United States Government Accountability Office

Report to Congressional Requesters

December 2020

CHEMICAL ASSESSMENTS

Annual EPA Survey Inconsistent with Leading Practices in Program Management

Accessible Version

GAO-21-156

GAO Highlights

Highlights of GAO-21-156, a report to congressional requesters

December 2020

CHEMICAL ASSESSMENTS

Annual EPA Survey Inconsistent with Leading Practices in Program Management

Why GAO Did This Study

EPA's IRIS Program prepares chemical toxicity assessments that contain EPA's scientific position on the potential human health effects of exposure to chemicals; at present, the IRIS database contains more than 570 chemical assessments. In March 2019, GAO reported on the IRIS Program's changes to increase transparency about its processes and methodologies, including the use of systematic review. However, GAO also found that EPA decreased the number of ongoing assessments in December 2018 from 22 to 13 and continued to face challenges in producing timely assessments.

This report evaluates (1) EPA's progress in completing IRIS chemical assessments since 2018; and (2) EPA's recent actions to manage the IRIS Program, and the extent to which these actions help the Program meet EPA user needs.

GAO reviewed and analyzed EPA documents and interviewed officials from EPA; GAO also selected three standards for program management, found commonalities among them, and compared ORD's management of the IRIS Program against these leading practices.

What GAO Recommends

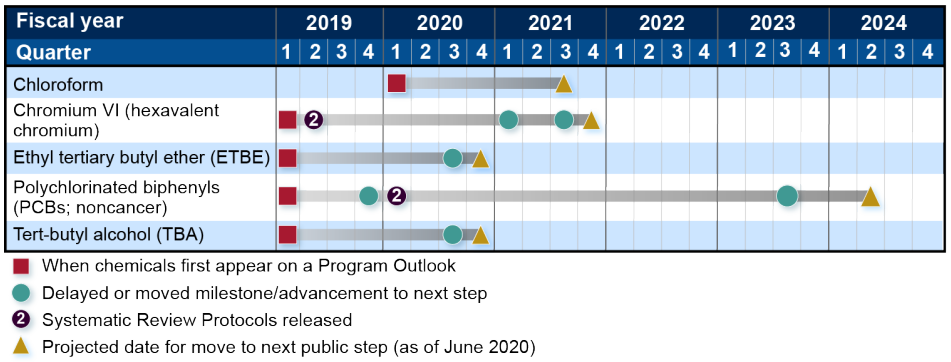
GAO is making five recommendations, including that EPA provide more information publicly about where chemical assessments are in the development process; and issue guidance for selecting chemicals for nomination and criteria for selecting nominations for assessment. EPA partially agreed with two of our recommendations and disagreed with the other three.

View GAO-21-156. For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program has not produced timely chemical assessments, and most of its 15 ongoing assessments have experienced delays. As we reported in March 2019, the IRIS Program has taken some actions to make the assessment process more transparent, such as increasing communication with EPA offices and releasing supporting documentation for review earlier in the draft development process, but the need for greater transparency in some steps of the assessment process remains. Specifically, the IRIS Program does not publicly announce when assessment drafts move to certain steps in their development process or announce reasons for delays in producing specific assessments. Without such information, stakeholders who may be able to help fill data and analytical gaps are unable to contribute. This could leave EPA without potential support that could help overcome delays.

Delays of Milestones by Quarter for a Selection of the Integrated Risk information System's Assessments in Development 2019 - 2024



Source: GAO analysis of Environmental Protection Agency data. | GAO-21-156

Text of Delays of Milestones by Quarter for a Selection of the Integrated Risk information System's Assessments in Development 2019 - 2024

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
Chloroform (inhalation)	June 2020 (FY2020 Q3)	Step 1: IRIS Assessment Plan	Released September 18, 2017. Public Meeting on September 27, 2017
		Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
		Step 1: IRIS Assessment Plan	Released September 18, 2017. Public Meeting on September 27, 2017

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released September 18, 2017
		Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Chromium VI	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q1
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY22 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY22 - Q1
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q3
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	FY19 - Q2
		Step 4: Public Comment Draft	FY20 - Q1
		Step 4: External Peer Review	FY20 - Q3

