



Highlights of GAO-08-743T, a testimony before the Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

The Environmental Protection Agency's (EPA) mission includes evaluating and regulating toxic chemicals. EPA's Integrated Risk Information System (IRIS) program is a chemical evaluation program that is a critical component of EPA's capacity to support scientifically sound environmental regulations and policies. The IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals.

This testimony highlights GAO's work on toxic substances, focusing on (1) its March 2008 report, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System* and (2) key changes to the IRIS assessment process EPA included in its revised IRIS assessment process released on April 10, 2008. It also highlights the findings of two GAO reports on EPA's regulation of toxic chemicals. For the IRIS report, GAO analyzed EPA data and interviewed officials at relevant agencies, including the Office of Management and Budget (OMB). For this testimony, GAO supplemented the IRIS report with a review of EPA's revised IRIS assessment process announced earlier this month.

Given the importance of the IRIS program to EPA's ability to protect public health and the environment, Congress should consider requiring EPA to suspend its new process and develop one that is responsive to GAO's recommendations.

To view the full product, including the scope and methodology, click on [GAO-08-743T](#). For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

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TOXIC CHEMICALS

EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals

What GAO Found

The IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments—a total of 4 were completed in fiscal years 2006 and 2007. In addition, recent assessment process changes, as well as other changes EPA was considering at the time of GAO's review, further reduce the timeliness and credibility of IRIS assessments.

- Although EPA has taken steps to improve the IRIS program since 2000 and has developed a number of draft assessments for external review, its efforts to finalize assessments have been thwarted by a combination of factors, including two new OMB-required reviews of IRIS assessments by OMB and other federal agencies; EPA management decisions, such as delaying some assessments to await new research; and the compounding effect of delays—even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science and methods.
- The OMB/interagency reviews of draft assessments involve other federal agencies in EPA's IRIS assessment process in a manner that limits the credibility of IRIS assessments and hinders EPA's ability to manage them. For example, the OMB/interagency reviews lack transparency, and OMB required EPA to terminate five assessments EPA had initiated to help it implement the Clean Air Act.
- The changes to the IRIS assessment process that EPA was considering, but had not yet issued at the time of GAO's review, would have added to the already unacceptable level of delays in completing IRIS assessments and further limited the credibility of the assessments.

On April 10, 2008, EPA issued a revised IRIS assessment process, effective immediately. In its February 2008 comments on GAO's draft report, EPA said it would consider the report's recommendations, which were aimed at streamlining the process and better ensuring that EPA has the ability to develop transparent, credible assessments. However, EPA's new process is largely the same as the draft GAO evaluated, and some key changes also are likely to further exacerbate the productivity and credibility concerns GAO identified. For example, while the draft process would have made comments on IRIS assessments from other federal agencies part of the public record, EPA's new process expressly defines such comments as "deliberative" and excludes them from the public record. GAO continues to believe it is critical that input from all parties—particularly agencies that may be affected by the outcome of IRIS assessments—be publicly available. As recommended in GAO's March 2008 report, to effectively maintain IRIS, EPA must, among other things, streamline its lengthy assessment process and adopt transparency practices that provide assurance that IRIS assessments are appropriately based on the best available science and that they are not inappropriately biased by policy considerations. Since EPA's new process is not responsive to GAO's recommendations, the viability of this critical database has been further jeopardized.