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

APR 19 2012

THE INSPECTOR GENERAL

MEMORANDUM

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

TO: James Jones
Acting Assistant Administrator for Chemical Safety and Pollution Prevention

Thank you for your recent response to the above report. We appreciate the additional information provided by the Office of Chemical Safety and Pollution Prevention (OCSPP) in the revised corrective action plan. We accept the revised corrective action plans and timeframes for recommendations 1 and 2. We previously accepted recommendations 4 and 5 pending the agreed-to corrective action when we issued the final report. We subsequently closed recommendations 3.a. and 6 based on OCSPP's first corrective action plan and closed recommendation 3.b. based on OCSPP's second corrective action plan. All of the report's recommendations are now closed. Additional discussion of these points is in the attached Office of Inspector General (OIG) action plan analysis.

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 Elizabeth Grossman, Acting Assistant Inspector General for Program Evaluation, at (202) 566-0838; 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
Mary Manibusan, Director, Exposure Assessment and Policy Division, Office of Science Coordination and Policy, OCSPP
Janet Weiner, Audit Liaison, OSCPP
Elizabeth Grossman, Acting Assistant Inspector General for Program Evaluation, OIG
Rick Beusse, Director for Program Evaluation, Air and Research Issues, OIG
Renee McGhee-Lenart, Project Manager, Office of Program Evaluation, OIG

OIG Report, "EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results" (Report No. 11-P-0215)

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.	In response to the OIG recommendation to better define and identify the universe of chemicals to be evaluated in the program, the Agency provided a characterization of the universe of chemicals for screening and testing under the EDSP in the EDSP21 Work Plan. The Agency believes that the universe of approximately 6,000 to 9,700 chemicals defined in the EDSP21 Work Plan is sufficient for the longer term, strategic planning envisioned by the OIG for the EDSP, and allows the Agency to adequately estimate its resource needs and timelines in the context of the 5-year Comprehensive Management Plan for the Endocrine Program. To clarify how this universe relates to the broader universe of 87,000 chemicals that was noted in the 1998 Endocrine Disruptors Screening and Testing Advisory Committee's final report, the Agency will provide a more detailed discussion in a short paper tentatively entitled "EDSP Chemicals Prioritization." At the OIG's request, it will also provide further information on the following issues identified by the OIG in previous comments: • The Agency's planned use of its discretionary authority to address chemicals that may have effects that are cumulative to those of pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA); • The Agency's planned use of its discretionary authorities under the Toxic Substances Control Act (TSCA); and • Further clarification about how the numerical range of 6,000 to 9,700 chemicals in the universe was developed. This paper will be posted to the EDSP website: (www.epa.gov/endo). In addition, a citation to this paper and a hyperlink will be included in the Comprehensive Management Plan for the Endocrine Program. **Deliverable**: "EDSP Chemicals Prioritization" paper to be posted to the EDSP website. Document will also be cited in the Endocrine Program Comprehensive Management Plan, which will include a hyperlink to the EDSP website. **Schedule for Completion**: September 30, 2012	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 4/19/12.

OIG Report, "EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results" (Report No. 11-P-0215)

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
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.	On September 30, 2011, in response to the OIG recommendation to develop a standardized prioritization methodology, EPA issued the EDSP21 Work Plan. This document details the Agency's plans for prioritizing the universe of chemicals for screening and testing, including the recommended consideration of exposure and hazard concerns. A central focus for the EDSP21 Work Plan is to explain how new technologies will be used for chemical sorting and prioritization, and ultimately, for screening. The use of predictive *in silico* models and *in vitro* high throughput assays is an area of emerging technologies, and its use in the Endocrine Disruptor Screening Program (EDSP) is, in many respects, cutting edge science. The OIG requested that the Agency provide additional clarification on the program's prioritization methodology and public nominations processes. To explain how the universe of chemicals for screening and testing will be prioritized under the EDSP, and to clarify how 21st century tools will be validated for use, the Agency will develop a short paper tentatively entitled "EDSP Chemicals Prioritization." This paper will describe the key principles[1] that will be used to develop the validation framework for *in silico* and high throughput (HTP) modeling. It will further clarify how the universe of chemicals will be prioritized, by providing additional information about the predictive models for effects and exposure that may be used to indicate that one particular chemical is a better prospect for potential endocrine-disrupting activity than another, and therefore, is likely to be subjected to Tier 1 screening earlier in the process. The paper also will provide further information about the existing public participation processes and how the public can use these processes to nominate chemicals for EDSP screening, or to suggest changes in priorities for EDSP screening. This paper, "EDSP Chemicals Prioritization," will be posted on the EDSP website (www.epa.gov/endo). In addition, the Comprehensive Management Plan for the Endocrine Program will include a citation and hyperlink to the document.	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 4/19/12.

[1] OCSPP stated that several of these principles, such as OECD's QSAR Validation Principles, already have international acceptance.

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
	Deliverable: Paper tentatively entitled "EDSP Chemicals Prioritization" will be posted on the EDSP website. In addition, a citation and hyperlink to this paper will be provided in the Endocrine Program Comprehensive Management Plan. **Schedule for Completion**: September 30, 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.	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. 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, a 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, conclusions will be made, based on this collective evaluation, as to whether additional testing is necessary, for what endpoint(s), and for which taxa.	3.(a) - We accept OCSPP's planned actions and the timeline for completion of the corrective action. 3.(b) - We accept OCSPP's planned actions and the timeline for completion of the correction action. The 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.	3.(a) - Recommendation closed 08/19/11. 3.(b) – Recommendation closed 12/20/11.

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
	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 guidances 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		
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.	We accept OCSPP's planned actions and the timeline for completion of the corrective action.	Recommendation closed 05/03/11.

OIG Recommendation	Agency Action(s) Taken, Ongoing, or Planned	OIG Analysis	Status
	Deliverable: Performance Measures, articulated in the EDSP Management Plan Schedule for completion: June 30, 2012		
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.