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
Ethyl tertiary butyl ether	June 2020 (FY2020 Q3)	Step 7: Final	FY20 - Q4
	February 2020 (FY2020 Q2)	Step 7: Final	FY20 - Q4
	December 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	October 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	April 2019 (FY2019 Q3)	Step 7: Final	FY20 - Q3
	December 2018 (FY2019 Q1)	Step 7: Final	TBD
Polychlorinated biphenyls (PCBs; noncancer)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on December 19, 2019
		Step 4: Public Comment Draft	FY24 - Q2
		Step 4: External Peer Review	FY24 - Q4
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on December 19, 2019
		Step 4: Public Comment Draft	FY23 - Q3
		Step 4: External Peer Review	FY23 - Q4
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY22 - Q4
		Step 4: External Peer Review	FY22 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY22 - Q3
		Step 4: External Peer Review	FY22 - Q4
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY22 - Q2
		Step 4: External Peer Review	FY22 - Q4
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY21 - Q1

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
		Step 4: External Peer Review	FY21 - Q2
Tert-butyl alcohol	June 2020 (FY2020 Q3)	Step 7: Final	FY20 - Q4
	February 2020 (FY2020 Q2)	Step 7: Final	FY20 - Q4
	December 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	October 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	April 2019 (FY2019 Q3)	Step 7: Final	FY20 - Q4
	December 2018 (FY2019 Q1)	Step 7: Final	TBD

In mid-2018, EPA's Office of Research and Development (ORD) instituted changes to the way it solicits nominations for chemical assessments prepared by the IRIS Program but did so without providing sufficient guidance or criteria, raising questions about its ability to meet EPA user needs. For example, ORD issued a new survey to EPA program and regional offices but did not provide them with guidance for selecting chemicals for nomination, and ORD did not make explicit the criteria it was using for selecting nominations to include in the IRIS Program's list of assessments in development. Furthermore, despite a significant decline in survey participation between 2018 and 2019, EPA did not indicate whether the agency has assessed the quality of information generated by the survey. Leading program management practices state that agency management should internally communicate the necessary, quality information to achieve the entity's objectives and should monitor and evaluate program activities. Without evaluating the quality of the information produced by the survey, ORD cannot know if the survey is achieving its intended purpose and whether ORD has the information necessary to meet user needs.

Contents

Tables

Figures

Abbreviations

ELMS	Environmental Protection Agency Lean Management System
EPA	Environmental Protection Agency
ETBE	ethyl tertiary butyl ether
GPRA	Government Performance and Results Act of 1993
HERA	Strategic Research Action Plan for the Health and Environmental Risk Assessment
IRIS	Integrated Risk Information System
NAS	National Academies of Sciences
OCHP	Office of Children's Health Protection
OCIR	Office of Congressional and Intergovernmental Relations
OMB	Office of Management and Budget
ORD	Office of Research and Development
PFAS	per- and polyfluoroalkyl substances
PFBA	perfluorobutanoic acid
PFDA	perfluorodecanoic acid
PFHxA	perfluorohexanoic acid
PFHxS	perfluorohexane sulfonic acid
PFHNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonate acid
PCBs	polychlorinated biphenyls
PMIAA	Program Management Improvement Accountability Act
SAB	Science Advisory Board
TBA	tert-butyl alcohol
TSCA	Toxic Substances Control Act

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

December 18, 2020

Congressional Requesters

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. 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 571 final IRIS assessments.

While chemicals contribute to virtually every aspect of modern life, exposures to certain chemicals can have negative health and environmental consequences. EPA's ability to effectively implement its mission of protecting public health and the environment depends on its timely assessments of the risks posed by such chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations under a variety of statutes, such as the Clean Air Act, the Safe Drinking Water Act, and the Toxic Substances Control Act (TSCA).[1] Transparency in understanding how EPA is evaluating chemical risks, as well as the timely delivery of assessments, helps inform the federal government, industry, and the public about how chemical management policies are developed.

The IRIS Program identifies and characterizes the health hazards of environmental contaminants and produces toxicity assessments (which we refer to as chemical assessments in this report) that contain this information. IRIS is the preferred source of chemical toxicity information that EPA uses to prepare chemical risk assessments; these are used to establish air and water quality standards, and inform Superfund cleanup efforts. IRIS is also an important source of chemical toxicity information used by other federal agencies as well as state and local health agencies, and international health organizations. IRIS assessments generally include (1) hazard identification and (2) dose-response assessment.

[1]EPA is authorized under the Toxic Substances Control Act (TSCA) to obtain information on the risks of chemicals and to control chemicals the agency determines pose an unreasonable risk of injury to health or the environment. This act was amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Lautenberg Act provides EPA with greater authority to address chemical risks.

Hazard identification identifies credible health hazards associated with exposures to a chemical; dose-response assessment characterizes the quantitative relationship between chemical exposure and each credible health hazard. The Program derives toxicity values through this quantitative relationship, and the IRIS database of chemical assessments contains EPA's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment.

