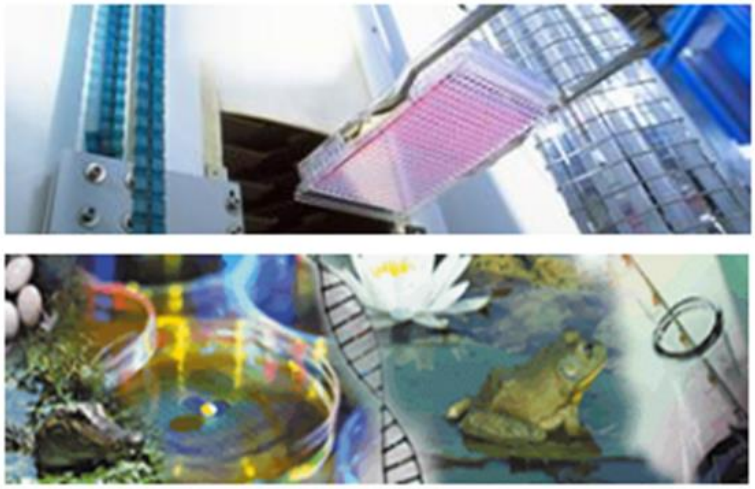
U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Chemical Safety

EPA Should Assess Needs and Implement Management Controls to Ensure Effective Incorporation of Chemical Safety Research Products

Report No. 17-P-0294 **June 23, 2017**



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Abbreviations

BoSC	Board of Scientific Counselors
CSS	Chemical Safety for Sustainability
EDSP21	Endocrine Disrupter Screening Program for the 21st Century
EPA	U.S. Environmental Protection Agency
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
ORD	Office of Research and Development

Cover photos: Endocrine Disruptor Screening Program for the 21st Century. (EPA photos)

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U.S. Environmental Protection Agency
Office of Inspector General

17-P-0294
June 23, 2017

At a Glance

Why We Did This Review

We conducted this review to determine whether the U.S. Environmental Protection Agency's (EPA's) Office of Chemical Safety and Pollution Prevention (OCSPP) effectively incorporates products developed to meet its priority settings, toxicity testing and risk assessment needs. Our scope focused on the computer analysis programs (also called "products") included in the EPA Office of Research and Development's (ORD's) Chemical Safety for Sustainability (CSS) Plan.

More than 80,000 chemicals are currently registered for use under the EPA's authorities. OCSPP is making progress in identifying the risks these chemicals pose, but tens of thousands of these chemicals have yet to be evaluated. To support OCSPP, ORD is working to develop new CSS products to improve this risk assessment process.

This report addresses the following EPA goal or cross-agency strategy:

- *Ensuring the safety of chemicals and preventing pollution.*

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EPA Should Assess Needs and Implement Management Controls to Ensure Effective Incorporation of Chemical Safety Research Products

What We Found

With management controls that ensure the collaborative development of research products and prioritize chemical safety research needs, the EPA would be better able to conduct faster chemical risk assessments.

As part of its chemical safety research effort, ORD works with OCSPP to design research products that meet OCSPP's priority settings, toxicity testing and risk assessment needs. These products are designed to rapidly and accurately support risk analyses, search for chemical testing data across multiple databases, and compare previous research results to current risk assessments. ORD's CSS development process enables OCSPP staff to be actively involved in customizing the products as they are developed.

A 2014–2016 collaboration between OCSPP and ORD successfully produced the Endocrine Disrupter Screening Program for the 21st Century. However, OCSPP does not have management controls to ensure continued, effective collaboration with ORD to develop and customize other CSS products. Further, OCSPP has not conducted an officewide needs assessment to identify CSS product development priorities, determine training and resource needs, and detect challenges. Without management controls that ensure consistent interoffice collaboration and assess CSS product needs, OCSPP is at risk of not effectively incorporating products in a way that could rapidly improve how the EPA assesses chemical risks to human health and the environment.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention conduct a needs assessment that identifies and addresses the challenges, timeframes, training and resources necessary to effectively incorporate ORD products into OCSPP programs. In addition, we recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention develop and implement management controls that formalize OCSPP's processes for collaborating with ORD to maintain current products and for developing future products. The agency agreed with our recommendations and provided acceptable corrective actions. All recommendations are resolved.

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

THE INSPECTOR GENERAL

June 23, 2017

MEMORANDUM

SUBJECT: EPA Should Assess Needs and Implement Management Controls to Ensure Effective Incorporation of Chemical Safety Research Products
Report No. 17-P-0294

FROM: Arthur A. Elkins Jr.

