OIG's thoughtful evaluation of the EDSP, and its interest in improving the program. Over the past several months, your staff provided helpful and concrete suggestions to improve the clarity of the deliverables, so that these documents now fully address the OIG's concerns.

¹ The OIG had previously accepted OCSPP's planned corrective actions for recommendations 4 and 5 in Appendix B of the Final Report.

My staff and I remain committed to being responsive to the recommendations contained in the report “EPA’s Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results.” If you have any questions regarding this memorandum, or if further dialogue would benefit the review process, please have your staff contact Janet L. Weiner, OCSPP’s Audit Liaison, at (202) 564-2309.

Attachments: Revised Corrective Action Plan
EDSP 21 Work Plan Summary
Weight of Evidence Document

cc: Wade T. Najjum, Assistant Inspector General for Program Evaluation, OIG
Elizabeth Grossman, Deputy Assistant Inspector General for Program Evaluation, OIG
Rick Beusse, Director for Program Evaluation, Air & Research Issues, OIG
Renee McGhee-Lenart, Project Manager, Office of Program Evaluation, OIG
Frank Sanders, Director, OCSP/OCSP
Steven Knott, Deputy Director, OCSP/OCSP
Doug Wolf, OCSP

Revised Corrective Action Plan
To Implement Recommendations from the OIG Final Evaluation Report
“EPA’s Endocrine Disruptor Screening Program Should Establish Management Controls to
Ensure More Timely Results”
Office of Chemical Safety and Pollution Prevention
November 17, 2011

OIG Recommendation 1: Define and identify the universe of chemicals for screening and testing to establish the scope of the program.

OCSPP Response: A characterization of the universe of chemicals for screening and testing under the EDSP will be provided in a public summary of the EDSP21 Work Plan. The Agency believes that the statutory requirements and discretionary authorities conveyed through the Federal Food, Drug, and Cosmetic Act (FFDCA) and Safe Drinking Water Act (SDWA) provide a clear scope for the Endocrine Disruptor Screening Program (EDSP). The universe of approximately 6,000 to 9,700 chemicals defined by these statutes is sufficient for longer term, strategic planning for the EDSP. This characterization of the universe will allow the Agency to estimate resource needs and timelines in the context of the 5-year comprehensive Management Plan for the program. In addition, the Agency believes this characterization of the universe addresses such factors as public nominations and exposure considerations.

Deliverable: Characterization (including numerical estimate) of the universe of chemicals for screening and testing under the EDSP, in the EDSP21 Work Plan Summary.
Schedule for Completion: September 30, 2011 (Completed)

OIG Recommendation 2: Develop and publish a standardized methodology for objectively prioritizing the universe of chemicals for screening and testing, including elements recommended by the federal advisory committees such as use of effects and exposure data, as well as public nominations.

OCSPP Response: The EDSP21 Work Plan provides a road map for the incorporation of *in silico* models and *in vitro* high throughput assays in the Endocrine Disruptor Screening Program (EDSP). A central focus for the Work Plan is to build confidence in (or validate) 21st century tools to progress from their current and near term use for prioritization to ultimately serving as regulatory accepted approaches for screening. For the near term, the Work Plan proposes a contemporary and standardized approach to objectively prioritize pesticide active ingredients, pesticide inert ingredients and Safe Drinking Water Act Chemicals for EDSP Tier 1 screening. The approach is based on advances in computational modeling and molecular biology,

understanding of endocrine-specific initiating events and adverse outcome pathways as well as robotics for conducting rapid in vitro assays on hundreds of chemicals simultaneously. It includes consideration of exposure, probability of effects, and, where applicable, public input processes, as well as schedules associated with the registration review process for pesticides. Exposure evaluation has been the major criterion for selection of which pesticides were screened for List 1 and was the major criterion for establishing the CCL Universe.

Deliverable: An overview of a framework for prioritizing chemicals for screening, and validating new screening methods, in the EDSP21 Work Plan Summary.

Schedule for Completion: September 30, 2011 (Completed)

OIG Recommendation 3:

a. Finalize specific criteria for evaluating the Tier 1 screening data received

Deliverable: Weight of Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing. Document ID EPA-HQ-OPPT-2010-0877-0021, Docket ID EPA-HQ-OPPT-2010-0877, www.regulations.gov

Completed: September 30, 2011.

b. [A]nd establish specific criteria for evaluating Tier 2/hazard assessment testing data received.

OCSPP Response: EPA has a long history of conducting hazard and risk assessments of the type that would be performed after receiving additional test data, if needed, to make hazard evaluations and risk management decisions in Tier 2 of the EDSP. If, after Tier 1 Screening, including a weight of evidence evaluation, it is determined that a chemical has the potential to disrupt the estrogen, androgen or thyroid systems and sufficient information is not available to determine the magnitude of hazard and risk, then additional studies may be required. Specifically, the Weight of Evidence approach will be used to evaluate all relevant data. These data include the results of the Tier 1 Screening assays, scientifically relevant information on associated effects related to the endocrine system, and information regarding exposure, if available. The collected information evaluated through the Weight of Evidence approach will be used to determine if the chemical has the potential to disrupt the estrogen, androgen, or thyroid hormone systems. Once this determination is made, and consistent with the EDSP and the Weight of Evidence evaluation, a conclusion based on this collective evaluation will be made regarding whether additional testing is necessary, for what endpoint(s), and for which taxa.

