



Highlights of [GAO-09-774T](#), a 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. GAO's 2008 report on the IRIS program identified significant concerns that, coupled with the importance of the program, caused GAO to add EPA's processes for assessing and controlling toxic chemicals as a high-risk area in its January 2009 biennial status report on governmentwide high-risk areas requiring increased attention by executive agencies and Congress.

This testimony discusses (1) the findings from 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 related testimonies and (2) GAO's preliminary evaluation of the revised IRIS assessment process EPA issued on May 21, 2009. For this testimony, GAO supplemented its prior audit work with a preliminary review of the new assessment process and some IRIS productivity data.

View [GAO-09-774T](#) or key components. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

EPA CHEMICAL ASSESSMENTS

Process Reforms Offer the Potential to Address Key Problems

What GAO Found

In March 2008, GAO reported that the viability of the IRIS program is at risk because EPA has been unable to complete timely, credible chemical assessments or decrease its backlog of ongoing assessments. In addition, assessment process changes EPA had recently made, and other changes it was considering at the time of GAO's review, would have further reduced the timeliness, credibility, and transparency of IRIS assessments. Among other things, GAO found that EPA's efforts to finalize IRIS assessments have been impeded by a combination of factors, including the Office of Management and Budget's (OMB) requiring two additional reviews of IRIS assessments by OMB and other federal agencies with an interest in the assessments, such as the Department of Defense. Moreover, the two OMB/interagency reviews involved other federal agencies in EPA's IRIS assessment process in a manner that hindered EPA's ability to manage its assessments and limited their credibility and transparency. For example, the input these agencies provided to EPA was treated as "deliberative" and was not released to the public. In April 2008, EPA issued a revised IRIS assessment process. As GAO testified before this subcommittee in May 2008, the new process did not respond to GAO's March 2008 recommendations, and some key changes were likely to further exacerbate the credibility and productivity concerns GAO had identified.

Overall, EPA's May 2009 IRIS assessment process reforms represent significant improvements and, if implemented effectively, would be largely responsive to GAO's March 2008 recommendations. For example, under the new process EPA is to manage the entire assessment process, including the interagency reviews. Under EPA's prior process, these reviews were required and managed by OMB—and at various stages, EPA was not allowed to proceed with assessments until OMB notified EPA that it had sufficiently responded to comments from OMB and other agencies. The independence restored to EPA under the new process will be critical to ensuring that EPA has the ability to develop transparent, credible IRIS chemical assessments. While the broad reforms provide a sound general framework for conducting IRIS assessments, the manner in which EPA implements the new process will determine whether the agency will be able to overcome its long-standing productivity problems and complete credible and transparent assessments. Specifically, certain aspects of the new process are incomplete or lack clarity and thus warrant management attention. For example, EPA has likely understated the time required to complete an assessment because its estimated time frames do not include the time required to complete two key steps. Overall, the viability of the IRIS program will depend on effective and sustained management and oversight, especially given the number of factors that can impede the progress of IRIS assessments. For example, even one delay in an assessment can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. In addition, unlike some other EPA programs with statutory deadlines for completing various activities, the IRIS program is discretionary. GAO believes the absence of legal consequences for delays in completing assessments may contribute to EPA's failure to complete timely IRIS assessments.