



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

JUL 28 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to "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

A handwritten signature in black ink, appearing to read "S. A. Owens".

TO: Arthur A. Elkins, Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG) May 3, 2011 Final Report entitled "EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results."

The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's thoughtful review of the Endocrine Disruptor Screening Program (EDSP), and shares the OIG's interest in improving the program.

As required by EPA Order 2750, "EPA's Audit Management Process," this memorandum transmits a Corrective Action Plan which provides specific dates and milestones for implementing the recommendations expressed in the Final Report. In addition, the Corrective Action Plan seeks to provide clarifying information to respond to additional OIG comments in Appendix B of the Final Report.

Please know that my staff and I are committed to being fully responsive to the recommendations contained in the Final Report. If you have any questions regarding the attached Corrective Action Plan, or if you believe the review process for the plan would benefit from further dialogue, please contact Janet L. Weiner of my staff at (202) 564-2309.

Attachment: Corrective Action Plan

cc: Wade T. Najjum, Assistant Inspector General for Program Evaluation
Rick Beusse, Director for Program Evaluation (Air & Research Issues)
Frank Sanders, Director, Office of Science Coordination and Policy

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
July 28, 2011

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

OCSPP Response: The 1996 Food Quality Protection Act (FQPA) amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA) required EPA to *"develop a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator may designate"* and to *"provide for the testing of all pesticide chemicals."* In addition, amendments to the Safe Drinking Water Act (SDWA) specified that *"the Administrator may provide for testing under the screening program ... of any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance."*

The Agency believes that the statutory requirement and discretionary authority conveyed through these amendments provide a clear scope for the Endocrine Disruptors Screening Program (EDSP). As part of the Agency's workplan focused on integrating high throughput and computational tools into the EDSP (now known as the EDSP 21 Workplan), the Agency will provide a narrative, including a numerical estimate, characterizing the current universe of chemicals for screening and testing in the EDSP.

Deliverable: Characterization (including numerical estimate) of the universe of chemicals for screening and testing under the EDSP, in the EDSP21 Workplan.

Schedule for completion: September 30, 2011.

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: A thorough and objective process for prioritizing the universe of chemicals for EDSP screening and testing may ultimately consider a number of factors, including physical chemical properties, predicted exposure, use, predicted biological

activity, and public input. Computer models, computational methods, and high-throughput screening assays are among the tools that may be used as part of this process to help the Agency make more informed choices regarding which chemicals should be given priority for EDSP screening.

The EDSP 21 Workplan will describe the Agency's approach to prioritizing the universe of chemicals. The Workplan will include milestones that clearly convey to the public the considerations and tools that the Agency will apply to the universe of chemicals, in the near term, to develop a prioritized list. A number of the methods that will be available to efficiently prioritize the universe of chemicals are being, and will continue to be, developed and refined as part of the Chemical Safety for Sustainability Research Program lead by ORD.¹ Therefore, the EDSP 21 Workplan and the broader EDSP Management Plan will also address how these tools may lead to future refinements of priorities and, ultimately, to changes in the Agency's approach to screening and testing.

Deliverable: EDSP21 Work Plan

Schedule for completion: September 30, 2011.

OIG Recommendation 3:

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

OCSPP Response: The Agency is developing a Weight of Evidence Guidance Document that will provide the framework for making the determination as to which chemicals that were subjected to the Tier 1 screenings should be further evaluated with Tier 2 testing.

Deliverable: The Weight of Evidence Guidance Document

Schedule for completion: 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 envisioned in Tier 2 of the EDSP. Chemicals that are ultimately selected to

¹ ORD (2011). Chemical Safety for Sustainability Research Action Plan, <http://v26265ncay001.aa.ad.epa.gov/opencms/export/ord@work/ordtoday/hotspot/CSSDraftResearchActionPlan.pdf>

undergo Tier 2 testing will be evaluated using longstanding hazard evaluation criteria that are routinely used by EPA's regulatory programs to assess risk to human and ecological health². EPA's risk assessment guidances and underlying scientific rationale for them are publicly available and have been extensively peer reviewed over several years.

In the EDSP Management Plan, the Agency will include a section that addresses types of evaluations and assessments that are envisioned for Tier 2 of the EDSP. This section will provide more specific references to relevant guidance materials.

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 Workplan for integrating computational toxicology

² See EPA's Risk Assessment Forum website (<http://www.epa.gov/raf/pubhumanhealth.htm>; <http://www.epa.gov/raf/pubecological.htm>) for specific risk assessment guidance.

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 ¹	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.	TBD	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11	EDSP21 Workplan
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.	TBD	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11	EDSP21 Workplan
3	19	(a) Finalize specific criteria for evaluating the Tier 1 screening data received and (b) establish specific criteria for evaluating Tier 2/hazard assessment testing data received.	TBD	Assistant Administrator for Chemical Safety and Pollution Prevention	9/30/11 6/30/12	(a) WOE Document (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.	TBD	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.

TBD= status of recommendation to be determined by OIG review of CAP