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

DEC 20 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: Jim Jones
Acting Assistant Administrator for Chemical Safety and Pollution Prevention

Thank you for your recent response to the Office of Inspector General's (OIG's) August 19, 2011, memorandum regarding the subject report. We appreciate the additional information provided by the Office of Chemical Safety and Pollution Prevention (OCSPP) in the revised corrective action plan dated November 22, 2011.

We previously accepted recommendations 4 and 5 pending the agreed-to corrective action when we issued the final report, and we subsequently closed recommendations 3.a. and 6 based on OCSPP's first corrective action plan. We are closing recommendation 3.b. based on OCSPP's second corrective action plan referenced above. The Agency's response to recommendations 1 and 2 shows progress toward a mutually satisfactory solution, but we are seeking additional information/clarification of OCSPP's planned corrective actions for these recommendations.

The attached OIG action plan analysis describes the clarification we are seeking for recommendations 1 and 2. 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, OCSPP
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

Attachment

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

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.	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)	The EDSP21 Work Plan does not address how the Agency will use its authority under the Toxic Substances Control Act (TSCA). If the Agency will not be using this authority, this should be stated in the EDSP21 Work Plan. If the Agency is using this authority, the universe of chemicals that could potentially be tested should be defined. In addition, the Agency's description of the use of discretionary authority under FFDCA is vague. The EDSP21 Work Plan states the following: "Anticipated to add minimally to the universe over the next 5 years. Will be dependent on case by case determinations regarding cumulative effects and exposure." OCSPP should describe why this authority will only add minimally to the universe over the next 5 years. In our previous response to OCSPP's Corrective Action Plan dated August 19, 2011, we stated that the Agency should provide the basis for not using the authorities it has been given to address potential endocrine disruptors. OCSPP also has not clearly described how it developed the number of chemicals that could potentially be screened and tested under each authority in its EDSP21 Workplan (table 1, page 3). While the EDSP21 Workplan included References for the Universe of Chemicals (page 6), the Agency did not explain how these references were used to estimate the universe of chemicals for screening and testing (see table 1).	Additional information/ clarification needed.

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.	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)	OCSPP's response laid out a process for prioritizing chemicals. As part of the prioritization process, OCSPP plans to replace *in vitro* screening assays with validated *in silico* and *in vitro* high throughput (HTP) assays. However, the EDSP21 Work Plan does not describe how or provide a timeline of when it will validate those assays for screening. We asked the Agency in our previous response to OCSPP's corrective action plan dated August 19, 2011, to address how these tools will be validated. The EDSP21 Work Plan also states that prioritization will be based on re-registration, existing exposure and effects information, and results from *in silico* and *in vitro* HTP methods, but does not describe how those elements will be incorporated into the overall prioritization method. In addition, the EDSP21 Work Plan does not address the public nomination of chemicals, though it does state that the Agency will allow for public comment and peer review before regulatory acceptance.	Additional information/ clarification needed.
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.	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.	3.a.: We accept OCSPP's planned actions and the timeline for completion of the corrective action.	3.a.: Recommendation closed 08/19/11.
	b. [A]nd establish specific criteria for evaluating Tier	3.b.: We accept OCSPP's planned actions and the timeline for completion of the correction action. The	3.b.: Recommendation

2/hazard assessment testing data received.

PA 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

EDSP Management Plan should clearly establish the criteria that the Agency will use to evaluate chemicals during Tier 2 testing, including references and links to specific guidance documents, targeted studies, risk assessment guidance, and hazard evaluation criteria to be used during Tier 2 testing.

closed 12/20/11.

	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		
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.	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	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 05/03/11.

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.	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	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 05/03/11.
6. Annually review the EDSP program results, progress toward milestones, and achievement of performance measures, including explanations for any missed milestones or targets.	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	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 08/19/11.