



Highlights of GAO-08-1168T, testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, 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*; (2) key aspects of EPA's revised IRIS assessment process, released on April 10, 2008; and (3) progress EPA has made in completing assessments in fiscal year 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. We also updated our information on EPA's assessment productivity through September 12, 2008.

To view the full product, including the scope and methodology, click on [GAO-08-1168T](#). For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

September 18, 2008

EPA SCIENCE

New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals

What GAO Found

In March 2008, GAO concluded that the IRIS database was at serious risk of becoming obsolete because EPA had not been able to 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, assessment process changes EPA had recently made, as well as other changes EPA was considering at the time of GAO's review, would further reduce the credibility and timeliness of IRIS assessments. We concluded the following:

- 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 and by EPA management decisions, such as delaying some assessments to await new research.
- 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.

EPA issued its revised IRIS assessment process in April 2008. The new process is largely the same as the draft GAO evaluated and does not respond to the recommendations in GAO's March 2008 report. Moreover, 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 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 streamlining the process, as GAO recommended, EPA has institutionalized a process that from the outset is estimated to take 6 to 8 years. This is problematic because of the substantial rework such cases often require to take into account changing science and methodologies.

EPA's progress in completing assessments continues to be slow—only four assessments have been completed in fiscal year 2008. Further, these assessments cover a group of four related chemicals that were processed and peer reviewed together but finalized individually. Little or no progress has been made on assessments of chemicals highlighted in our report, including naphthalene, formaldehyde, and trichloroethylene (TCE).