

Why GAO Did This Study

The Toxic Substances Control Act (TSCA), as amended, directs EPA to make a formal determination on the risk of injury to health or the environment on each new chemical before it can be manufactured. However, GAO reported in February 2023 ([GAO-23-105728](#)) that EPA typically made its determination within the 90-day TSCA review period less than 10 percent of the time.

GAO was asked to review EPA's implementation of its TSCA New Chemicals Program. This report (1) summarizes the perspectives of selected manufacturers on EPA's review process and (2) evaluates the extent to which EPA follows key practices for managing and assessing the program. GAO identified a random, nongeneralizable sample of notices submitted to EPA from October 2021 to April 2024 and interviewed 19 manufacturers that submitted these notices. GAO also compared EPA's management and assessment activities to key practices it developed based on federal laws, federal guidance, and prior GAO work.

What GAO Recommends

GAO is making two recommendations, including that EPA's NCD address, as it finalizes its strategic plan, relevant key management and assessment practices; and implement a systematic performance management process that aligns with the key practices. EPA agreed with both recommendations.

View [GAO-25-106839](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

NEW CHEMICALS PROGRAM

EPA Needs a Systematic Process to Better Manage and Assess Performance

What GAO Found

Representatives from 19 manufacturers GAO interviewed identified a range of challenges, strengths, and potential improvements for the U.S. Environmental Protection Agency's (EPA) new chemicals review process. For example, most (16 of 19) representatives told GAO they experienced review delays and described effects of these delays on their businesses. Effects manufacturers cited included harming customer relations, creating a competitive advantage for existing chemical alternatives at the expense of new chemicals, and hindering market participation.

Representatives also identified strengths in how EPA implements the program and potential process improvements. For example, almost all (18 of 19) representatives found EPA's public information sources somewhat or very helpful. Representatives suggested that EPA improve the new chemicals review process by clarifying review requirements, providing realistic time frames for completing reviews, and improving communication, among other improvements.

EPA's New Chemicals Division (NCD) has taken some important initial planning steps, but NCD does not follow most key practices for managing and assessing the results of its New Chemicals Program.

Extent to Which the U.S. Environmental Protection Agency (EPA) Follows Key Management and Assessment Practices for Its New Chemicals Program

| Foster a culture of learning and continuous improvement | Plan for results | Assess and build evidence | Use evidence |
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| Demonstrate leadership commitment | Define goals | Assess the sufficiency of existing evidence | Use evidence to learn |
| Promote accountability | Identify strategies and resources | Identify and prioritize evidence needs | Apply learning to decision-making |
| Involve stakeholders | Assess the environment | Generate new evidence | Communicate learning and results |
| Build and maintain capacity | | | |

■ Does not follow
 ■ Partially follows
 ■ Generally follows

Source: GAO analysis of EPA performance planning and monitoring documents. | GAO-25-106839

For example, in August 2024, NCD drafted a strategic plan that identifies five strategic goals and how to achieve them. However, NCD did not follow some relevant key practices in developing the plan, including involving external stakeholders and identifying resources needed to achieve each draft goal. Moreover, NCD officials told GAO that they had not developed a systematic process to ensure that it consistently follows all key practices. Addressing relevant key practices—including involving stakeholders and identifying resources—as NCD finalizes its strategic plan could position the division to better manage and assess the program. Further, implementing a systematic performance process could better position NCD to ensure that it achieves program goals, such as improving the timeliness of reviews.