TO: Wendy Cleland-Hamnett, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY16-0029. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The offices responsible for the issues evaluated in this report are the Office of Pesticide Programs, Office of Pollution Prevention and Toxics, and Office of Science Coordination and Policy, all within the Office of Chemical Safety and Pollution Prevention. Further, this report discusses topics and issues directly related to computer analysis programs ("products") developed as part of the Office of Research and Development's implementation of its Chemical Safety for Sustainability Plan.

Action Required

In accordance with EPA Manual 2750, your office provided planned corrective actions in response to the OIG recommendations. All recommendations are considered resolved. You are not required to provide a written response to this final report because you provided agreed-to corrective actions and a planned completion date for the report recommendations. The OIG may make periodic inquiries on your progress in implementing these corrective actions. Please update the EPA's Management Audit Tracking System as you complete planned corrective actions.

We will post this report to our website at www.epa.gov/oig.

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Appendices

Purpose

The U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (OIG) conducted this evaluation to determine whether the Office of Chemical Safety and Pollution Prevention (OCSPP) uses the Office of Research and Development's (ORD's) Chemical Safety for Sustainability (CSS) Strategic Research Action Plan to effectively develop and incorporate products that meet OCSPP's priority settings, toxicity testing and risk assessment needs.

Background

Improving the safe production, use and disposal of chemicals is a major priority for the EPA. More than 80,000 chemicals are registered for use under the EPA's regulatory authorities, with thousands more introduced every year. OCSPP's mission is to protect people and the environment from the potential risks these chemicals pose.

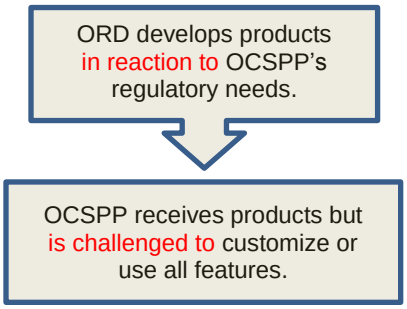
In support of its mission, OCSPP is responsible for implementing laws that regulate pesticides, food and cosmetic additives, and toxic substances; and for promulgating regulations under the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act. OCSPP is also responsible for identifying the risks that chemicals pose by conducting risk assessments. While OCSPP continues to make progress in completing these assessments, tens of thousands of chemicals have yet to be thoroughly evaluated for their potential risks to human health and the environment.

Chemical risk assessment work is time-consuming, as a variety of analyses must be done to review the potential impact of each chemical. For example, using current methods, OCSPP may spend up to 2 years to complete the required human health and environmental risk assessments to approve a new pesticide made with an original chemical formulation. To support OCSPP's chemical safety mission, ORD partners with OCSPP to provide technical assistance that will help conduct those assessments more quickly and accurately. Specifically, ORD is working to develop new ways to improve the risk assessment process.

In 2012, ORD created a CSS Strategic Research Action Plan (CSS Plan) to begin planning for and developing new products for OCSPP. As a result of this 2012 CSS Plan, ORD designed several CSS databases and software applications (hereafter referred to as "products"[1]) that rapidly support risk analyses, search for chemical testing data across multiple databases, and compare and apply previous research results to inform current risk assessment. However, the implementation of the CSS Plan and the use of the CSS products experienced challenges.

[1] The word "products" refers to dashboards (interactive websites that provide access to tools and data necessary to carry out specific analyses) or other ORD tools provided to OCSPP through ORD's CSS Plan.

Figure 1: Initial CSS product development process



Source: OIG-generated diagram.

Under the initial process (Figure 1), once ORD delivered the CSS products, OCSPP program offices were responsible for customizing the products to meet their individual needs. However, the program office customization process was time-consuming and challenging.

By 2014, ORD concluded that its program office clients were not able to fully use the products, and that those products might not be as usable or as functional as intended. As a result, ORD developed a new development process that includes customizing products by directly involving the program office staff who will use the products. This revised process—which is detailed in the "Results of Evaluation" section below—has resulted in the development of products such as the following two:

- *Endocrine Disruptor Screening Program for the 21st Century (EDSP21).* Developed for OCSPP's Office of Science Coordination and Policy, EDSP21 uses mathematical models to assess how various chemicals will disrupt the human endocrine system. EDSP21 also determines the impacts those chemicals have on estrogen, androgen and thyroid bioactivity.
- *RapidTox.* This product is still in development, but ORD anticipates that RapidTox will be able to access large volumes of data to mathematically predict potential chemical risks and then rank and prioritize those risks.