The IRIS Program's process for soliciting requests for chemical assessments from EPA program and regional offices was changed in 2018 at the request of the EPA Administrator. Prior to mid-2018, the IRIS Program typically solicited requests for assessments every 2 to 3 years, through surveys of program and regional offices and through more frequent, informal communication with program and regional office staff. This outreach by the IRIS Program helped to ensure that program and regional office needs had not changed and to gain a sense of future needs based on upcoming regulatory decisions and the priorities of Assistant Administrators. Nominations for assessments came from program and regional office staff, and were sent to IRIS Program staff, where they were compiled and prioritized. IRIS's criteria for prioritizing which chemicals to assess were publicly available as part of the Multi-Year Agenda that the Program released.

Beginning in mid-2018, EPA's Office of Research and Development (ORD) instituted an annual survey process to solicit nominations for chemical assessments that is then used in determining the IRIS Program's priorities. The survey is sent from the Assistant Administrator in ORD to Assistant Administrators in program and regional offices requesting nominations for any new, high-priority chemical assessments.[2] The Assistant Administrator in each program and regional office is required to support each individual chemical nomination from their office, and regional offices are required to submit their nominations to program offices, who submit nominations back to the Assistant Administrator in ORD. Officials in ORD then determine which nominations will be added to the IRIS Program's list of chemical assessments in development.

We added EPA's processes for assessing and controlling toxic chemicals to GAO's list of programs at high risk for waste, fraud, abuse, and mismanagement or most in need of transformation in 2009, where it

[2]The August 2018 survey also requested reaffirmation of ongoing assessments.

remains today.[3] We and the National Academies of Sciences (NAS) have also made numerous recommendations regarding the IRIS Program.[4] As part of EPA's response to NAS and GAO recommendations, in 2017, the IRIS Program made changes designed to increase transparency about the Program's processes and methodologies, increase the use of a systematic review process,[5] and modernize chemical data and literature collection. We detailed these changes to the IRIS Program in our March 2019 report.[6] However, many of our recommendations remain open, including a 2008 recommendation to ensure that any revision to the IRIS draft development process periodically assess the level of resources that the program requires to meet user needs and maintain a viable IRIS database, and a 2011 recommendation that ORD ensure that assessment time frames are realistic and provide greater predictability to stakeholders.[7] At present, the Program continues to face challenges in producing timely assessments of the toxicity that chemicals pose. We also previously recommended that EPA develop an agency-wide chemical management strategy to address the unmet needs of EPA program and regional offices. This recommendation also remains open.[8]

You asked us to review progress that EPA's IRIS Program has made in producing assessments and changes to Program processes since our last update in March 2019. We envision this report to be one in a series of reports that examine EPA's chemical management efforts. Specifically,

[3]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009); and *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: March 2019).

[4]National Academies Press, *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (Washington, D.C.: 2018); GAO, *Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments*, GAO-13-369 (Washington, D.C.: May 10, 2013); and GAO-19-157SP.

[5]Systematic review is a type of literature review that uses systematic methods to collect secondary data, critically appraise research studies, and synthesize studies.

[6]GAO, *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act,* GAO-19-270 (Washington, D.C.: March 2019).

[7]GAO, *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program,* GAO-12-42 (Washington, D.C.: Dec. 9, 2011); *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); and GAO-13-369.

[8]GAO-13-369.

this report evaluates (1) EPA's progress in completing IRIS chemical assessments since 2018 and (2) EPA's recent actions to manage the IRIS Program and the extent to which these actions help the Program meet EPA user needs.

To address the first objective, we reviewed documentary evidence—specifically publicly available information on IRIS assessments in development and time frames for completion of those assessments—in order to understand progress the Program was making toward producing assessments. We carried out one interview with officials from ORD and the IRIS Program. We also conducted semistructured interviews with officials in five EPA program and 10 regional offices that request and use IRIS assessments, and we analyzed the results of these interviews in order to ascertain officials' views on how IRIS's progress in completing assessments has affected the EPA-wide user community. Unlike in previous reviews, EPA's process for providing us with requested documents involved a review by its Office of Congressional and Intergovernmental Relations (OCIR), which typically delayed receipt of documents.

To address the second objective, we reviewed documentary evidence, including some documentation pertaining to changes in the way ORD solicited nominations for chemical assessments from program and regional offices that OCIR provided to us. We also reviewed EPA's congressional budget requests to analyze changes in the Program's requested and actual funding levels across 9 years. We conducted one interview with officials from ORD and the IRIS Program. We conducted semistructured interviews with officials in five EPA program and 10 regional offices that request and use IRIS assessments, and we analyzed the results of these interviews in order to ascertain how changes in the program's assessment nomination process (primarily through the introduction of an annual survey) are perceived by program and regional office staff and how those changes are affecting officials who rely on IRIS assessments to do their work. We also met with two relevant stakeholder groups, one from the chemical industry and one environmental advocacy organization, to solicit their views regarding the availability of chemical assessment information by the IRIS Program. We identified these two groups through past GAO work to get different views on this topic. For both objectives, we reviewed data and information through September 2020.

