The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions

August 2, 2023 | 23-P-0026

OFFICE OF INSPECTOR GENERAL
U.S. ENVIRONMENTAL PROTECTION AGENCY

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Abbreviations

EPA	U.S. Environmental Protection Agency
FTE	Full-Time Equivalent
GAO	U.S. Government Accountability Office
NCD	New Chemicals Division
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
TSCA	Toxic Substances Control Act
U.S.C.	United States Code

Cover Image

Resource constraints impact the EPA's New Chemicals Program's recordkeeping and quality assurance. (EPA OIG image)

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At a Glance

The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions

Why We Did This Audit

To accomplish this objective:

The U.S. Environmental Protection Agency Office of Inspector General conducted this audit to determine the extent to which the EPA is using and complying with applicable records management requirements, quality assurance requirements, and employee performance standards to review and approve new chemicals under the Toxic Substances Control Act of 1976. This audit was initiated in response to several complaints submitted to the OIG Hotline.

The Toxic Substances Control Act requires the EPA to, upon receipt of a premanufacture notice for a new chemical, determine within 90 days whether the chemical presents an unreasonable risk to human health or the environment. The EPA's New Chemicals Program, as mandated by section 5 of the Act, "helps manage the potential risk to human health and the environment from chemicals new to the marketplace." The New Chemicals Division manages the New Chemicals Program. For fiscal year 2023, the EPA received $82.8 million for its chemical review programs.

To support this EPA mission-related effort:

- *Ensuring the safety of chemicals.*

To address these top EPA management challenges:

- *Providing for safe use of chemicals.*
- *Safeguarding scientific integrity.*

Address inquiries to our public affairs office at (202) 566-2391 or OIG.PublicAffairs@epa.gov.

List of OIG reports.

What We Found

The EPA has not complied with applicable recordkeeping and quality assurance requirements when implementing the New Chemicals Program. Specifically, the New Chemicals Division, or NCD, has not finalized guidance for many of the program's activities, such as standard operating procedures for recordkeeping and conducting exposure and hazard assessments. According to the EPA's *Guidance for Preparing Standard Operating Procedures (SOPs)*, developing and using standard operating procedures are integral parts of a successful quality system, as they provide individuals with the information to properly perform a job. They also facilitate consistency in the quality and integrity of a product or end result.

In addition, prior to September 2021, the NCD's Toxic Substances Control Act recordkeeping applications did not track edits to records that were developed during the new chemicals review process, which affected transparency. The NCD also used multiple recordkeeping applications, which were not integrated and were frequently inaccessible. The EPA's *Records Management Policy* requires each EPA program office to create, receive, and maintain records that provide adequate and proper documentation of its activities and decisions.

These deficiencies existed because the NCD lacked sufficient staff resources to conduct reviews within the statutory time frames, as well as to develop and finalize guidance. The absence of final guidance increases the risk that the New Chemicals Program does not meet its legislative intent to prevent unreasonable risk to human health and the environment. Furthermore, the EPA has the authority to collect fees to offset the costs of implementing the requirements under the Toxic Substances Control Act, but it has fallen short of collecting the amount of fees it originally projected.

Finally, complaints submitted to the OIG Hotline alleged that NCD staff were pressured to focus on deadlines instead of potential risks when conducting new chemical reviews. We found no evidence that the NCD explicitly includes the Toxic Substances Control Act statutory 90-day review requirement as an employee performance standard.

The EPA's NCD lacks assurance that the new chemicals review process operates as intended and achieves its objective to protect human health and the environment.

Recommendations and Planned Agency Corrective Actions

We make four recommendations to the assistant administrator for Chemical Safety and Pollution Prevention, including that the EPA develop, update, and finalize guidance for the New Chemicals Program; assess and update the NCD's recordkeeping applications, as needed; and address workload issues. The Agency agreed to all four recommendations, which are resolved with corrective actions pending.

OFFICE OF INSPECTOR GENERAL
U.S. ENVIRONMENTAL PROTECTION AGENCY

August 2, 2023

MEMORANDUM

SUBJECT: The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions
Report No. 23-P-0026

FROM: Sean W. O'Donnell, Inspector General

TO: Michal Ilana Freedhof, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

This is our report on the subject audit conducted by the U.S. Environmental Protection Agency Office of Inspector General. The project number for this audit was OA-FY22-0025. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Pollution Prevention and Toxics, within the Office of Chemical Safety and Pollution Prevention, manages the New Chemicals Program.

In accordance with EPA Manual 2750, your office provided acceptable planned corrective actions and estimated milestone dates in response to OIG recommendations. All recommendations are resolved, and no final response to this report is required. If you submit a response, however, it will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

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

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Chapter 1
Introduction

Purpose

The U.S. Environmental Protection Agency Office of Inspector General initiated this audit to determine the extent to which the EPA is using and complying with applicable records management requirements, quality assurance requirements, and employee performance standards to review and approve new chemicals under the Toxic Substances Control Act of 1976, or TSCA, to manage human health and environmental risks.

We conducted this audit in response to complaints submitted to the OIG Hotline in the summer of 2021 regarding the EPA's new chemicals review process. The complaints expressed concerns about recordkeeping and quality assurance activities, including potential violations of the EPA's *Records Management Policy*, improper quality assurance processes, and the prioritization of reviews of new chemicals over the development of standard operating procedures. The hotline complaints also expressed concerns related to employee performance standards, such as the use of the TSCA statutory deadlines to perform reviews quickly rather than for the purpose of protecting human health and the environment. We used these three main areas of concern—recordkeeping, quality assurance, and employee performance standards—to develop our audit objective. Appendix A summarizes the OIG Hotline allegations relevant to each area of concern.

Top Management Challenges Addressed

This audit addresses the following top management challenge(s) for the Agency, as identified in the OIG's *U.S. Environmental Protection Agency Fiscal Year 2023 Top Management Challenges* report, issued October 28, 2022:

- Providing for safe use of chemicals.
- Safeguarding scientific integrity.

Background

TSCA became law on October 11, 1976, and became effective on January 1, 1977. TSCA covers the manufacture, processing, commercial distribution, use, and disposal of chemical substances, such as asbestos, lead, mercury, and formaldehyde. The Act also outlines requirements for recordkeeping, testing, and restrictions related to these chemicals. The Act excludes certain substances, such as food, drugs, cosmetics, and pesticides. To improve TSCA, particularly in the areas of evaluating chemicals and performing risk-based chemical assessments, Congress amended it with the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016.

The Lautenberg Act

Pursuant to the Lautenberg Act, section 5 of TSCA, 15 U.S.C. § 2604(a)–(c), as amended, requires that any person intending to manufacture or import either a new chemical or an existing chemical for a significant new use must first notify the EPA. This notice is known as a ***premanufacture notice*** or a ***significant new use notice***. Section 5 of TSCA also requires the EPA to make an affirmative determination within 90 days, with an opportunity for 90 days of extensions in the aggregate, on whether each new chemical for which it receives a premanufacture or significant new use notice presents an unreasonable risk to human health or the environment.

Pre-Lautenberg Act

The EPA did not have a time-bound requirement for determining whether a new chemical or a significant new use of an existing chemical presents an unreasonable risk to human health or the environment.

Post-Lautenberg Act

The EPA must determine within 90 days whether a new chemical or a significant new use of an existing chemical presents an unreasonable risk to human health or the environment.

The EPA receives hundreds of premanufacture notices each year. According to EPA data, from June 22, 2016, to November 1, 2022, the EPA received 4,514 premanufacture notices and completed 3,830 new chemical reviews. The EPA told us that, before the Lautenberg Act, it typically only completed new chemical reviews for about 20 percent of the premanufacture notices it received. The other approximately 80 percent of notices were "dropped" from the review process. Pursuant to the Lautenberg Act, however, the EPA must now make an affirmative determination regarding the risk for 100 percent of new chemicals before they enter commerce. In addition, the Act requires the EPA's new chemical reviews to encompass all "conditions of use"—in other words, the intended, known, or reasonably foreseen circumstances of the manufacture, processing, distribution in commerce, and use and disposal of new chemicals.