Responsible Offices

Within OCSPP, the three program offices responsible for the issues evaluated in this report are the Office of Science Coordination and Policy, Office of Pesticide Programs, and Office of Pollution Prevention and Toxics. Further, this report discusses topics and issues directly related to computer analysis programs ("products") developed as part of ORD's implementation of its CSS Plan.

Scope and Methodology

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based upon our objectives. We conducted this evaluation from September 2016 to May 2017.

We met with OCSPP management, as well as management staff in OCSPP's Office of Science Coordination and Policy, Office of Pesticide Programs, and Office Pollution Prevention and Toxics. We reviewed ORD's CSS Plan and were

briefed about the development process used to create EDSP21, as well as the progress made in developing RapidTox. Further, we interviewed end-user stakeholders in OCSPP's Office of Science Coordination and Policy, Office of Pesticide Programs, and Office of Pollution Prevention and Toxics; gathered the necessary information to describe the relationship between OCSPP offices and ORD; and met with a former OCSPP Assistant Administrator.

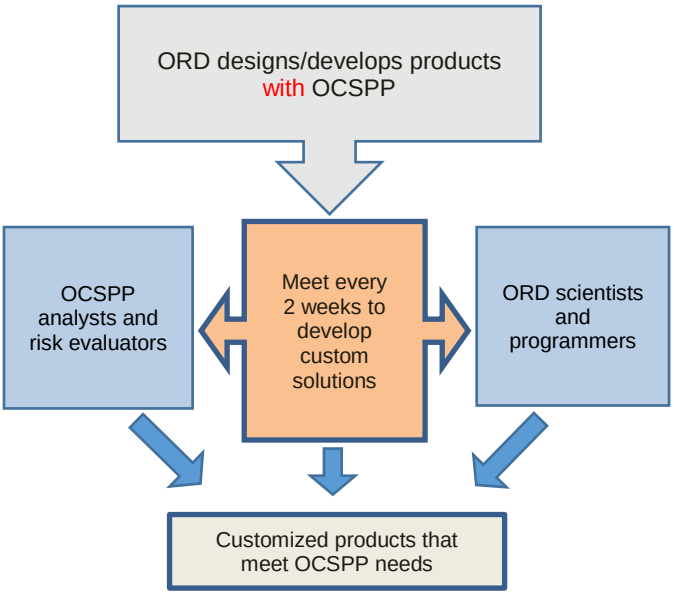
Results of Evaluation

OCSPP's initial collaboration with ORD successfully produced the EDSP21 product. Ensuring that this collaborative process continues to be effective requires action from both ORD and OCSPP. However, we found that OCSPP has not formalized a collaborative product development process. Also, OCSPP has not assessed its overall CSS product needs to detect any challenges, determine the timeframes, and identify the training and resources necessary to ensure effective incorporation of ORD products into OCSPP programs.

Management Controls Are Needed to Ensure Consistent Collaboration in Product Development

OCSPP has not developed a formal process to ensure that it consistently collaborates with ORD to use the revised CSS development process. ORD describes this revised process—which it calls "translation"—as a way to integrate a wide variety of analytical tools, research results and risk assessment data into applicable decision-making and policy-making information. ORD's revisions to the product development process provide an initial framework to engage program offices in the joint development of specific CSS products (Figure 2).

Figure 2: Revised CSS product development process



Source: OIG-generated diagram.

The revised CSS product development process reflects recommendations proposed by the EPA's Board of Scientific Counselors (BoSC). BoSC is tasked with providing advice and recommendations to ORD on technical and management issues. In 2016, after reviewing the newly published 2016–2019 CSS Plan and the coordination between ORD and agency customers, BoSC recommended that ORD "develop a consistent, multidirectional communication strategy."[2] In addition, BoSC recommended that the EPA invest in more effective within-agency interactions, improve program office engagement, and articulate a consistent communication process.

The challenge of effective communication does not reside with OCSPP alone; it resides with both ORD and OCSPP. Therefore, it is important that ORD continues to refine its communication strategy, as BoSC recommended. To enhance the communication strategy being developed by ORD, OCSPP needs to develop its own process for collaborating with ORD. A formal OCSPP process would better ensure that the OCSPP program offices consistently collaborate with ORD to use the revised CSS product development process. The lack of a consistent collaboration process can inhibit OCSPP and ORD from effectively achieving the desired results.

