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Report to the Chairman, Committee on Environment and Public Works, U.S. Senate

May 2013

CHEMICAL ASSESSMENTS

An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments

GAO-13-369

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GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-13-369, a report to the Chairman, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

EPA created the IRIS database in 1985 to help develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. The health effects information in IRIS—referred to as IRIS toxicity assessments—provides fundamental scientific information EPA needs to develop human health risk assessments. GAO was asked to review the effectiveness of EPA's implementation of its IRIS toxicity assessment process. This report determines the extent to which (1) EPA has evaluated demand for IRIS toxicity assessments from users inside and outside EPA; (2) EPA's process for nominating and selecting chemicals for IRIS toxicity assessment accurately reflects demand; and (3) EPA has implemented a strategy for addressing any unmet agency needs when IRIS toxicity assessments are not available, applicable, or current. To do this work, GAO reviewed and analyzed IRIS nomination data, among other things, and interviewed EPA officials. GAO did not evaluate the scientific content or quality of IRIS toxicity assessments.

What GAO Recommends

GAO recommends that EPA evaluate demand for IRIS assessments; document how the agency applies its selection criteria, including the circumstances under which an IRIS toxicity assessment is or is not needed and; develop an agencywide strategy including, at a minimum, coordination across EPA offices, as well as with other federal agencies, to identify and fill data gaps, and providing guidance that describes alternative sources of toxicity information. EPA agreed with the first two recommendations and partially agreed with the third.

View GAO-13-369. For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

The Environmental Protection Agency (EPA) has not conducted a recent evaluation of demand for Integrated Risk Information System (IRIS) toxicity assessments with input from users inside and outside EPA. Specifically, EPA issued a needs assessment report in 2003, which estimated that 50 new or updated IRIS toxicity assessments were needed each year to meet users' needs. However, GAO did not find sufficient support for the estimate. In addition, IRIS Program officials recognize that the 2003 estimate does not reflect current conditions, but the agency does not plan to perform another evaluation of demand. Without a clear understanding of current demand for IRIS toxicity assessments, EPA cannot adequately measure the program's performance; effectively determine the number of IRIS toxicity assessments required to meet the needs of IRIS users; or know the extent of unmet demand.

The IRIS Program's chemical nomination and selection process, which the agency uses to gauge interest in the IRIS Program from users inside and outside of EPA, may not accurately reflect current demand for IRIS toxicity assessments. The 75 chemicals that were nominated in response to EPA's most recent 2011 nomination period may not reflect demand for a number of reasons. For example, given the long-standing challenges the IRIS Program has had in routinely starting new assessments, according to some EPA IRIS users, they chose not to nominate new chemicals for assessment. Also, EPA has not clearly articulated how the IRIS Program applies the criteria it uses to prioritize the selection of chemicals for IRIS toxicity assessment—including how it determines the circumstances under which an IRIS toxicity assessment is or is not needed. Consequently, for chemicals that were nominated but not selected for assessment, it is not clear how many, if any, were excluded from consideration because they did not meet the IRIS Program's selection criteria because the IRIS Program determined that an IRIS toxicity assessment was not needed—or, alternatively, if they were not selected due to resource constraints or other reasons.

EPA has not implemented an agencywide strategy for addressing the unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current. Specifically, EPA does not have a strategy for identifying and filling data gaps that would enable it to conduct IRIS toxicity assessments for nominated chemicals that are not selected for assessment because sufficient data from health studies are not available. IRIS Program officials stated that no agencywide mechanism exists for EPA to ensure that chemicals without sufficient scientific data during one nomination period will have such information by the next nomination period or even the one after that. These officials acknowledged that better coordination across EPA and with other federal agencies could help address the issue. EPA also does not have agencywide guidance for addressing unmet needs when IRIS toxicity assessments are not available, applicable, or current. In the absence of agencywide guidance, officials from select EPA offices stated that they used a variety of alternatives to IRIS toxicity assessments to meet their needs, including using toxicity information from other EPA offices or other federal agencies.

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
Cal/EPA	California Environmental Protection Agency
CAS	Chemical Abstracts Service
DIPE	diisopropyl ether
EPA	Environmental Protection Agency
ETBE	ethyl tertiary butyl ether
GPRA	Government Performance and Results Act of 1993
IRIS	Integrated Risk Information System
MTBE	methyl tertiary butyl ether
OMB	Office of Management and Budget
PART	Program Assessment Rating Tool
PPRTV	Provisional Peer Reviewed Toxicity Value
TAME	tertiary amyl methyl ether
TBA	tertiary butyl alcohol

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Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

May 10, 2013

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

Dear Madam Chairman:

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS)—a database integral to the agency's mission of protecting human health and the environment—contains EPA's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment.[1] EPA created the IRIS database in 1985 to help it develop consensus opinions within the agency about the health effects from chronic exposure to chemicals and currently includes information on more than 550 chemicals. The health effects information in the IRIS database—referred to as IRIS toxicity assessments—provides fundamental scientific information EPA needs to develop human health risk assessments on particular chemicals.[2] These human health risk assessments, in turn, provide the foundation for EPA's risk management decisions, such as whether EPA should establish air and water quality standards to protect the public from exposure to particular toxic chemicals. EPA's IRIS Program develops new IRIS toxicity assessments and, as needed, updates information in existing IRIS toxicity assessments contained in the IRIS database.[3] The importance of

[1]Under its IRIS Program, EPA (1) identifies a chemical's toxicity, or hazardous properties, which are the potential noncancer and cancer human health effects of exposure to a chemical, and (2) assesses the dose-response relationship between exposure to a chemical and the resultant health effects, which describes the magnitude of hazard for potential noncancer effects and increased cancer risk.

[2]A human health risk assessment characterizes the nature and magnitude of health risks to humans from exposure to chemical contaminants that may be present in the environment. IRIS toxicity assessments are used along with other information to prepare human health risk assessments. Toxicity represents the degree to which a chemical is harmful. In this report, the terms toxicity and hazard are used synonymously.

[3]According to IRIS Program officials, new assessments are added to the IRIS database after an evaluation of the available scientific literature, and existing assessments are revised based on an evaluation of new studies that have been published since the original assessment was completed.

EPA's IRIS Program has increased over time as EPA program offices and regions have increasingly relied on IRIS toxicity assessments in making environmental protection and risk management decisions. In addition, state and local environmental programs, as well as some international regulatory bodies, rely on IRIS toxicity assessments in managing their environmental protection programs.

Although the information in the IRIS database is a critical primary component of EPA's capacity to support scientifically sound decisions, policies, and regulations, we have reported previously on EPA's difficulty producing timely, credible IRIS toxicity assessments. Specifically, in March 2008, we reported that the IRIS database was at serious risk of becoming obsolete because EPA had not been able to (1) keep its existing assessments current or (2) complete assessments of the most important chemicals of concern.[4] Further, we reported that because EPA staff time continued to be dedicated to completing ongoing assessments, EPA's ability to both keep existing assessments (at that time more than 540) up to date and initiate new assessments was limited. We also reported that, although the number of program staff quadrupled from 8 to 37 and program funding increased from $1.7 million to $9.6 million for fiscal years 2000 to 2007, EPA had on average completed about five assessments annually during this period. For these and other reasons, in 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.[5] In response to our 2008 report and subsequent high-risk designation, EPA revised its IRIS toxicity assessment process in May 2009.

In December 2011, we reported, among other things, that EPA's initial productivity gains under the May 2009 revised process had not been sustained and that the agency continued to face challenges in implementing the IRIS Program.[6] For example, from May 2009 through

[4]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).

[5]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: Jan. 22, 2009). This high-risk area addresses EPA's implementation of the IRIS Program, as well as implementation of the Toxic Substances Control Act.

[6]GAO, *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program*, GAO-12-42 (Washington, D.C.: Dec. 9, 2011).

September 2011, EPA completed 20 IRIS toxicity assessments—more than doubling the total productivity it achieved during the two fiscal years immediately preceding the adoption of the revised process. However, 16 of these toxicity assessments were completed in the first year and a half of implementing the revised process, and productivity fell sharply during fiscal year 2011, with EPA issuing 4 IRIS toxicity assessments. We reported that, even if EPA were to overcome the significant productivity difficulties it has experienced in recent years and met its goal of completing 40 assessments in fiscal year 2012, it was not clear that this level of productivity would meet the needs of IRIS users inside and outside EPA.[7] We noted that beyond EPA's ongoing assessments, and some that were on hold, the demand for additional IRIS toxicity assessments was unclear.

With tens of thousands of chemicals listed with EPA for commercial use in the United States, and about 1,000 new chemicals listed for commercial use each year, demand for IRIS toxicity assessments is potentially very high. In this context, you asked us to review the effectiveness of EPA's implementation of its IRIS toxicity assessment process. Our objectives were to determine the extent to which (1) EPA has evaluated demand for IRIS toxicity assessments from users inside and outside EPA; (2) EPA's process for nominating and selecting chemicals for IRIS toxicity assessment accurately reflects demand; and (3) EPA has implemented a strategy for addressing any unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current.

To determine the extent to which EPA has evaluated demand for IRIS toxicity assessments, we reviewed EPA's 2003 evaluation of demand for IRIS toxicity assessments. We also interviewed officials at the National Center for Environmental Assessment, which manages the IRIS Program and develops IRIS toxicity assessments (henceforth IRIS Program officials). Specifically, we interviewed these officials to determine whether they had conducted other evaluations of demand since 2003, how they derived the 2003 estimate, and whether that estimate reflects current conditions. We reviewed the report to determine its basis for estimating

[7]For purposes of this report, "IRIS users" represent EPA program offices and regions and non-EPA entities that submit chemical nominations to the IRIS Program. Such non-EPA entities include other federal agencies, White House offices, and the public.

IRIS demand and the number of assessments it needed to conduct in order to meet demand.

To determine the extent to which EPA's process for nominating and selecting chemicals for IRIS toxicity assessments accurately reflects current demand, we reviewed data provided by the IRIS Program and from the IRIS Program's website on the number of IRIS toxicity assessments completed annually from fiscal years 2002 through 2012. In addition, we analyzed all chemical nomination forms submitted by EPA program offices and regions to the IRIS Program from 2005, 2007, and 2011—which were the last three times that the IRIS Program solicited nominations for new and updated IRIS toxicity assessments.[8] For additional perspective on user needs, we reviewed non-EPA IRIS users' chemical nomination forms from 2011. In addition, we reviewed the IRIS Program's processes for soliciting nominations and selecting chemicals for toxicity assessments, including the agency's selection criteria. We also reviewed agency guidance and interviewed IRIS Program officials to better understand the chemical nomination and selection process.

To determine the extent to which EPA has implemented a strategy for addressing any unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current, we reviewed the IRIS Program's efforts to analyze IRIS user chemical nominations. For context, we interviewed IRIS Program officials. For additional perspective, we interviewed officials using a standard set of questions from a nonprobability sample of three EPA program offices and one region: the Office of the Administrator, the Office of Water, the Office of Solid Waste and Emergency Response, and EPA's Region 2.[9] We

[8]According to IRIS Program documents, the IRIS Program solicits opinions from EPA offices, other federal agencies, and the public on an annual basis. However, since 2004, the IRIS Program has solicited nominations from IRIS users three times: in 2004, 2006, and 2010. In their nomination forms, IRIS users send EPA the names of chemicals and the reasons for requesting that IRIS toxicity assessments be developed or updated, among other information. In 2004, the IRIS Program solicited nominations only from EPA program offices and regions. In 2006 and 2010, the IRIS Program solicited nominations from all IRIS users. The IRIS Program refers to these nomination periods as being for fiscal years 2005, 2007, and 2011, which are the years we also refer to in this report.

[9]We interviewed officials both at the Office of Policy and the Office of Children's Health Protection, which are suboffices within the Office of the Administrator. We also received a written response from the Office of Underground Storage Tanks, which is a suboffice within the Office of Solid Waste and Emergency Response.

selected these program offices and region because they submitted 78 percent of the chemical nominations to the IRIS Program during the period we reviewed—2005, 2007, and 2011. These offices and region ranked the highest in terms of the number of chemical nominations submitted and, in some cases, nominated chemicals more than once during different nomination years. Because this is a nonprobability sample, it is not generalizable to all EPA program offices and regions, but it can provide illustrative examples of the experience of those EPA program offices and one region that nominated 78 percent of chemical nominations for IRIS toxicity assessment during the period we reviewed. For example, we received information from officials from these offices about how EPA program offices and one region nominate chemicals for IRIS toxicity assessment, how the IRIS Program meets the needs of these offices and region over the course of nomination periods, and what alternative toxicity assessments these offices and region turn to when IRIS toxicity assessments are not available.

Separately from our nonprobability sample, we also interviewed officials from the Office of Pollution Prevention and Toxics, within the Office of Chemical Safety and Pollution Prevention, because it did not nominate any chemicals for IRIS toxicity assessment for any of the last three nomination periods. We did not evaluate the scientific content or quality of IRIS toxicity assessments. A more detailed description of our scope and methodology can be found in appendix I. For a summary of approaches used by selected EPA program offices and regions to address their unmet needs regarding IRIS toxicity assessments, see appendix II.

We conducted this performance audit from April 2012 to May 2013 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.

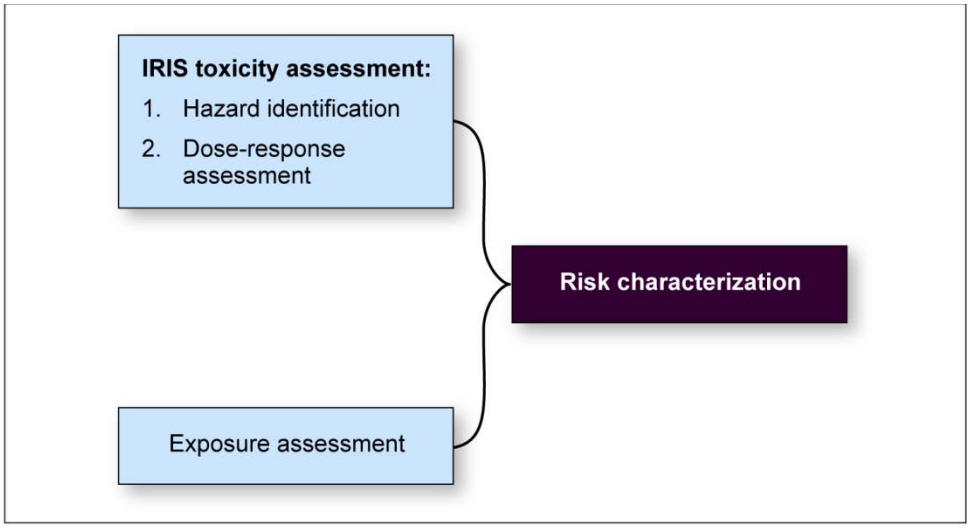
Background

This section discusses EPA's human health risk assessment and risk management practices and its processes for soliciting nominations and selecting chemicals for new and updated IRIS toxicity assessments.

EPA's Human Health Risk Assessment and Risk Management Practices

EPA's ability to effectively implement its mission of protecting public health and the environment is critically dependent on credible and timely assessments of the risks posed by chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations under a variety of statutes, such as the Safe Drinking Water Act, the Toxic Substances Control Act, and the Clean Air Act. EPA assesses the human health risks of chemicals using a model from the National Academies.[10] This model includes four components: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization (see fig. 1).

Figure 1: National Academies' Risk Assessment Model Used by EPA



Sources: GAO presentation of the risk assessment component of the National Academies' risk assessment and risk management model used by EPA.

[10]The National Academies comprise four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council. EPA uses the model that was initially outlined in the 1983 National Academies' National Research Council, *Risk Assessment in the Federal Government* (commonly known as the Red Book). The National Research Council's subsequent 2009 report presented by the National Academies in *Science and Decisions: Advancing Risk Assessment* (Washington, D.C.: The National Academies Press, 2009) reiterated this process. This publication is also known as the Silver Book.

For some, but not all chemicals, EPA conducts the first two sequential analyses of a human health risk assessment—that is, the hazard identification and dose-response assessment—under its IRIS Program. Taken together, these two steps are commonly referred to as IRIS toxicity assessments. EPA's IRIS Program—managed by EPA's National Center for Environmental Assessment within the Office of Research and Development—develops new IRIS toxicity assessments and updates existing IRIS toxicity assessments if revisions are warranted on the basis of newly published peer-reviewed studies.

EPA program offices and regions combine information from IRIS toxicity assessments with the results from chemical exposure assessments to characterize risk, which provides information on the probability that the adverse effects described in hazard identification will occur under the conditions described in the exposure assessment.[11] These four steps—hazard identification, dose-response assessment, exposure assessment, and risk characterization—comprise human health risk assessments, which EPA offices use to make risk management decisions. Risk management, as opposed to risk assessment, involves integrating the risk assessment information with other information—such as economic information on the costs and benefits of mitigating a risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders—to determine whether the health risks identified in a chemical risk assessment warrant EPA taking regulatory or other risk management actions.

A typical IRIS toxicity assessment contains a qualitative hazard identification and quantitative dose-response assessment. The qualitative hazard identification identifies noncancer and cancer health effects that may be caused by exposure to a given chemical. For cancer effects, EPA qualitatively describes the carcinogenic potential of a chemical in a narrative that includes selecting a weight-of-evidence descriptor, ranging

[11]Exposure represents the magnitude, frequency, and duration of contact with a chemical.

from “carcinogenic to humans” to “not likely to be carcinogenic to humans.”[12]

Following hazard identification, a dose-response assessment is conducted for both noncancer and cancer effects assuming adequate data are available. A quantitative dose-response assessment characterizes the quantitative relationship between the exposure to a chemical and the resultant health effects. The quantitative dose-response assessment relies on experimental data, primarily from either animal (toxicity) or human (epidemiology) studies. The noncancer dose-response assessment may include the following:

- an oral reference dose—an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily oral exposure to a chemical that is likely to be without an appreciable risk of deleterious effects during a person’s lifetime—expressed in terms of milligrams per kilogram per day, and
- an inhalation reference concentration—an estimate (with uncertainty spanning perhaps an order of magnitude) of the continuous inhalation exposure to a chemical that is likely to be without an appreciable risk of deleterious effects during a person’s lifetime—expressed in terms of milligrams per cubic meter.

According to EPA officials, the quantitative cancer dose-response assessment typically includes estimates of a chemical’s carcinogenic potency by both the oral and inhalation routes of exposure. For oral exposures, the “oral slope factor” is an estimated 95 percent upper bound on the increased cancer risk per increased unit of exposure (in mg/kg-day) to a chemical over a lifetime. For inhalation exposures, the “inhalation unit risk” is an estimated 95 percent upper bound on the increased cancer risk per increased unit of exposure (in $\mu g/m^3$ in air) to a chemical over a lifetime. The toxicity values derived in both noncancer and cancer dose-response assessments—that is, the oral reference dose, inhalation reference concentration, oral slope factor, and inhalation unit risk—are often referred to as IRIS values.

[12]According to IRIS Program officials, one of the following five descriptors is selected based on the extent of human and animal data available: (1) “carcinogenic to humans,” (2) “likely to be carcinogenic to humans,” (3) “suggestive evidence of carcinogenic potential,” (4) “inadequate information to assess carcinogenic potential,” or (5) “not likely to be carcinogenic to humans.”

IRIS toxicity assessments estimate the potential health effects of lifelong (chronic) exposure to chemicals. According to the Office of Management and Budget (OMB), the IRIS Program is the only federal program that provides qualitative and quantitative assessments of both cancer risks and noncancer effects of chemicals.[13] In addition, according to EPA's Human Health Risk Assessment Strategic Research Action Plan, no other federal health assessment program has (1) a similar mission and scope or (2) internal and external peer review processes that are as rigorous.[14] Specifically, the IRIS toxicity assessment process includes internal EPA review; two interagency reviews by other federal agencies and White House offices (e.g., OMB); public review and comment; and a rigorous, independent, external peer review.[15] However, IRIS is not the only source of toxicity information available to EPA program offices and regions. For many chemicals, IRIS toxicity assessments are not available, applicable, or current; therefore, in some cases, EPA program offices and regions rely on toxicity information from other sources. Other sources include, but are not limited to the following:

- Toxicological Profiles and Minimal Risk Levels. The Agency for Toxic Substances and Disease Registry (ATSDR)—a federal public health agency of the U.S. Department of Health and Human Services—prepares Toxicological Profiles for hazardous substances in response to statutory requirements under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund.[16] ATSDR's Toxicological Profiles typically evaluate three different exposure durations—acute (14 days or less), intermediate (15-364 days), and chronic (365 days or more). According to ATSDR's website, during the development of toxicological profiles, if the agency determines that reliable and sufficient data exist to identify the specific health effects that result from exposure to a hazardous substance, the agency will derive Minimal Risk Levels. Minimal Risk

[13]OMB, Fiscal Year 2006 Program Assessment Rating Tool (PART) assessment of EPA's Human Health Risk Assessment Program.

[14]EPA Office of Research and Development, *Human Health Risk Assessment Strategic Research Action Plan 2012-2016*, EPA 601/R-12/007, June 2012.

[15]EPA decides the type of independent peer review an IRIS toxicity assessment will undergo. The peer reviews are conducted by (1) a peer review panel assembled by an EPA contractor, (2) EPA's Science Advisory Board, or (3) the National Academies.

[16]42 U.S.C. § 9604 (i)(3).

Levels are an ATSDR estimate of daily human exposure to a hazardous substance at or below which that substance will likely not pose a measurable risk of adverse noncancerous effects—such as neurological, respiratory, and reproductive effects—over a specified time period. Minimal Risk Levels are substance-specific estimates, which according to ATSDR's website are intended to serve as screening levels used by ATSDR health assessors and others to identify contaminants and potential health effects that may be of concern at hazardous waste sites. According to ATSDR's website, for non-carcinogens, ATSDR adopted a practice similar to that of EPA's oral reference dose and inhalation reference concentration. Unlike EPA's IRIS Program, however, ATSDR does not develop quantitative cancer toxicity values.[17]

- Provisional Peer Reviewed Toxicity Values (PPRTV). PPRTVs are toxicity values that EPA's National Center for Environmental Assessment ordinarily prepares on an ongoing basis to support cleanup decisions at Superfund sites. PPRTVs are derived for chronic and subchronic exposure durations in instances where IRIS toxicity assessments are not available, and are sometimes derived for subchronic exposure durations when an IRIS toxicity assessment on chronic exposure exists.[18] Also, while PPRTVs receive internal review by EPA scientists and external peer review by independent scientific experts, they differ from IRIS values in that they do not undergo the same rigorous process of peer review and public participation.
- California Environmental Protection Agency (Cal/EPA) Toxicity Assessments. Cal/EPA prepares toxicity assessments, which are peer-reviewed and provide quantitative values for both cancer and noncancer effects. According to Cal/EPA's website, Cal/EPA's Office of Environmental Health Hazard Assessment is responsible for developing and providing managers in state and local government agencies with toxicological and medical information relevant to managing risks and making decisions involving public health. The office develops procedures and practices for performing health risk assessments for those involved in environmental health issues, including policymakers, businesspeople, members of community

[17]Toxicity values are a numerical expression of a substance's exposure-response relationship that is used in risk assessments.

[18]The specific definition for each exposure duration category may vary depending on the source of the toxicity value being used. In general, subchronic is used to describe periods of repeated exposure by the oral, dermal, or inhalation route for more than 30 days up to approximately 90 days in laboratory animals or 10 percent of the life span in humans.

groups, news reporters, and others with an interest in the potential health effects of toxic chemicals. Specifically, the office publishes "A Guide to Health Risk Assessment," which outlines in a generalized form the four risk assessment steps in the National Academies model described above.

EPA's Process for Soliciting Nominations and Selecting Chemicals for New and Updated IRIS Toxicity Assessments

EPA's IRIS Program invites IRIS users to submit nominations for chemicals to be considered for new or updated IRIS toxicity assessments. The IRIS Program solicits nominations from EPA program offices and regions and other federal agencies by issuing a memorandum and solicits nominations from the public by publishing a solicitation in the Federal Register. Generally, the IRIS Program includes a list of criteria that the agency plans to use to prioritize chemicals for selection as part of the solicitation. The IRIS Program included the following criteria in its most recent 2011 nomination solicitation: (1) potential public health impact; (2) EPA statutory, regulatory, or program-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change the current IRIS information; (4) interest to other governmental agencies or the public; (5) availability of other scientific assessment documents that could serve as a basis for development of an IRIS toxicity assessment; and (6) other factors such as widespread exposure to the chemical.[19]

After receiving nominations, IRIS Program staff conducts a preliminary literature search to determine whether there is sufficient information to develop toxicity values for the chemicals nominated. According to IRIS Program officials, the purpose of the literature search is to determine if there is sufficient scientific data from health studies that could be used to develop new IRIS toxicity assessments or update existing assessments. Following the preliminary literature search, the IRIS Program separates the nominated chemicals into two groups: (1) those for which health studies are available and could be used to develop or update an IRIS toxicity assessment and (2) those for which there are not enough data to develop an assessment. Next, according to IRIS Program officials, they provide EPA program offices and regions with an annotated list of chemical nominations that specifies the degree to which health studies are available for each chemical and ask for feedback regarding which

[19]The IRIS Program also included these criteria, with slight variation, for the 2005 and 2007 nomination solicitations.

chemicals are the highest priorities. After considering such feedback, the IRIS Program selects chemicals for new or updated IRIS toxicity assessments. The IRIS chemical nomination and selection process culminates in the publication in the Federal Register of the IRIS agenda—which contains, among other things, a list of chemicals for which the IRIS Program intends to initiate IRIS toxicity assessments, as well as a list of ongoing IRIS toxicity assessments. For example, the most recent IRIS agenda, published in May 2012, lists 15 IRIS toxicity assessments—with planned start dates ranging from fiscal year 2012 to fiscal year 2014—as well as a list of the 52 IRIS toxicity assessments that were already under way.[20] According to the IRIS agenda, EPA considers its own resources and the availability of guidance, guidelines, and policy decisions in deciding when to start assessments for the selected chemicals.

EPA's Most Recent Evaluation of Demand for IRIS Toxicity Assessments Is a Decade Old

EPA has not done a recent evaluation of demand for IRIS toxicity assessments with input from users inside and outside the agency. EPA conducted its most recent evaluation of demand for IRIS toxicity assessments in September 2003, which included input from users inside and outside EPA, but it has not performed a similar review since that time. Without a clear understanding of current demand for IRIS toxicity assessments, EPA cannot adequately measure the program's performance; effectively determine the number of IRIS assessments required to meet the statutory, regulatory, and programmatic needs of IRIS users; or know the extent to which unmet demand exists.

EPA conducted its last evaluation of demand in 2003 at the request of Congress. In September 2000, due to concerns that EPA and state regulators were relying on potentially outdated scientific information, the Senate Committee on Appropriations requested that EPA conduct a needs assessment with public input to determine the need for increasing the annual rate of new and updated IRIS toxicity assessments.[21] In response to the Senate request, EPA conducted a needs assessment—the results of which are discussed in its September 2003 report, *Needs*

[20]Of the 15 IRIS toxicity assessments listed in the 2012 IRIS agenda, 7 were updates of assessments already in the IRIS database. Of the 52 IRIS toxicity assessments that were already under way, 34 were updates of assessments already in the IRIS database.

[21]S. Rep. No. 106-410 at 90 (2000).

Assessment for U.S. EPA's Integrated Risk Information System.[22] According to the report, EPA estimated that 50 new or updated IRIS toxicity assessments a year were needed to meet user needs. Specifically, EPA estimated that completing 50 assessments annually would allow the agency to routinely update existing toxicity assessments in the IRIS database, as well as respond to immediate user needs for new or updated assessments.[23] This estimate, according to the report, was based on EPA's past experience soliciting nominations from EPA program offices and regions and information obtained through a July 2001 query of EPA program offices and regions and the public that requested information on which chemicals they considered priorities for assessment.[24] However, based on our review of the report, we did not find sufficient support for the estimate. Specifically, the report did not describe how EPA's past experience or its 2001 query were used to derive the report's estimate that about 50 IRIS toxicity assessments per year were needed to meet demand. In addition, the report stated that because EPA received a small number of responses to the agency's 2001 query, it is not clear if the responses received are necessarily representative of the broad range of IRIS users.

Although EPA's 2003 needs assessment is a decade old, EPA officials told us that the agency does not currently have plans to perform another evaluation of demand for the IRIS Program and that, due to changing conditions over the last 10 years the 2003 evaluation was not applicable to current conditions. IRIS officials stated that the IRIS Program's primary mechanism for monitoring the needs of EPA's program and regional offices at present is to perform outreach with EPA program offices and regions, such as holding quarterly meetings with program office representatives from each EPA program office and holding internal scoping meetings with representatives from EPA program offices and regions for certain chemicals. In response to our questions regarding current demand, IRIS Program officials told us that the annual need for

[22]EPA, *Needs Assessment for U.S. EPA's Integrated Risk Information System* (Washington, D.C.: September 2003).

[23]For example, the report called for developing a schedule for updating potentially outdated assessments at least once every 10 years and updating some every 5 years.

[24]EPA received responses from 10 EPA program offices, 7 EPA regions, and 22 public and private organizations. Non-EPA respondents included the U.S. Army, state agencies, industries, trade organizations, public interest and nonprofit organizations.

IRIS toxicity assessments may likely be in the hundreds, though officials did not describe how they derived this number.

We have previously reported on the need for EPA to comprehensively analyze its workload and workforce to effectively carry out its strategic goals and objectives. Specifically, in July 2011, we reported that the agency did not have a workload analysis to help determine the optimal numbers and distribution of staff among its laboratory enterprise—which is responsible for providing the scientific research, technical support, and analytical services that underpin its policies and regulations.[25] In addition, we have previously reported that, in developing new initiatives, agencies can benefit from following leading practices for strategic planning.[26] Congress enacted the Government Performance and Results Act (GPRA) in 1993 to improve efficiency and accountability of federal programs.[27] We have reported that these requirements also can serve as leading practices for strategic planning at lower levels within federal agencies, such as planning for individual divisions, programs, or initiatives.[28] Of these leading practices, it is particularly important for agencies to define strategies that address management challenges that threaten their ability to meet long-term goals—including a description of the resources needed to meet established goals. Without an evaluation of current demand for

[25]GAO, *Environmental Protection Agency: To Better Fulfill Its Mission, EPA Needs a More Coordinated Approach to Managing Its Laboratories*, GAO-11-347 (Washington, D.C.: July 25, 2011).

[26]GAO, *Environmental Protection: EPA Should Develop a Strategic Plan for Its New Compliance Initiative*, GAO-13-115 (Washington, D.C.: Dec. 10, 2012); GAO, *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

[27]We have reported in the past that, taken together, the strategic planning elements established under GPRA and associated OMB guidance, and practices identified by GAO provide a framework of leading practices in federal strategic planning. For example, see GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1, 1996); GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures*, GAO-03-143 (Washington, D.C.: Nov. 22, 2002); and GAO, *Managing for Results: Strengthening Regulatory Agencies' Performance Management Practices*, GAO/GGD-00-10 (Washington, D.C.: Oct. 28, 1999).

[28]Leading practices in federal strategic planning include defining mission and goals, defining strategies that address management challenges and identify resources needed to achieve goals, ensuring leadership involvement and accountability, involving stakeholders, coordinating with other federal agencies, and developing and using performance measures.

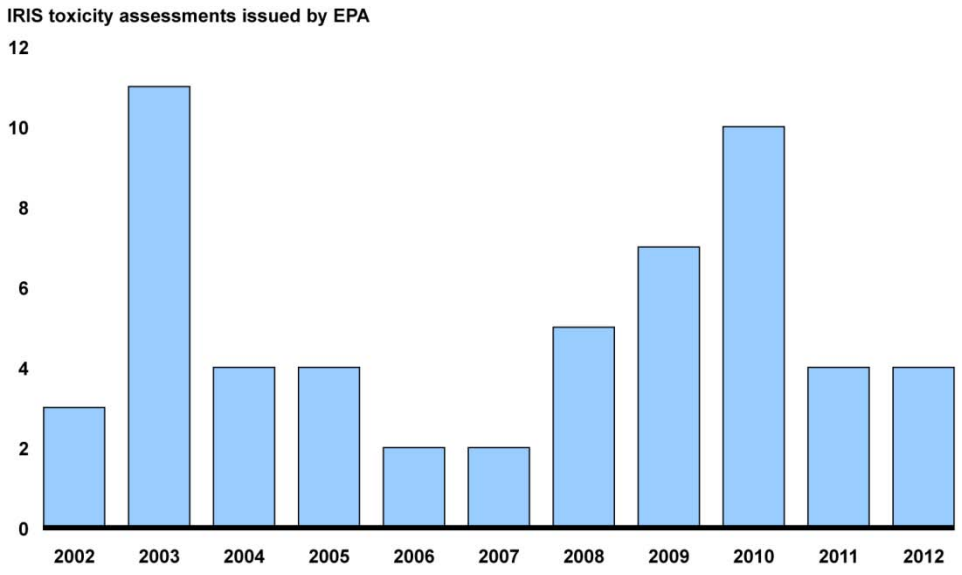
IRIS toxicity assessments that takes into account resource constraints, the IRIS Program risks not being able to develop a plan that lays out realistic goals based on current conditions.

EPA's Chemical Nomination and Selection Process May Not Accurately Reflect Current Demand for IRIS Toxicity Assessments

The IRIS Program's chemical nomination and selection process, which the agency uses to gauge interest in the IRIS Program from users inside and outside of EPA, may not accurately reflect current demand for IRIS toxicity assessments. Our analysis of IRIS Program data indicates that the IRIS Program received nominations for 75 chemicals from EPA and non-EPA IRIS users in response to its most recent 2011 nomination period. However, the 75 chemicals received for the 2011 nomination period may not accurately reflect current demand for IRIS toxicity assessments. As about 1,000 new chemicals are listed for commercial use each year, demand for IRIS toxicity assessments is potentially very high, but the number of chemicals nominated may either overstate or understate actual demand. For example, it is not clear how many chemicals IRIS users did not nominate due to concerns that the IRIS toxicity assessment would not be completed in a timely manner. Officials from EPA's Office of Water told us that even though they may need an IRIS toxicity assessment, they sometimes develop their own chemical toxicity assessments to meet their urgent or time-critical needs, such as meeting statutory deadlines.

Also, given the long-standing challenges the IRIS Program has had in routinely starting new assessments, according to some EPA IRIS users, they chose not to nominate new chemicals for assessment and instead nominated chemicals that were already listed on the IRIS agenda as under way. For example, according to officials from EPA's Office of Solid Waste and Emergency Response, due to the large number of chemicals already listed on the IRIS agenda and the IRIS Program's limited resources, in some cases, they reiterated support for chemicals that were already listed on the agenda as under way rather than nominate new chemicals. IRIS Program officials told us that, although EPA program offices and regions and other IRIS users would like to see the IRIS Program produce more IRIS toxicity assessments each year, current resources constrain the speed at which the IRIS Program can complete them. For example, EPA issued 4 IRIS toxicity assessments in fiscal year 2012 (see fig. 2). EPA has issued from 2 to 11 IRIS toxicity assessments annually since fiscal year 2002.

Figure 2: Number of IRIS Toxicity Assessments EPA Issued, Fiscal Years 2002 to 2012



Source: GAO analysis of EPA data.

Note: EPA's Integrated Risk Information System (IRIS) contains toxicity assessments that provide fundamental scientific information EPA needs for assessing the risks chemicals pose to human health (i.e., develop human health risk assessments).

In addition, as we reported in December 2011, EPA fell short of its productivity goal in fiscal year 2011—completing 4 of the 20 IRIS toxicity assessments it had originally planned to complete that year.[29] Similarly, in completing 4 IRIS toxicity assessments in fiscal year 2012, EPA fell short of its fiscal year 2012 goal of completing 40 assessments. Given the challenges the IRIS Program has experienced issuing IRIS assessments, for many chemicals, the IRIS Program is not fulfilling the goal of providing a common scientific foundation for decision making within EPA programs—which is the stated purpose of an IRIS toxicity assessment according to EPA's strategic planning document for human health risk assessment research.[30] Instead, because the IRIS Program has been

[29]GAO-12-42. EPA originally planned to issue 20 IRIS toxicity assessments in fiscal year 2011: 4 were issued, 1 was dropped, 2 were given "TBD"—to be determined—completion dates, and 13 were added to the fiscal year 2012 completion goal, bringing it to 40 assessments.

[30]EPA Office of Research and Development, *Human Health Risk Assessment Strategic Research Action Plan 2012-2016*, EPA 601/R-12/007, June 2012.

unable to keep up with demand for IRIS toxicity assessments, the agency had to prioritize its selection of chemicals for IRIS toxicity assessment.

Furthermore, EPA has not clearly articulated under what circumstances IRIS toxicity assessments are not needed, and the IRIS Program's process for prioritizing chemicals does not provide clarity regarding why specific chemicals are selected for assessment and others are not.[31] According to IRIS Program officials, some chemicals may not need IRIS toxicity assessments. While the IRIS Program has developed criteria that are used to prioritize its selection of chemicals for IRIS toxicity assessment, it is not clear how it applies these criteria—including how it determines the circumstances under which program offices and regions may or may not need an IRIS toxicity assessment. As discussed earlier, the IRIS Program published its chemical selection criteria when it solicited nominations for IRIS toxicity assessment for its 2011 nomination period. However, in announcing that it had selected 15 IRIS toxicity assessments in its 2012 IRIS agenda, the IRIS Program did not explain and has not published information on, how the agency applied its selection criteria. OMB's implementing guidance for internal control requirements for federal agencies emphasizes the need for agencies to develop policies that ensure the effectiveness and efficiency of their operations and, as part of that, emphasizes that information related to guidance should be communicated to relevant personnel at all levels within an organization and outside the agency in a relevant, reliable, and timely manner.[32] In August 2012, IRIS Program officials told us that they were working to develop a better description of the nomination and selection process that will clarify how the agency applied the six criteria but, as of March 2013, had not done so. Consequently, for the chemicals that were nominated during the most recent 2011 nomination period, but not selected, it is not clear how many, if any, were excluded from consideration because they did not meet the IRIS Program's selection criteria, because the IRIS Program determined that an IRIS toxicity assessment was not needed—

[31]As discussed earlier, EPA's IRIS Program was originally created to develop consensus across the Agency regarding health effects resulting from chronic exposures to chemicals. IRIS Program officials have recently told us that IRIS no longer formally requires Agency consensus for its assessments, but consensus is still sought and often achieved through the existing Agency review process.

[32]OMB, *Memorandum to the Chief Financial Officers, Chief Operation Officers, Chief Information Officers, and Program Managers*, December 21, 2004.

or, alternatively, if they were not selected because of resource constraints or other reasons.

EPA Has Not Implemented an Agencywide Strategy for Addressing Unmet Needs for IRIS Toxicity Assessments

EPA has not implemented an agencywide strategy for addressing the unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current. Specifically, EPA does not have (1) a strategy for identifying and filling data gaps that would enable it to conduct IRIS toxicity assessments for nominated chemicals that were not selected for IRIS toxicity assessment due to insufficient data and (2) agencywide guidance for addressing unmet needs when IRIS toxicity assessments are not available, applicable, or current—which is consistent with findings reported recently by EPA's Inspector General and Science Advisory Board.

EPA Does Not Have a Strategy for Identifying and Filling Data Gaps

EPA does not have a strategy for identifying and filling data gaps that would enable it to conduct IRIS toxicity assessments for nominated chemicals that were not selected for IRIS toxicity assessment because of insufficient scientific data from health studies. As discussed earlier, as part of the IRIS chemical nomination and selection process, IRIS Program officials separate nominated chemicals into two groups: (1) those for which sufficient scientific data from health studies exist that could be used to develop or update an IRIS toxicity assessment and (2) those for which sufficient data do not exist for developing an assessment. For example, as a part of its most recent 2011 nomination period, the IRIS Program dropped 11 of the 75 chemicals nominated from consideration because sufficient scientific data from health studies were not available to develop an IRIS toxicity assessment.[33] One of the chemicals dropped from consideration due to insufficient data was nominated in 2005, 2007, and 2011.[34] The chemical—iso-octane, or 2,2,4-trimethylpentane, which is a constituent of motor fuels—was nominated, according to officials with EPA's Office of Underground Storage Tanks, within the Office of Solid Waste and Emergency Response, so that the office can determine

[33]As discussed earlier, the IRIS Program has not published information on how the agency applied its selection criteria but, upon request, provided us with information regarding chemicals dropped from consideration due to insufficient data.

[34]2,2,4-Trimethylpentane (iso-octane).

appropriate cleanup levels for leaking underground storage tank sites.[35] Moreover, Section 1505 of the Energy Policy Act of 2005 directed the EPA Administrator to, among other things, conduct a study on the effects on public health (e.g., the effects on children, pregnant women, minority or low-income communities, and other sensitive populations) of increased use of iso-octane and six other fuel additives as substitutes for methyl tertiary butyl ether (MTBE).[36]

While the IRIS Program prepared and issued an IRIS toxicity assessment that contained the qualitative hazard identification description of iso-octane in 2007, it was unable to derive quantitative IRIS values due to insufficient data on the chemical's health effects in humans. According to EPA's 2007 IRIS assessment of iso-octane, the IRIS Program did not develop quantitative estimates of noncancer and cancer risks because

[35]According to EPA's website, 2,2,4-trimethylpentane is released to the environment through the manufacture, use, and disposal of products associated with the petroleum and gasoline industry. During an accident, 2,2,4-trimethylpentane penetrated the skin of a human which caused necrosis of the skin and tissue in the hand and required surgery. No other information is available on the acute (short-term) effects in humans. Irritation of the lungs, edema, and hemorrhage has been reported in rodents acutely exposed by inhalation and injection. No information is available on the chronic (long-term), reproductive, developmental, or carcinogenic effects of 2,2,4-trimethylpentane in humans. Kidney and liver effects have been observed in rats chronically exposed via gavage (experimentally placing the chemical in the stomach) and inhalation.

[36]42 U.S.C. § 7545(b)(4). These substances are (1) ethyl tertiary butyl ether (ETBE); (2) tertiary amyl methyl ether (TAME); (3) diisopropyl ether (DIPE); (4) tertiary butyl alcohol (TBA); (5) ethanol; (6) iso-octane (2,2,4-trimethylpentane); and (7) alkylates. According to EPA's website, MTBE is a fuel additive made by combining methanol and isobutylene and has been used since 1979 in the United States as an octane-enhancing replacement for lead. According to the website, the use of MTBE in gasoline sold in the United States has virtually ceased in recent years. According to IRIS Program officials, ETBE, TAME, DIPE, TBA, and ethanol are currently on the IRIS agenda in the draft development step. The ETBE assessment is being revised because important new data became available after the external peer review. New schedules for ETBE and TBA were posted on the IRIS website in February 2013. Taking into account the complexity of the ethanol dataset, IRIS Program officials told us that they are considering various approaches to conducting the ethanol assessment and will revisit the priority of the ethanol assessment in fiscal year 2013. Alkylates were added to the IRIS agenda in 2007 but were withdrawn in 2012 because there are multiple chemicals in this class, many with limited databases. If individual alkylates with sufficient data to support an IRIS assessment are nominated in the future, the IRIS Program will consider these nominations individually.

the studies needed to support such estimates were not available.[37] Consequently, EPA's Office of Underground Storage Tanks nominated iso-octane again in 2011. In response, according to IRIS Program officials, the IRIS Program evaluated the literature since the 2007 IRIS toxicity assessment was completed and determined that no new studies were available to support development of quantitative IRIS values. Therefore, iso-octane was not considered for an IRIS toxicity assessment in 2011. According to officials with the Office of Underground Storage Tanks, they meet with IRIS Program officials regularly, and the IRIS Program is aware of their need for IRIS toxicity assessments related to these chemicals. However, should officials with the Office of Underground Storage Tanks nominate iso-octane again; EPA cannot ensure that the data needed to prepare an IRIS toxicity assessment that includes quantitative IRIS values will be available and thus, allow EPA to address this unmet need. Without quantitative IRIS toxicity values for these chemicals, it is unclear how EPA will conduct a study of these chemicals on the effects on public health as required by the Energy Policy Act of 2005.

IRIS Program officials told us that no mechanism exists for EPA to ensure that chemicals without sufficient health studies during one nomination period will have those data gaps filled by the next nomination period or even the one after that. As discussed earlier, as part of its solicitation process, the IRIS Program circulates an annotated list of chemical nominations that specifies the degree to which health studies are available for each chemical. However, IRIS Program officials told us that they do not have a process in place for filling research gaps and acknowledged that better coordination across EPA offices and with other federal research agencies, such as the Department of Health and Human Services' National Toxicology Program, could help address this issue.[38] Other agencies within the Department of Health and Human Services

[37]According to EPA's 2007 IRIS assessment on iso-octane, no subchronic or chronic oral or inhalation studies were identified that demonstrated a dose-response effect that could be used to determine the noncarcinogenic risk for iso-octane and no studies were available on the carcinogenic effects of iso-octane on which to base a cancer assessment.

[38]The National Toxicology Program was created in 1978 as a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and to provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public.

may also be a potential research source. Without such research—which is necessary to fill data gaps needed to develop IRIS toxicity assessments—the agency will be unable to ensure that it can respond to unmet EPA program offices' and regions' programmatic and public health needs in the future.

EPA Does Not Have Agencywide Guidance for Addressing Unmet Needs

EPA does not have agencywide guidance for addressing the needs of its program offices and regions when IRIS toxicity assessments are not available, applicable, or current. IRIS Program officials told us that, while there is no agencywide guidance, they work with staff from program offices and regions on a case-by-case basis to find alternatives to IRIS toxicity assessments. For example, IRIS Program officials told us that, in some cases, the Superfund Technical Support Center may be able to partially address the needs of the Office of Solid Waste or Emergency Response or regions by summarizing peer reviewed studies.[39] In other cases, they said that they may work with the Office of Solid Waste and Emergency Response, as well as other program offices and regions, to determine if a PPRTV would meet their needs.[40] In 2008, EPA's Board of Scientific Counselors recommended that EPA consider using PPRTVs as an interim measure to meet its needs for some chemicals, if an IRIS toxicity assessment was not available, and recommended that well-developed PPRTVs be considered as a source of prioritization in the development of full IRIS documents.[41] However, it is unclear how frequently program offices and regions use PPRTVs to support their statutory, regulatory, or programmatic needs—beyond their use in Superfund risk assessments—because EPA does not collect information on or have agencywide guidance on when a PPRTV, or other toxicity

[39]According to officials at the Office of Solid Waste and Emergency Response, summaries of toxicity literature are more useful than no information about toxicity of a particular chemical, but typically the summaries do not completely address the needs of the program offices of regions.

[40]PPRTVs are developed for EPA's Superfund program and, therefore, the Superfund program determines the chemicals that are nominated for development. Other EPA program offices are not included in the nomination process in the same fashion as they are for the IRIS nomination process. However, once a PPRTV is posted to the Office of Solid Waste and Emergency Response's Superfund website, they are publicly available.

[41]EPA Board of Scientific Counselors, *Review of the Office of Research and Development's Human Health Risk Assessment Program at the U.S. Environmental Protection Agency: Final Report*, April 1, 2008.

assessment, might be an appropriate alternative to an IRIS toxicity assessment. Without such guidance, EPA cannot ensure that it has a consistent approach for addressing the needs of program offices and regions when IRIS toxicity assessments are not available, applicable, or current. Under federal standards of internal control, agencies are to clearly document in writing internal control in management directives, administrative policies, or operating manuals and have it readily available for examination.[42]

In the absence of agencywide guidance, officials from the three EPA program offices and one region we met with said they used a variety of different approaches to meet their needs when an IRIS toxicity assessment was not available or current. That is, EPA offices operate in much the same way as they operated before the IRIS Program was formed to develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. For example, when IRIS toxicity assessments are not available or current, Office of Solid Waste and Emergency Response officials stated that their office refers to a hierarchy of toxicity values it established to perform human health risk assessments for Superfund sites. In 2003, the Office of Solid Waste and Emergency Response updated this hierarchy, which is intended to help risk assessors identify appropriate sources of toxicology information and lists the sources in order of preference as: (1) IRIS toxicity values, (2) PPRTVs, and (3) other EPA and non-EPA sources of toxicity information—with priority given to those sources of information that are the most current, publicly available, and peer reviewed.[43] Similarly, Region 2 officials told us that they generally follow the Office of Solid Waste and Emergency Response's hierarchy of values to guide their decisions regarding other toxicology sources to meet their needs when an IRIS toxicity assessment is not available. For example, Region 2 officials told us that there are a number of chemicals for which their office has used PPRTVs and values from ATSDR and Cal/EPA to address high–

[42]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

[43]Other non-EPA sources of toxicity information include ATSDR Minimal Risk Levels and Cal/EPA toxicity values. Although the Office of Solid Waste and Emergency Response developed the hierarchy of toxicity values specifically for the Superfund Program, officials stated that the hierarchy is generally used by all suboffices within the Office of Solid Waste and Emergency Response when IRIS toxicity assessments are not available or current.

profile issues in their region because an IRIS toxicity assessment was not available. However, the officials noted that ATSDR does not develop cancer values.

According to officials with the Office of Water—which is responsible for implementing, among other mandates, the Clean Water Act and Safe Drinking Water Act—they develop toxicity assessments for chemicals to meet statutory deadlines. For example, under the 1996 amendments to the Safe Drinking Water Act, every 5 years, EPA is to determine for at least five unregulated contaminants, including chemicals, whether regulation is warranted, considering those that present the greatest public health concern. Because of the limited number of IRIS toxicity assessments the IRIS Program can select and develop at one time, the Office of Water created the scheme to prioritize and nominate for IRIS toxicity assessment those chemicals that are the most controversial and high-profile, have a high economic impact, and will take more time and staff to complete. The Office of Water can then, according to officials from that office, develop its own assessments for chemicals that have less controversy surrounding them and take less time and staff to complete in order to meet some of its programmatic needs. Officials from the Office of Water told us that the office develops its own assessments for some chemicals because the IRIS Program would not be able to complete most of the needed toxicity assessments in time to meet the office's statutory deadlines.

Similarly, the Office of Pollution Prevention and Toxics, within the Office of Chemical Safety and Pollution Prevention, has developed its own toxicity assessments. The Office of Pollution Prevention and Toxics is responsible for implementing the Toxic Substances Control Act, which provides EPA with the authority to obtain more information on chemicals and to regulate those chemicals that the agency determines pose unreasonable risks to human health or the environment. In February 2012, the office announced plans to develop risk assessments on 83 chemicals. While the office has not nominated any chemicals for IRIS toxicity assessment over the past three nomination periods through the formal nomination process, according to EPA officials with the office, in developing its risk assessments, it plans to incorporate information from IRIS toxicity assessments to the extent such information is available, recent, and relevant. These officials told us that the risk assessments they are conducting in support of the Toxic Substances Control Act are

often based on intermittent exposure to workers and consumers who are subject to chemicals contained in products.[44] However, they also told us that, while the IRIS values contained in the database may not always be applicable, often other data available in the IRIS database are applicable, such as toxicity information for shorter term exposure scenarios that have long-lasting/persistent effects (e.g., development toxicity).[45] In these cases, they said that they have used the hazard and dose-response information described in an IRIS toxicity assessment for a particular chemical to develop their own toxicity assessment. IRIS Program officials said that they are working with the Office of Pollution Prevention and Toxics and other EPA offices to find other options for assessing toxicity, such as PPRTVs, when IRIS toxicity assessments are not available, applicable, or current. While IRIS toxicity assessments may not be applicable in all situations, EPA does not have agencywide guidance that outlines the circumstances under which program offices and regions may or may not need IRIS toxicity assessments, or describes appropriate alternative sources to IRIS toxicity assessments.

Our finding concerning the various approaches EPA program offices and regions use to address their need for toxicity assessments is consistent with findings reported recently by EPA's Inspector General and Science Advisory Board. EPA's Office of the Inspector General conducted a survey of 300 respondents from EPA program offices and regions in January 2013. The survey found that 34 percent of the 300 survey respondents indicated that they had experienced a situation in which they or their team researched a substance that was listed in IRIS but used toxicity values from another source instead of those available in IRIS. Of those respondents, 68 percent indicated that one of their top three

[44]This focus is consistent with the fact that media-specific environmental laws such as the Clean Air Act and Clean Water Act are available to limit the concentration of contaminants in water or the ambient air, and the Toxic Substances Control Act requires EPA to defer action to such other laws if the agency determines that it can use them to adequately address a given risk. However, information on such continuous exposures is still critical for regulation under the Toxic Substances Control Act. For example, to promulgate a rule under section 6 of the Toxic Substances Control Act, EPA must have information on, among other things, the effects of the chemical on human health and the magnitude of human exposure to the chemical.

[45]IRIS toxicity values are generally used to estimate risks associated with continuous exposures to a pollutant in the air or water. In most cases, the information used to develop the dose-response assessments is based on intermittent exposures to workers or animals in a controlled environment. IRIS assessments include an adjustment to continuous exposure in the derivation of toxicity values.

reasons for doing so was because the alternate system source is more up-to-date with current scientific practice or other information. Additionally, 28 percent of all survey respondents indicated that they had experienced a situation in which they or their team developed their own toxicity values. However, more than a third of respondents indicated that there were no standard operating procedures or other guidance regarding how to choose a source of toxicity values for their office's work.

EPA's Science Advisory Board has also reported on differences across the agency regarding the use of scientific information for decision making.[46] For example, in July 2012, the Science Advisory Board reported that available resources for developing toxicity assessments, the number of scientific staff engaged in the work, and the institutional and legal framework supporting these assessments differ across the agency.[47] The report also noted that some EPA programs and regions do not have the infrastructure required to generate all assessments needed to support their own activities and that scientists in these offices work within statutory constraints, often on an extremely short timetable and with limited budgets. Within those constraints, according to the report, they either assess available scientific information themselves or rely on the Office of Research and Development, other parts of EPA, or other federal or state agencies for the science assessments needed to support decision making.

We have also reported on EPA's fragmented and largely uncoordinated science activities. Specifically, in July 2011, we reported that EPA had not fully addressed the findings and recommendations of five independent evaluations over the past 20 years regarding long-standing planning, coordination, or leadership issues that hamper the quality, effectiveness, and efficiency of EPA's science activities, including its laboratory operations. We recommended, among other things, that EPA establish a top-level science official with the authority and responsibility to coordinate, oversee, and make management decisions regarding major scientific activities throughout the agency, including the work of all program, regional, and Office of Research and Development

[46]EPA's Science Advisory Board is a federal advisory committee established by Congress in 1978 with a broad mandate to advise the agency on technical matters.

[47]Science Advisory Board, Science Integration for Decision Making at the U.S. Environmental Protection Agency, EPA-SAB-12-008 (Washington, D.C.: July 6, 2012).

laboratories.[48] While EPA agreed with our recommendation, it has not fully implemented it. In particular, while EPA expanded the responsibilities of the agency's science advisor to coordinate, oversee, and make recommendations to EPA's Administrator regarding the agency's major scientific activities, as of March 2013, the agency had not given this official the authority to make management decisions regarding scientific activities across EPA as we recommended. In the absence of such authority, there is no agency mechanism for understanding and addressing the unmet needs for IRIS toxicity assessments. As a result, EPA may not be maximizing its limited resources or addressing the statutory, regulatory, and programmatic needs of EPA program offices and regions in a consistent manner.

Conclusions

With tens of thousands of chemicals listed with EPA for commercial use in the United States and about 1,000 new chemicals listed for commercial use each year, demand for IRIS toxicity assessments is potentially very high. EPA's IRIS Program develops new toxicity assessments and, as needed, updates information on existing toxicity assessments contained in the IRIS database. EPA has not evaluated demand for IRIS toxicity assessments with input from users inside and outside the agency since 2003, and although IRIS Program officials recognize that the 2003 estimate does not reflect current conditions, the agency does not plan to perform another evaluation of demand. Without a clear understanding of current demand for IRIS toxicity assessments, EPA cannot measure the program's performance; determine the number of IRIS assessments required to meet the statutory, regulatory, and programmatic needs of IRIS users; or know the extent of unmet demand.

The IRIS Program's chemical nomination and selection process, which the agency uses to gauge interest in the IRIS Program from users inside and outside EPA, may not accurately reflect current demand for IRIS toxicity assessments. For example, it is not clear how many chemicals IRIS users did not nominate due to concerns that the IRIS toxicity assessment would not be completed in a timely manner. Furthermore, EPA has not clearly articulated how the IRIS Program applies the criteria it uses to prioritize the selection of chemicals for IRIS toxicity assessment—including how it determines the circumstances under which

[48]GAO-11-347.

program offices and regions may or may not need an IRIS toxicity assessment. Consequently, for chemicals that are nominated, but not selected for IRIS toxicity assessment, it is not clear how many, if any, are excluded from consideration because they do not meet the IRIS Program's selection criteria, because the IRIS Program determined that an IRIS toxicity assessment was not needed—or, alternatively, if they are not selected because of resource constraints or other reasons.

EPA has not implemented an agencywide strategy for addressing the unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current. Specifically, EPA does not have a strategy for identifying and filling data gaps that would enable it to conduct IRIS toxicity assessments for nominated chemicals that were not selected for assessment due to insufficient data. Because EPA does not have a process in place for identifying and filling research gaps, it is unable to ensure it can respond to any unmet EPA program offices' and regions' programmatic and public health needs in the future. Also, EPA does not have guidance that outlines the circumstances under which program offices and regions may or may not need an IRIS toxicity assessment, or that describes appropriate alternative sources to IRIS toxicity assessments. Without guidance, EPA cannot ensure a consistent approach for addressing the needs of program offices and regions when IRIS toxicity assessments are not available, applicable, or current.

Recommendations for Executive Action

We are making three recommendations to the EPA Administrator.

To ensure that EPA can measure the IRIS program's performance and determine the number of IRIS toxicity assessments required to meet the statutory, regulatory, and programmatic needs of IRIS users, we recommend that the EPA Administrator direct the Office of Research and Development to implement the following two actions without impeding the progress of ongoing assessments:

- Identify and evaluate demand for the IRIS Program to determine the number of IRIS toxicity assessments and resources required to meet users' needs.

- Document how EPA applies its IRIS toxicity assessment selection criteria, including the circumstances under which program offices and regions may or may not need an IRIS toxicity assessment.

To ensure that EPA maximizes its limited resources and addresses the statutory, regulatory, and programmatic needs of EPA program offices and regions when IRIS toxicity assessments are not available, we recommend that the EPA Administrator direct the Deputy Administrator, in coordination with EPA's Science Advisor, to implement the following action:

- Once demand for the IRIS Program is determined, develop an agencywide strategy to address the unmet needs of EPA program offices and regions that includes, at a minimum:
  - coordination across EPA offices and with other federal research agencies to help identify and fill data gaps that preclude the agency from conducting IRIS toxicity assessments, and
  - guidance that describes alternative sources of toxicity information and when it would be appropriate to use them when IRIS values are not available, applicable, or current.

Agency Comments and Our Evaluation

We provided a draft of this report to EPA for its review and comment. EPA's written comments and our detailed response to them are presented in appendix III. EPA also provided technical comments on our draft report, which we incorporated, as appropriate.

In its written comments, EPA agreed with our findings and two of our recommendations and partially agreed with our third recommendation. Specifically, EPA agreed with our recommendations that the Office of Research and Development (1) identify and evaluate demand for the IRIS Program to determine the number of IRIS toxicity assessments and resources required to meet users' needs and (2) document how EPA applies its IRIS toxicity assessment selection criteria, including the circumstances under which program offices and regions may or may not need an IRIS toxicity assessment. In its written comments, EPA stated that the Office of Research and Development this year will evaluate the potential future demand for IRIS toxicity assessments and the resources required to meet that demand. EPA also stated that it will better describe for internal and external stakeholders and the public the nomination and selection process for chemicals for IRIS toxicity assessments, including the rationale for not selecting nominated chemicals for IRIS assessment.

With respect to our third recommendation, that EPA develop an agencywide strategy to address unmet need for IRIS toxicity assessments, in its written comments, EPA requested that we provide

additional clarification and consider refining our recommendation. Specifically, EPA stated that it understood and supported the goal of developing an agencywide strategy to help identify and fill data gaps that preclude the agency from conducting IRIS toxicity assessments, but urged us to clarify more precisely the extent to which it must rely on others to conduct research to fill data gaps on IRIS chemicals. As we note in the report, IRIS Program officials told us that they do not have a process in place for filling research gaps and acknowledged that better coordination across EPA offices and with other federal research agencies, such as the Department of Health and Human Services' National Toxicology Program, could help address this issue. We acknowledge that EPA has limited resources, which may preclude the agency from making substantial investments in research into how individual chemicals affect human health. As such, to ensure that the agency maximizes its limited resources, we have recommended that EPA develop a strategy to coordinate with other federal research agencies to help identify and fill data gaps. In this context, EPA acknowledged that it must look to other federal agencies, academic institutions, and chemical product producers to fund research into how chemicals affect human health, as we have recommended. EPA also stated, in its written comments, that the agency can and will do a more effective job to make data needs known to relevant federal agencies and nonfederal organizations that either fund or conduct chemical research.

Also regarding our third recommendation that EPA develop an agencywide strategy to address unmet needs for IRIS toxicity assessments, based on technical comments provided by EPA officials prior to receiving the agency's letter dated April 16, 2013, we refined the wording of our third recommendation. The original text recommended that EPA develop guidance that describes alternative sources of toxicity information and *procedures for preparing toxicity assessments* when IRIS values are not available, applicable, or current. We refined the wording of this recommendation to read: guidance that describes alternative sources of toxicity information and *when it would be appropriate to use them* when IRIS values are not available, applicable, or current. The revised language more accurately reflects the intent of our recommendation. In addition, in its written comments, EPA stated that it understood our interest in the agency developing guidance that describes alternative sources of toxicity information and agreed that such guidance might be helpful. However, EPA stated that the development of such guidance is best left to individual EPA programs. We disagree. In the absence of agencywide guidance that addresses unmet demand for IRIS assessments, EPA offices operate in much the same way they operated

before the IRIS Program was formed to develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. As we note in this report, we have previously reported on EPA's fragmented and largely uncoordinated science activities and recommended, among other things, that EPA establish a top-level science official with the authority and responsibility to coordinate, oversee, and make management decisions regarding major scientific activities throughout the agency.[49] Consistent with our prior report and recommendation, we believe that guidance regarding major scientific activities should also come from a top-level science official. However, as we note in our current report, EPA has not provided its Science Advisor with the authority to make management decisions regarding scientific activities across EPA as we previously recommended. Therefore, we believe that agencywide guidance should come from EPA's Deputy Administrator in coordination with EPA's Science Advisor.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Acting Administrator of EPA, the appropriate congressional committees, and other interested parties. In addition, this report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Sincerely yours,

J. Alfredo Gómez
Director, Natural Resources and Environment

[49]GAO-11-347.

Appendix I: Scope and Methodology

To determine the extent to which the Environmental Protection Agency (EPA) has evaluated demand for IRIS toxicity assessments, we reviewed EPA's 2003 evaluation of demand for IRIS toxicity assessments. We also interviewed IRIS Program officials to determine whether they had conducted other evaluations of demand since 2003, how they derived the 2003 estimate, and whether that estimate reflects current conditions. Because the 2003 evaluation did not provide sufficient information on its methodology, we were unable to fully assess its estimate. We corroborated EPA officials' assertion that the 2003 assessment no longer reflects current conditions based on our understanding of the IRIS Program. As we discussed earlier, the importance of EPA's IRIS Program has increased over time as EPA program offices and regions have increasingly relied on IRIS toxicity assessments in making environmental protection and risk management decisions. In addition, as about 1,000 new chemicals are listed for commercial use each year, potential for changes in demand over time are likely.

To determine the extent to which EPA's process for nominating and selecting chemical for IRIS toxicity assessment accurately reflects current demand, we reviewed data provided by the IRIS Program and from the IRIS Program's website on the number of IRIS toxicity assessments it completed annually from fiscal years 2002 through 2012. In addition, we analyzed all chemical nomination forms submitted by EPA program offices and regions to the IRIS Program from 2005, 2007 and 2011—which were the last three times that EPA solicited nominations for new and updated IRIS toxicity assessments.[1] For additional perspective on user needs, we reviewed non-EPA IRIS users' chemical nomination forms from 2011. To select and count the number of nominations, two analysts reviewed information EPA provided us to determine which documents to include in our analysis. We used the following inclusion and exclusion criteria to determine which documents to include in our analysis:

- Documents labeled as being a nomination were included while documents labeled as being another document were excluded. For

[1]According to IRIS Program documents, the IRIS Program solicits opinions from EPA offices, other federal agencies, and the public on an annual basis. However, since 2004, the IRIS Program has solicited nominations from IRIS users three times: in 2004, 2006, and 2010. In 2004, the IRIS Program solicited nominations only from EPA program offices and regions. In 2006 and 2010, the IRIS Program solicited nominations from all IRIS users. The IRIS Program refers to these nomination periods as being for fiscal years 2005, 2007, and 2011, which are the years we also refer to in this report.

example, some documents were the IRIS Program's request for nominations or Federal Register Notices, which were not included in our analysis. In other instances, a nominating entity indicated that the chemicals were being prioritized and not nominated (i.e., they clearly stated "this is a list of our priorities"), and were not included in our analysis.
- We included individual nomination sheets for our analysis, but we did not include nomination cover sheets or separate documents that IRIS Program officials sent us separately from the individual nomination sheets.
- We did not include the nomination form if the nominating entity indicated on the form that there was no new nomination and instead was a reiteration of support for a previous nomination.

