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EPA HEALTH RISK ASSESSMENTS

Oversight and Sustained Management Key to Overcoming Challenges

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Chairman Shimkus, Ranking Member Green, and Members of the Subcommittee:

I am pleased to be here today to discuss our prior work on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program and database. As you know, IRIS is one of the most significant tools that EPA has developed to 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 that may result from exposure to more than 550 chemicals in the environment and is a critical component of EPA's capacity to support its mission. IRIS assessments provide the scientific input to risk management decisions, such as whether EPA should establish air and water quality standards to protect the public from exposure to toxic chemicals or set cleanup standards for hazardous waste sites. Consequently, IRIS assessments are a critical component of EPA's capacity to support scientifically sound decisions, policies, and regulations.

EPA created IRIS in 1985 to help the agency develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. Over time, the importance of the program has increased as EPA program offices, state and local environmental programs, and some international regulatory bodies have increasingly relied on IRIS health risk assessment information to support risk-based decision making to protect public health and the environment. As the IRIS database became more widely used and accepted, EPA took steps, beginning in the early 1990s, to improve and maintain the IRIS program and database. Over the years, the agency has implemented a variety of new operational procedures aimed at improving the IRIS program and database—with the most recent change to its IRIS assessment process occurring in May 2009.

Because of the potential for EPA's health risk assessments to lead to regulations that can significantly affect certain industries or federal agencies, IRIS assessments have frequently received considerable attention. For example, in recent months, much attention has been focused on EPA's draft health risk assessment of formaldehyde and the National Academies' review of the draft assessment.[1] In addition to reviewing the draft assessment of formaldehyde,

[1]The National Academies comprises four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

the National Academies' report also offered some suggestions for improving the preparation and presentation of draft health risk assessments in general. Our work to date has not focused on these aspects of IRIS assessments.

Instead, our body of work on the IRIS program has more broadly evaluated the overall IRIS assessment process and the challenges the program has faced in implementing it. In March 2008, we reported that the IRIS database was at serious risk of becoming obsolete because EPA had not been able to routinely complete timely, credible assessments.[2] After subsequent reports,[3] in January 2009 we added EPA's processes for assessing and controlling toxic chemicals to our list of areas at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation.[4] We are currently undertaking a review of EPA's revised 2009 IRIS assessment process and the agency's progress in implementing it and plan to issue a report later this year.

In this context, my testimony today discusses our past work on (1) the timeliness and credibility of IRIS assessments and (2) EPA's May 2009 IRIS assessment process. We conducted the performance audit work that supports this statement in accordance with generally accepted government auditing standards. Additional information on our scope and methodology is available in each issued product.

Summary

From March through September 2008, we reported on shortcomings in EPA's IRIS process that limited the agency's ability to complete timely and credible IRIS assessments. For example, the

[2]GAO, *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).

[3]GAO, *Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals,* GAO-08-743T (Washington, D.C.: Apr. 29, 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); and *EPA Science: New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals,* GAO-08-1168T (Washington, D.C.: Sept. 18, 2008).

[4]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009). This high-risk area addresses EPA's implementation of the IRIS program as well as implementation of the Toxic Substances Control Act (TSCA).

Office of Management and Budget (OMB) required and managed interagency reviews of IRIS assessments, and OMB determined when assessments could proceed to the next process step, frequently resulting in delayed IRIS assessments. Such shortcomings contributed to our decision to designate the IRIS program as a high-risk area in January 2009. In June 2009 and July 2011, we testified that EPA's May 2009 IRIS assessment process reforms, if implemented effectively, would represent a significant improvement over the previous IRIS process by restoring EPA control, establishing transparency, and streamlining the process. We are currently undertaking a review of EPA's revised 2009 IRIS assessment process and the agency's progress in implementing it and plan to issue a report later this year.

EPA's Inability to Complete Timely, Credible IRIS Assessments Contributed to the Program's High-Risk Designation

From March through September 2008, we reported on shortcomings in EPA's IRIS process that limited the agency's ability to complete timely and credible IRIS assessments.[5] These shortcomings contributed to our decision to designate the IRIS program as a high-risk area. Specifically, beginning in 2004, OMB began requiring and managing two interagency reviews of IRIS assessments by OMB and other federal agencies with an interest in these assessments, such as the Department of Defense. These reviews contributed to concerns about the timeliness and credibility of IRIS assessments. In particular, EPA was not allowed to move forward with an assessment until OMB determined that EPA had satisfactorily addressed all OMB and other federal agency comments. As a result, IRIS assessments were frequently delayed. In addition, the content of the OMB-required reviews was not publicly available, thus limiting the transparency and the credibility of IRIS assessments. The credibility of the assessments was further limited by the involvement of other federal agencies that could be affected by the assessments if they led to regulatory actions. That is, if EPA issued an IRIS assessment that resulted in a decision to regulate a chemical to protect the public, some of the agencies participating in these reviews, such as the Department of Defense, could face increased cleanup costs and other legal liabilities.

[5]GAO-08-440, GAO-08-743T, GAO-08-810T, and GAO-08-1168T.

In addition, some EPA management decisions to suspend ongoing IRIS assessments to wait for new and ongoing scientific studies to be completed also limited the timeliness of IRIS assessments. In fact, EPA's decisions to await the results of new and ongoing studies before completing some IRIS assessments resulted, in some cases, in delaying them for years. We understand that there may be exceptional circumstances under which 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. However, 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 would best support a goal of completing assessments within reasonable time periods and minimizing the need to conduct significant levels of rework, as we reported in March 2008.

Moreover, in April 2008, EPA revised its IRIS assessment process, but the revised process did not address the issues we raised in our March 2008 report.[6] More specifically, our report contained recommendations for EPA to reevaluate its proposed revisions to the IRIS assessment process and to streamline the process to better ensure that EPA had the ability to develop transparent, credible assessments. However, in April 2008, EPA issued a revised IRIS assessment process that was largely the same as the proposed revisions that we had evaluated and had taken issue with during our review.

As a result of these and other issues, in January 2009 we added transforming EPA's processes for assessing and controlling toxic chemicals to our list of high-risk areas.

EPA's May 2009 IRIS Assessment Process Reforms Appeared to Represent Significant Improvement, but the Viability of the IRIS Program Will Depend on Effective and Sustained Management and Oversight

As we testified before the House Subcommittee on Investigations and Oversight in July 2011,[7] the IRIS assessment process reforms instituted by EPA in May 2009 appeared to represent a

[6]GAO-08-440.

[7]GAO, *EPA Health Risk Assessments: Sustained Management and Oversight Key to Overcoming Challenges*, GAO-11-824T (Washington, D.C.: July 14, 2011).

significant improvement over the previous IRIS process and, if implemented effectively, with sustained management and oversight, could help EPA restore the credibility and increase the timeliness of this important program. The reforms included the following:

- *Restored EPA control*. The new process and the memorandum announcing it indicated that the IRIS assessment process would be entirely managed by EPA, including the interagency science consultations (formerly called interagency reviews). Under EPA's prior process, these two interagency reviews were required and managed by OMB, and OMB determined when assessments could proceed to the next process step. The control 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.

- *Established transparency*. The new process addressed a key transparency concern highlighted in our 2008 report and subsequent testimonies. As we recommended, the new process expressly required that all written comments on draft IRIS assessments provided during interagency science consultations by other federal agencies and OMB be part of the public record.

- *Streamlined process*. The new process streamlined the previous one by consolidating and eliminating some steps. Importantly, EPA eliminated the step under which other federal agencies could cause IRIS assessments to be 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 noted previously, long delays to await the results of new scientific research do not support a goal of completing assessments within reasonable time periods and minimizing the need to conduct significant levels of rework.

Although EPA's May 2009 IRIS assessment process appeared to represent a significant improvement over the previous IRIS process, we testified in July 2011 that the viability of the IRIS program would depend on effective and sustained management and oversight. We

identified the following factors that collectively could present significant management challenges to EPA's ability to complete timely, credible IRIS assessments.

- Unlike a number of other EPA programs with statutory deadlines for completing various activities, no enforceable deadlines apply to the IRIS program. 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 frequently are. Chronic delays in completing IRIS assessments have detrimental consequences for EPA's ability to develop timely and scientifically sound decisions, policies, and regulations.

- Because science and methodologies are constantly changing, there will always be a tension between assessing the best available science and waiting for more information. The IRIS program will remain viable only if it continues to use 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 affected 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, obtaining credible expert review, and completing the assessments.

- IRIS process reforms, such as those issued in May 2009, are not established in regulation or statute and thus can easily be altered. As we have reported, continual changes to the process have presented a challenge to the chemical managers who

undertake the assessments.[8] To produce timely, credible IRIS assessments over a sustained period of time, it will be important for EPA to maintain a stable, consistent process going forward.

In addition to these challenges, in our May 2011 report on EPA's implementation of the Safe Drinking Water Act,[9] we noted that the inability of the IRIS program to provide the Office of Water with new and updated IRIS assessments in a timely manner has impeded effective implementation of EPA's regulatory determinations for drinking water contaminants.[10] When publishing the latest list of chemicals being considered for regulation (contaminant candidate list) in 2009, EPA identified health effects information gaps for 44 of the 104 chemicals on the list. We also note that EPA must address its backlog of demand for IRIS assessments. Moreover, EPA program offices and state and local entities have identified needs for assessments of hundreds of chemicals not yet in IRIS. In addition, as we previously reported, chemicals currently in the IRIS database may potentially need to be updated with new information that would either (1) change an existing risk estimate and/or (2) allow EPA to develop additional risk estimates.

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

For further information on this statement, please contact David Trimble at (202) 512-3841 or trimbled@gao.gov. Contact points for our Congressional Relations and Public Affairs offices may be found on the last page of this statement. Other staff that made key contributions to this testimony include Diane LoFaro, Assistant Director; Summer Lingard; Antoinette C. Capaccio; Lorraine Ettaro; Robert Grace; Carol Kolarik; and Jamie Meuwissen.

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[8]GAO-09-774T.

[9]*GAO, Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants*, GAO-11-254 (Washington, D.C.: May 27, 2011).

[10]Under the 1996 amendments to the Safe Drinking Water Act, which remain in effect, EPA is to select for consideration those unregulated contaminants that present the greatest public health concern, evaluate their occurrence and the potential health risks associated with them, and decide whether a regulation is needed for at least five contaminants every 5 years.

Related GAO Products

EPA Health Risk Assessments: Sustained Management and Oversight Key to Overcoming Challenges. GAO-11-824T. Washington, D.C.: July 14, 2011.

Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants. GAO-11-254. Washington, D.C.: May 27, 2011.

High-Risk Series: An Update. GAO-11-278. Washington, D.C.: February 2011.

EPA Chemical Assessments: Process Reforms Offer the Potential to Address Key Problems. GAO-09-774T. Washington, D.C.: June 11, 2009.

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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