TSCA sets forth five possible determinations that the EPA can make regarding new chemicals or significant new uses of existing chemicals. Those five determinations and examples of possible actions that the EPA can take are shown in Table 1.

Table 1: EPA determinations and actions after reviews of new chemicals or significant new uses

Determinations	Examples of EPA actions *according to the Office of Chemical Safety and Pollution Prevention*
1. The chemical or significant new use presents an unreasonable risk of injury to health or the environment. 2. Available information is insufficient to allow the Agency to make a reasoned evaluation of the health and environmental effects associated with the chemical or significant new use.	The EPA can issue an order pursuant to section 5(e) of TSCA to the person who submitted the premanufacture notice to address the risks to public health or the environment. This order, which is binding, may place conditions on the manufacture and use of the chemical, including testing; use of personal protective equipment; hazard communication language; distribution and use restrictions; restrictions on releases to water, air, or land; and recordkeeping, among others.

Determinations	Examples of EPA actions *according to the Office of Chemical Safety and Pollution Prevention*
3. In the absence of sufficient information, the chemical or significant new use may present an unreasonable risk of injury to health or the environment. 4. The chemical is or will be produced in substantial quantities and enters or may enter the environment in substantial quantities. There also is or may be significant or substantial exposure to the chemical.	The EPA can issue a Significant New Use Rule extending the requirements of section 5(e) of TSCA to all manufacturers and processors of the new chemical or require these manufacturers and processors to explain why such a rule is unnecessary. Significant New Use Rules require companies to submit notice to the EPA before the chemical is used in a significant new way that could be of concern. Like premanufacture notices, TSCA requires that the EPA review and make a determination on the notice.
5. The chemical or significant new use is not likely to present an unreasonable risk of injury to health or the environment.	Where the EPA determines that a chemical is "not likely" to present an unreasonable risk, the company may begin manufacturing the chemical without restriction.

Source: The EPA; OIG analysis of section 5 of TSCA. (EPA OIG table)

A key provision of the Lautenberg Act is the EPA's authorization to collect user fees from chemical manufacturers to help defray the costs of new chemical reviews and other activities related to existing chemicals. In this report, we refer to this part of the Lautenberg Act as the ***fees rule***. Each year, the EPA is authorized to collect the lesser of either 25 percent of the cost to implement sections 4, 5, and 6 of the Act or $25 million. The EPA can assess user fees from chemical manufacturers and processors when they submit test data for EPA review, submit a premanufacture notice or significant new use notice, manufacture or process a chemical substance that is the subject of a risk evaluation, or request that the EPA conduct a chemical risk evaluation.

The EPA started collecting fees in fiscal year 2019. From fiscal year 2019 through 2022, the EPA collected, in total, the following TSCA user fees:

- Fiscal year 2019: $2.7 million.
- Fiscal year 2020: $5.5 million.
- Fiscal year 2021: $28.6 million.
- Fiscal year 2022: $5 million.

On November 16, 2022, the EPA issued a supplemental proposed rule modifying and adjusting certain aspects of the fees rule. This supplemental rule is intended to ensure that collected fees provide the Agency with 25 percent of authorized TSCA costs, consistent with direction in the fiscal year 2022 appropriations bill, to consider the "full" implementation costs of the law.

The EPA's New Chemicals Program

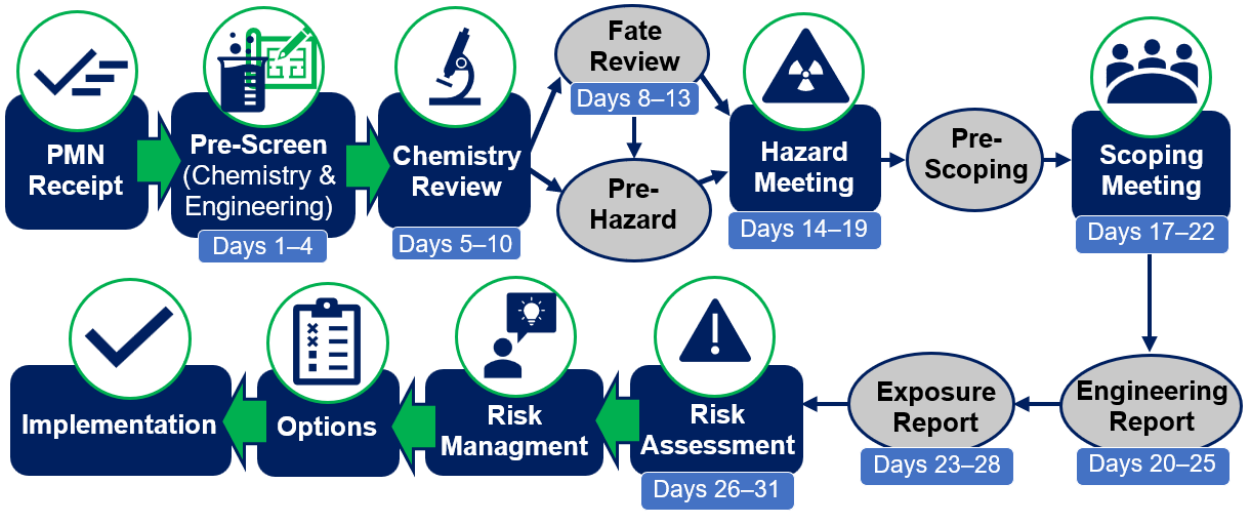
The New Chemicals Division, or NCD, manages the EPA's New Chemicals Program. The New Chemicals Program, as mandated by section 5 of TSCA, "helps manage the potential risk to human health and the environment from chemicals new to the marketplace." To carry out its mandate, the New Chemicals

Program determines, by conducting risk assessments as part of its new chemicals review process, whether new chemicals pose unreasonable risks. The EPA then takes appropriate action, as outlined previously in Table 1.

Risk assessments characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants that may be present in the environment.[1] The EPA conducts both human health and ecological risk assessments. According to the EPA, "a human health risk assessment is the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future." The EPA defines "an ecological risk assessment [as] the process for evaluating how likely it is that the environment might be impacted as a result of exposure to one or more environmental stressors, such as chemicals, land-use change, disease, and invasive species."

According to the EPA's Office of Chemical Safety and Pollution Prevention, or OCSPP, the NCD's new chemicals review process pursuant to the Lautenberg Act comprises 14 steps, including risk assessment. The NCD stated that in 2019 the EPA streamlined the workflow for new chemical reviews under TSCA. As part of this streamlining, the EPA estimated time frames for most steps of the new chemical reviews process. Figure 1 shows the new chemicals review process and the estimated time frames. For example, the scoping meeting step, which is when staff determine risk assessment methodology, takes six days.

Figure 1: The NCD's new chemicals review process



Note: PMN = Premanufacture notice.

Source: NCD documentation on the new chemicals review process. (OIG graphic adapted from EPA graphic)

[1] Ecological receptors are plant and animal populations and communities, habitats, and sensitive environments.

The EPA's Environmental Information Quality Procedure and the NCD's Quality Management Plan

The NCD stated that to meet the requirements of the Lautenberg Act, all of which became effective immediately upon the Act's enactment in June 2016, the NCD had to revise and adjust its New Chemicals Program policies, guidance, and processes. Part of this effort involved the development of a quality program and quality management plan, which is guided by the EPA's *Environmental Information Quality Procedure*, Directive No. CIO 2105-P-01.3,last updated April 10, 2023.

The EPA's *Environmental Information Quality Procedure* outlines the EPA's quality program requirements, which ensure that environmental information operations products and services have known and documented quality for their intended uses. The policy requires EPA organizations that produce environmental information to develop, implement, and maintain a quality program.

> The EPA defines ***quality assurance*** as a management or oversight function that deals with setting policy and running an administrative system of management controls that cover the planning, implementation, and review of data collection activities and the use of data in decision-making.
>
> The EPA defines ***quality control*** as a technical function that includes all the scientific precautions that are needed to acquire data of known and adequate quality.

