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

AUG 19 2011

THE INSPECTOR GENERAL

MEMORANDUM

SUBJECT: Response to Corrective Action Plan for OIG Report No. 11-P-0215, *EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results*, May 3, 2011

TO: Stephen A. Owens
Assistant Administrator for Chemical Safety and Pollution Prevention

Thank you for your recent response to the subject report. We appreciate the additional information provided by the Office of Chemical Safety and Pollution Prevention (OCSPP) in the revised corrective action plans for all recommendations. We previously accepted recommendations 4 and 5 pending the agreed-to corrective action when we issued the final report. We are also closing recommendations 3(a) and 6 based on OCSPP's recent response.

The Agency's responses to Recommendations 1, 2, and 3(b) show progress toward a mutually satisfactory solution, but we are seeking additional information regarding OCSPP's planned corrective actions for these recommendations. Also, we seek clarification of the planned completion dates for recommendations 1 and 2. From the information provided, recommendations 1 and 2 will be completed September 30, 2011; however, the deliverables for recommendations 1 and 2 are scheduled to be included in the Management Plan that is to be published by June 30, 2012. We wanted to confirm that we would be receiving deliverables for recommendations 1 and 2 by September 30, 2011.

We appreciate your commitment to address the OIG report recommendations. In accordance with OIG policy, we will periodically follow up to determine how well the Agency's ongoing and planned actions have addressed the recommendations.

If you or your staff have any questions regarding this memo, please contact Wade Najjum, Assistant Inspector General for Program Evaluation, at (202) 566-0827, Rick Beusse at (919) 541-5747, or Renee McGhee-Lenart at (913) 551-7534.

Arthur A. Elkins, Jr.

Attachment

cc: Frank Sanders, Director, Office of Science Coordination and Policy, OCSPP
Janet Weiner, Audit Liaison, OSCPP
Wade 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

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
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. Proposed Corrective Action: OCSPP agreed to provide a characterization (including numerical estimate) of the universe of chemicals for screening and testing as part of its EDSP21 Workplan. Timeline: Schedule for completion date of September 30, 2011.	In addition to the quoted passages from the FQPA and SDWA amendments in your response, there are other chemical categories within the EDSP program's scope which remain unaddressed. For example: • The FQPA also grants authority to test "*any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.*" • The SDWA amendments also provide EPA with the authority to test *any other substance that may be found in sources of drinking water*," which includes substances in addition to those listed on the third Contaminant Candidate List or regulated with a national primary drinking water regulation. • In addition to these authorities, the Agency has also considered using its authority under the Toxic Substances Control Act to test chemicals. We continue to believe that OCSPP needs to define which authorities it will use to establish the scope of the program and, for those authorities not used, OCSPP should provide the basis for deleting potential substances from the universe of potential endocrine disruptors. Also, for authorities exercised, OCSPP needs to define how and when they will be used. We believe it will be difficult to arrive at a reasonable numerical estimate of the universe of chemicals without this extent of assessment. We request that OCSPP include this information in their future response to Rec. 1. Our recommendation also called for identifying the universe of chemicals for screening and testing. OCSPP's proposed corrective action is to provide a characterization of the universe. While including a numerical estimate of the universe is useful, we would also need a list of the chemicals that will be screened and tested. In our exit conference, OCSPP staff stated that the Agency does not have a fixed list for certain types of chemicals. We understand that some types of chemicals may require a numerical estimate, and the chemicals may not be able to be listed. However, to the extent that chemicals can be listed, we believe that information should be included as an appendix to the EDSP Management Plan (Management Plan). In addition, OCSPP	Additional information/ clarification needed.

