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EPA CHEMICAL ASSESSMENTS

Process Reforms Offer the Potential to Address Key Problems

Statement of John B. Stephenson, Director
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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.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our prior findings and recommendations on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program as well as the results of our preliminary review of EPA's most recent IRIS reforms, announced on May 21, 2009. As you know, IRIS is one of the most significant tools that EPA has developed to effectively support its mission to protect people and the environment from harmful chemical exposures. The IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals in the environment and is, therefore, a critical component of EPA's capacity to support scientifically sound risk management decisions, policies, and regulations.

In a March 2008 report, we identified significant deficiencies in EPA's IRIS assessment process that threatened the viability of the program, and we made a number of recommendations to correct them.¹ In response, EPA issued a revised assessment process in April 2008 that did not respond to our recommendations but rather made changes likely to further exacerbate the problems we had identified. Largely as a result of the agency's lack of responsiveness, we added transforming EPA's processes for assessing and controlling toxic chemicals as a high-risk area in our January 2009 biennial status report on governmentwide high-risk areas requiring increased attention by executive agencies and Congress.² In announcing new reforms to the IRIS assessment process on May 21, 2009, EPA echoed our findings—that the April 2008 assessment changes reduced the transparency, timeliness, and scientific integrity of the IRIS process—and highlighted both our high-risk designation of this important EPA program and the President's recent emphasis on the importance of transparency and scientific integrity in government decision making.

In this context, my testimony today discusses (1) the findings from our 2008 report and testimonies on the prior IRIS assessment processes³ and (2) our preliminary evaluation of EPA's May 2009 process reforms. For this statement, we have supplemented our prior work with a preliminary

¹GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, [GAO-08-440](#) (Washington, D.C.: Mar. 7, 2008).

²GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

³See the Related GAO Products section later in this statement.

review of the EPA process reforms and some IRIS productivity data. We conducted our work from May 28 to June 11, 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform our work to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Viability of the IRIS Program Is at Risk

In March 2008, we reported that the IRIS program is at serious risk of becoming obsolete because the agency has not been able to complete timely, credible chemical assessments or decrease its backlog of 70 ongoing assessments. In addition, assessment process changes EPA had recently made, as well as other changes EPA was considering at the time of our review, would have further reduced the timeliness, credibility, and transparency of IRIS assessments. Among other things, we concluded the following:

- EPA was unable to routinely complete IRIS assessments in a timely manner. From 2000 to 2007, EPA completed on average about five IRIS assessments a year. The more recent trend has been a decline in productivity: In fiscal years 2006 and 2007, EPA completed two assessments each year; in 2008, EPA completed five assessments—four of which were related chemicals assessed and peer reviewed together but finalized individually; and thus far in fiscal year 2009, EPA has finalized one assessment.
- Further, as we reported in 2008, because EPA staff time was dedicated to completing assessments in the backlog, EPA's ability to both keep the more than 540 existing assessments up to date and initiate new assessments was limited. We found that 48 of the 70 assessments being conducted as of December 2007 had been in process for more than 5 years—and 12 of those, for more than 9 years. These time frames have lengthened. Currently, of those 70 assessments, 58 have now been ongoing for more than 5 years—and 31 of those for more than 9 years.
- We also found that EPA's efforts to finalize IRIS assessments have been thwarted by a combination of factors. These factors include (1) 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, and (2) EPA management decisions, such as delaying some assessments to await the results of new research.

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- 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 and transparency of, and hinders EPA's ability to manage, IRIS assessments. For example, some of these agencies' review comments could be influenced by the potential for increased environmental cleanup costs and other legal liabilities if EPA issued an IRIS assessment for a chemical that resulted in a decision to regulate the chemical to protect the public. Moreover, the input these agencies provide to EPA is treated as "deliberative" and is not released to the public. Regarding EPA's ability to manage its IRIS assessments, in 2007 OMB required EPA to terminate five assessments that for the first time addressed acute, rather than chronic, exposure—even though EPA had initiated this type of assessment 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 2008 review would have added to the already unacceptable level of delays in completing IRIS assessments and further limited the credibility of the assessments. For example, the changes would have allowed potentially affected federal agencies to have assessments suspended for up to 18 months to conduct additional research. As we reported in 2008, even one delay can have a domino effect, requiring the assessment process to essentially be repeated to incorporate changing science.