One of the requirements of an EPA quality program is a quality management plan that describes the program. For the applicable time period of this audit, the EPA's *Requirements for Quality Management Plans*, EPA QA/R-2, issued March 2001, provides guidance for developing quality management plans, in accordance with the EPA's *Environmental Information Quality Procedure*.[2] The quality management plan documents the structure of the quality program; the quality policies and procedures; the criteria for and areas of application; and the roles, responsibilities, and authorities. The quality management plan also documents all technical activities to be performed under the quality program and how the program will integrate quality assurance and quality control procedures and plans into its environmental information operations activities.

Accordingly, the NCD has developed a quality management plan and assigned the division director to oversee its quality program. The NCD's quality management plan discusses several tools for ensuring that the NCD's work meets the level of quality required for its intended use. As outlined in the quality management plan, some of the NCD's principal tools for ensuring quality include:

- Quality assurance project plans.
- Standard operating procedures for personnel, procurement, and records management activities.
- Standard operating, quality assurance, and quality control procedures for the development and review of deliverables, records management, and project management.

[2] For grants issued on or after February 17, 2023, CIO 2105-S-01.0, *Quality Management Plan Standard*, will apply.

According to the EPA's *Guidance for Preparing Standard Operating Procedures (SOPs),* EPA QA/G-6, dated April 2007, standard operating procedures, as related to quality management plans, "describe both technical and fundamental programmatic operational elements of an organization."

The NCD's Recordkeeping

As noted in the NCD's quality management plan, risk assessment, risk management, and regulatory actions can involve significant records-management activities. According to the quality management plan, NCD management ensures that records are properly managed throughout their life cycle, which includes records creation, maintenance, storage, use, and disposition. As explained in the quality management plan, the Federal Records Act, as amended, provides the statutory basis for the Agency's records and information program. Further, the EPA's *Records Management Policy*, Directive CIO 2155.5, dated August 17, 2021, requires each EPA program office to "create, receive and maintain records providing adequate and proper documentation and evidence of EPA's activities and decisions." The U.S. Government Accountability Office's, or GAO's, *Standards for Internal Control in the Federal Government* requires that management clearly document all transactions in a manner that allows the documentation to be readily available.

> 44 U.S.C. § 3102 *et seq.* requires every federal agency to establish and maintain an active, continuing program for the economical and efficient management of the records of the agency, including controls over the creation, maintenance, and use of records in the conduct of current business.

Until October 2021, the NCD used multiple information technology applications to maintain its records. Although disparate, these information technology applications are all housed within the NCD's TCSA Confidential Business Information systems. In September 2021, the NCD began using the New Chemical Review application as its official recordkeeping system. The New Chemical Review application is also housed within the NCD's TCSA Confidential Business Information systems.

The NCD's Employee Performance Standards

The Performance Appraisal and Recognition System, which is the EPA's employee performance evaluation program, must be fair, equitable, and solely related to job performance.

Responsible Offices

The Office of Pollution Prevention and Toxics, within the OCSPP, manages the TSCA programs. Within the Office of Pollution Prevention and Toxics, the NCD manages the New Chemicals Program. The NCD was created in October 2021 as a result of an OCSPP reorganization to consolidate the New Chemicals Program responsibilities into one division. For fiscal year 2023, the EPA received $82.8 million for its chemical review programs.

Scope and Methodology

We conducted this performance audit from October 2021 to May 2023 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

We assessed the internal controls necessary to satisfy our audit objective.[3] In particular, we assessed the internal control components—as outlined in the GAO's *Standards for Internal Control in the Federal Government*—significant to our audit objective. Any internal control deficiencies we found are discussed in this report. Because our audit was limited to the internal control components deemed significant to our audit objective, it may not have disclosed all internal control deficiencies that may have existed at the time of the audit.

From the OIG Hotline complaints, we identified three areas of concern: records management, quality assurance, and employee performance standards. We used these areas of concern to develop our audit objective. Appendix A provides an additional summary of some of the hotline allegations submitted to the OIG Hotline.

To answer our objective, we reviewed TSCA, the Lautenberg Act, previous OIG reports, and the EPA's TSCA and New Chemicals Program websites. To understand the EPA's requirements for records management and quality assurance, as well as the NCD's employee performance standards for the New Chemicals Program, we reviewed the Federal Records Act, the NCD's quality management plan, the EPA's *Guidance for Preparing Standard Operating Procedures*, and NCD staff and management employee performance standards. We also interviewed NCD staff and management about recordkeeping, quality assurance, and employee performance standards. In addition, we analyzed EPA budget documentation and the NCD's March 2022 workforce and workload analysis to understand program resources.

To assess the hotline allegations related to employee performance standards, our audit focused on whether the NCD's employee performance standards included a time-bound requirement to complete new chemical reviews. We requested employee performance standards for NCD staff and management. The performance standards that we received were not attributed to any specific individual.

We did not assess whether the reviews for the chemicals identified in the hotline complaints complied with applicable requirements for internal records management, quality assurance, and quality control, as those reviews were completed prior to the creation of the NCD in October 2021 and were conducted under different policies and procedures for records management and quality assurance. We did, however, assess the quality of the NCD's guidance for recordkeeping and quality assurance. We requested that the NCD provide us with program guidance, including standard operating procedures, for the new chemicals review process. We received access to the NCD's guidance documents through an internal site that was organized into folders for each step of the new chemicals review process. To assess the quality of the NCD's guidance for recordkeeping and quality assurance, we analyzed

[3] An entity designs, implements, and operates internal controls to achieve its objectives related to operations, reporting, and compliance. The GAO sets internal control standards for federal entities in GAO-14-704G, *Standards for Internal Control in the Federal Government*, issued September 10, 2014.

52 guidance documents judgmentally selected from the exposure, environmental hazard, and human health hazard and risk assessment steps of the new chemicals review process. We analyzed the 52 guidance documents to assess whether the documents were current or finalized. In April 2022, the NCD informed us that it completed a comprehensive inventory of over 200 standard operating procedures, including 100 related to human health, for review and update. The NCD provided us its inventory list of these procedures, which we reviewed.

To understand the various applications housed within the TSCA Confidential Business Information systems, we were provided access to the systems and received a demonstration from Office of Pollution Prevention and Toxics information technology staff.

Prior Reports

On August 17, 2020, the OIG issued Report No. 20-P-0247, *Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines*. This report recommended that the assistant administrator for Chemical Safety and Pollution Prevention (1) publish the annual existing chemical plan, including the anticipated implementation efforts and required resources; (2) conduct a workforce analysis to assess the Office of Pollution Prevention and Toxics' capability to implement TSCA; and (3) specify what skill gaps must be filled in fiscal year 2021 to meet TSCA requirements. The EPA certified on February 7, 2022, that all corrective actions to address the OIG's recommendations were completed.

In its 2019 report, *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substance Control Act*, GAO-19-270, issued March 4, 2019, the GAO cited concerns about appropriate resources and staff capacity within the two EPA divisions responsible for risk management and risk assessment. The report noted that the EPA faced challenges in developing guidance to ensure consistency in implementing the Lautenberg Act. Specifically, the GAO said that staff from four of the five technical teams it interviewed were either in the process of updating their guidance, still developing their guidance, or had never developed their guidance. Further, the GAO noted that staff from two teams said that they were developing their guidance as they applied it to their work.

On December 29, 2022, the OIG issued Report No. 23-F-0005, *The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements*, which detailed how the fees that the EPA collected in fiscal years 2019 and 2020 did not meet the intent of TSCA to defray 25 percent of the specified costs of implementing the applicable parts of sections 4, 5, 6, and 14. The EPA anticipated collecting approximately $20 million for fiscal years 2019 and 2020, which represents around 25 percent of its estimated annual TSCA costs for those years ($80.2 million). However, during fiscal years 2019 and 2020, the EPA collected relevant TSCA service fees totaling significantly less than estimated. This difference largely occurred because the EPA overestimated the number of actions that would trigger fees under the TSCA fees rule. We recommended that the EPA correct the methodology for accounting for TSCA expenses from other appropriations to ensure that all costs for administering the applicable parts of sections 4, 5, 6, and 14 are properly recorded and reported in the financial statements. The EPA agreed with our recommendation and provided acceptable planned corrective actions. As of May 2023, this recommendation was resolved with corrective actions pending.