In some instances, EPA program offices and regions nominated two chemicals on one nomination form or listed two chemicals together. Chemicals were counted as a single nomination if they had the same Chemical Abstracts Service (CAS) registry number and as separate nominations if they had different CAS registry numbers. According to the CAS registry website, the CAS registry is the most authoritative collection of disclosed chemical substance information, containing more than 70 million organic and inorganic substances and 64 million sequences. In cases where it was not clear to both analysts whether to include a document in our analysis, IRIS Program officials provided confirmation. While we used this methodology to determine the number of nominations in the 2005, 2007, and 2011 nomination periods, using a different methodology might result in a different number of nominations. As about 1,000 new chemicals are listed for commercial use each year, the chemicals nominated may either overstate or understate actual demand. In addition, we reviewed the IRIS Program's processes for soliciting nominations and selecting chemicals for IRIS toxicity assessments, including the agency's selection criteria. We also reviewed agency guidance and interviewed IRIS Program officials to better understand the chemical nomination and selection process.

To determine the extent to which EPA has implemented a strategy for addressing any unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current, we reviewed the IRIS Program's efforts to analyze IRIS user chemical nominations. For context, we interviewed officials from EPA's National Center for Environmental Assessment, which manages the IRIS Program and develops IRIS toxicity assessments. For additional perspective, we interviewed officials using a standard set of questions from a

nonprobability sample of three EPA program offices and one region: the Office of the Administrator, the Office of Water, the Office of Solid Waste and Emergency Response, and EPA's Region 2.[2] We selected these program offices and region because they submitted 78 percent of the chemical nominations to the IRIS Program during the period we reviewed—2005, 2007, and 2011. These offices and region ranked the highest in terms of the number of chemical nominations submitted, and, in some cases, nominated chemicals more than once during different nomination years. Because this is a nonprobability sample, it is not generalizable to all EPA program offices and regions, but it can provide illustrative examples of the experience of those EPA program offices and one region that nominated 78 percent of chemicals for IRIS toxicity assessment during the period we reviewed. For example, we received information from officials from these offices about how EPA program offices and one region nominate chemicals for IRIS toxicity assessment, how the IRIS Program meets the needs of these offices and region over the course of nomination periods, and what alternative toxicity assessments these offices and region turn to when IRIS toxicity assessments are not available. For a summary of approaches used by selected EPA program offices and regions to address their IRIS toxicity assessment needs, see appendix II.

Separately from our nonprobability sample, we also interviewed officials from the Office of Pollution Prevention and Toxics, within the Office of Chemical Safety and Pollution Prevention, because it did not nominate any chemicals for IRIS toxicity assessment for any of the last three nomination periods. We did not evaluate the scientific content or quality of IRIS toxicity assessments.

We conducted this performance audit from April 2012 to May 2013 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.

[2]We interviewed officials both at the Office of Policy and the Office of Children's Health Protection, which are suboffices within the Office of the Administrator. We also received a written response from the Office of Underground Storage Tanks, which is a suboffice within the Office of Solid Waste and Emergency Response.

Appendix II: Summary of Approaches Used by Select EPA Program Offices and Regions to Address Toxicity Assessment Needs

Office of Solid Waste and Emergency Response

According to officials at the Office of Solid Waste and Emergency Response, the office nominated 18 chemicals over the course of the 2005, 2007, and 2011 nomination periods.[1] The Office of Solid Waste and Emergency Response provides policy, guidance, and direction for the agency's emergency response and waste programs, including managing the Superfund Program, which responds to abandoned and active hazardous waste sites and accidental oil and chemical releases. IRIS toxicity assessments are used by the Office of Solid Waste and Emergency Response to, among other things, support mandated regulatory actions. For example, the Office of Underground Storage Tanks, within the Office of Solid Waste and Emergency Response, submitted chemicals during the 2011 nomination period to support the requirement under Section 1505 of the Energy Policy Act of 2005 that the EPA Administrator conduct a study on the effects on public health of increased use of iso-octane and six other fuel additives as substitutes for methyl tertiary butyl ether (MTBE).[2] When IRIS toxicity assessments are not available or current, Office of Solid Waste and Emergency Response officials stated they rely on other toxicity values to meet their programmatic needs. For example, officials at the Office of Underground Storage Tanks stated that, in the absence of IRIS values, states must resort to other sources for toxicological information, and this can lead to inconsistencies state-to-state. Officials also stated that, when an IRIS toxicity assessment is not available, the office refers to a hierarchy of

[1]The Office of Solid Waste and Emergency Response has suboffices including the Office of Underground Storage Tanks, which submitted separate nominations (inclusive of the 18 chemicals) to the IRIS Program.

[2]42 U.S.C. § 7545(b)(4). These substances are (1) ethyl tertiary butyl ether (ETBE); (2) tertiary amyl methyl ether (TAME); (3) diisopropyl ether (DIPE); (4) tertiary butyl alcohol (TBA); (5) ethanol; (6) iso-octane (2,2,4-trimethylpentane); and (7) alkylates. According to EPA's website, MTBE is a fuel additive made by combining methanol and isobutylene and has been used since 1979 in the United States as an octane-enhancing replacement for lead. According to the website, the use of MTBE in gasoline sold in the United States has virtually ceased in recent years. According to IRIS Program officials, ETBE, TAME, DIPE, TBA, and ethanol are currently on the IRIS agenda in the draft development step. The ETBE assessment is being revised because important new data became available after the external peer review. New schedules for ETBE and TBA were posted on the IRIS website in February 2013. Taking into account the complexity of the ethanol dataset, IRIS Program officials told us that they are considering various approaches to conducting the ethanol assessment and will revisit the priority of the ethanol assessment in fiscal year 2013. Alkylates were added to the IRIS agenda in 2007 but were withdrawn in 2012 because there are multiple chemicals in this class, many with limited databases. If individual alkylates with sufficient data to support an IRIS assessment are nominated in the future, the IRIS Program will consider these nominations individually.

toxicity values to be used in performing human health risk assessments for Superfund sites. In 2003, the Office of Solid Waste and Emergency Response updated this hierarchy, which is intended to help risk assessors identify appropriate sources of toxicology information and lists the sources as: (1) IRIS toxicity values, (2) Provisional Peer Reviewed Toxicity Values (PPRTVs), and (3) other EPA and non-EPA sources of toxicity information—with priority given to those sources of information that are the most current, publicly available, and peer reviewed. Such values include the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels and California Environmental Protection Agency (Cal/EPA) toxicity values. Although developed specifically for the Superfund Program, officials stated that this guidance is generally used by all suboffices within the Office of Solid Waste and Emergency Response.

EPA Region 2

According to Region 2 officials, the region nominated 22 chemicals over the course of the 2005, 2007, and 2011 nomination periods. EPA's Region 2 serves New Jersey, New York, Puerto Rico, the U.S. Virgin Islands, and eight tribal nations. Region 2 nominates chemicals for IRIS assessment on behalf of risk assessors throughout their region—that is, EPA and officials throughout the region, primarily at Superfund sites, that evaluate chemical risks. For example, Region 2 stated in its chemical nomination form for the 2011 nomination period that it needed IRIS toxicity assessments to support cleanup decisions for chemicals present in residential properties and in groundwater. Region 2 officials indicated that, when IRIS toxicity values are not available, they may rely on other toxicity values to meet their programmatic needs and follow the Office of Solid Waste and Emergency Response's hierarchy of values in consultation with the IRIS Program as appropriate.[3] Officials also told us that there are number of high-profile chemicals where the office has used PPRTVs and values from ATSDR and Cal/EPA, because an IRIS toxicity assessment is not available. However, officials noted that ATSDR does not develop cancer values.

[3]Region 2 officials stated that in some cases, other organizations such as ATSDR or Cal/EPA may develop a quantitative value before the IRIS toxicity assessment is revised. In that case, the Region would consider the use of the quantitative value based on discussions with the IRIS program.

Office of Water

According to Office of Water officials, the office nominated 23 chemicals over the course of the 2005, 2007, and 2011 nomination periods. EPA's Office of Water is responsible for drinking water safety, and it restores and maintains oceans, watersheds, and their aquatic ecosystems. The Office of Water is responsible for implementing, among other mandates, the Clean Water Act and Safe Drinking Water Act. For example, in its chemical nomination form for the 2011 nomination period, the Office of Water stated that it needed IRIS toxicity assessments to develop regulations. The Office of Water develops assessments for chemicals it needs to meet statutory deadlines. Because of the limited number of IRIS toxicity assessments the IRIS Program can select and develop at one time, the Office of Water created the scheme to prioritize those chemicals that are the most controversial and high-profile, have a high economic impact, and will take more staff and time to complete. The Office of Water can then develop its own assessments for chemicals that have less controversy surrounding them and take less time and staff to complete in order to meet some of its programmatic needs. Officials stated that developing the office's own assessments for some chemicals was based on the reality that the IRIS Program would not complete most of the needed toxicity assessments in time to meet the office's statutory deadlines.

Office of the Administrator

According to officials at the Office of the Administrator, the office nominated 26 chemicals over the course of the 2005, 2007, and 2011 nomination periods.[4] EPA's Office of the Administrator provides executive and logistical support for the EPA Administrator. The office supports the leadership of EPA's programs and activities to protect human health and the environment. An official from the Office of Policy, within the Office of the Administrator, stated that rationales for nominating chemicals varied widely—for example, the increasing or widespread exposure to a chemical or the availability of new data to develop a new or update an existing IRIS toxicity assessment. The official noted that the Office of Policy's programmatic needs differed from other EPA offices' needs in that it does not develop regulations or risk assessments. Instead, the office provides assistance for other EPA offices' assessments and reviews assessments that other offices perform. In the absence of an

[4]The Office of the Administrator has suboffices including the Office of Policy and the Office of Children's Health Protection, which each submitted separate nominations (inclusive of the 26 chemicals) to the IRIS Program.

IRIS toxicity assessment, the Office of Policy relied on the original literature, review articles, and assessments prepared by other agencies. Such values include the ATSDR Minimal Risk Levels and Cal/EPA toxicity values. An official with the Office of Children's Health Protection, also within the Office of the Administrator, stated that most of its nominations were for chemicals that were under the Toxic Substances Control Act or the Safe Drinking Water Act and were based on children's health concerns. The official stated that, in the absence of an IRIS toxicity assessment, the Office of Children's Health Protection goes directly to the literature or work done by other government agencies or programs, such as the National Toxicology Program.

Office of Pollution Prevention and Toxics

The Office of Pollution Prevention and Toxics is responsible for implementing the Toxic Substances Control Act, which provides EPA with the authority to obtain more information on chemicals, and to regulate those chemicals that the agency determines pose unreasonable risks to human health or the environment, announced in February 2012 its plans to develop risk assessments on 83 chemicals. While the office has not nominated any chemicals for IRIS toxicity assessment over the past three nomination periods through the formal nomination process, according to EPA officials with the Office of Pollution Prevention and Toxics, in developing its risk assessments, it plans to incorporate information from IRIS toxicity assessments to the extent such information is available, recent, and relevant. Officials at the Office of Pollution Prevention and Toxics, and senior staff of the Office of Research and Development, which houses the IRIS Program, have compared the list of existing and ongoing IRIS toxicity assessments in order to share relevant literature and hazard reviews for upcoming risk assessments related to the Toxic Substances Control Act. These officials told us that the risk assessments they are conducting in support of the Toxic Substances Control Act are often based on intermittent exposure to workers and consumers who are subject to chemicals contained in products. However, they also told us that, while the IRIS values contained in the database may not always be applicable, often other data available in the IRIS database are applicable, such as toxicity information for shorter term exposure scenarios that have long-lasting/persistent effects (e.g., development toxicity). In these cases, they said that they have used the hazard and dose response information described in an IRIS toxicity assessment for a particular chemical to develop their own toxicity assessment.