In April 2008, EPA issued a revised IRIS assessment process. As we testified before this subcommittee in May 2008, the new process was largely the same as the draft we had evaluated during our review and did not respond to the recommendations in our March 2008 report. Moreover, some key changes were likely to further exacerbate the credibility and productivity concerns we had identified. For example, EPA's revised process formally defined comments on IRIS assessments from OMB and other federal agencies as "deliberative" and excluded them from the public record. As we have stated, it is critical that input from all parties—particularly agencies that may be directly affected by the outcome of IRIS assessments—be publicly available. In addition, the estimated time frames under the revised process, especially for chemicals of key concern, would have likely perpetuated the cycle of delays to which the majority of ongoing assessments have been subject. Instead of streamlining the process, as we had recommended, EPA institutionalized a process that from the outset was estimated to take 6 to 8 years for some chemicals of key concern that are both widespread and likely to cause cancer or other serious health effects. This was particularly problematic because of the substantial rework often required to take into account changing science and methodologies.

EPA's Latest IRIS Process Reforms Appear Largely Responsive to Our Recommendations, but Their Success Will Depend on Effective Management

Overall, EPA's May 2009 IRIS assessment process reforms represent significant improvements and, if implemented effectively, would be largely responsive to the recommendations made in our March 2008 report.

- First, the new process and the memorandum announcing it indicate that the IRIS assessment process will be entirely managed by EPA, including the interagency consultations (formerly called OMB/interagency reviews). Under EPA's prior process, these two interagency reviews were required and managed by OMB—and EPA was not allowed to proceed with assessments at various stages 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 is critical in ensuring that EPA has the ability to develop transparent, credible IRIS chemical assessments that the agency and other IRIS users, such as state and local environmental agencies, need to develop adequate protections for human health and the environment.
- Second, the new process addresses a key transparency concern highlighted in our 2008 report and testimonies. As we recommended, it expressly requires that all written comments on draft IRIS assessments provided during the interagency consultation process by other federal agencies and White House offices be part of the public record.
- Third, the new process streamlines the previous one by consolidating and eliminating some steps. Importantly, EPA eliminated the step under which other federal agencies could have IRIS assessments suspended in order to conduct additional research, thus returning to EPA's practice in the 1990s of developing assessments on the basis of the best available science. As we highlighted in our report, as a general rule, requiring that IRIS assessments be based on the best science available at the time of the assessment is a standard that best supports the goal of completing assessments within reasonable time periods and minimizing the need to conduct significant levels of rework.⁴
- Fourth, as outlined in the EPA Administrator's memorandum announcing the new IRIS process, the President's budget request for fiscal year 2010 includes an additional \$5 million and 10 full-time-equivalent staff positions for the IRIS program, which is responsive to our recommendation to assess the level of resources that should be dedicated to the IRIS program in order to meet user needs and maintain a viable IRIS database.

⁴As also stated in our report, we understand that under exceptional circumstances, it may be appropriate to wait for the results of an important ongoing study, such as a major epidemiological study that will provide new, critical data for an assessment.

We are encouraged by the efforts EPA has made to adopt most of our recommendations, including those addressing EPA's ability to manage its IRIS assessment process, transparency practices, and streamlining the lengthy IRIS assessment process. The changes outlined above reflect a significant redirection of the IRIS process that, if implemented effectively, can help EPA restore the credibility and increase the productivity of this important program. While these 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, management attention is warranted on certain aspects of the new process that are incomplete or lack clarity.

- EPA's estimated time frames of about 2 years for standard IRIS assessments—those that are not particularly complex or controversial—do not include the time required to complete two steps that are nonetheless included in the assessment process. As a result, EPA has likely understated the time required to complete an assessment. The steps lacking time frames—the scientific literature review and the request to the public and other agencies to submit relevant research (the data call-in)—are integral to developing an assessment. In prior IRIS assessment processes, EPA provided time frames for these steps. Importantly, including the time frames for these steps would likely bring the estimated overall time for completing standard assessments closer to 3 years. We note that this more realistic time frame may be problematic because when assessments take longer than 2 years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies.
- While EPA states that some IRIS assessments may take longer because of their complexity, large scientific literature base, or high profile, the agency does not provide any guidance on likely or expected time frames for assessments of these chemicals. This is noteworthy because we found that EPA has not been able to complete assessments of the most important chemicals of concern, such as those likely to cause cancer or other significant health effects. For example, EPA's assessment of dioxin has been ongoing for 18 years. It is critical that EPA establish time frames to enable the agency to manage complex assessments.
- EPA's new process does not include a discussion of key planning steps. Specifically, it omits important preassessment steps included in prior processes—such as a call for nominations of chemicals to be assessed and the establishment of the IRIS agenda, which is list of chemicals that EPA plans to assess. Accordingly, it is not clear whether or when EPA will

implement our recommendation that it provide at least 2 years' notice of planned assessments. Among other things, doing so would give agencies and the public more advance notice of planned assessments and enable external parties with an interest in a given chemical to, for example, complete relevant research before the start of an IRIS assessment.