In its 2023 report, *EPA Chemical Reviews: Workforce Planning Gaps Contributed to Missed Deadlines*, GAO-23-105728, issued February 23, 2023, the GAO found that since 2016, the EPA has missed most TSCA deadlines for reviewing existing and new chemicals. The GAO said that, from 2017 through 2022, the EPA completed premanufacture reviews within the statutory 90-day review period less than 10 percent of the time. Among the reasons noted for the missed deadlines are a lack of modernized information systems and a lack of resources, including sufficient staff capacity. The GAO recommended that the "EPA develop a process and timeline to fully align its workforce planning efforts for implementing its TSCA chemical review responsibilities with workforce planning principles." The EPA agreed with the GAO's recommendation.

Chapter 2
NCD Guidance for Conducting New Chemical Reviews Was Not Consistently Developed, Updated, or Finalized; TSCA Information Technology Systems Lacked Efficiencies for Recordkeeping

The EPA did not comply with applicable quality assurance and recordkeeping requirements for the New Chemicals Program. Specifically, the NCD did not have, update, or finalize guidance for many of the activities that comprise the new chemicals review process. According to the EPA's *Guidance for Preparing Standard Operating Procedures*, the development and use of standard operating procedures are integral parts of a successful quality system, as they provide individuals with the information to perform a job properly, and they facilitate consistency in the quality and integrity of products or end results.

Furthermore, the NCD had not finalized guidance for recordkeeping of scoping meetings, and it used multiple recordkeeping applications that were not integrated and were frequently inaccessible. The EPA's *Records Management Policy* requires that each EPA program office create, receive, and maintain records providing adequate and proper documentation and evidence of the EPA's activities and decisions. In addition, prior to September 2021, the NCD's TSCA recordkeeping applications did not track edits to documents that were developed during the new chemicals review process to support the EPA's decisions about the risks of new chemicals.

These deficiencies existed because the NCD lacked sufficient staff resources to both conduct reviews within statutory time frames and develop and finalize its guidance for conducting the activities that comprise the review process. Although the EPA has the authority to collect fees to offset the costs of implementing the requirements under the Toxic Substances Control Act, it has fallen short of collecting the amount of fees it originally projected. The absence of final guidance and the lack of resources increase the risk that the new chemicals review process does not meet its legislative intent to prevent unreasonable risk to human health and the environment.

EPA Policy Requires Guidance to Implement Quality Assurance and Recordkeeping Requirements

Quality Management Plans Outline Development of Standard Operating Procedures and Maintenance of Records

The EPA's *Requirements for Quality Management Plans* lays out the content requirements of a program's quality management plan, including:

- An "Implementation of Work Processes" section that documents "how work processes will be implemented … to ensure that data or information collected" meet quality requirements

to support their intended use. This includes processes for identifying, developing, reviewing, and revising standard operating procedures.

- A "Documents and Records" section that outlines "appropriate controls for quality-related documents and records" that are significant to the program's mission, including the process for "ensuring that records and documents accurately reflect completed work" and are properly maintained.

Standard Operating Procedures Are Integral Parts of a Quality Assurance Program

According to the EPA's *Guidance for Preparing Standard Operating Procedures*, "[t]he development and use of SOPs [standard operating procedures] are an integral part of a successful quality system," as they provide "individuals with the information to perform a job properly," and they facilitate "consistency in the quality and integrity of a product or end-result." Standard operating procedures are intended to be specific to the organization or facility whose activities are described, to assist that organization in maintaining its processes for quality control and quality assurance, and to ensure compliance with governmental regulations.

The NCD's quality management plan states that standard operating procedures should be reviewed on a yearly basis and that inadequate or out-of-date standard operating procedures should be removed from use. For the purposes of this report, we considered any standard operating procedure that was not reviewed annually, as prescribed in the NCD's quality management plan, to be outdated. Supervisors must approve any new standard operating procedures before they are used, and in some cases, the division quality assurance coordinator, who supports the quality assurance manager, must also approve new procedures.

The Federal Records Act and the EPA's Records Management Policy Require that Documents Be Preserved

According to the Federal Records Act, 44 U.S.C. § 3101 *et seq*., "The head of each Federal agency shall make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities." The Federal Records Act further requires every federal agency to establish and maintain an active, continuing program for the economical and efficient management of the records of the agency, including controls over the creation, maintenance, and use of records in the conduct of current business. Furthermore, the EPA's *Records Management Policy*, Directive CIO 2155.5, dated August 17, 2021, requires each EPA program office to "create, receive and maintain records providing adequate and proper documentation and evidence of EPA's activities and decisions." In addition, the GAO's *Standards for Internal Control in the Federal Government* requires that management clearly document all transactions in a manner that allows the documentation to be readily available for examination.

The NCD Needs Improved Guidance and Recordkeeping to Ensure the Quality of the New Chemicals Review Process

The EPA did not comply with applicable quality assurance and recordkeeping requirements for the New Chemicals Program. Specifically, the NCD did not have, update, or finalize standard operating procedures for conducting many of the activities that comprise the new chemicals review process, such as standard operating procedures for conducting exposure and hazard assessments.

Furthermore, the NCD did not finalize guidance for recordkeeping of scoping meetings, and it used multiple recordkeeping applications that were not integrated and that experienced frequent accessibility problems. Also, prior to September 2021, the NCD's TSCA applications did not track edits to records developed during the new chemicals review process.

The NCD Did Not Have, Update, or Finalize Standard Operating Procedures for Key Activities in the New Chemicals Review Process

The NCD has over 100 guidance documents related to the 14 steps of the new chemicals review process, which we previously illustrated in Figure 1. Each of these steps consists of multiple processes, and the NCD addresses many of these processes with guidance documents, including standard operating procedures. According to the EPA's *Guidance for Preparing Standard Operating Procedures*, standard operating procedures are intended to detail regularly recurring work processes that are to be conducted or followed, such as actions related to quality assurance and recordkeeping.

Despite the number of guidance documents available and despite the EPA's *Guidance for Preparing Standard Operating Procedures*' emphasis on the importance of standard operating procedures to an organization's quality management plan, NCD managers and staff told us that standard operating procedures did not exist for many activities in the new chemicals review process. For example, we were informed that, although there is guidance that generally defines what a scoping meeting is, there is no guidance that lays out procedures for documenting what occurs at scoping meetings, such as the decisions made. We reviewed the guidance documents that the NCD provided us, and we verified that procedures for scoping meetings did not exist, as indicated in Row 8 of Table 2. As another example, we were informed that guidance did not exist until 2020 for how to conduct exposure assessments and that when the guidance was finally created, it was developed by staff, not management. We verified that guidance for exposure assessments was created in 2020; however, it had not been signed and finalized as of September 2022, as indicated in Row 7 of Table 2.

As demonstrated by the lack of finalized guidance for exposure assessments, even when guidance does exist, it may not be up to date or finalized. We analyzed 52 NCD guidance documents for activities in the new chemicals review process to determine whether they had been last reviewed within a year, as the NCD's quality management plan requires. We also analyzed whether the guidance documents

During the ***scoping meeting***, staff determine how the risk assessments will be conducted and check that the new chemical reviews are on appropriate schedules.

An ***exposure assessment*** is the process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent and the size and characteristics of the population exposed.

were signed and finalized. Of these 52 documents, 36 (about 70 percent) had not been reviewed within a year and are outdated, and 48 (over 90 percent) were not signed and finalized. Table 2 lists examples of the deficiencies we identified.