To examine the extent to which ORD's management of IRIS follows selected program management leading practices—especially with regard

to the survey process introduced in 2018—we selected three sets of standards for program management. These include (1) Lean Management Techniques, because EPA is using Lean principles and tools to promote continuous improvement; (2) program management standards adopted by the Office of Management and Budget (OMB), as required under the Program Management Improvement Accountability Act (PMIAA), because these standards apply government-wide; and (3) *Standards for Internal Control in the Federal Government*, because the principles described are directly relevant to EPA's actions.[9] We found commonalities among all three program management standards and used those to describe overarching principles of program management in areas like communication with stakeholders, use of quality information, monitoring program activities, and strategic planning. We then compared ORD's management of the IRIS Program from mid-2018 to the present against the leading practices we identified and analyzed the extent to which efforts, such as ORD's survey process for soliciting chemical nominations, followed these leading practices. We determined that the information and communication, and control activities components of internal control were significant to this objective, along with the underlying related principles that management should internally and externally communicate necessary quality information to achieve its objectives and that management should design control activities to achieve objectives and respond to risks. We assessed the content of EPA's policies, procedures, and guidance against these principles. We requested an interview with ORD and IRIS officials to learn more about their understanding and implementation of program management leading practices; in lieu of a meeting, officials provided some information in writing.

We conducted this performance audit from December 2019 to December 2020, 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

[9]Thomas L. Jackson and Karen R. Jones. *Implementing a Lean Management System* (Portland, OR: 1996); Office of Management and Budget, *Memorandum: Improving the Management of Federal Programs and Projects through Implementing the Program Management Improvement Accountability Act (PMIAA),* M-18-19 (Washington, D.C.: June 25, 2018); and GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014).

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

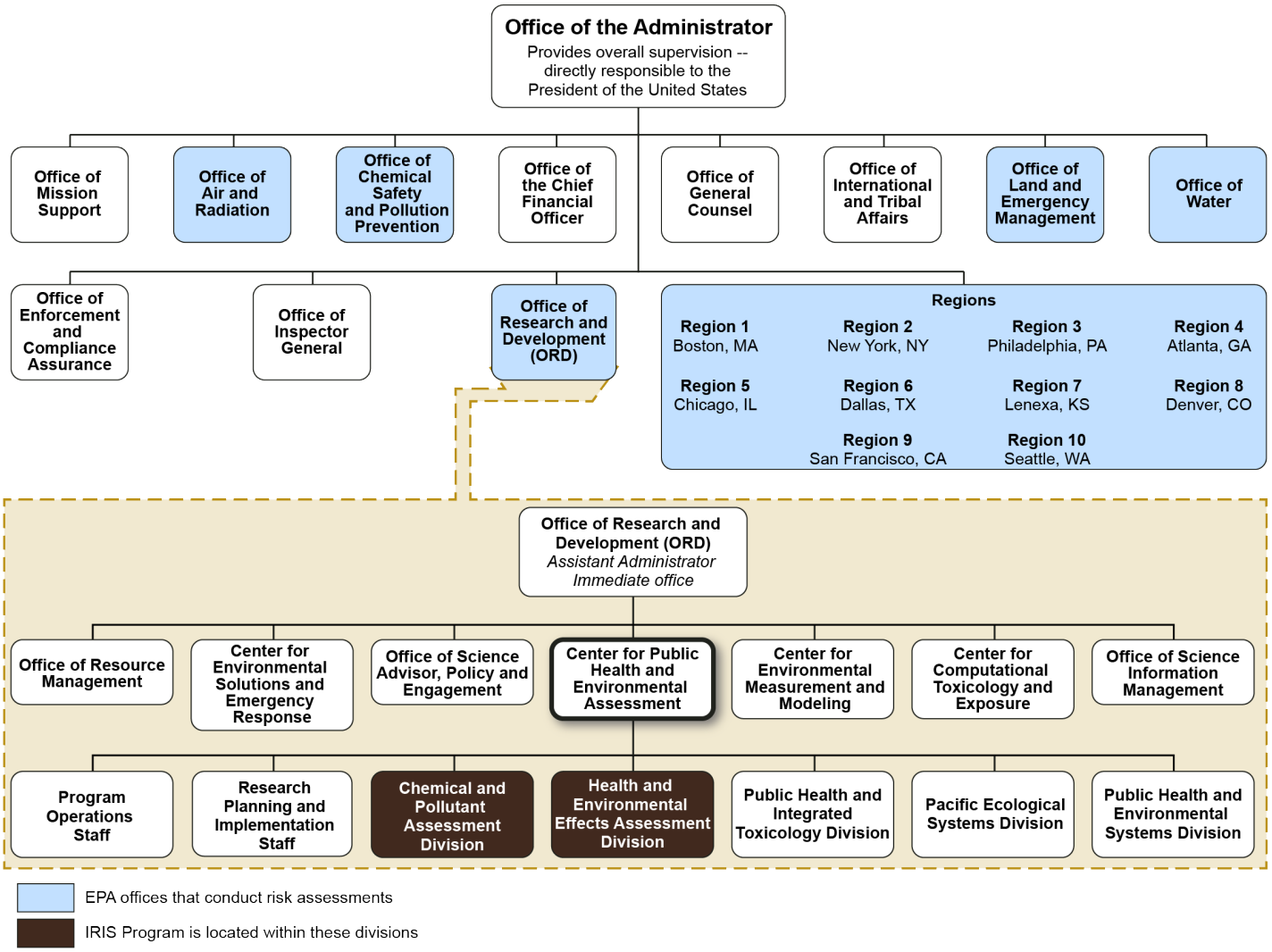
History of the IRIS Program and Its Chemical Assessment Process