- Particularly in light of the fact that EPA's estimates for completing assessments are likely understated, we believe that the agency should continue to look for additional opportunities to streamline its process. For example, it is not clear why EPA could not solicit comments from other federal agencies at the same time it sends the initial draft assessment to independent peer reviewers and publishes it in the *Federal Register* for public comment. In addition to reducing overall assessment time frames, this change could enhance transparency. Specifically, by obtaining the first draft of the assessment at the same time as the other federal agencies, the public and peer reviewers could have greater assurance that the draft had not been inappropriately biased by policy considerations of these agencies, including ones that may be affected by the assessment's outcome, such as the Departments of Defense and Energy. Some of these agencies and their contractors could, for example, face increased cleanup costs and other legal liabilities if EPA issued an IRIS assessment for a chemical that resulted in a decision to regulate the chemical to protect the public.
- The new assessment process states that "White House offices" will be involved in the interagency consultation process but does not indicate which offices. Given that (1) EPA will be performing the coordinating role that OMB exercised under the prior process and (2) the purpose of these consultations is to obtain scientific feedback, it is unclear whether OMB will continue to be involved in the interagency consultation process.
- EPA has specified in its new assessment process that written comments provided by other federal agencies will become part of the public record. However, it is silent as to the purpose of the consultation meetings and, if applicable, whether EPA plans to document for the public record any significant oral agreements or decisions made at the consultation meetings. In order to ensure transparency and alleviate any concerns of potential bias in the assessments, it will be important for EPA to be clear on these matters.

In addition to addressing these issues, the viability of the IRIS program will depend on effective and sustained management and oversight. Collectively, a number of factors that can impede the progress of IRIS assessments present significant management challenges. These include the following:

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- Unlike a number of other EPA programs with statutory deadlines for completing various activities, no enforceable deadlines apply to the IRIS program. We have stated in previous testimonies on the IRIS program that if EPA is not able to effectively maintain this critical program, other approaches, including statutory requirements, may need to be explored. We believe the absence of statutory deadlines may contribute to EPA's failure to complete timely IRIS assessments. For example, assessment schedules can easily be extended—and consistently are. These chronic delays in completing IRIS assessments have detrimental consequences for EPA's ability to develop timely and scientifically sound decisions, policies, and regulations.
 - Science and methodologies are constantly changing. Thus, there will always be a tension between assessing the best available science and waiting for more information. IRIS will remain viable only if it returns to its model of using the best science available at the time of its assessments and plans for periodic updates of assessments to identify the need for revisions.
 - An overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is the compounding effect of delays—even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. For example, delays often require repeating reviews of the scientific literature on a chemical to take into account the time that has passed since the literature review was completed; this, in turn, may require detailed analyses of any new studies found to be relevant.
 - Long-standing difficulties in completing assessments of chemicals of key concern—those that are both widespread and likely to cause significant health issues—stem in part from challenges by external parties, including those that may be impacted by EPA regulation of chemicals should an assessment lead to such action. Such challenges are to be expected and can be best addressed by EPA's focusing on the best available science, credible expert review, and completing the assessments.
 - The IRIS assessment process has been frequently changed in recent years; IRIS process reforms, such as those recently issued, are not established in a regulation or statute and thus can easily be altered. As we have reported, EPA's continual changes present a challenge to the chemical managers who are undertaking the assessments, particularly in the absence of current operating procedures to guide chemical managers on basic procedures and program management responsibilities for the development, review, and finalization of IRIS assessments.

In conclusion, EPA's most recent changes to the IRIS assessment process appear to represent a significant improvement over the process put in place in 2008. That is, if implemented effectively, the changes may appropriately restore to EPA its control of the IRIS process, increase the transparency of the process, and streamline aspects of the process, among other things. We believe that the agency's ability to produce timely, credible, and transparent assessments will also depend in large measure on clear implementation procedures and rigorous management oversight, given the numerous factors that can impede EPA's ability to complete timely IRIS assessments and the lack of clarity on some aspects of the new process. Perhaps most importantly, EPA needs to hold itself more accountable to the public and Congress for carrying out this important component of its mission, especially since the IRIS program is discretionary.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or other Members of the Subcommittee may have at this time.

GAO Contact and Staff Acknowledgments

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Related GAO Products

Scientific Integrity: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes. [GAO-09-773T](#). Washington, D.C.: June 9, 2009.

High-Risk Series, An Update. [GAO-09-271](#). Washington, D.C.: January 2009.

EPA Science: New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals. [GAO-08-1168T](#). Washington, D.C.: September 18, 2008.

Chemical Assessments: EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System. [GAO-08-810T](#). Washington, D.C.: May 21, 2008.

Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals. [GAO-08-743T](#). Washington, D.C.: April 29, 2008.

Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System. [GAO-08-440](#). Washington, D.C.: March 7, 2008.

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