OCSPP Has Not Conducted a Needs Assessment to Determine CSS Product Management Priorities

OCSPP must successfully balance multiple priorities, scopes, resources and regulatory responsibilities. We found that OCSPP has not conducted a comprehensive needs assessment that would allow OCSPP to consider the order of research, prioritize future needs and resources, determine what training and data are needed to make the systems function, and identify the potential of developing applications. In addition, OCSPP's three program offices are in different stages of CSS product adoption, further demonstrating the importance of determining and prioritizing overall office needs.

As of April 2017, the Office of Science Coordination and Policy was the only OCSPP program office to have participated in the collaborative CSS product development process and to have received a completed, jointly developed CSS product. The office stated that it has incorporated EDSP21 into its current work and has used EDSP21 for two main purposes:

- To demonstrate the potential benefits that result from endocrine disruptor research.
- To rapidly access and present data on chemicals of interest.

[2] BoSC Executive Committee, *Review of U.S. EPA Office of Research and Development's Research Programs*, issued January 8, 2016 (last accessed February 14, 2017).

However, as more data become available for incorporation into the EDSP21, new product iterations and analytical parameters will need to be determined. The Office of Science Coordination and Policy stated its intent to expand the product in a way that provides ever-broader analytical applications and uses increasing amounts of data.

The OCSPP Office of Pesticide Programs has also started working with ORD to develop the RapidTox product. RapidTox is moving toward the pilot and testing phase for selected inert pesticide additives. If the pilot is successful, the Office of Pesticide Programs expects to continue to broaden the scope of RapidTox and increase its capabilities.

The OCSPP Office of Pollution Prevention and Toxics is working with ORD to determine how RapidTox and other CSS products can be incorporated into its programs. This office identified several challenges to developing effective CSS products, including Confidential Business Information constraints and the June 2016 passage of the Lautenberg Act, which significantly revises and broadens the authority of the Office of Pollution Prevention and Toxics over chemicals. In a recent report to Congress,[3] the Office of Pollution Prevention and Toxics said that it planned to use CSS products to help meet these new statutory requirements.

As demonstrated above, the three program offices have stated intentions to either develop new CSS products and/or enhance existing CSS products. However, a comprehensive OCSPP assessment that examines and prioritizes overall needs has not been developed. As a result, the products developed may not be the products that are most urgently needed to meet OCSPP's mission.

Conclusion

OCSPP needs additional management controls to ensure effective collaboration with ORD in customizing research products. Further, OCSPP has not conducted an overall needs assessment to prioritize future efforts, identify training and resource requirements, or assess the potential of other product applications. Without management controls that ensure consistent interoffice collaboration and assess CSS product needs, OCSPP is at risk of not effectively incorporating products in a way that could rapidly improve how the EPA assesses chemical risks to human health and the environment.

[3] *Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act*, issued January 2017 (last accessed March 27, 2017).

Recommendations

We recommend that the Assistant Administrator for Chemical Safety and Pollution Prevention:

1. Conduct a needs assessment that identifies and addresses the challenges, timeframes, training and resources necessary to effectively incorporate Office of Research and Development products into Office of Chemical Safety and Pollution Prevention programs.

2. Develop and implement management controls that formalize the Office of Chemical Safety and Pollution Prevention's processes for collaborating with the Office of Research and Development to maintain current products and develop future products.

Agency Response and OIG Evaluation

OCSPP agreed with our recommendations, and provided corrective actions and estimated completion dates that meet the intent of the recommendations. Based on the agency's written response, the recommendations are resolved and open with corrective actions ongoing. The agency also provided technical comments on the draft report, which we incorporated into our final report as appropriate. The agency's detailed response is in Appendix A.