EPA created the IRIS Program in 1985 to help develop consensus opinions within EPA about the health effects from lifetime exposure to chemicals. The IRIS database of chemical assessments contains EPA's scientific positions on the potential human health effects that may result from exposure to various chemicals in the environment and, as of September 2020, it included information on 571 final IRIS assessments.[10] Based on our body of work on the IRIS Program, the program's importance has grown over time as EPA program and regional offices have increasingly relied on IRIS chemical 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 chemical assessments in managing their environmental protection programs.

As seen in figure 1, a number of program and regional offices at EPA prepare chemical risk assessments, which 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 toxic chemicals.

[10]This is a list of final IRIS chemical assessments in alphabetical order by chemical name: https://cfpub.epa.gov/ncea/iris_drafts/AtoZ.cfm.

Figure 1: Environmental Protection Agency's (EPA) Organizational Structure



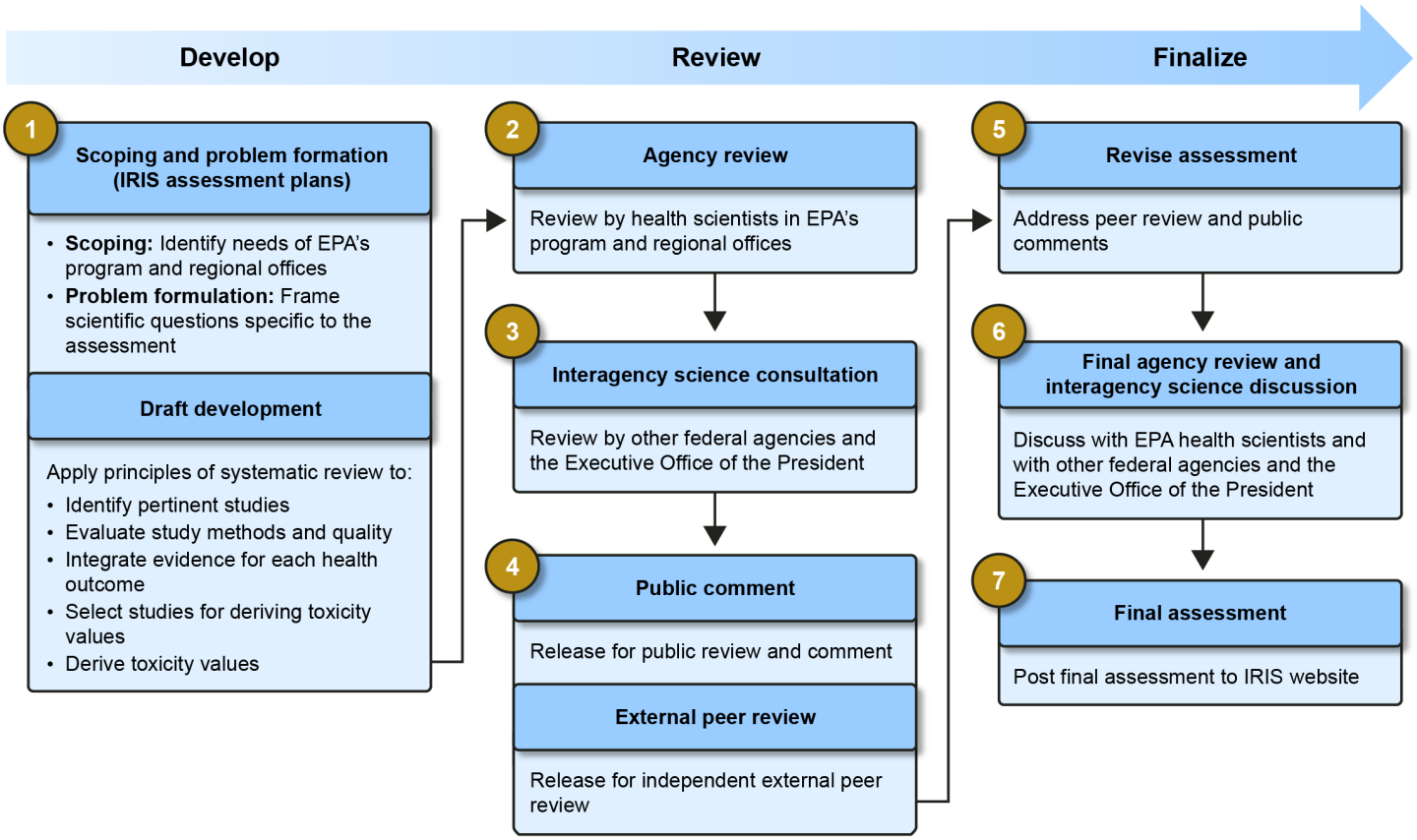
Source: GAO analysis of EPA information. | GAO-21-156

