



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.

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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.