If additional testing is determined to be necessary, this additional testing is the second tier of data collection or EDSP Tier 2. This is not a battery but rather the selection of a targeted study or studies to provide the data needed to inform risk assessment and management decisions. Federal Advisory Committees convened by EPA noted that for some endpoints in some species, available tests were not adequate. This resulted in the development and validation of additional test systems to expand the Agency's tool box. These Tier 2 test systems are not designed or desired to be used as a battery but rather to be made available, along with the current OECD and OCSPP test guidelines, for testing of selected chemicals for specific endpoints as needed. Chemicals that are ultimately selected to undergo Tier 2 testing will then be evaluated, after completion of the selected Tier 2 Tests, using longstanding hazard evaluation criteria that are routinely used by EPA's regulatory programs to assess risk to human and ecological health. EPA's risk assessment guidance's and underlying scientific rationale for them are publicly available and have been extensively peer reviewed over several years. The EDSP Management Plan will include references and links to guidance documents that are relevant to the types of assessments to be conducted in Tier 2 of the EDSP.

Deliverable: EDSP Management Plan

Schedule for completion: June 30, 2012

OIG Recommendation 4: Develop short-term, intermediate, and long-term outcome performance measures, and additional output performance measures, with appropriate targets and timeframes, to measure the progress and results of the program.

OCSPP Response: As the Agency develops its comprehensive Management Plan for the EDSP, existing performance measures will be re-evaluated with the goal of developing a set of measures that more comprehensively addresses EDSP activities across all offices and includes more outcome measures. Our initial thinking with respect to applying the guidance OIG has provided, in the context of the EDSP, is that short-term outcomes could consist of making weight-of-evidence determinations to decide whether a chemical will move on to EDSP Tier 2 testing (this is currently captured under our existing measures). Intermediate outcomes could consist of the hazard assessments that will result from Tier 2. Long-term outcomes could include a characterization of the regulatory actions that result from EDSP screening and testing, the impact of such actions on human health and the environment and other metrics.

Deliverable: Performance Measures, articulated in the EDSP Management Plan

Schedule for completion: June 30, 2012

OIG Recommendation 5: Develop and publish a comprehensive management plan for EDSP, including estimates of EDSP's budget requirements, priorities, goals, and key activities covering at least a 5-year period.

OCSPP Response: EPA plans to develop a comprehensive Management Plan for the EDSP. The aforementioned EDSP21 Work Plan for integrating computational toxicology tools into the EDSP will be a key, initial component of the EDSP Management Plan. The EDSP Management Plan will cover at least 5 years into the future of the EDSP and will include the continued issuance of test orders, the development of a consolidated information infrastructure for the EDSP, and other aspects of the program. The Management Plan will address budget requirements for the EDSP and performance management, including performance measures and annual reviews.

Deliverable: EDSP Management Plan

Schedule for completion: June 30, 2012

OIG Recommendation 6: Annually review the EDSP program results, progress toward milestones, and achievement of performance measures, including explanations for any missed milestones or targets.

OCSPP Response: The EDSP Management Plan will include a section that outlines the specifics for a new annual review process for the EDSP. 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. The schedule for this annual review, including the date of the first presentation of its conclusions to the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, will be outlined in the Management Plan.

Deliverable: EDSP Management Plan

Schedule for completion: June 30, 2012

Corrective Action Plan Deliverables

Rec. No.	Page No.	Recommendation	Status	Action Official	Planned Completion Date	Agency Vehicle for Response
1	19	Define and identify the universe of chemicals for screening and testing to establish the scope of the program.		Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11	EDSP21 Work Plan
2	19	Develop and publish a standardized methodology for objectively prioritizing the universe of chemicals for screening and testing, including elements recommended by the federal advisory committees such as use of effects and exposure data, as well as public nominations.		Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11	EDSP21 Work Plan
3	19	(a) Finalize specific criteria for evaluating the Tier 1 screening data received and	O	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11	(a) WOE Document
		(b) establish specific criteria for evaluating Tier 2/hazard assessment testing data received.			6/30/12	(b) EDSP Management Plan
4	19	Develop short-term, intermediate, and long-term outcome performance measures, and additional output performance measures, with appropriate targets and timeframes, to measure the progress and results of the program.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	6/30/12	EDSP Management Plan
5	20	Develop and publish a comprehensive management plan for EDSP, including estimates of EDSP's budget requirements, priorities, goals, and key activities covering at least a 5-year period.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	6/30/12	EDSP Management Plan
6	20	Annually review the EDSP program results, progress toward milestones, and achievement of performance measures, including explanations for any missed milestones or targets.	O	Assistant Administrator for Chemical Safety and Pollution Prevention	6/30/12	EDSP Management Plan

O = recommendation is open with agreed-to corrective actions pending

C = recommendation is closed with all agreed-to actions completed

U = recommendation is undecided with resolution efforts in progress.