

Highlights of [GAO-12-42](#), a report to the Ranking Member, Subcommittee on Energy and Environment, Committee on Science, Space, and Technology, House of Representatives

Why GAO Did This Study

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program supports EPA's mission to protect human health and the environment by providing the agency's scientific position on the potential human health effects from exposure to various chemicals in the environment. The IRIS database contains quantitative toxicity assessments of more than 550 chemicals and provides fundamental scientific components of human health risk assessments. In response to a March 2008 GAO report on the IRIS program, EPA revised its IRIS assessment process in May 2009. GAO was asked to evaluate (1) EPA's progress in completing IRIS assessments under the May 2009 process and (2) the challenges, if any, that EPA faces in implementing the IRIS program. To do this work, GAO reviewed and analyzed EPA productivity data, among other things, and interviewed EPA officials.

What GAO Recommends

GAO recommends, among other things, that EPA assess the feasibility of the established time frames for each step in the IRIS assessment process and make changes if necessary, submit for independent review to an entity with scientific and technical credibility a plan for how EPA will implement the National Academies' suggestions, and ensure that current and accurate information on chemicals that EPA plans to assess through IRIS is available to IRIS users. EPA agreed with GAO's recommendations and noted specific actions it will take to implement them.

View [GAO-12-42](#). For more information, contact David C. Trimble at (202) 512-3841 or trimbled@gao.gov.

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CHEMICAL ASSESSMENTS

Challenges Remain with EPA's Integrated Risk Information System Program

What GAO Found

EPA's May 2009 revisions to the IRIS process have restored EPA's control of the process, increased its transparency, and established a new 23-month time frame for its less challenging assessments. Notably, EPA has addressed concerns GAO raised in its March 2008 report and now makes the determination of when to move an assessment to external peer review and issuance—decisions that were made by the Office of Management and Budget (OMB) under the prior IRIS process. In addition, EPA has increased the transparency of the IRIS process by making comments provided by other federal agencies during the interagency science consultation and discussion steps of the IRIS process available to the public. Progress in other areas, however, has been limited. EPA's initial gains in productivity under the revised process have not been sustained. After completing 16 assessments within the first year and a half of implementing the revised process, EPA completed 4 assessments in fiscal year 2011. Further, the increase in productivity does not appear to be entirely attributable to the revised IRIS assessment process and instead came largely from (1) clearing the backlog of IRIS assessments that had undergone work under the previous IRIS process and (2) issuing assessments that were less challenging to complete. EPA has taken longer than the established time frames for completing steps in the revised process for most of its less challenging assessments. However, EPA has not analyzed its established time frames to assess the feasibility of the time frame for each step or the overall 23-month process. The agency's progress has also been limited in completing assessments that it classifies as exceptionally complex and reducing its ongoing assessments workload. Beyond the 55 ongoing IRIS assessments, the backlog of demand for additional IRIS assessments is unclear. With existing resources devoted to addressing its current workload of ongoing assessments, EPA has not been in a position to routinely start new assessments.

EPA faces both long-standing and new challenges in implementing the IRIS program. First, EPA has not fully addressed recurring issues concerning the clarity and transparency of its development and presentation of draft IRIS assessments. For example, as part of its independent scientific review of EPA's draft IRIS assessment of formaldehyde, the National Academies provided suggestions for improving EPA's development and presentation of draft IRIS assessments in general, including that EPA use a standardized approach to evaluate and describe study strengths and weaknesses and the weight of evidence. EPA announced that it planned to respond to the National Academies' suggestions by implementing changes to the way it develops draft IRIS assessments. Given that many of the issues raised by the National Academies have been long-standing, it is unclear whether any entity with scientific and technical credibility, such as an EPA advisory committee, will have a role in conducting an independent review of EPA's planned response to the suggestions. In addition, EPA has not addressed other long-standing issues regarding the availability and accuracy of current information to users of IRIS information, such as EPA program offices, on the status of IRIS assessments, including when an assessment will be started, which assessments are ongoing, and when an assessment is projected to be completed.