



Highlights of [GAO-08-810T](#), testimony before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, House of Representatives

Why GAO Did This Study

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals. Toxicity assessments in the IRIS database constitute the first two critical steps of the risk assessment process, which in turn, provides the foundation for risk management decisions. Thus, IRIS is a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations.

This testimony discusses (1) highlights of GAO's 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 aspects of EPA's revised IRIS assessment process, released on April 10, 2008. For the March 2008 report, GAO reviewed and analyzed EPA data and interviewed officials at relevant agencies, including the Office of Management and Budget (OMB). For this testimony, GAO supplemented the prior audit work with a review of EPA's revised IRIS assessment process announced on April 10, 2008.

To view the full product, including the scope and methodology, click on [GAO-08-810T](#). For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

CHEMICAL ASSESSMENTS

EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System

What GAO Found

In its March 2008 report, GAO concluded that 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.

- EPA's 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.
- The two new 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 our 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 its 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 are likely to further exacerbate the productivity and credibility concerns GAO identified. For example, while the draft process would have made comments from other federal agencies on IRIS assessments 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 that it is critical that input from all parties—particularly agencies that may be affected by the outcome of IRIS assessments—be publicly available. In addition, the estimated time frames under the new process, especially for chemicals of key concern, will likely perpetuate the cycle of delays to which the majority of ongoing assessments have been subject. Instead of significantly streamlining the process, which GAO recommended, EPA has institutionalized a process that from the outset is estimated to take 6 to 8 years to complete. This is problematic because of the substantial rework such cases often require to take into account changing science and methodologies. Since EPA's new process is not responsive to GAO's recommendations, the viability of this critical database has been further jeopardized.