



Highlights of [GAO-08-440](#), a report to the Chairman, Committee on Environment and Public Works, U.S. Senate

## 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. IRIS is a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations. GAO was asked to examine (1) the outcome of steps EPA has taken to ensure that IRIS contains current, credible chemical risk information, to address the backlog of ongoing assessments, and to respond to new requirements from the Office of Management and Budget (OMB); and (2) the potential effects of planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information. To do this work, GAO reviewed and analyzed EPA data and interviewed officials at relevant agencies.

## What GAO Recommends

GAO recommends that EPA (1) clearly define and document an IRIS assessment process that, among other things, can be conducted within a time frame that minimizes the need for rework and (2) ensure that it can develop transparent, credible assessments by, for example, determining the types of IRIS assessments it will conduct based on EPA program needs and defining the appropriate role of other federal agencies in its IRIS assessment process. EPA agreed to consider GAO's recommendations in revising the IRIS assessment process.

To view the full product, including the scope and methodology, click on [GAO-08-440](#). For more information, contact John B. Stephenson at (202) 512-3841 or [stephensonj@gao.gov](mailto:stephensonj@gao.gov).

## CHEMICAL ASSESSMENTS

### Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System

#### What GAO Found

EPA's actions since 2000 to ensure that IRIS contains current, credible risk information, to address its backlog of 70 ongoing assessments, and to respond to new OMB requirements—including increasing funding and revising the assessment process—have not enabled EPA to routinely complete credible IRIS assessments or decrease its backlog. Although in fiscal years 2006 and 2007 EPA sent 32 assessments to OMB for the first of three required external reviews, EPA finalized only 4 assessments during this period. This low level of productivity jeopardizes the viability of the IRIS database. Further, an EPA analysis indicated that many existing assessments may need to be updated, and EPA program offices and other IRIS users have requested assessments of hundreds of chemicals not yet in IRIS. Factors contributing to EPA's inability to complete IRIS assessments in a timely manner include new OMB-required reviews of IRIS assessments by OMB and other federal agencies; certain 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. As of December 2007, most of the 70 ongoing assessments had been in progress for over 5 years.

Regarding new OMB requirements, the IRIS assessment process now includes two OMB/interagency reviews of draft assessments. These reviews have resulted in involvement of 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. That is, the OMB/interagency reviews lack transparency—OMB considers agencies' comments on IRIS assessments to be internal executive branch documents that may not be made public. Given the importance of IRIS assessments, it is essential that input from all parties, including other federal agencies, be part of the public record. Transparency is especially important because agencies providing input include those that may be affected by the assessments should they lead to regulatory or other actions. Also, without communicating its rationale for doing so, OMB directed EPA to terminate five assessments that for the first time addressed acute, rather than chronic, exposure—even though EPA initiated this type of assessment to help it implement the Clean Air Act. Most OMB/interagency reviews completed to date have added 6 or more months to the IRIS time frames.

Such delays and credibility concerns would likely be exacerbated by further changes EPA is planning to respond to continuing concerns of other federal agencies, such as providing them with an expanded role in EPA's IRIS assessment process and discretion to suspend assessments to develop new studies for some chemicals. EPA estimates that such assessments would take up to 6 years, an estimate GAO believes is conservative in light of the assessment time frames under the current process. Suspending assessments is inefficient; alternatively, with longer-term planning, EPA could provide agencies and the public with more advance notice of assessments, enabling them to complete relevant research before IRIS assessments are started.