In addition, according to IRIS program officials, they have compared the list of chemicals for which the Office of Pollution Prevention and Toxics

plans to conduct risk assessments with the list of existing and ongoing toxicity assessments and shared relevant literature and hazard reviews. IRIS program officials also said that the Office of Pollution Prevention and Toxics participates with other EPA offices in prioritizing their needs for ongoing IRIS toxicity assessments. IRIS toxicity values are generally used to estimate risks associated with continuous exposures to a pollutant in the air or water. In most cases, according to IRIS Program officials, the information used to develop the dose-response assessments is based on intermittent exposures to workers or animals in a controlled environment, and IRIS assessments include an adjustment to continuous exposure in the derivation of toxicity values. IRIS Program officials said that they are working with the Office of Pollution Prevention and Toxics and other EPA offices to find other options for assessing toxicity, such as PPRTVs, when IRIS toxicity assessments are not available, applicable, or current.

Appendix III: Comments from the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 16 2013

OFFICE OF
THE ADMINISTRATOR

Mr. Alfredo Gomez
Director
Natural Resources and Environment
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Mr. Gomez:

Thank you for the opportunity to review and comment on the U.S. Government Accountability Office's 13-369 draft report, *Chemical Assessments: An Agency-wide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments.* The U.S. Environmental Protection Agency appreciates the GAO's analysis of the agency's effectiveness in implementing its Integrated Risk Information System, known as IRIS, toxicity-assessment process.

In the report, the GAO identifies several areas of concern and recommends that the EPA address those concerns at two levels.

First, to ensure that the EPA can measure the IRIS program's performance and determine the number of IRIS toxicity assessments required to meet the statutory, regulatory and programmatic needs of IRIS users, the GAO recommends that the EPA Administrator direct the Office of Research and Development to implement the following two actions, without impeding the progress of ongoing assessments:

- identify and evaluate demand for the IRIS program to determine the number of IRIS toxicity assessments and resources required to meet users' needs; and
- document how the EPA applies its IRIS toxicity-assessment selection criteria, including the circumstances under which national-program offices and regions may or may not need an IRIS toxicity assessment.

Second, to maximize resources and address unmet needs for IRIS toxicity assessments, the GAO recommends that the Deputy Administrator, in coordination with the EPA's science advisor, develop an agencywide strategy to identify and fill data gaps that preclude the EPA from conducting IRIS toxicity assessments, and develop guidance describing alternative sources of toxicity information and procedures for preparing toxicity assessments when IRIS values are not available, applicable or current.

The EPA appreciates that the GAO recognizes the importance of the IRIS program and agrees there is a need to identify and evaluate the demand for IRIS assessments, including improving the transparency of decisions to select or not select chemicals for IRIS assessment development. One of our priorities is to improve the IRIS program's productivity and to increase the number of assessments. Understanding the needs of IRIS users and responding to their expectations enables the EPA and external stakeholders to better assess the program's productivity and the need for new or different steps to improve program

results. To obtain current and accurate information on IRIS users' needs and expectations, ORD this year will evaluate the potential future demand for IRIS toxicity assessments and the resources required to meet that demand. As the GAO suggested, the EPA will then use the evaluation outcome to estimate the number and types of IRIS assessments required to meet the needs of the EPA and external IRIS users.

As recommended, the EPA will better describe for internal and external stakeholders and the public the nomination and selection process for chemicals for IRIS toxicity assessments, including the rationale for not selecting nominated chemicals for a full IRIS assessment. For those chemicals not selected for IRIS assessment specifically because data gaps preclude undertaking an assessment, the EPA will identify the data gaps and research needs and will make these known to EPA researchers, the administrators of the EPA's external research grant program, other EPA programs, other federal research agencies such as the National Institute of Environmental Health Sciences and the public. Also, as the GAO has recommended, the EPA will ensure that these efforts do not impede the progress of ongoing assessments.

We understand and support the goal of the GAO's recommendation that the EPA develop an "agency-wide strategy … to help identify and fill data gaps that preclude development of IRIS toxicity assessment." Where data gaps prevent an informed assessment of the health effects of an IRIS candidate chemical, filling those data gaps should be a priority both to support the IRIS program and to improve the public's understanding of chemical risks. The EPA's limited resources, however, preclude the agency from substantial investments in health-effects research on individual chemicals. We must, therefore, look to other federal agencies, academic institutions and chemical-products producers to fund such research. The EPA can and will do a more effective job to make data needs known to relevant federal agencies and nonfederal organizations that either fund or conduct chemical research.

We urge the GAO to clarify more precisely the extent to which the EPA must rely on others to conduct research to fill data gaps on IRIS chemicals and can best encourage that research by publicizing data gaps and working with other organizations with research capabilities rather than use our own limited resources to conduct testing. In addition, recognizing that necessary research can take many years to conduct and publish, it is important that the GAO recommendations emphasize more strongly that, in some cases, IRIS assessment development may need to proceed on the basis of available information and should not be held in abeyance awaiting new research. This will create an incentive for manufacturers and others to anticipate the needs of the IRIS program and not wait until assessments are imminent before investing in needed research.

See comment 1.

The GAO should also note that one tool available to the EPA, the Toxic Substances Control Act, is limited in its ability to require industry to submit available data on chemicals and to conduct health effects testing to fill data-gaps. As the Obama Administration has articulated in its goals for TSCA reform, manufacturers should provide the EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment. TSCA reform, combined with robust collaboration between the IRIS and TSCA programs, could improve the EPA's ability to develop chemical assessments in a timely manner.

See comment 2.

The EPA also understands the GAO's interest in the agency developing "guidance that describes alternative sources of toxicity information and procedures for preparing toxicity assessments when IRIS values are not available, applicable or current." We agree that such guidance might be helpful but believe its development is best left to individual EPA programs, many of which are already meeting the need described by the GAO.

See comment 3.

As the GAO recognizes, IRIS assessments, while important and influential, are not the only authoritative sources of hazard information on chemicals and need not be available in all instances to meet the needs of the public and government agencies. The draft report itself recognizes that there are already such alternate sources as documented in the recent EPA's Office of Inspector General report summarizing a survey of EPA national-program offices and regions about their use of IRIS and other toxicity information.

Moreover, the EPA's programs and offices do not currently lack "procedures for preparing toxicity assessments when IRIS values are not available, applicable or current." The draft report already points out some of these procedures such as toxicity assessments produced by the EPA's Office of Pollution Prevention and Toxics. Others not mentioned in the report include the health effects support documents for drinking-water contaminants, published by EPA's Office of Water, and the Superfund program's guidance in identifying a hierarchy of toxicity values, in addition to those in IRIS, to support cleanup decisions. As these efforts reflect, EPA programs at times have targeted, special-purpose needs that can be satisfied without the comprehensive literature reviews and toxicity evaluations in IRIS assessments.

See comment 4.

The EPA is responsible for assessing and managing environmental risks based on many laws with different requirements. The recommendation to develop guidance "describing alternative sources of toxicity information" suggests a uniformity in risk-management requirements that does not exist. That said, while the EPA believes relevant offices and programs are already aware of the range of internal and external sources of toxicity information, the EPA will take steps to ensure EPA national programs and regions are well-informed about the results of the OIG survey and the availability of IRIS and other toxicity information.

We urge the GAO to consider refining these two recommendations.

In the meantime, I thank you once more for enabling the EPA to review and comment on the GAO's draft report. We at the EPA fully recognize the IRIS program's importance and value to our critical mission and to the work of many public-health agencies and organizations. The EPA remains committed to strengthening the IRIS program and to addressing the agency's needs for toxicity assessments, and we are grateful for the GAO's thoughts and recommendations.

Sincerely,

Bob Perciasepe
Acting Administrator

The following are GAO's comments on the letter from the Environmental Protection Agency dated April 16, 2013.

1. In this report, we do not discuss the challenges associated with suspending the development of an ongoing IRIS toxicity assessment to await new research and, therefore, our recommendations are not aimed at addressing this issue. Instead, our report is concerned with data gaps that preclude EPA from starting an IRIS assessment. However, we have addressed issues concerning suspending the development of an ongoing IRIS assessment in a prior report. Specifically, in our 2008 report on EPA's IRIS Program,[1] we note that, 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 minimizes the need to conduct significant levels of rework. In our 2008 report, we recommended that EPA establish a policy that endorses conducting IRIS assessments on the basis of peer-reviewed scientific studies available at the time of the assessment and develop criteria for allowing assessments to be suspended to await the completion of scientific studies only under exceptional circumstances. As of the date of this report, EPA has not implemented our 2008 recommendation.
2. We have reported in the past that EPA has found many provisions of the Toxic Substances Control Act difficult to implement, and we have suggested that Congress consider making statutory changes to strengthen EPA's authority to obtain toxicity information from the chemical industry. However, as we note in our March 2013 report on the Toxic Substances Control Act,[2] EPA has not pursued all opportunities to obtain chemical data using its existing authorities under the law. We agree that robust collaboration between the IRIS and Toxic Substances Control Act Programs could improve EPA's ability to develop chemical assessments in a timely manner.
3. We continue to believe that agencywide guidance is needed that describes alternative sources of toxicity information and when it would be appropriate to use them when IRIS values are not available, applicable or current. As we note in this report, we have previously reported on EPA's fragmented and largely uncoordinated science activities and recommended, among other things, that EPA establish a top-level science official with the authority and responsibility to coordinate, oversee, and make management decisions regarding major scientific

[1] GAO-08-440.

[2] GAO, *Toxic Substances: EPA Has Increased Efforts to Asses and Control Chemical but Could Strengthen Its Approach*, GAO-13-249 (Washington, D.C.: Mar. 22, 2013).

activities throughout the agency.[3] Consistent with our prior report and recommendation, we believe that guidance regarding major scientific activities should also come from a top-level science official. However, as we note in our current report, EPA has not provided its Science Advisor with the authority to make management decisions regarding scientific activities across EPA as we previously recommended. Therefore, we believe that agencywide guidance should come from EPA's Deputy Administrator in coordination with EPA's Science Advisor.

4. We recognize that EPA is responsible for assessing and managing environmental risks based on many laws with different requirements and that program offices and regions may not always need IRIS toxicity assessments. However, as we note in our report, EPA has not clearly articulated under what circumstances IRIS toxicity assessments are not needed. Moreover, in cases where program offices and regions have indicated a need for an IRIS toxicity assessment, but an assessment is not available, applicable, or current, EPA does not have guidance that describes alternative sources of toxicity information and when it would be appropriate to use them.

[3]GAO-11-347.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

J. Alfredo Gómez, (202) 512-3841 or gomezj@gao.gov

Staff Acknowledgments

In addition to the individual named above, Diane G. LoFaro, Assistant Director; Summer Lingard-Smith; and Marie Webb made key contributions to this report. Important contributions were also made by Mark Braza, Janice Ceperich, Nirmal Chaudhary, Richard Johnson, Cynthia Norris, Aaron Shiffrin, and Kiki Theodoropoulos.