

GAO Highlights

Highlights of [GAO-19-270](#), a report to the Ranking Member, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

EPA is responsible for reviewing chemicals in commerce and those entering the marketplace. Currently there are more than 40,000 active chemical substances in commerce, with more submitted to EPA for review annually. EPA's IRIS database contains the agency's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment. EPA's IRIS Program, which produces toxicity assessments, has been criticized in the past for timeliness and transparency issues. In response, the IRIS Program committed to making program improvements starting in 2011, which the National Academy of Sciences (NAS) recently commended. TSCA as amended in 2016 provides EPA with additional authority to review both existing and new chemicals and to regulate those that EPA determines pose unreasonable risks to human health or the environment.

This report describes (1) the extent to which the IRIS Program has addressed identified challenges and made progress toward producing chemical assessments; and (2) the extent to which EPA has demonstrated progress implementing TSCA. GAO reviewed NAS and EPA documents and interviewed officials from EPA and representatives from two environmental and two industry stakeholder organizations.

What GAO Recommends

GAO made recommendations previously to improve the IRIS Program and TSCA implementation. EPA provided comments, which GAO incorporated as appropriate.

View [GAO-19-270](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

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CHEMICAL ASSESSMENTS

Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act

What GAO Found

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program, which prepares human health toxicity assessments of chemicals, has made progress addressing historical timeliness and transparency challenges in the assessment process. Efforts to address timeliness include employing project management principles and specialized software to better plan assessments and utilize staff. To address the need for greater transparency in how the program conducts assessments, IRIS officials and the IRIS Program have implemented systematic review, which provides a structured and transparent process for identifying relevant studies, reviewing their methodological strengths and weaknesses, and integrating these studies as part of a weight of evidence analysis.

Since the process improvements were implemented, the program made progress toward producing chemical assessments through May 2018. In June 2018, the EPA Administrator's office told IRIS officials that they could not release any IRIS-associated documentation without a formal request from EPA program office leadership. In August 2018, according to IRIS officials, program office leadership was asked to reconfirm which ongoing chemical assessments their offices needed. In late October 2018, these offices were asked to limit their chemical requests further, to the top three or four assessments. At the same time—4 months after IRIS assessments were stopped from being released—28 of approximately 30 IRIS staff were directed to support implementation of the Toxic Substances Control Act of 1976 (TSCA), as amended, with 25 to 50 percent of their time, according to officials. Then on December 19, 2018, the Office of Research and Development released its IRIS Program Outlook, which provided an updated list of 13 assessments. Eleven of the 13 chemicals on the IRIS Program Outlook were requested by two EPA program offices. A memorandum issued earlier in December, gave no indication of when additional assessments could be requested or what the IRIS Program's workflow would be in the near term.

EPA has demonstrated progress implementing TSCA, which was amended in June 2016, by responding to statutory deadlines. For example, EPA finalized rules detailing the general processes for prioritizing and evaluating chemicals, known as the Framework Rules, but three of the four rules have been challenged in court. Environmental organizations have argued, among other things, that TSCA requires EPA to consider all conditions of use in prioritizing and evaluating chemicals, rather than excluding, for example, uses that EPA believes are "legacy uses," for which a chemical is no longer marketed. EPA argued that TSCA grants it discretion to determine what constitutes a chemical's conditions of use. Amendments to TSCA in 2016 increased EPA's responsibility for regulating chemicals and in turn, its workload. As such, EPA is required to prioritize and evaluate existing chemicals by various deadlines over an extended period and to make a regulatory determination on all new chemicals. Senior management told GAO that they were confident that ongoing hiring and reorganization would better position the office that implements TSCA.