OCSPP expressed concern that the report's recommendations were confined only to their office, and did not include any recommendations to ORD. As the scope of our evaluation was to assess OCSPP's incorporation of ORD CSS products, our recommendations were necessarily confined to that office. However, the OIG acknowledges that successful collaborative efforts encompass regular coordination and effective communication between the collaborating partners. We will provide a copy of this report to ORD leadership.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	6	Conduct a needs assessment that identifies and addresses the challenges, timeframes, training and resources necessary to effectively incorporate Office of Research and Development products into Office of Chemical Safety and Pollution Prevention programs.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	5/31/18	
2	6	Develop and implement management controls that formalize the Office of Chemical Safety and Pollution Prevention's processes for collaborating with the Office of Research and Development to maintain current products and develop future products.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	5/31/18	

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Appendix A

Agency Response to Draft Report

[June 5, 2017]

MEMORANDUM

SUBJECT: Comments on the OIG Draft Report: "EPA Should Assess Needs and Implement Management Controls to Ensure Effective Incorporation of Chemical Safety Research Products."
Project No. OPE-FY16-0029

FROM: Wendy Cleland-Hamnett, Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention

TO: Arthur A. Elkins, Jr.
Inspector General

This memorandum is in response to the Office of Inspector General's (OIG's) May 3, 2017 Draft Report entitled, "EPA Should Assess Needs and Implement Management Controls to Ensure Effective Incorporation of Chemical Safety Research Products." The Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating our use of the Office of Research and Development's (ORD's) Chemical Safety for Sustainability (CSS) research products. We agree that effective coordination and collaboration between OCSPP and ORD is important to our mission.

I. General Comments

As noted in the Draft Report, OCSPP is composed of three program offices which have had somewhat different experiences in successfully coordinating with ORD. The Office of Science Coordination and Policy (OSCP) and the Office of Pesticide Programs (OPP) have had significant successes early on, while the Office of Pollution Prevention and Toxics (OPPT) has faced greater challenges. While OCSPP agrees with the OIG's recommendations, and has accordingly proposed corrective actions to implement them in this response, we are concerned that the Draft Report's discussion of the differences in CSS product adoption misses a critical point: that this must be a partnership between OCSPP and ORD. It is OCSPP's belief that when ORD products are developed in collaboration with OCSPP scientists, they have the best likelihood of success in meeting OCSPP's regulatory science needs.

As we stated in our March 2017 comments on the Discussion Document, there have been valuable lessons learned from the successes in OSCP and OPP, such as:

- Coordination requires a significant investment of time by management and staff to resolve issues in key areas.
- Coordination is enhanced by practices such as sharing of staff between offices on detail and temporary assignment through Skills Marketplace;

- Frequent webinars improve coordination; and
- In-person visits improve communication and coordination.

Collaboration and coordination between ORD and OPPT is especially critical as we work to implement a new TSCA Statute. Such understanding entails an investment of ORD researchers' time in communicating with OPPT scientists on how OPPT does its new and existing chemicals assessments. ORD has to date been able to commit some time to such an effort. Such understanding is a prerequisite to the translation of ORD science into approaches that will work within OPPT's assessment and decision constructs. Because the OIG's recommendations are confined to OCSPP, with no recognition or appreciation of what ORD needs to contribute to the effort other than to "refine its communication strategy, as [EPA's Board of Scientific Counselors] recommended," we are concerned that critical investments of resources and staff time by ORD may not occur and will impede progress forward. For example, there is a need for ORD to consider more investment in training and translational research, so its products can readily be applied to fit OCSPP's needs.

II. OCSPP's Response to the Recommendations

Recommendation 1: OCSPP should conduct a needs assessment that identifies and addresses the challenges, timeframes, training, and resources necessary to effectively incorporate Office of Research and Development products into Office of Chemical Safety and Pollution Prevention programs.

OCSPP Response and Proposed Timeline for Corrective Action: By May 31, 2018, OCSPP will conduct a needs assessment which, at a minimum, identifies and addresses the challenges, timeframes, training, and resources necessary to effectively incorporate Office of Research and Development products into OCSPP's programs. This effort will be led by OCSPP's Office of Science Coordination and Policy (OSCP) in cooperation with ORD, OPPT and OPP.

OIG Recommendation 2: Develop and implement management controls that formalize the Office of Chemical Safety and Pollution Prevention's processes for collaborating with the Office of Research and Development to maintain current products and develop future products.

OCSPP Response and Proposed Corrective Action: By May 31, 2018, OCSPP will develop a document that describes and formalizes OCSPP's processes for consistently collaborating with ORD to most effectively utilize its revised CSS product development process for current and future products. This effort will be led by OCSPP's Office of Science Coordination and Policy in cooperation with ORD, OPPT and OPP. This document will specify that the processes described therein will be implemented by all three OCSPP offices within 6 months, or by November 30, 2018.

III. Contact Information If you have any questions, please contact Janet Weiner, OCSPP's Audit Liaison, at Weiner.janet@epa.gov

Appendix B

Distribution

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