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		should identify what information they have and do not have about the chemicals that they cannot list and include that information in the Management Plan. Also, OCSPP's response states that the Agency's EDSP21 Workplan will focus on integrating high throughput and computational tools into the EDSP. While a promising technology, our report points out that these tools have not yet been validated. We believe that OCSPP's EDSP21 Workplan should also address how these tools will be validated. We request additional information / clarification regarding OCSPP's planned corrective actions for Recommendation 1. In addition, we seek clarification on when the OIG will receive the information concerning this recommendation. The schedule for completion shows September 30, 2011, but the schedule for the Management Plan (in which the deliverables are to be published) will not be released until June 2012.	
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. 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	OCSPP's response does not specifically commit to developing and publishing a standardized methodology for prioritizing the universe of chemicals for screening and testing. We believe the Agency needs to commit to the use of effects and exposure data as well as public nominations. Technically, OCSPP's recent response lists a number of promising prioritization tools, but only states that they may be considered. In addition, we understand that there may be changes in the available techniques over time, and we endorse a transparent communication of how and when OCSPP's chemicals prioritization could change. As information and events change, OCSPP could revise its methodology as long as it was done with transparency for interested and affected parties. Nonetheless, we continue to believe that OCSPP needs to clearly explain how it will achieve the standardized methodology for objectively prioritizing chemicals as called for in the recommendation. We request additional information / clarification regarding OCSPP's planned corrective actions for Recommendation 2. In addition, we seek clarification on when the OIG will receive the information concerning this recommendation. The schedule for completion shows September 30, 2011, but the	Additional information/ clarification needed.

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
	Proposed Corrective Action: OCSPP agreed to describe the Agency's near-term prioritization approach as part of its EDSP 21 Workplan. OCSPP agreed to further elaborate on future prioritization strategies in its EDSP Management Plan, scheduled for completion on June 30, 2012. Timeline: Schedule for completion date of September 30, 2011.	schedule for the Management Plan (in which the deliverables are to be published) will not be released until June 2012.	
3. Finalize specific criteria for evaluating the Tier 1 screening data received and establish specific criteria for evaluating Tier 2/hazard assessment testing data received.	3.(a) - OCSPP Response (Tier 1): 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. 3.(b) - OCSPP Response (Tier 2): 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 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 health. 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 Proposed Corrective Action: OCSPP stated that it will meet the Tier 1 recommendation with the publication of the Weight of Evidence Guidance Document in September 30, 2011. OCSPP agreed to include a section that addresses the types of evaluations and assessments that are envisioned for Tier 2 in its EDSP Management Plan. Timeline: Schedule for completion date of September 30, 2011 / June 30, 2012.	3.(a) - We accept OCSPP's plans to finalize specific criteria for the evaluation of Tier 1 screening data through the publication of the Weight of Evidence Guidance Document. 3.(b) - We appreciate the Agency's commitment to addressing the types of evaluations and assessments envisioned for Tier 2 in its Management Plan. We recommended that EPA establish criteria for evaluation of Tier 2/hazard assessment testing data. If OCSPP is using existing criteria, we believe OCSPP needs to commit to identifying where the criteria came from and how it will be used. If OCSPP plans to establish new criteria, it needs to clearly establish the basis of the criteria. Whether OCSPP uses existing criteria or develops new criteria, it should be made public before Tier 2 testing commences. If the Management Plan will be published before Tier 2 testing begins, then publishing this information in the plan would be acceptable. We request that OCSPP clarify its intentions relative to the specific criteria for the evaluation of Tier 2 data.	3.(a) - Recommendation closed. 3.(b) - Additional information/ clarification needed.

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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 Proposed Corrective Action: OCSPP agreed to articulate the performance measures described in the Recommendation in its EDSP Management Plan. Timeline: Schedule for completion date of June 30, 2012.	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed.
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 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 Proposed Corrective Action: OCSPP agreed to publish the comprehensive management plan described in the Recommendation in its EDSP Management Plan.	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed.

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	Timeline: Schedule for completion date of June 30, 2012.		
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 Proposed Corrective Action: OCSPP agreed to outline a new annual review process in its EDSP Management Plan, which will be designed to ensure proper management controls are in place to determine progress and accountability within EDSP. 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. Timeline: Schedule for completion date of June 30, 2012.	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed.