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TOXIC CHEMICALS

EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals

Statement of John B. Stephenson, Director
Natural Resources and Environment

April 29, 2008

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Highlights

Highlights of GAO-08-743T, a testimony before the Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

The Environmental Protection Agency's (EPA) mission includes evaluating and regulating toxic chemicals. EPA's Integrated Risk Information System (IRIS) program is a chemical evaluation program that is a critical component of EPA's capacity to support scientifically sound environmental regulations and policies. The IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals.

This testimony highlights GAO's work on toxic substances, focusing on (1) its 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 (2) key changes to the IRIS assessment process EPA included in its revised IRIS assessment process released on April 10, 2008. It also highlights the findings of two GAO reports on EPA's regulation of toxic chemicals. For the IRIS report, GAO analyzed EPA data and interviewed officials at relevant agencies, including the Office of Management and Budget (OMB). For this testimony, GAO supplemented the IRIS report with a review of EPA's revised IRIS assessment process announced earlier this month.

Given the importance of the IRIS program to EPA's ability to protect public health and the environment, Congress should consider requiring EPA to suspend its new process and develop one that is responsive to GAO's recommendations.

To view the full product, including the scope and methodology, click on GAO-08-743T. For more information, contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov.

What GAO Found

The IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely 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, recent assessment process changes, as well as other changes EPA was considering at the time of GAO's review, further reduce the timeliness and credibility of IRIS assessments.

- Although EPA has taken steps to improve the IRIS program since 2000 and has developed a number of draft assessments for external review, its 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; 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 and methods.
- The 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 GAO's review, would have added to the already unacceptable level of delays in completing IRIS assessments and further limited the credibility of the assessments.

On April 10, 2008, EPA issued a revised IRIS assessment process, effective immediately. In its February 2008 comments on GAO's draft report, EPA said it would consider the report's recommendations, which were aimed at streamlining the process and better ensuring that EPA has the ability to develop transparent, credible assessments. However, EPA's new process is largely the same as the draft GAO evaluated, and some key changes also are likely to further exacerbate the productivity and credibility concerns GAO identified. For example, while the draft process would have made comments on IRIS assessments from other federal agencies part of the public record, EPA's new process expressly defines such comments as "deliberative" and excludes them from the public record. GAO continues to believe it is critical that input from all parties—particularly agencies that may be affected by the outcome of IRIS assessments—be publicly available. As recommended in GAO's March 2008 report, to effectively maintain IRIS, EPA must, among other things, streamline its lengthy assessment process and adopt transparency practices that provide assurance that IRIS assessments are appropriately based on the best available science and that they are not inappropriately biased by policy considerations. Since EPA's new process is not responsive to GAO's recommendations, the viability of this critical database has been further jeopardized.

Madam Chairman and Members of the Committee:

I am pleased to be here today to discuss issues associated with the Environmental Protection Agency's (EPA) evaluation and regulation of toxic chemicals. Over the past few years, GAO has issued a number of reports on this topic. Today I will focus primarily on our most recent report in this area that examined EPA's Integrated Risk Information System (IRIS)—one of the most significant tools that EPA has developed to effectively support its mission of protecting people and the environment from harmful chemical exposures. IRIS contains EPA's scientific position on the potential human health effects that may result from exposure to more than 540 chemicals in the environment and is a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations. It is also relied upon by state and local environmental programs and some international regulatory bodies for managing their environmental protection programs.

The toxicity assessments in the IRIS database fulfill the first two critical steps of the risk assessment process—providing hazard identification and quantitative dose-response assessments. IRIS information can then be used with the results of exposure assessments (typically conducted by EPA's program or regional offices) to provide an overall characterization of the public health risks for a given chemical in a given situation. The development of health risk assessments is thus directly dependent on the development of toxicity assessments such as those developed in the IRIS program. With risk assessment information, decision makers can make informed risk management decisions on how to protect public health, reflecting other important data and considerations, such as the costs and benefits of mitigating identified risks, the technological feasibility of managing risks, and the concerns of various stakeholders. Examples of risk management decisions include deciding how much of a chemical a company may discharge into a river, determining the extent to which a hazardous waste site must be cleaned up, and setting allowable levels of contamination in drinking water. Thus, as EPA has recognized, although IRIS assessments are not regulatory in nature, the quantitative IRIS values may influence many risk management decisions and serve as a basis for regulatory consideration. However, EPA's productivity in finalizing IRIS assessments is poor, and EPA has a significant backlog of incomplete IRIS assessments and a growing number of outdated assessments. Importantly, EPA has not been able to complete assessments of key chemicals of concern to public health, including dioxin, formaldehyde, trichloroethylene (TCE), naphthalene, and tetrachloroethylene (perc) (see app. I).

In the last several years, GAO issued a number of reports on EPA's toxics programs, highlighting program shortcomings and recommending management improvements. My testimony today addresses (1) the highlights of our March 2008 report, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*,[1] being released today, and (2) key changes to the IRIS assessment process that EPA included in its revised process released on April 10, 2008. We are also providing information on two of our prior reports on EPA's regulation of toxic chemicals (see app. II).[2] For our March 2008 report, we examined 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). We also examined the potential effects of planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information. In conducting our work, we obtained and analyzed information on EPA's productivity and the resources provided to the program for fiscal years 2000 through 2007, user needs, and EPA's assessment completion goals. We also interviewed EPA's National Center for Environmental Assessment officials who manage the IRIS assessment program; officials from other EPA program offices and federal science and health agencies involved in the IRIS assessment process; and officials from the Department of Defense, the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and OMB. For this testimony, we supplemented our report with an analysis of the IRIS assessment process that EPA released on April 10, 2008. We conducted this work from April 16 to April 29, 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit 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.

[1]GAO-08-440 (Washington, D.C.: Mar. 7, 2008).

[2]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005); and GAO, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, GAO-06-217R (Washington, D.C.: Nov. 4, 2005).

Background

IRIS was created in 1985 to help EPA develop consensus opinions within the agency about the health effects of chronic exposure to chemicals. Its importance has increased over time as EPA program offices and the states have increasingly relied on IRIS information in making environmental protection decisions. Currently, the IRIS database contains assessments of more than 540 chemicals. According to EPA, national and international users access the IRIS database approximately 9 million times a year. EPA's Assistant Administrator for the Office of Research and Development has described IRIS as the premier national and international source for qualitative and quantitative chemical risk information; other federal agencies have noted that IRIS data are widely accepted by all levels of government across the country for application of public health policy, providing benefits such as uniform, standardized methods for toxicology testing and risk assessment, as well as uniform toxicity values. Similarly, a private-sector risk assessment expert has stated that the IRIS database has become the most important source of regulatory toxicity values for use across EPA's programs and is also widely used across state programs and internationally.

A typical IRIS assessment contains a qualitative hazard identification description and quantitative dose-response assessments. Historically and currently, the focus of IRIS toxicity assessments has been on the potential health effects of long-term (chronic) exposure to chemicals. According to OMB, EPA is the only federal agency that develops qualitative and quantitative assessments of both cancer and noncancer risks of exposure to chemicals, and EPA does so largely under the IRIS program. Other federal agencies develop quantitative estimates of noncancer effects or qualitative cancer assessments of exposure to chemicals in the environment. While these latter assessments provide information on the effects of long-term exposures to chemicals, they provide only qualitative assessments of cancer risks (known human carcinogen, likely human carcinogen, etc.) and not quantitative estimates of cancer potency, which are required to conduct quantitative risk assessments.

EPA's IRIS assessment process has undergone a number of formal and informal changes during the past several years. While the process used to develop IRIS chemical assessments includes numerous individual steps or activities, major assessment steps include (1) a review of the scientific literature; (2) preparation of a draft IRIS assessment; (3) internal EPA reviews of draft assessments; (4) two OMB/interagency reviews, managed by OMB, that provide input from OMB as well as from other federal agencies, including those that may be affected by the IRIS assessments if they lead to regulatory or other actions; (5) an independent peer review

conducted by a panel of experts; and (6) the completion of a final assessment that is posted to the IRIS Web site.

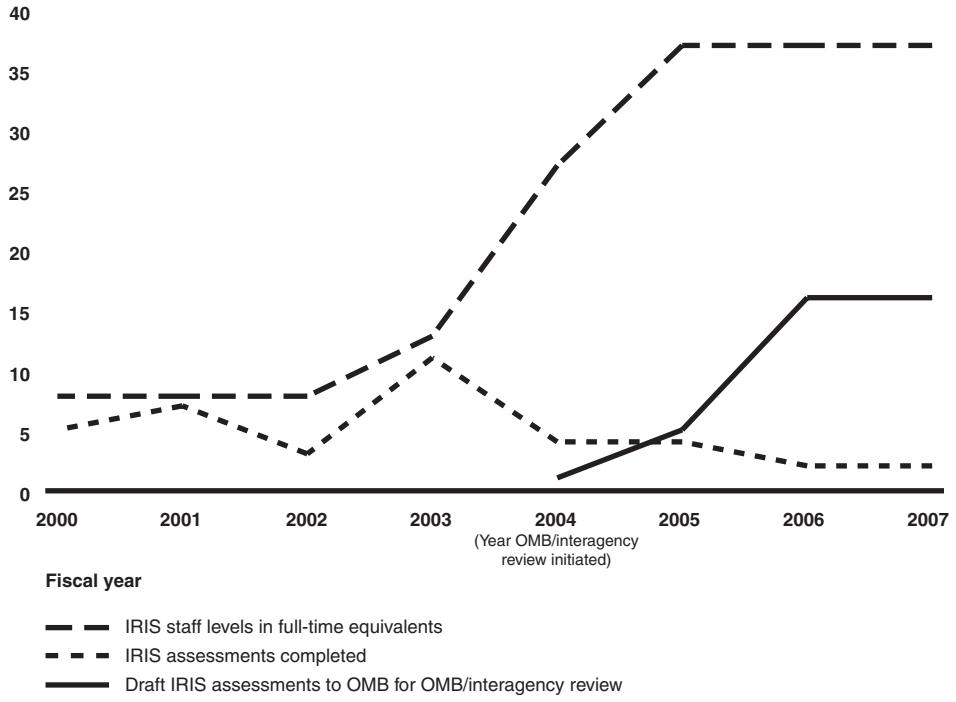
Findings and Recommendations from Our March 2008 Report on the Productivity and Credibility of EPA's Integrated Risk Information System

The IRIS database is at serious risk of becoming obsolete because the agency has not been able to routinely complete timely, credible assessments or decrease a backlog of 70 ongoing assessments. Specifically, although EPA has taken important steps to improve the IRIS program and productivity since 2000 and has developed a number of draft assessments for external review, its efforts to finalize the assessments have been thwarted by a combination of factors including the imposition of external requirements, the growing complexity and scope of risk assessments, and certain EPA management decisions. In addition, the changes to the IRIS assessment process that EPA was considering 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's Efforts to Improve the IRIS Assessment Program Have Not Produced the Desired Results

EPA has taken a number of steps to help ensure that IRIS contains current, credible chemical risk information; to address its backlog of ongoing assessments; and to respond to new OMB requirements. However, to date, these changes—including increasing funding, centralizing staff conducting assessments, and revising the assessment process—have not enabled EPA to routinely complete credible IRIS assessments or decrease the backlog. That is, although EPA sent 32 draft assessments for external review in fiscal years 2006 and 2007, the agency finalized only 4 IRIS assessments during this time (see fig. 1).

Figure 1: Number of Completed IRIS Assessments, Draft Assessments to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007



Source: GAO analysis of EPA data.

Several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database: new OMB-required reviews of IRIS assessments by OMB and other federal agencies; the growing complexity and scope of risk assessments; certain EPA management decisions and issues, including delaying completion of some assessments to await new research or to develop enhanced analyses of uncertainty in the assessments; and the compounding effect of delays. Regarding the last factor, even a single delay in the assessment process can lead to the need to essentially repeat the assessment process to take into account changes in science and methodologies.

A variety of delays have impacted the majority of the 70 assessments being conducted as of December 2007—48 had been in process for more than 5 years, and 12 of those for more than 9 years. These time frames are problematic because of the substantial rework such cases often require to take into account changing science and methodologies before they can be completed. Further, because EPA staff time continues to be dedicated to completing these assessments, EPA's ability to both keep the more than

540 existing assessments up to date and initiate new assessments is limited. Importantly, EPA program offices and state and local entities have requested assessments of hundreds of chemicals not yet in IRIS, and EPA data as of 2003 indicated that the assessments of 287 chemicals in the database may be outdated—that is, new information could change the risk estimates currently in IRIS or enable EPA to develop additional risk estimates for chemicals in the database (for example, developing a cancer potency estimate for assessments with only noncancer estimates). In addition, because EPA's 2003 data are now more than 4 years old, it is likely that more assessments may be outdated now.

One of the factors that has contributed to EPA's inability to complete assessments in a timely manner—the new OMB-directed OMB/interagency review process—also limits the credibility of the assessments because it lacks transparency. Specifically, neither the comments nor the changes EPA makes to the scientific IRIS assessments in response to the comments made by OMB and other federal agencies, including those whose workload and resource levels could be affected by the assessments, are disclosed. In addition, the OMB/interagency reviews have hindered EPA's ability to independently manage its IRIS assessments. For example, without communicating its rationale for doing so, OMB directed EPA to terminate five IRIS 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.

The Expansion of Agencies' Roles in IRIS Assessments That EPA Was Considering at the Time of Our Review Would Have Caused Further Delays and Limited the Assessments' Credibility

For our March 2008 report, we reviewed the additional assessment process changes EPA was planning and concluded that they would likely exacerbate delays in completing IRIS assessments and further affect their credibility. Specifically, despite the OMB/interagency review process that OMB required EPA to incorporate into the IRIS assessment process in 2005, certain federal agencies continued to believe they should have greater and more formal roles in EPA's development of IRIS assessments. Consequently, EPA had been working for several years to establish a formal IRIS assessment process that would further expand the role of federal agencies in the process—including agencies such as DOD, which could be affected by the outcome of IRIS assessments. For example, some of these agencies and their contractors could 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. In addition, the agencies could be required to, for example, redesign systems and processes to eliminate hazardous materials; develop material substitutes; and improve personal protective clothing, equipment, and

procedures. Under the changes that EPA was planning at the time of our review, these potentially affected agencies would have the opportunity to be involved, or provide some form of input, at almost every step of EPA's IRIS assessment process. Most significantly, the changes would have provided federal agencies, including those facing potential regulatory liability, with several opportunities during the IRIS assessment process to subject particular chemicals of interest to additional process steps. These additional process steps, which would have lengthened assessment times considerably, include

- giving federal agencies and the public 45 days to identify additional information on a chemical for EPA's consideration in its assessment or to correct any errors on an additional assessment draft that would provide qualitative information;[3]

- giving potentially affected federal agencies 30 days to review the public comments EPA received and initiate a meeting with EPA if they want to discuss a particular set of comments;

- allowing potentially affected federal agencies to have assessments suspended for up to 18 months to fill a data gap or eliminate an uncertainty factor that EPA plans to use in its assessment; and

- allowing other federal agencies to weigh in on (1) the level of independent peer review that would be sought (that is, whether the peer reviews would be conducted by EPA Science Advisory Board panels, National Academies' panels, or panels organized by an EPA contractor); (2) the areas of scientific expertise needed on the panel; and (3) the scope of the peer reviews and the specific issues they would address.

EPA estimated that assessments that undergo these additional process steps would take up to 6 years to complete. While it is important to ensure that assessments consider the best science, EPA has acknowledged that waiting for new data can result in substantial harm to human health, safety, and the environment. Further, although coordination with other

[3]This represents an additional review of a new draft product and comment period that had not existed previously.

federal agencies about IRIS assessments could enhance their quality,[4] increasing the role of agencies that may be affected by IRIS assessments in the process itself reduces the credibility of the assessments if that expanded role is not transparent. In this regard, while EPA's proposed changes would have allowed for including federal agencies' comments in the public record, the implementation of this proposal was delayed for a year, in part, because of OMB's view that agencies' comments about IRIS assessments represent internal executive branch communications that may not be made public—a view that is inconsistent with the principle of sound science, which relies on, among other things, transparency.

Recommendations Made in Our March 2008 Report

To address the productivity and credibility issues we identified, we recommended that the EPA Administrator require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in our report and ensure that any revised process, among other things, clearly defines and documents an IRIS assessment process that will enable the agency to develop the timely chemical risk information it needs to effectively conduct its mission. One of our recommendations—that EPA provide at least 2 years' notice of IRIS assessments that are planned—would, among other things, provide an efficient alternative to suspending assessments while waiting for new research because interested parties would have the opportunity to conduct research before assessments are started.

In addition, we recommended that the EPA Administrator take steps to better ensure that EPA has the ability to develop transparent, credible IRIS assessments—an ability that relies in large part on EPA's independence in conducting these important assessments. Actions that are key to this ability include ensuring that EPA can (1) determine the types of assessments it needs to support EPA programs and (2) define the appropriate role of external federal agencies in EPA's IRIS assessment process and manage an interagency review process in a manner that enhances the quality, transparency, timeliness, and credibility of IRIS assessments. In its February 21, 2008, letter providing comments on our

[4]We recommended in our 2006 report on human health risk assessment that EPA consistently involve stakeholders as appropriate to the risk assessment. We made this recommendation in the context of improving the overall quality, consistency, and transparency of risk assessments. GAO, *Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process, but Improvements Needed in Planning, Data Development, and Training*, GAO-06-595 (Washington, D.C.: May 31, 2006).

draft report, EPA said it would consider each of our recommendations in light of the new IRIS process the agency was developing.

Key Changes to the IRIS Assessment Process That EPA Implemented in April 2008

On April 10, 2008, EPA issued a revised IRIS assessment process, effective immediately (see app. III for a flow chart of the process). Overall, EPA's revised process is not responsive to the recommendations made in our March 2008 report. While the revised process is largely the same as the draft proposed process we evaluated in our March 2008 report, there are several key differences that are likely to further exacerbate the productivity and credibility issues we identified in our report. These changes are as follows.

- While the draft process we reviewed provided that comments on IRIS assessments from OMB and other federal agencies would be part of the public record, under the recently implemented process, comments from federal agencies are expressly defined as "deliberative" and will not be included in the public record. (Making these comments public would have been a change from the OMB/interagency review process that has been in place since 2004.) Given the importance and sensitivity of IRIS assessments, we believe it is critical that input from all parties, particularly agencies that may be affected by the outcome of IRIS assessments, be publicly available. Thus, under EPA's new process, input from some IRIS assessment reviewers—representatives of federal agencies, including those facing potential regulatory liability, and private stakeholders associated with these agencies—will continue to receive less public scrutiny than all other comments.

- The newly implemented IRIS assessment process broadens EPA's characterization of IRIS assessments from "the Agency's scientific positions on human health effects that may result from exposure to environmental contaminants" to "the Agency's science and science policy positions" on such effects. As we highlighted in our report, under the National Academies' risk assessment and risk management paradigm, policy considerations are relevant in the risk management phase—which occurs after the risk assessment phase that encompasses IRIS assessments. EPA's new, broader characterization of IRIS raises concerns about the agency's intent to ensure that scientific assessments are appropriately based on the best available science and that they are not inappropriately impacted by policy issues and considerations.

- The new process includes several revisions to the time frames associated with various process steps. Most notably, while EPA has estimated that under the new process assessments may take up to 6 years to complete,

the estimated time frames do not factor in the time needed for peer reviews conducted by the National Academies, which can take 2 years to plan and complete.[5] EPA typically uses reviews by the National Academies for highly controversial chemicals or complex assessments. Therefore, assessments reviewed by the National Academies are likely to take at least 8 years to complete. However, as discussed in our report, 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. As a result, we concluded that it was critical that EPA streamline its process to routinely support timely completion of assessments and avoid being caught in an endless cycle of delays. Further, EPA's lengthy assessment time frames must be considered in light of OMB's view that health assessment values in IRIS are out of date if they are more than 10 years old and if new scientific information exists that could change the health assessment values. EPA's new process institutionalizes time frames that could essentially require the agency to start assessment updates as soon as 2 years after assessments are finalized in order to keep the IRIS database current. Such time frames are not consistent with our recommendation that EPA clearly define and document a streamlined IRIS process that can be conducted within time frames that minimize the need for wasteful rework. Further, the agency would need a significant increase in resources to support such an assessment cycle.

In addition, EPA had previously emphasized that, in suspending assessments to allow agencies to fill in data gaps, it would allow no more than 18 months to complete the studies and have them peer reviewed. However, under the new process, EPA states that it *generally* will allow no more than 18 months to complete the studies and have them peer reviewed. As we concluded in our report, we believe the ability to suspend assessments for up to 18 months would add to the already unacceptable level of delays in completing IRIS assessments. Further, we and several agency officials with whom we spoke believe that the time needed to plan, conduct, and complete research that would address significant data gaps, and have it peer reviewed, would likely exceed 18 months. Therefore, the less rigid time frame EPA included in its new process could result in additional delays.

[5]It is not clear whether the time frames exclude reviews conducted by EPA's Science Advisory Board, which can also add considerably more time than the most basic level of peer review used by the IRIS program—panels organized by an EPA contractor.

- The new process expands the scope of one of the additional steps that initially was to apply only to chemicals of particular interest to federal agencies.[6] Specifically, under the draft process we reviewed, EPA would have provided an additional review and comment opportunity for federal agencies and the public for what EPA officials said would be a small group of chemicals. However, under EPA's new process, this additional step has been added to the assessment process for all chemicals and, therefore, will add time to the already lengthy assessments of all chemicals.

- Finally, EPA and OMB had planned for EPA to release a draft revised IRIS assessment process to the public, hold a public meeting to discuss EPA's proposed changes, and seek and incorporate public input before finalizing the process. For example, in its letter commenting on our draft report, OMB emphasized that EPA had not completed the development of the IRIS assessment process, adding: "Indeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments." However, as stated above, EPA released its new assessment process without obtaining public input and made it effective immediately.

Conclusions

The new IRIS assessment process that EPA implemented in April 2008 will not allow the agency to routinely and timely complete credible assessments. In fact, it will exacerbate the problems we identified in our March 2008 report and sought to address with our recommendations—all of which were aimed at preserving the viability of this critical database, which is integral to EPA's mission of protecting the public and the environment from exposure to toxic chemicals. Specifically, under the new process, assessment time frames will be significantly lengthened, and the lack of transparency will further limit the credibility of the assessments because input from OMB and other agencies at all stages of the IRIS assessment process is now expressly defined as deliberative and therefore not subject to public disclosure. To effectively maintain IRIS, EPA must streamline its lengthy assessment process and adopt transparency practices that provide assurance that IRIS assessments are appropriately based on the best available science and that they are not

[6]The new IRIS assessment process refers to such chemicals as "mission critical." A mission-critical chemical is one that is an integral component to the successful and safe conduct of an agency's mission in any or all phases of its operations. Impacts on the use of mission-critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints.

inappropriately biased by policy issues and considerations. Federal agencies may appropriately participate in policy dialogues through the rule-making process and other interagency working groups, which are risk management activities that should occur after the risk assessment process that encompasses IRIS assessments. Finally, 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.

Matter for Congressional Consideration

In light of the importance of the IRIS program to EPA's ability to protect the public health and the environment, the Congress should consider requiring EPA to suspend implementation of its new IRIS assessment process and develop a process that is responsive to our recommendations for a streamlined process that is transparent and otherwise responsive to our recommendations aimed at improving the timeliness and credibility of IRIS assessments. In addition, the Congress should consider requiring EPA to obtain and be responsive to input from the Congress and the public before finalizing a revised IRIS assessment process.

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

GAO Contact and Staff Acknowledgments

For further information about this testimony, please contact John B. Stephenson on (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Contributors to this testimony include Christine Fishkin (Assistant Director), Laura Gatz, Richard P. Johnson, Nancy Crothers, David Bennett, and Crystal M. Huggins.

Appendix I: Examples of Key IRIS Assessments That Have Been Delayed

Some key IRIS assessments have been in progress for a number of years, in part because of delays stemming from one or more of the key factors we identified that have hindered EPA's productivity.[1] Examples include the following:

Naphthalene. EPA started the IRIS assessment of cancer risks stemming from the inhalation of naphthalene in 2002. Naphthalene is used in jet fuel and in the production of widely used commercial products such as moth balls, dyes, insecticides, and plasticizers. According to a presentation delivered at the 2007 annual meeting of the Society for Risk Analysis by an Army Corps of Engineers toxicologist,[2] "The changing naphthalene regulatory environment includes a draft EPA risk assessment that if/when finalized, will change naphthalene's status from 'possible' to 'likely' human carcinogen."[3] Thus, according to this presentation, one potential impact of this IRIS assessment on DOD is that DOD would need to provide many employees exposed to naphthalene with equipment measuring their exposure to the chemical. In addition, because many military bases are contaminated with naphthalene, a component of jet fuel (approximately 1 percent to 3 percent) used by all DOD services, DOD could face extensive cleanup costs. By 2004, 2 years after starting the assessment, EPA had drafted a chemical assessment that had completed internal peer reviews and was about to be sent to an external peer review committee. Once it returned from external review, the next step, at that time, would have been a formal review by EPA's IRIS Agency Review Committee. If approved, the assessment would have been completed and released.

[1]The factors we identified that have hindered EPA's efforts to improve productivity are the OMB/interagency review process managed by OMB, the growing complexity and scope of risk assessments, certain management decisions and issues regarding the IRIS program, congressional action that has delayed some assessments with potentially significant economic effects, and the compounding effect of delays.

[2]Presentations at the Society for Risk Analysis meeting reflect the views of the authors and "do not necessarily reflect the views of any other organization or agency."

[3]Using its 1996 Proposed Guidelines for Carcinogen Risk Assessment, EPA concluded in the 1998 IRIS assessment of naphthalene that its human carcinogenic potential could not be determined at that time, but noted that there was suggestive evidence of potential human carcinogenicity. (EPA also noted that under its 1986 cancer guidelines, EPA classified naphthalene as a possible human carcinogen.) Subsequently, in 2002, the International Agency for Research on Cancer (IARC), part of the World Health Organization, concluded that naphthalene is possibly carcinogenic to humans; in 2004, the Department of Human Health and Services' National Toxicology Program concluded that naphthalene can reasonably be anticipated to be a human carcinogen. EPA's current assessment will be subject to the agency's 2005 cancer guidelines.

However, in part because of concerns raised by DOD, OMB asked to review the assessment and conducted an interagency review of the draft. In their 2004 reviews of the draft IRIS assessment, both OMB and DOD raised a number of concerns about the assessment and suggested to EPA that it be suspended until additional research could be completed to address what they considered to be significant uncertainties associated with the assessment. Although all of the issues raised by OMB and DOD were not resolved, EPA continued with its assessment by submitting the draft for external peer review, which was completed in September 2004.[4] However, according to EPA, OMB continued to object to the draft IRIS assessment and directed EPA to convene an additional expert review panel on genotoxicity to obtain recommendations about short-term tests that OMB thought could be done quickly.[5] According to EPA, this added 6 months to the process, and the panel, which met in April 2005, concluded that the research that OMB was proposing could not be conducted in the short term. Nonetheless, EPA officials said that the second expert panel review did not eliminate OMB's concerns regarding the assessment, which they described as reaching a stalemate. In September 2006, EPA decided, however, to proceed with developing the assessment. By this time, the naphthalene assessment had been in progress for over 4 years; EPA decided that the IRIS noncancer assessment, issued in 1998, was outdated and needed to be revisited. Thus, EPA expanded the IRIS naphthalene assessment to include both noncancer and cancer assessments. As a result, 6 years after the naphthalene assessment began, it is now back at the drafting stage. The assessment now will need to reflect relevant research completed since the draft underwent initial external peer review in 2004, and it will have to undergo all of the IRIS assessment steps again, including additional internal and external reviews that are now required. This series of delays has limited EPA's ability to conduct its mission. For example, the Office of Air and Radiation has identified the naphthalene assessment as one of its highest-priority needs for its air toxics program. In addition, the Office of Solid Waste and Emergency Response considers the naphthalene assessment a high priority for the Superfund program—naphthalene has been found in at least 654 of Superfund's current or

[4]According to DOD, EPA did not specifically ask the peer reviewers to address some of the technical questions DOD had raised and wanted the peer review to address.

[5]Genotoxic substances are a type of carcinogen, specifically those capable of causing genetic mutation and of contributing to the development of tumors. This includes both certain chemical compounds and certain types of radiation.

former National Priorities List sites.[6] Although EPA currently estimates that it will complete the assessment in 2009, meeting this revised estimate will be challenging, given all of the steps that are yet to be completed and the extensive external scrutiny to which it will continue to be subjected.

Royal Demolition Explosive. This chemical, also called RDX or hexahydro-1,3,5-trinitrotriazine, is a highly powerful explosive used by the U.S. military in thousands of munitions. Currently classified by EPA as a possible human carcinogen, this chemical is known to leach from soil to groundwater. Royal Demolition Explosive can cause seizures in humans and animals when large amounts are inhaled or ingested, but the effects of long-term, low-level exposure on the nervous system are unknown. As is the case with naphthalene, the IRIS assessment could potentially require DOD to undertake a number of actions, including steps to protect its employees from the effects of this chemical and to clean up many contaminated sites. Although EPA started an IRIS assessment of Royal Demolition Explosive in 2000, it has made minimal progress on the assessment because EPA agreed to a request by DOD to wait for the results of DOD-sponsored research on this chemical. In 2007, EPA began to actively work on this assessment, although some of the DOD-sponsored research is still outstanding.

Formaldehyde. EPA began an IRIS assessment of formaldehyde in 1997 because the existing assessment was determined to be outdated.[7] Formaldehyde is a colorless, flammable, strong-smelling gas used to manufacture building materials, such as pressed wood products, and used in many household products, including paper, pharmaceuticals, and leather goods. While EPA currently classifies formaldehyde as a probable human carcinogen, the International Agency for Research on Cancer (IARC), part of the World Health Organization, classifies formaldehyde as a known human carcinogen. Since 1986, studies of industrial of workers have suggested that formaldehyde exposure is associated with nasopharyngeal cancer, and possibly with leukemia. For example, in 2003 and 2004, the National Cancer Institute (NCI) and the National Institute of Occupational Safety and Health (NIOSH) released epidemiological studies following up on earlier studies tracking about 26,000 and 11,000 industrial workers, respectively, exposed to formaldehyde; the updates showed

[6]The National Priorities List is EPA's list of seriously contaminated sites.

[7]The cancer portion of the formaldehyde assessment was originally issued in 1989 and updated in 1991; the noncancer assessment was added in 1990.

exposure to formaldehyde might also cause leukemia in humans, in addition to the cancer types previously identified. According to NCI officials, the key findings in their follow-up study were an increase in leukemia deaths and, more significantly, an exposure/response relationship between formaldehyde and leukemia—as exposure increased, the incidence of leukemia also rose. As with the earlier study, NCI found more cases of a rare form of cancer, nasopharyngeal cancer, than would usually be expected. The studies from NCI and NIOSH were published in 2003 and 2004,[8] around the time that EPA was still drafting its IRIS assessment. In November 2004, the Chairman of the Senate Environment and Public Works Committee requested that EPA delay completion of its IRIS assessment until an update to the just-released NCI study could be conducted, indicating that the effort would take, at most, 18 months. EPA agreed to wait—and more than 3 years later, the NCI update is not yet complete. As of December 2007, NCI estimates that the study will be completed in two stages, one in mid-2008 and the second one later that year. An NCI official said that the additional leukemia deaths identified in the update provide "greater power" to detect associations between exposure to formaldehyde and cancer. EPA's inability to complete the IRIS assessment it started more than 10 years ago in a timely manner has had a significant impact on EPA's air toxics program. Specifically, when EPA promulgated a national emissions standard for hazardous air pollutants covering facilities in the plywood and composite wood industries in 2004, EPA's Office of Air and Radiation took the unusual step of not using the existing IRIS estimate but rather decided to use a cancer risk estimate developed by an industry-funded organization, the CIIT Centers for Health Research (formerly, the Chemical Industry Institute of Toxicology) that had been used by the Canadian health protection agency. The IRIS cancer risk factor had been subject to criticism because it was last revised in 1991 and was based on data from the 1980s. In its final rule, EPA stated that

[8]NCI published the results of its study in two publications. The first study, published in November 2003, focused on the association between formaldehyde exposure and leukemia. M. Hauptmann, J. H. Lubin, P. A. Stewart, R. B. Hayes, A. Blair, "Mortality from Lymphohematopoietic Malignancies among Workers in Formaldehyde Industries," *Journal of the National Cancer Institute* (2003). The second study, published in June 2004, evaluated the association between formaldehyde exposure and other cancers—including nasopharyngeal cancer. M. Hauptmann, J. H. Lubin, P. A. Stewart, R. B. Hayes, A. Blair, "Mortality from Solid Cancers among Workers in Formaldehyde Industries," *American Journal of Epidemiology* (2004). The results of the NIOSH study were described in one publication, dated March 2004, which assessed mortality from all causes and all cancers. L. E. Pinkerton, M. J. Hein, L. T. Stayner, "Mortality among a Cohort of Garment Workers Exposed to Formaldehyde: an Update," *Occupational and Environmental Medicine* (2004).

"the dose-response value in IRIS is based on a 1987 study, and no longer represents the best available science in the peer-reviewed literature." The CIIT quantitative cancer risk estimate that EPA used in its health risk assessment in the plywood and composite wood national emissions standard indicates a potency about 2,400 times lower than the estimate in IRIS that was being re-evaluated and that did not yet consider the 2003 and 2004 NCI and NIOSH epidemiological studies. According to an EPA official, an IRIS cancer risk factor based on the 2003 and 2004 NCI and NIOSH studies would likely be close to the current IRIS assessment, which EPA has been attempting to update since 1997. The decision to use the CIIT assessment in the plywood national emissions standard was controversial, and officials in EPA's National Center for Environmental Assessment said the center identified numerous problems with the CIIT estimate. Nonetheless, the Office of Air and Radiation used the CIIT value, and that decision was a factor in EPA exempting certain facilities with formaldehyde emissions from the national emissions standard. In June 2007, a federal appellate court struck down the rule, holding that EPA's decision to exempt certain facilities that EPA asserted presented a low health risk exceeded the agency's authority under the Clean Air Act.[9] Further, the continued delays of the IRIS assessment of formaldehyde—currently estimated to be completed in 2010 but after almost 11 years still in the draft development stage—will impact the quality of other EPA regulatory actions, including other air toxics rules and requirements.

Trichloroethylene. Also known as TCE, this chemical is a solvent widely used as a degreasing agent in industrial and manufacturing settings; it is a common environmental contaminant in air, soil, surface water, and groundwater. TCE has been linked to cancer, including childhood cancer, and other significant health hazards, such as birth defects. TCE is the most frequently reported organic contaminant in groundwater, and contaminated drinking water has been found at Camp Lejeune, a large Marine Corps base in North Carolina. TCE has also been found at Superfund sites and at many industrial and government facilities, including aircraft and spacecraft manufacturing operations. In 1995, the International Agency for Research on Cancer classified TCE as a probable human carcinogen, and in 2000, the Department of Health and Human Services' National Toxicology Program concluded that it is reasonably

[9]*Natural Resources Defense Council v. E.P.A.*, 489 F.3d 1364, 1372-73 (D.C. Cir, 2007). The court did not specifically address EPA's reliance on the CIIT study, holding instead that the Clean Air Act prohibited establishment of the exemptions at issue.

anticipated to be a human carcinogen. Because of questions raised by peer reviewers about the IRIS cancer assessment for TCE, EPA withdrew it from IRIS in 1989 but did not initiate a new TCE cancer assessment until 1998. In 2001, EPA issued a draft IRIS assessment for TCE that proposed a range of toxicity values indicating a higher potency than in the prior IRIS values and characterizing TCE as "highly likely to produce cancer in humans." The draft assessment, which became controversial, was peer reviewed by EPA's Scientific Advisory Board and released for public comment. A number of scientific issues were raised during the course of these reviews, including how EPA had applied emerging risk assessment methods—such as assessing cumulative effects (of TCE and its metabolites) and using a physiologically based pharmacokinetic model—and the uncertainty associated with the new methods themselves.[10] To help address these issues, EPA, DOD, DOE, and NASA sponsored a National Academies review to provide guidance. The National Academies report, which was issued in 2006, concluded that the weight of evidence of cancer and other health risks from TCE exposure had strengthened since 2001 and recommended that the risk assessment be finalized with currently available data so that risk management decisions could be made expeditiously. The report specifically noted that while some additional information would allow for more precise estimates of risk, this information was not necessary for developing a credible risk assessment. Nonetheless, 10 years after EPA started its IRIS assessment, the TCE assessment is back at the draft development stage. EPA estimates this assessment will be finalized in 2010. More in line with the National Academies' recommendation to act expeditiously, five senators introduced a bill in August 2007 that, among other things, would require EPA to both establish IRIS values for TCE and issue final drinking water standards for this contaminant within 18 months.

Tetrachloroethylene. EPA started an IRIS assessment of tetrachloroethylene—also called perchloroethylene or "perc"—in 1998. Tetrachloroethylene is a manufactured chemical widely used for dry cleaning of fabrics, metal degreasing, and making some consumer products and other chemicals. Tetrachloroethylene is a widespread groundwater contaminant, and the Department of Health and Human Services' National Toxicology Program has determined that it is

[10]Physiologically based pharmacokinetic models are a class of dosimetry models that are useful for predicting internal doses to target organs. With the appropriate data, these models can be used to extrapolate across species and exposure scenarios and address various sources of uncertainty in risk assessments.

reasonably anticipated to be a carcinogen. The IRIS database currently contains a 1988 noncancer assessment based on oral exposure that will be updated in the ongoing assessment. Importantly, the ongoing assessment will also provide a noncancer inhalation risk and a cancer assessment. The IRIS agency review of the draft assessment was completed in February 2005, the draft assessment was sent to OMB for OMB/interagency review in September 2005, and the OMB/interagency review was completed in March 2006. EPA had determined to have the next step, external peer review, conducted by the National Academies—the peer review choice reserved for chemical assessments that are particularly significant or controversial. EPA contracted with the National Academies for a review by an expert panel, and the review was scheduled to start in June 2006 and be completed in 15 months. However, as of December 2007, the draft assessment had not yet been provided to the National Academies. After verbally agreeing with both the noncancer and cancer assessments following briefings on the assessments, the Assistant Administrator, Office of Research and Development, subsequently requested that additional uncertainty analyses—including some quantitative analyses—be conducted and included in the assessment before the draft was released to the National Academies for peer review. As discussed in our March 2008 report on IRIS (GAO-08-440), quantitative uncertainty analysis is a risk assessment tool that is currently being developed, and although the agency is working on developing policies and procedures for uncertainty analysis, such guidance currently does not exist. The draft tetrachloroethylene assessment has been delayed since early 2006 as EPA staff have gone back and forth with the Assistant Administrator trying to reach agreement on key issues such as whether a linear or nonlinear model is most appropriate for the cancer assessment and how uncertainty should be qualitatively and quantitatively characterized. EPA officials and staff noted that some of the most experienced staff are being used for these efforts, limiting their ability to work on other IRIS assessments. In addition, the significant delay has impacted the planned National Academies peer review because the current contract, which has already been extended once, cannot be extended beyond December 2008. The peer review was initially estimated to take 15 months. As a result, a new contract and the appointment of another panel may be required.

Dioxin. The dioxin assessment is an example of an IRIS assessment that has been, and will likely continue to be, a political as well as a scientific issue. Often the byproducts of combustion and other industrial processes, complex mixtures of dioxins enter the food chain and human diet through emissions into the air that settle on soil, plants, and water. EPA's initial dioxin assessment, published in 1985, focused on the dioxin TCDD

(2,3,7,8-tetrachlorodibenzo-p-dioxin) because animal studies in the 1970s showed it to be the most potent cancer-causing chemical studied to date. Several years later, EPA decided to conduct a reassessment of dioxin because of major advances that had occurred in the scientific understanding of dioxin toxicity and significant new studies on dioxins' potential adverse health effects. Initially started in 1991, this assessment has involved repeated literature searches and peer reviews. For example, a draft of the updated assessment was reviewed by a scientific peer review panel in 1995, and three panels reviewed key segments of later versions of the draft in 1997 and 2000. In 2002, EPA officials said that the assessment would conclude that dioxin may adversely affect human health at lower exposure levels than had previously been thought and that most exposure to dioxins occurs from eating such American dietary staples as meats, fish, and dairy products, which contain minute traces of dioxins. These foods contain dioxins because animals eat plants and commercial feed and drink water contaminated with dioxins, which then accumulate in animals' fatty tissue. It is clear that EPA's dioxin risk assessment could have a potentially significant impact on consumers and on the food and agriculture industries. As EPA moved closer to finalizing the assessment, in 2003 the agency was directed in a congressional appropriations conference committee report to not issue the assessment until it had been reviewed by the National Academies. The National Academies provided EPA with a report in July 2006. In developing a response to the report, which the agency is currently doing, EPA must include new studies and risk assessment approaches that did not exist when the assessment was drafted. EPA officials said the assessment will be subject to the IRIS review process once its response to the National Academies' report is drafted. As of 2008, EPA has been developing the dioxin assessment, which has potentially significant health implications for all Americans, for 17 years.

Appendix II: Summary of Two GAO Reports on EPA's Toxic Substances Control Act and Chemical Control Regulations in the EU

This appendix summarizes information presented in two prior GAO reports and related work on EPA's regulation of toxic chemicals. In 1976, Congress passed the Toxic Substances Control Act (TSCA) to authorize the Environmental Protection Agency (EPA) to obtain information on chemicals and regulate chemicals that pose an unreasonable risk to human health or the environment. In 2005, we reviewed EPA's efforts to assess the risks of new chemicals—those not yet in commerce—and the risks of existing chemicals—those already being used in commerce.[1] In summary, EPA faces challenges in obtaining the information necessary to assess the human health and environmental risks of chemicals.

Like the United States, the European Union has laws governing the production and use of chemicals. The European Union has recently revised its chemical control policy through legislation known as Registration, Evaluation and Authorization of Chemicals (REACH). In another report, we provided comparative information on TSCA and REACH.[2] In summary, REACH generally requires that chemical companies develop and provide government regulators with information on chemicals' effects on human health and the environment, while TSCA generally does not. REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place in the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use. The findings of these reports are summarized below.

Key Findings in GAO's 2005 Report and Related Testimony

Overall, we found that EPA has limited information on the health and environmental risks of chemicals. EPA does not routinely assess the human health and environmental risks of existing chemicals and faces challenges in obtaining the information to do so. TSCA's authorities for collecting data on existing chemicals do not facilitate EPA's review

[1]GAO, *Chemical Regulation: Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program*, GAO-06-1032T (Washington, D.C.: Aug. 2, 2006); and GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

[2]GAO, *Chemical Regulation: Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, GAO-07-825 (Washington, D.C.: Aug. 17, 2007); and GAO, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, GAO-06-217R (Washington, D.C.: Nov. 4, 2005).

process because they generally place the costly and time-consuming burden of obtaining data on EPA, rather than requiring chemical companies to develop and submit such data to EPA. Consequently, EPA has used its authorities to require testing for few of the over 60,000 chemicals already in commerce when EPA began reviewing chemicals under TSCA in 1979. Recognizing the need for additional information on existing chemicals, EPA has initiated voluntary programs. While these programs are a laudable effort to develop data on these chemicals, several problems remain, including that the chemical industry may not provide testing results in a timely manner for all chemicals in these programs and that even with additional test data, EPA would need to demonstrate that the chemicals pose unreasonable risks in order to control their production or use under TSCA. While TSCA does not define what risk is unreasonable, EPA has found it difficult to meet this standard. In order to withstand judicial scrutiny, a TSCA rule must be supported by substantial evidence in the rule-making record. In this regard, EPA officials say the act's legal standards are so high that they have generally discouraged EPA from using its authorities to ban or restrict the manufacture or use of chemicals.

Further, EPA's reviews of new chemicals can provide only limited assurance that health and environmental risks are identified before the chemicals enter commerce because TSCA does not require chemical companies to test new chemicals before notifying EPA of their intent to manufacture a chemical. Furthermore, chemical companies generally do not voluntarily perform such testing. Because of a general lack of data, EPA has developed scientific models to predict the potential exposure and toxicity levels of new chemicals. However, the use of these models can present weaknesses in the assessment because the models are not always accurate in predicting physical chemical properties and the evaluation of general health effects is contingent on the availability of information on chemicals with similar molecular structures. Additionally, chemical company estimates of a chemical's production volume and anticipated uses provided in the premanufacture notices that EPA uses to assess exposure can change substantially after EPA completes its review and manufacturing begins. However, these estimates do not have to be amended by companies unless EPA promulgates a rule determining that a use of a chemical constitutes a significant new use, which EPA has done for only a small percentage of new chemicals. Despite limitations in the information available on new chemicals, EPA's reviews have resulted in some action being taken to reduce the risks of over 3,600 new chemicals submitted for review.

EPA's ability to provide the public with information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA, which generally prohibits the disclosure of confidential business information. According to EPA officials, about 95 percent of the premanufacture notices for new chemicals contain some information that is claimed as confidential. While EPA has the authority to evaluate the appropriateness of confidentiality claims, these efforts are time and resource-intensive, and the agency does not have the resources to challenge a significant number of claims. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. Chemical companies recently have expressed interest in working with EPA to identify ways to enable other organizations to use the information given the adoption of appropriate safeguards.

In our June 2005 report, we recommended that Congress consider providing EPA with additional authorities under TSCA to improve its ability to assess chemical risks, such as providing the EPA Administrator with the authority to require that chemical companies develop test data when production volumes reach certain levels. We also recommended that the EPA Administrator take several actions to improve EPA's management of its chemical program, including revising its regulations to require that companies reassert confidentiality claims under TSCA within a certain time period after the information is initially claimed as confidential. EPA did not disagree with the report's findings and is in the process of implementing several of our recommendations.

Key Findings in GAO's 2007 Report and Related Correspondence

Overall, we found that REACH, the legislation through which the European Union has recently revised its chemical control policy, requires chemical companies to develop more information than TSCA on the effects of chemicals on human health and the environment. REACH generally requires that chemical companies develop and provide government regulators information on chemicals' effects on human health and the environment, while TSCA generally does not. For example, under REACH, chemical companies provide, and in some cases develop, information on chemicals' physical/chemical properties and health and environmental effects for both new and existing chemicals produced over specified volumes. REACH also provides regulators the general authority to require chemical companies to provide additional test data and other information when necessary to evaluate a chemical's risk to human health

and the environment. In contrast, TSCA places the burden on EPA to demonstrate that data on health and environmental effects are needed before requiring chemical companies to develop the data. In this regard, while TSCA requires chemical companies to notify EPA before producing or importing a new chemical, it does not require chemical companies to develop and provide data on health and environmental effects unless EPA promulgates a rule requiring them to do so. In promulgating such a rule, EPA must demonstrate that data already available are insufficient and that either (1) the chemical may present an unreasonable risk or (2) the chemical is or will be produced in substantial quantities and that there is or may be substantial human or environmental exposure to the chemical.

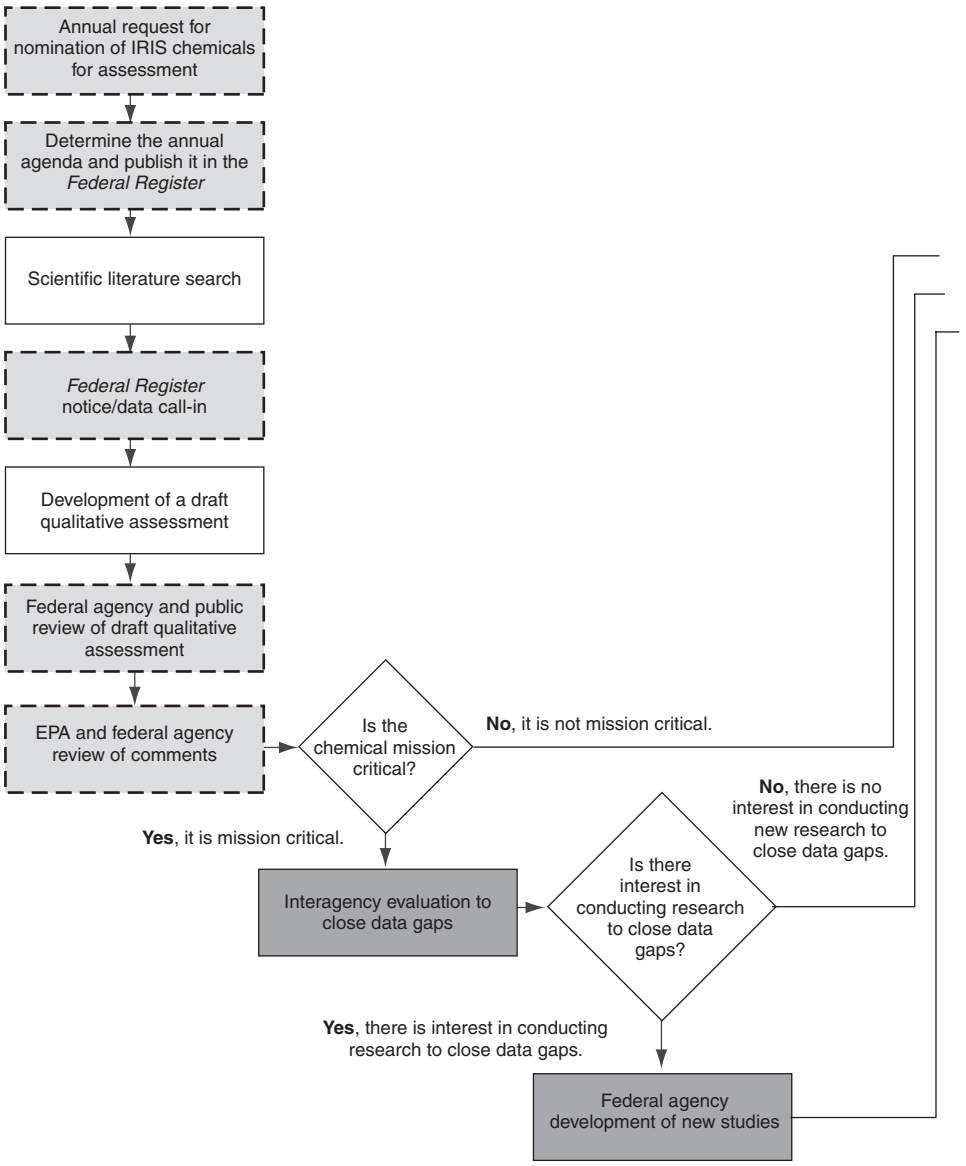
REACH is based on the principle that chemical companies have the responsibility to demonstrate that the chemicals they place in the market, distribute, or use do not adversely affect human health or the environment, while TSCA generally requires EPA to demonstrate that chemicals pose risks to human health or the environment prior to controlling risks related to their production, distribution, or use. Under REACH, chemical companies must obtain authorization to continue to use a chemical of very high concern, such as a chemical for which there is scientific evidence of probable serious health or environmental effects. Generally, to obtain such authorization, each chemical company needs to demonstrate that it can adequately control risks posed by the chemical, such as by requiring that workers wear safety equipment when working with the chemical or otherwise ensuring that the chemical is produced under safe conditions. If the chemical company cannot provide evidence of adequate control, authorization would be granted only if the socioeconomic advantages of a specific use of the chemical are greater than its potential risks, and if there are no suitable alternatives or technologies.