Table 2: Guidance documents not developed, updated, or finalized as of September 2022

	Risk assessment area covered	Guidance document name	Deficiencies identified
1.	Human health and risk assessment	*Evaluation Protocol - Exposure Quality of Inhalation Toxicity Studies*	Outdated; not finalized.
2.	Human health and risk assessment	*Checklist for QCing Human Health Risk Assessments (Part Bs)*	Outdated; not finalized.
3.	Exposure assessment	*New Chemical Workflow Summary RAD Exposure Assessor*	Outdated; not finalized.
4.	Exposure assessment	*CEM Use Frequency and Inhalation Concentration*	No file date; unable to determine if current; not finalized.
5.	Environmental hazard assessment	*Hazard and Risk Determination Language for Ecotox Report in NCR*	Outdated.
6.	Environmental hazard assessment	*Options when Determining a Toxicity (T) Score a*	Not finalized.
7.	Exposure assessment	*New Chemicals Step Action Guide*	Guidance document did not exist prior to 2020. Staff developed guidance in 2020, but the document is not signed and finalized.
8.	Scoping meetings	—	Guidance document did not exist. According to management, the guidance was in development.

Notes: CEM = Consumer Exposure Model; NCR = New Chemical Review; RAD = Risk Assessment Division.
Source: OIG analysis of NCD guidance documents. (EPA OIG table)

In its 2019 report, the GAO reported that the EPA faced challenges in developing guidance to ensure consistency as the Agency implemented its new responsibilities under the Lautenberg Act. The GAO also reported that Office of Pollution Prevention and Toxics officials said they had not yet created all the necessary guidance for staff implementing the Act. We found that the EPA still lacks final guidance on how to conduct many activities under the NCD's New Chemicals Program.

The NCD Had Not Developed Recordkeeping Guidance for Scoping Meetings, and Its Recordkeeping Systems Were Often Inaccessible

The NCD has worked to improve its TSCA recordkeeping processes, but more improvements are needed. Prior to September 2021, TSCA applications within the NCD's TSCA Confidential Business Information systems could not track edits to records that were developed during the new chemicals review process. Further, the NCD maintained records on several different applications within the TSCA Confidential Business Information systems, creating inefficiencies in workflow. As of October 2021, the NCD had corrected these deficiencies: it can now track and maintain edits to records and has designated one

application, the New Chemical Review, as its official recordkeeping application. The New Chemical Review application is housed within the TSCA Confidential Business Information systems.

Despite these improvements, the NCD still lacks guidance on how to maintain certain records. As mentioned previously, there is NCD guidance that generally defines and describes the scoping meeting, including that a person attending the scoping meeting should record items from the meeting, such as human health concerns or final decisions about the review steps necessary to assess a chemical's risk. However, there are no specific standard operating procedures that outline how these records should be developed. Having standard operating procedures that describe how to create and maintain records from the scoping meetings is essential to ensure that concerns associated with each chemical's risk are documented, as well as to ensure compliance with the Federal Records Act.

The NCD's information technology applications and systems also lacked features essential for proper recordkeeping, such as version control capabilities and a global search function to easily locate records. For example, in the EPA's February 11, 2022 response to letters that the National Archives and Records Administration sent in September and October 2021 about allegations of unauthorized destruction of records related to chemical risk assessments, the Agency said that "at times, EPA staff would not place drafts in the correct folder or would inadvertently save changes to the original file, instead of creating a new file," and would store draft risk assessments in two separate locations within the TSCA Confidential Business Information systems. However, as noted previously, as of October 2021, the NCD implemented version control capabilities and designated one application to serve as its official recordkeeping application. Maintaining the use of version controls and having an official recordkeeping system can help rectify past issues with the retention and storage of records.

In addition, we found that the NCD's applications within the TSCA Confidential Business Information systems were often inaccessible. Although the NCD has designated the New Chemical Review application as its official recordkeeping application, records developed before October 2021 are still stored among the various applications housed in the TSCA Confidential Business Information systems. During our audit, we received 19 email notifications between December 6, 2021, and August 31, 2022, that various applications within the TSCA Confidential Business Information systems were not available. Sixteen of those 19 emails reported that various applications were unavailable during working hours, including one instance where the issue remained unresolved for two consecutive days. Some examples of issues reported included an inability to log in to access TSCA Confidential Business Information systems, email issues, and nonoperational recordkeeping applications. We also found that support for the NCD's information technology systems needs to be improved to address technical issues. Without developing plans of action and milestones to correct issues and without prioritizing issues based on severity, the risk increases that the NCD is not complying with the Federal Records Act or GAO mandates that records be properly maintained and readily accessible.

In the OCSPP's "Summary and Initial Response" to the *OCSPP Looking Forward: A Climate Assessment Summary Report*,[4] the OCSPP discussed the New Chemicals Program's technological challenges, stating that "the information technology systems that the program relies on – including those that support new chemical workflows, review of confidential business information, the ChemView database and various existing chemical program functions are frequently inoperable, making it difficult to function at the speed of modern times." Therefore, we determined that it remains imperative for the NCD to continue optimizing the functionality of its recordkeeping systems—both its designated official recordkeeping system and the information technology systems that still contain records—so that it is easy to search and locate documents, as well as to maintain version control to enable transparency in its recordkeeping.

Lack of Resources Hindered Guidance Development and TSCA Information Technology System Updates

Staff Shortages Hinder Needed Improvements for the NCD

In its March 2022 workforce and workload analysis, the NCD estimated that its Risk Assessment Branch, which conducts the risk assessment step of the new chemicals review process, needs an additional 16 full-time equivalent, or FTE, staff to execute its new chemicals review work. This includes an additional 3.4 FTE staff to complete guidance development, as well as an additional 4.8 FTE staff to complete information technology updates. The NCD's March 2022 workforce and workload analysis is shown in Appendix B. In speaking with NCD management, we learned that the number of FTE staff needed was calculated based on estimates provided from each branch for each program area of work included in the new chemicals review process.

Despite staff shortages, the NCD made progress in terms of its quality program. According to an EPA press release dated October 14, 2021, the NCD updated and finalized some guidance related to recordkeeping, quality assurance and quality control, and scientific disagreements. In addition, in September 2021, the NCD implemented the NCD's New Chemical Review application as the official recordkeeping application within the TSCA Confidential Business Information systems.

Even so, the OCSPP previously documented how staff and financial constraints affected its work under TSCA. For example:

- The OCSPP assistant administrator testified in October 2021 before the House of Representatives Committee on Energy and Commerce about how resource constraints contributed to missed TSCA deadlines, how the office has less than 50 percent of the resources needed for the New Chemicals Program to operate as Congress intended, and

[4] The climate assessment was provided to current EPA employees and management who contributed to the New Chemicals Program from 2016 to when the climate assessment was conducted. Responses were provided via a survey, in listening sessions, or in individual interviews. The OCSPP's report listed the challenges most often identified in the responses, along with the OCSPP's efforts to address them.

how the information technology systems upon which the OCSPP relies to conduct its new chemicals work are frequently inoperable.

- The *OCSPP Looking Forward: A Climate Assessment Summary Report* said that more staff are needed, that workload should be mitigated to manage day-to-day stress on the workforce, that information technology systems need to be modernized, and that the OCSPP should eliminate the use of multiple systems for tracking processes.
- The EPA's *Fiscal Year 2023 Justification of Appropriation Estimates for the Committee on Appropriation* said that "to ensure that EPA can achieve the statutory requirements under TSCA, the Agency needs a substantial increase in scientific expertise and financial resources. To facilitate this need, the FY [fiscal year] 2023 Budget provides an additional $64.0 million and 201 FTE to the TSCA program."

In its 2019 report, the GAO reported that the EPA faced challenges in providing sufficient staffing and resources to meet the requirements of the Lautenberg Act. EPA management told the GAO that a planned reorganization of the Office of Pollution Prevention and Toxics would help alleviate these concerns. However, the GAO also reported that some staff voiced concerns as to whether the planned reorganization would sufficiently resolve staffing shortages. Despite the reorganization that occurred in October 2021, the EPA indicated to us that it still faces staffing challenges.