To prepare risk assessments, some EPA program and regional offices rely in part on chemical assessments that the IRIS Program prepares. IRIS assessments generally include two parts: (1) hazard identification and (2) dose-response assessment. Hazard identification identifies credible health hazards associated with exposures to a chemical; dose-response assessment characterizes the quantitative relationship between chemical exposure and each credible health hazard. The program derives toxicity values of chemicals through this quantitative relationship. EPA

program and regional offices are then able to use these toxicity values, in combination with exposure assessments that other EPA offices produce, to produce a risk assessment. In short, the IRIS Program provides peer-reviewed toxicity values that are an integral part of EPA's risk assessments and risk management decisions but are not risk assessments in themselves.

To prepare chemical assessments and derive toxicity values, the IRIS Program uses a seven-step process, as shown in figure 2.

Figure 2: Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Chemical Assessment Development Process



Source: EPA. | GAO-21-156

Note: According to EPA, early in step 1, the Program releases an IRIS Assessment Plan, which outlines what the assessment covers and is released for public comment and discussion at a public meeting. Later in step 1, the Program releases a systematic review protocol, which details how the assessment will be conducted and is released for public comment.

The first step in the assessment development process is developing a draft assessment, and this actually encompasses production of two supporting documents and then the full draft. First, IRIS Program staff determine the scope and initial problem formulation of an assessment in consultation with EPA program and regional offices, and this information is documented in an IRIS Assessment Plan that is released for agency and public comment. After obtaining feedback on the IRIS Assessment Plan, IRIS Program staff prepare an assessment protocol for public comment that describes the methods that the IRIS Program will use to conduct the assessment. Both the IRIS Assessment Plans and the assessment protocols, or scoping documents, detail the proposed scope of the chemical assessment and are important steps in developing the expectations of the IRIS assessments. During these initial phases of step 1 (scoping and problem formulation) IRIS Program staff conduct preliminary searches of scientific literature and screen relevant studies to understand the extent and nature of the available evidence. This informs the level of effort, identifies areas of scientific complexity, and helps the IRIS Program estimate time frames for conducting the assessment. After the initial supporting documentation is completed and reviewed, the Program staff select and extract relevant data and analyze and integrate the evidence into the draft assessment. The final step in preparing the draft assessment is deriving chemical toxicity values. After these draft development steps (step 1 in fig. 2), the draft assessment goes through internal agency and interagency review; public comment; and peer review, as shown in steps 2 through 4 in figure 2. After making revisions to address comments received (step 5), the assessment goes through another round of internal and interagency review (step 6), and then the program finalizes and posts the assessment to the IRIS website.[11] According to EPA, IRIS draft assessments are revised—sometimes extensively—between each step in the IRIS process. These revisions include separate and sequential reviews by other federal agencies, the public, and peer reviewers.