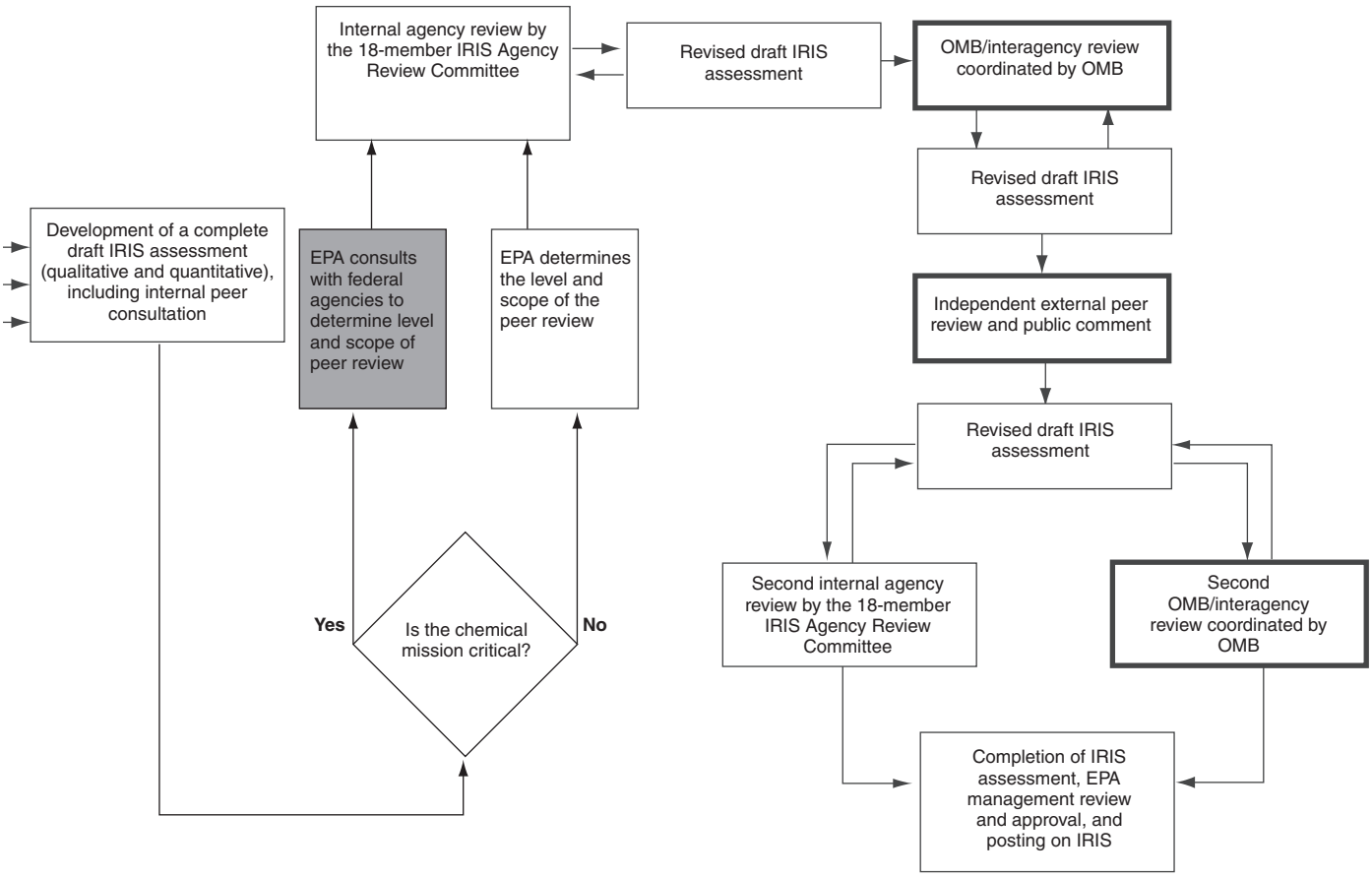
Under TSCA, EPA has differing authorities to control the risks posed by new and existing chemicals. For new chemicals, EPA can restrict a chemical's production or use if the agency determines that insufficient information exists to permit a reasoned evaluation of the health and environmental effects of the chemical and that, in the absence of such information, the chemical may present an unreasonable risk to human health or the environment; the chemical is or will be produced in substantial quantities and either enters or may reasonably be anticipated to enter the environment in substantial quantities; or there is or may be significant or substantial human exposure to the substance. For existing chemicals, EPA may regulate those chemicals for which it finds a reasonable basis exists to conclude that they present or will present an

unreasonable risk to human health or the environment. In this regard, EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, use, or disposal, or that requires warning labels be placed on the chemical. However, TSCA requires EPA to choose the least burdensome requirement on the chemical industry that will adequately protect against the risk.

TSCA and REACH both have provisions to protect information claimed by chemical companies as confidential or sensitive business information; however, REACH requires greater public disclosure of certain information, including information about (1) basic chemical properties such as melting and boiling points and (2) analytical methods that make it possible to detect a dangerous substance when discharged into the environment and to determine the effects of direct exposure to humans. In addition, REACH places greater restrictions on the kinds of information companies may claim as confidential or sensitive. For example, REACH generally does not allow confidentiality claims to apply to the chemical's trade name, and it does not allow such claims to apply to guidance on the chemical's safe use.

Appendix III: EPA's IRIS Assessment Process as of April 10, 2008





Darker shaded boxes are additional steps under EPA's changes to its assessment process and indicate where EPA has provided additional opportunity for input from potentially affected federal agencies for mission-critical chemicals.

Lighter shaded boxes with dotted lines indicate steps where EPA has provided additional opportunity for input from potentially affected federal agencies for all chemicals.

White boxes with heavy lines indicate steps where potentially affected federal agencies already had an opportunity for input.

Source: GAO analysis of EPA information.

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