The EPA Did Not Fully Use Its Authority Under TSCA to Collect Fees Needed to Offset Program Costs

The Lautenberg Act provides the EPA with the authority to collect user fees to defray the costs of implementing the Act. However, the amount of user fees collected has fallen short of what the EPA originally projected. A prior OIG audit of the fiscal years 2019 and 2020 TSCA fee fund financial statements found that the fees collected did not meet the intent of TSCA to defray 25 percent of the specified costs of carrying out the applicable parts of sections 4, 5, 6, and 14.[5] Specifically, although the EPA anticipated collecting approximately $20 million in each fiscal year 2019 and fiscal year 2020, which represents around 25 percent of its estimated costs of $80.2 million for those years, it collected far less. This difference occurred largely because the EPA overestimated the number of actions that would trigger fees in the TSCA fees rule. The prior OIG audit recommended that the EPA correct the methodology for accounting for TSCA expenses from other appropriations to ensure that all costs for administering the applicable parts of sections 4, 5, 6, and 14 are properly recorded and reported in the financial statements. Collecting user fees helps the EPA defray the costs of implementing TSCA; however, since the Agency collected fewer fees in fiscal years 2019 and 2020, it did not meet the intent to defray the costs of carrying out TSCA, including new chemical reviews under section 5. The EPA agreed with our prior audit recommendation and provided acceptable planned corrective actions with a completion date of October 1, 2023. As of May 2023, this recommendation was resolved with corrective actions pending.

[5] EPA OIG, *The EPA's Fiscal Years 2020 and 2019 Toxic Substances Control Act Service Fee Fund Financial Statements*, Report No. 23-F-0005, issued December 29, 2022.

The NCD Lacks Assurance that Quality Assurance and Recordkeeping Requirements Are Followed and Staff Can Consistently Access Records

Without updated, finalized guidance in place to ensure the consistency of new chemical reviews, the EPA does not have reasonable assurance that the new chemicals review process is properly considering and addressing risks to public health and the environment. Moreover, the information technology applications housed within the TSCA Confidential Business Information systems are often inaccessible, which impacts the NCD's access to records throughout the workday and hinders staff ability to document determinations made during the new chemicals reviews process.

According to EPA data, from June 22, 2016, through November 1, 2022, the EPA received 4,514 new premanufacture notices and completed 3,830 new chemical reviews. None of these 3,830 chemicals were barred from entering the marketplace. The significant number of new chemicals requiring review highlights the need for the EPA to have finalized and up-to-date standard operating procedures and effective recordkeeping processes to ensure the integrity and transparency of its new chemicals review process.

Conclusions

As outlined in TSCA, the intent of the new chemicals review process is to prevent unreasonable health and environmental risks from the introduction of new chemicals into commerce. Thus, it is important that the EPA has guidance in place to ensure the quality of the data it uses to determine the safety of new chemicals. This includes procedures for properly documenting and maintaining records of the decisions made during the new chemicals review process.

According to the NCD's March 2022 workload and workforce analysis, the NCD lacks the necessary staff resources to update and finalize the New Chemicals Program guidance and improve upon its TSCA information technology systems. The OCSPP can use or redistribute additional staff and financial resources awarded to TSCA programs and make staff adjustments to balance the New Chemicals Program's workload to better operate as intended—in other words, to conduct new chemical reviews that ensure the protection of human health and the environment, while also meeting statutory deadlines.

Recommendations

We recommend that the assistant administrator for Chemical Safety and Pollution Prevention:

1. Develop and implement a plan to regularly review the New Chemicals Division's guidance documents, including standard operating procedures, to ensure that all required guidance is developed, current, signed, and finalized.

2. Develop a process to periodically assess the effectiveness of the New Chemicals Division's official recordkeeping system within the Toxic Substances Control Act Confidential Business Information systems and update the applications and systems as needed, while maintaining the use of version controls to preserve edits made to records.

3. Develop and implement a plan to identify root causes for frequent technical issues and prioritize the creation and implementation of plans of action and milestones based on the severity of the technical issues within the Toxic Substances Control Act Confidential Business Information systems.

4. Conduct periodic reviews of the New Chemicals Division's workforce and workload analysis, and update as needed, to regularly balance the New Chemicals Division's workload with the staff resources needed to execute new chemicals review work, including updating and finalizing guidance and maintaining and updating Toxic Substances Control Act Confidential Business Information systems.

Agency Response and OIG Assessment

The OCSPP agreed with our four recommendations and proposed corrective actions and estimated completion dates that we believe will satisfy the intent of the recommendations. Therefore, all recommendations are considered resolved, with corrective action pending. The Agency's response to our draft report is included in Appendix C, and we summarize the proposed corrective actions in the below paragraphs.

The OCSPP agreed with Recommendation 1 to create a plan to regularly review the New Chemical Division's guidance documents and stated that the plan will be based on progress and approaches developed to date.

In its response to Recommendation 2, the OCSPP said that the Office of Pollution Prevention and Toxics and the Office of Program Support will regularly meet to identify improvements needed for future versions of the New Chemical Review application. The Office of Program Support will also report annually to the assistant administrator for Chemical Safety and Pollution Prevention on the effectiveness of the New Chemical Review application functions to ensure that recordkeeping within the TSCA Confidential Business Information systems is consistent with our recommendation.

In response to Recommendation 3, the OCSPP stated that the Office of Program Support will develop and initiate a plan as stipulated in the recommendation and that the plan will include the following:

> (1) a risk assessment to identify root causes for frequent technical issues to the TSCA CBI LAN availability; (2) a mitigation plan to prioritize hardware and software configuration changes to increase availability of the system and applications; and (3) a monitoring plan to control the improvements, detect disruptions early and often, and maintain stability within the system.

For Recommendation 4, the OCSPP provided two corrective actions: that the Office of Program Support, Mission Support Division, and the New Chemicals Division will develop a schedule for periodic workforce and workload analysis by December 31, 2023, and that the Office of Program Support will update and finalize guidance and a schedule for maintaining and updating the TSCA Confidential Business Information systems by December 31, 2023.

Chapter 3
The NCD's Employee Performance Standards Do Not Explicitly Address the TSCA Statutory 90-Day Review Requirement

Hotline complainants alleged that the TSCA statutory deadline was used to adversely affect performance reviews of staff, that staff were evaluated based on the percentage of new chemical reviews that were completed within the statutory deadline period, and that staff are rewarded for quickly finishing cases that do not find risks instead of for protecting human health and the environment. To address these complaints, we assessed whether the NCD's employee performance standards included a time-bound requirement to complete new chemical reviews. We found no evidence that the EPA uses employee performance standards to explicitly measure whether employees satisfy the TSCA statutory 90-day review requirement.

The NCD Employee Performance Standards and the TSCA Statutory 90-Day Review Requirement

The EPA and a union representing more than 8,000 EPA employees have a collective bargaining agreement. This agreement states that EPA management will establish—as well as communicate to the employees who belong to the union—the performance elements, critical elements, noncritical elements, and performance standards subject to law and regulations. According to the collective bargaining agreement, performance standards that assess an employee's performance must be job-related, documented, and measurable. There must also be a nexus between the expected manner of performance and the expected job results.

What is collective bargaining?

Collective bargaining is the mechanism or process for an organized group of workers and their employer to pursue mutual agreement over workplace issues. The collective bargaining agreement is a legally enforceable, written contract between a union representing a group of employees and an employer in a workplace.

As described earlier, TSCA requires the EPA to make, upon receipt of a premanufacture notice for a new chemical, an affirmative determination within 90 days on whether the new chemical substance presents an unreasonable risk to human health or the environment.

The NCD Employee Performance Standards Do Not Explicitly Address the TSCA Statutory 90-Day Review Requirement

We reviewed the NCD's employee performance standards from fiscal year 2021 to identify whether they included the TSCA statutory 90-day review requirement, a certain number or percentage of reviews that needed to be completed within the statutory requirement, or any other language that would indicate that employees have time-bound requirements to complete reviews quickly rather than with the goal of protecting human health and the environment.

Performance standards for NCD employees include requirements to comply with applicable statutes, regulations, policies, and procedures. Specifically, NCD employee performance standards reference the EPA's Strategic Objective 1.4, "Ensure Safety of Chemicals in the Marketplace," which states that the Agency will "[e]ffectively implement the Toxic Substances Control Act, and the Federal Insecticide, Fungicide, and Rodenticide Act, to ensure new and existing chemicals and pesticides are reviewed for their potential risks to human health and the environment and actions are taken when necessary."