Because the IRIS process is so rigorous, IRIS assessments are considered the gold standard for toxicity values, according to EPA

[11]The IRIS Program has not changed the process steps presented in fig. 2 since 2013, but the types of documents produced during step 1 (scoping and problem formulation) have evolved from preliminary assessment materials (before 2017) to IRIS Assessment Plans and protocols (after 2017) to better integrate systematic review approaches into the existing process. The IRIS Program Outlook provides a status update on the chemical assessments in development and the next projected public steps in the IRIS Assessment process they are expected to reach (steps 1, 4, and 7). However, the Outlook does not provide information on internal IRIS steps in the process (steps 2, 3, 5, and 6).

program and regional office staff who use IRIS assessments in their work. But IRIS's process is also noted for being slow; assessments can take years to complete. According to EPA, the IRIS process is uniquely rigorous and complex and is more extensive than almost any other assessment review process. IRIS Program management have implemented some changes in the past several years to streamline the process and speed up assessment production – we examined many of these process changes in our March 2019 report. But faced with delays in assessment production, states have begun to create their own toxicity values and standards that often differ with available IRIS values and one another.[12]

Leading Program Management Practices

IRIS refers to itself as a program, and IRIS's activities fit the generally accepted definition of a program: it includes multiple components, such as subprograms and projects (for example, each individual chemical assessment would be considered a project), which are interrelated and managed in a coordinated way.

There are numerous program management standards that are widely known and generally accepted. For example, the standards and policies set forth pursuant to PMIAA apply to EPA. PMIAA was enacted in December 2016. The law is intended to improve federal agency program and project management practices. Among other things, the act requires OMB to adopt and oversee implementation of government-wide standards, policies, and guidelines for program and project management in executive agencies. These standards are outlined in a 2018 memo from OMB to federal agencies and include a focus on customer service; requirements development and management; strategic planning; communications planning and stakeholder engagement; evaluation; and process improvement.

EPA has also used Lean Management techniques since 2014.[13] Agency documentation states that the EPA Lean Management System (ELMS) is

[12]415 ILCS 5/9.16; Texas Commission on Environmental Quality, Ethylene Oxide Carcinogenic Dose-Response Assessment (2020).

[13]EPA's "About Lean" website defined Lean Management as "a set of principles and methods used to identify and eliminate waste in any process. Lean helps organizations improve the speed and quality of their processes by getting rid of unnecessary activity such as document errors, extra process steps and waiting time."

a means to promote continuous improvement, which is one of the core principles of Lean Management. Other Lean Management principles include customer focus, leadership, partnering, and information architecture.

Finally, *Standards for Internal Controls in the Federal Government* provides managers criteria for designing, implementing, and operating an effective internal control system. *Standards for Internal Controls in the Federal Government* defines five components of internal controls that are control environment; risk assessment; control activities; information and communication; and monitoring.

The IRIS Program Has Not Produced Timely Assessments, and the Need for Greater Transparency in the Program Remains

The IRIS Program has been unable to produce assessments according to schedule, as some of the 15 current assessments have been in development for years, and most have experienced delays since 2018. Further, IRIS has taken some actions to make its assessment process more transparent, but ORD has only recently made available its *Handbook for Developing IRIS Assessments* (IRIS Handbook) for peer review; the Handbook has been in development since 2013, and the need for greater transparency in the Program remains.[14]

The IRIS Program Has Not Produced Timely Assessments, and Most Ongoing Assessments Have Experienced Delays

As of August 2020, the IRIS Program identified 15 chemical assessments as in development. One of these chemicals, vanadium and compounds, has two assessments for two different routes of exposure (inhalation exposure and oral exposure). Of the 15 ongoing assessments, 13 are in

[14]EPA issued the IRIS Handbook on November 30, 2020 for external peer review. As noted above, GAO reviewed IRIS Program documentation and information through September 2020 and did not have the opportunity to review this document.

the first step—draft development—of the seven-step process.[15] See table 1 for a list of the ongoing IRIS assessments. Since December 2018, no ongoing assessments have progressed to the next public step of the assessment development process or have been completed and issued to the public via the IRIS Program's website. In addition, between November and December 2018, seven chemical assessments were suspended, and eight were discontinued.[16] EPA provided only limited explanation about some assessments.