We found no evidence, however, that the standards explicitly address the 90-day requirement for new chemical reviews. In addition, we did not find that the NCD performance standards included a numeric value for how many new chemical reviews are required to be completed during the year. Furthermore, we did not find evidence that employees are rewarded for quickly completing risk assessments that do not find risks instead of with the goal of protecting human health and the environment.

As a result, we make no recommendations regarding the NCD's employee performance standards.

Status of Recommendations

Rec. No.	Page No.	Recommendation	Status*	Action Official	Planned Completion Date
1	17	Develop and implement a plan to regularly review the New Chemicals Division's guidance documents, including standard operating procedures, to ensure that all required guidance is developed, current, signed, and finalized.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	1/15/24
2	17	Develop a process to periodically assess the effectiveness of the New Chemicals Division's official recordkeeping system within the Toxic Substances Control Act Confidential Business Information systems and update the applications and systems as needed, while maintaining the use of version controls to preserve edits made to records.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/23
3	18	Develop and implement a plan to identify root causes for frequent technical issues and prioritize the creation and implementation of plans of action and milestones based on the severity of the technical issues within the Toxic Substances Control Act Confidential Business Information systems.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/23
4	18	Conduct periodic reviews of the New Chemicals Division's workforce and workload analysis, and update as needed, to regularly balance the New Chemicals Division's workload with the staff resources needed to execute new chemicals review work, including updating and finalizing guidance and maintaining and updating Toxic Substances Control Act Confidential Business Information systems.	R	Assistant Administrator for Chemical Safety and Pollution Prevention	12/31/23

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

Summary of Hotline Allegations by Area of Concern

Area of Concern 1: Records management allegations

There are apparent violations of the EPA's *Records Management Policy*, which requires the retention of substantive comments on draft documents that record important Agency decision-making processes. Many of the altered risk assessment documents have been overwritten, and intermediate comments have been erased.
Incoming cases are prioritized over developing critical process improvements and standard operating procedures within the NCD, which are distinctly lacking. Examples of necessary process improvements include items such as standardizing and updating assessment templates, developing a process for resolving internal scientific disagreements, and discipline-specific training on current agencywide guidance and policy.
Internal practices were crafted to minimize estimated risks rather than being primarily based on input or buy-in from technical staff.

Area of Concern 2: Quality assurance and quality control allegations

Quality control process allowed improper changes to be made and remain uncorrected.
Incoming cases are prioritized over developing critical process improvements and standard operating procedures within the NCD, which are distinctly lacking. Examples of necessary process improvements include items such as standardizing and updating assessment templates, developing a process for resolving internal scientific disagreements, and discipline-specific training on current agencywide guidance and policy.

Area of Concern 3: Employee performance allegations

The 90-day statutory deadline for assessing premanufacture notices has been used by the Office of Pollution Prevention and Toxics and NCD management to pressure assessors to accept unwarranted revisions to their risk assessments without pushing back. If the cases are not completed by the 90-day deadline, they are placed on the list of backlog cases and the performance reviews of the staff are adversely affected.
Human health hazard assessors were evaluated based on the percentage of cases that were completed within the 90-day review period, even when cases were delayed due to issues with work conducted by scientists in a different discipline or management interference.
Risk assessors are rewarded for getting cases out quickly that do not find risks, rather than for protecting human health and the environment.

Appendix B

The NCD's Workforce and Workload Analysis (updated March 2022)

Program Area/Casework	RAB		RMB		ICB		IO		NCD Balance (April 1 - Sept 30)	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
	26	$3,785,008	27	$588,544	13	$739,052	4.0	$33,456	70	$2,573,030
Casework Total (by 9/30/22)	**26.0**	**$2,247,042**	**20.0**	**$697,580**	**8.5**	**$257,600**	**0.5**		**15**	**($629,192)**
Biofuels RA process and report development	1.0	$211,210							14	($840,402)
Section 5 Inventory: Bona Fides, PMNs, NOCs	0.2				2.0	$310,980			12	($1,151,382)
Section 8: Inventory, Maintenance, Pubs, NOAs, & Special Projects)						$90,000				($1,241,382)
Rulemaking, Petition, Guidance			2.0	$69,000			0.5		9	($1,310,382)
Performance Metrics: Compliance Monitoring			0.1						9	($1,310,382)
Mgmnt, Operations, Admin	1.4		2.8		1.5		0.7	$9,075	3	($2,225,457)
Transparency Commitments			1.0	$99,000			0.4		8	($1,409,382)
SI Committements: Enhanced DSO, recordkeeping, NCAC, Tech Teams, Other							0.7		7	($1,409,382)
ORD-OCSPP NC Collaborative Research	0.5				0.1		0.5	$25,000	6	($1,434,382)
Science Training, Policy, SOPs Development	3.4	$100,000	0.4						2	($1,534,382)
Cross-cutting OPPT/OCSPP Support (PFAS, EC, OECD, Other)	1.2		0.2		1.0	$0			(0)	($1,534,382)
Tools & Models O&M, Testing, Enhancements	4.1	$682,000	0.4						(5)	($2,216,382)
NCR/CIS O&M, Testing, Enhancements	0.7								(5)	($2,216,382)
Succession Planning, Recruiting, Professional Development	2.9						0.7	$25,976	(1)	($2,251,433)
Cost per Sector (e.g., semi-conductor, EV, HFC) process development	1.0	$211,210							(2)	($2,462,643)
Sustainable Futures/Sector Specific Training		$50,000							(2)	($2,512,643)
Digitization/Records Management				$34,000					(2)	($2,546,643)
Supplies, Travel, Misc								$7,480	(2)	($2,554,123)
Subtotals by NCD Branch	42	$3,501,462	27	$899,580	13	$658,580	4	$67,531		
Balance by NCD Branch	(16)	283,546	0	(311,036)	(0)	80,472	4	(34,075)		

Notes: CIS = Chemical Information System; DSO = Differing Scientific Opinion; EC = Existing Chemicals; EV = Electric Vehicle; FTE = Full-Time Equivalent; HFC = Hydrofluorocarbon; ICB = Industrial Chemistry Branch; IO = Immediate Office; NC = New Chemical; NCAC = New Chemicals Advisory Committee; NCR = New Chemical Review; NOA = Notice of Activity; NOC = Notice of Commencement to Manufacture or Import; O&M = Operations and Maintenance; OECD = Organization for Economic Co-Operation and Development; ORD = Office of Research and Development; PFAS = Per- and Poly-Fluoro Alkylated Substances; PMN = Premanufacture Notice; RA = Risk Assessment; RAB = Risk Assessment Branch; RMB = Risk Management Branch; SI = Scientific Integrity; SOP = Standard Operating Procedure.

Source: OCSPP-provided data and table. (EPA table)

Agency Response to Draft Report

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Draft Report entitled "The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions."

FROM: Michal I. Freedhoff, Ph.D.
Assistant Administrator

MICHAL FREEDHOFF
Digitally signed by MICHAL FREEDHOFF
Date: 2023.07.07 13:36:10 -04'00'

TO: Sean W. O'Donnell
Inspector General

This memorandum provides EPA's response to the Office of Inspector General (OIG) Draft Report entitled "The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions," Report No. OA-FY22-0025, dated May 31, 2023.

I. General Comments

EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) appreciates the OIG's effort in evaluating:

- The extent to which EPA is using and complying with applicable records management requirements, quality assurance requirements, and employee performance standards to review and approve new chemicals under the Toxic Substances Control Act of 1976.

OCSPP agrees that the Office of Pollution Prevention and Toxics (OPPT's) New Chemicals Division (NCD) should have appropriate, accurate, and complete guidance, transparent documentation of decisions regarding the manufacture or uses of new chemicals, and proper maintenance of data and records. OCSPP has been working to address these needs and is committed to completing this work.

OCSPP also agrees with the OIG's assessment that determining the safety of chemicals in a timely manner requires sufficient staff and resources. To address staffing needs, NCD has hired additional staff, and is in the process of hiring more. While we have made good progress over the past six months, the hiring and training process is a lengthy one. It generally takes at least 3-6 months to recruit, select, conduct background checks for, and onboard a new hire, and sometimes takes even longer for a variety of reasons. After that, new hires require training and mentoring by more experienced staff to be able to perform their program responsibilities to ensure there are no unreasonable risks from new chemicals.

Funding for the new chemicals program also continues to be a challenge. The Lautenberg Act dramatically increased EPA's Toxic Substances Control Act (TSCA) new chemicals authorities, responsibilities, and workload by requiring the agency to complete formal risk determinations for 100% of all new chemical submissions prior to the commencement of manufacturing. This represented a notable increase in workload compared to the pre-2016 practice of completing formal risk determinations on only about 20% of such submissions. Despite this significant increase in responsibility, appropriations for EPA's TSCA program were flat for the first six and a half years of the new law, in no small part because the previous Administration did not once request any additional funding from Congress.

In the FY 2022 budget request, President Biden asked for an additional $15 million for TSCA, but EPA did not receive all it requested. In the FY 2023 budget request, using TSCA workforce and resource needs analyses conducted in late 2020 and early 2021, the President asked for an increase of $59.2 million and 175 full-time equivalents (FTE) to support the TSCA program. EPA received only $19.7 million, which is being used to support an additional 65 FTE across EPA's TSCA program (including 11 FTE for NCD). Although this does not fulfill all the program's staffing needs, over the past year, with new hires and detailees, the New Chemicals program has increased the number of human health assessors from only 2 or 3 to almost a dozen. The program is continuing to hire across other needed disciplines in FY23.

II. OCSPP's Response to the Recommendations:

Recommendation 1: Develop and implement a plan to regularly review the New Chemicals Division's guidance documents, including standard operating procedures, to ensure that all required guidance is developed, current, signed, and finalized.

OCSPP Response: OCSPP agrees with Recommendation 1. In early 2021, OCSPP initiated a process to conduct an inventory of the existing SOPs and guidance, grouping and organizing and screening all SOPs, and prioritizing review and revision of documents. Due to resource constraints in FY21 and FY22, NCD focused staff and resources on completing casework. In FY23, through hiring and training of new staff, NCD is now able to maintain casework at a pace which enables additional work on SOPs. OCSPP has not been able to complete the process of reviewing existing NCD guidance documents to ensure that that all required guidance is developed, current, signed, and finalized, but has made steady progress. For example, the New Chemicals program has publicly released standardized approaches for risk assessment and risk management of new alternative fuels, mixed metal oxides including cathode active materials, and most recently PFAS that serve as SOPs for these chemistries. Additionally, OCSPP has

developed an SOP for addressing differing scientific opinions (DSOs) that has been in practice since 2022.

By the end of the calendar year, OCSPP expects to complete its work on an eye irritation decision framework that describes the use of new approach methods (NAMs). OCSPP also initiated work on a framework for qualitatively assessing skin sensitization using NAMs and a skin irritation decision framework based on NAMs already available. Additionally, by end of the second quarter FY2024, OCSPP expects to complete its work on "hot sheet" (or mini-SOP), for conducting human health risk assessments for new chemical substances that use Carbon Nanotubes[6].

- **Proposed Corrective Action:** OCSPP will develop and implement a plan to regularly review the New Chemicals Division's guidance documents, including standard operating procedures, to ensure that all required guidance is developed, current, signed, and finalized. The plan will be based on the progress made and approaches developed to date under the current, ongoing, and comprehensive guidance/SOP review and update efforts described above. OPPT will submit this plan to the OCSPP Assistant Administrator for approval by January 15, 2024.

Recommendation 2: Develop a process to periodically assess the effectiveness of the New Chemicals Division's official recordkeeping system within the Toxic Substances Control Act Confidential Business Information systems and update the applications and systems as needed, while maintaining the use of version controls to preserve edits made to records.

- **OCSPP Response**: OCSPP agrees with Recommendation 2 and suggests that actions already taken and underway meet the OIG's expectations. OCSPP's Office of Program Support (OPS) has implemented software changes into the New Chemical Review (NCR) application to provide additional functionality for tracking and retaining all versions of risk assessment reports developed during the risk assessment process. To preserve edits made to records and ensure version control, a technical control was incorporated into the NCR application to prevent a document from being overwritten when a new version is created. This ensures that both the previous version and the new version of the document are retained to create a complete record trail. These initial updates of business rules within the NCR application were completed on September 17, 2021, with the implementation of NCR application Version 3.1.0.
- **Proposed Corrective Action 2**: OPPT and OPS will meet regularly to identify needed improvements for inclusion in future versions of the NCR application. OPS will report annually to the Assistant Administrator on the effectiveness of the NCR system application functions to ensure the New Chemicals Division's official recordkeeping system within the TSCA Confidential Business Information (CBI) systems is consistent with the OIG's recommendation. The first annual report shall be completed no later than December 31, 2023.

[6] Carbon Nanotube (CNT) uses include: applications in energy storage, automotive parts, boat hulls, sporting goods, water filters, thin-film electronics, and electromagnetic shields.

Recommendation 3: Develop and implement a plan to identify root causes for frequent technical issues and prioritize the creation and implementation of plans of action and milestones based on the severity of the technical issues within the Toxic Substances Control Act Confidential Business Information systems.

- **OCSPP Response**: OCSPP agrees with Recommendation 3 and has initiated work to address it utilizing the OCSPP IT Mission Support Contract. Datawiz was awarded the contract in September 2022 and began onboarding personnel in February 2023. Federal staff have prioritized the effort to stabilize the CBI systems performance issues.
- **Proposed Corrective Action 3**: OPS has begun a review of the CBI Local Area Network (LAN) with contractor support. OPS will develop and initiate a plan to identify the root causes for frequent technical issues and prioritize the creation and implementation of courses of action and milestones. The plan will include: (1) a risk assessment to identify root causes for frequent technical issues to the TSCA CBI LAN availability; (2) a mitigation plan to prioritize hardware and software configuration changes to increase availability of the system and applications; and (3) a monitoring plan to control the improvements, detect disruptions early and often, and maintain stability within the system. OPS will complete the development and implementation of a plan to identify root causes for frequent technical issues and prioritize the creation and implementation of plans of action and milestones based on the severity of the technical issues within the Toxic Substances Control Act Confidential Business Information systems by December 31, 2023.

Recommendation 4: Conduct periodic reviews of the New Chemicals Division's workforce and workload analysis, and update as needed, to regularly balance the New Chemicals Division's workload with the staff resources needed to execute new chemicals review work, including updating and finalizing guidance and maintaining and updating Toxic Substances Control Act Confidential Business Information systems.

- **OCSPP Response**: OCSPP agrees with Recommendation 4. OPPT has hired 49 new employees in FY23 (including both new priority hires and backfilling open positions), which has already contributed to increased throughput of completed risk assessments and risk management. In October 2022, OPPT had a backlog of 454 submittals that were submitted in FY 2022 or earlier. By June of this year, OPPT had closed out 161 of those cases, reducing our number of older cases to 293. In just 9 months, OPPT was able to cut outstanding older cases by just over a third. OPS will support OPPT in conducting periodic reviews of NCD's workforce and workload analysis as described in Recommendation 4. The analysis will be revised as needed to regularly balance the NCD's workload with the staff resources needed to execute new chemicals review work, including updating and finalizing guidance and maintaining and updating TSCA CBI systems. The actions include: (1) OPS's Mission Support Division (MSD) and OPPT/NCD will set a schedule for periodic reviews of the workforce based on workload analyses; and (2) OPS' Information Technology and Resources Management Division (ITRMD) will update and finalize guidance and a schedule to maintain and update the TSCA CBI systems.

- **Proposed Corrective Action 4a**: OPS/MSD and OPPT/NCD completed the first workforce and workload analysis in June 2023. OPS/MSD and OPPT/NCD will develop a schedule for periodic reviews of the workforce and workload analysis by December 31, 2023.
- **Proposed Corrective Action 4b**: OPS/ITRMD will update and finalize guidance and a schedule for maintaining and updating, as needed, the TSCA CBI systems by December 31, 2023.

Thank you very much for the opportunity to comment on the Draft Report. Please contact Janet L. Weiner, OCSPP's Senior Audit Advisor, if you have questions or need further information.

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