Table 1: Chemical Assessments in Development in December 2018, and in August 2020

	Chemical name	Step in IRIS assessment process (December 2018)	Step in IRIS assessment process (August 2020)	Most recent agency action and date
1	Tert-butyl alcohol (TBA)	Step 5	Step 5	Review of Draft Assessment: June 2017
2	Ethyl tertiary butyl ether (ETBE)	Step 5	Step 5	Review of Draft Assessment: June 2017
3	Chloroform	Step 1	Step 1	Added to Outlook: December 2019
4	Chromium VI (hexavalent chromium)	Step 1	Step 1	Release of Draft Systematic Review: March 15, 2019
5	Inorganic arsenic	Step 1	Step 1	Release of Draft Systematic Review: May 25, 2019
6	Inorganic mercury salts	Step 1	Step 1	Release of Draft IRIS Assessment Plan: October 8, 2019
7	Methylmercury	Step 1	Step 1	Release of Draft Systematic Review Protocol: May 28, 2019

[15]The draft development step (step 1) includes the public release of two documents: the IRIS Assessment Plan and the release of Systematic Review Protocol documents. Systematic Review Protocols present the methods EPA will use to conduct a systematic review of scientific literature. According to EPA technical comments, PFAB is at step 3 in the IRIS assessment process. However, GAO could not confirm this statement because step 3 is an internal EPA IRIS step.

[16]According to EPA, ammonia, ethylbenzene, formaldehyde, naphthalene, nitrate, nitrite, and polycyclic aromatic hydrocarbon (PAH) mixtures are suspended. According to EPA, "suspended" means the chemical assessment may be restarted as agency priorities change. According to EPA, acrylonitrile, butyl benzyl phthalate, dibutyl phthalate (DBP), diethyl phthalate (DEP), diisobutyl phthalate (DIBP), diisononyl phthalate (DINP), hexabromocyclododecane (HBCD), and n-butanol are discontinued. According to EPA, when a chemical assessment is discontinued, a new/updated assessment will not be added to the IRIS database at this time.

	Chemical name	Step in IRIS assessment process (December 2018)	Step in IRIS assessment process (August 2020)	Most recent agency action and date
8	Polychlorinated biphenyls (PCBs; noncancer)	Step 1	Step 1	Release of Draft Systematic Review: December 19, 2019
9	Vanadium and compounds (Oral exposure)	Step 1	Step 1	Release of draft IRIS Assessment Plan: July 24, 2020
10	Vanadium and compounds (Inhalation exposure)	Not Included	Step 1	Added to Outlook: December 18, 2019
11	Perfluorobutyrate (PFBA)	Step 1	Step 1	Release of Updated Systematic Review Protocols: July 28, 2020
12	Perfluorodecanoate (PFDA)	Step 1	Step 1	Release of Updated Systematic Review Protocols: July 28, 2020
13	Perfluorohexane sulfonic acid (PFHxS)	Step 1	Step 1	Release of Updated Systematic Review Protocols: July 28, 2020
14	Perfluorohexanoic acid (PFHxA)	Step 1	Step 1	Release of Updated Systematic Review Protocols: July 28, 2020
15	Perfluorononanoate (PFNA)	Step 1	Step 1	Release of Updated Systematic Review Protocols: July 28, 2020

Source: GAO analysis of Environmental Protection Agency data. | GAO-21-156

Note: The “Most recent agency action and date” column on the far right indicates the date of the most recent release of assessment-related documents for public comment, additions to the Integrated Risk Information System (IRIS) Program Outlooks, or Draft Assessment Reviews, This includes IRIS Assessment Plans and Systematic Review Documents and Protocols. This table provides information on public steps in the IRIS Process (steps 1, 4, 5, and 7).

IRIS Program staff said that in response to the 2019 annual survey for chemical nominations, which sought information for fiscal year 2020, two chemicals were added to the IRIS Program’s assessments in-development list: (1) chloroform and (2) vanadium and compounds for inhalation exposure. Both were identified as high-priority needs by EPA’s Office of Air and Radiation. The IRIS Program suspended an assessment for chloroform in 2018 due to shifting agency needs. It was then restarted in 2019. We were unable to determine the extent to which previously developed toxicity information was incorporated into the restarted assessment.[17] We were also unable to determine why chloroform was

[17]Prior to the 2018 suspension, the chloroform IRIS Assessment Plan was released in September 2017 and the Systematic Review Protocol was released in January 2018.

returned to step 1 of the process. EPA did not provide any reasons for delays or progress with the chloroform assessment.

Some of the assessments have been in development for over 10 years. This includes inorganic arsenic, which was initially started in 2003; and ETBE which was initially started in 2004. The IRIS Program started publishing public Program Outlook documents at least three times per calendar year in December 2018; prior to this, the Program periodically published agendas detailing their assessments in development. The Outlook documents provide a status update on the chemical assessments in development, the next projected public steps in the IRIS Assessment process they are expected to reach (steps 1, 4, and 7), and the fiscal year quarter they are projected to meet these steps. IRIS Program Outlooks are intended to maintain transparency and provide an update on the status of assessments in development, and the April 2019 Outlook provided information on assessments that had been suspended or removed from the IRIS Program's assessments in-development list.

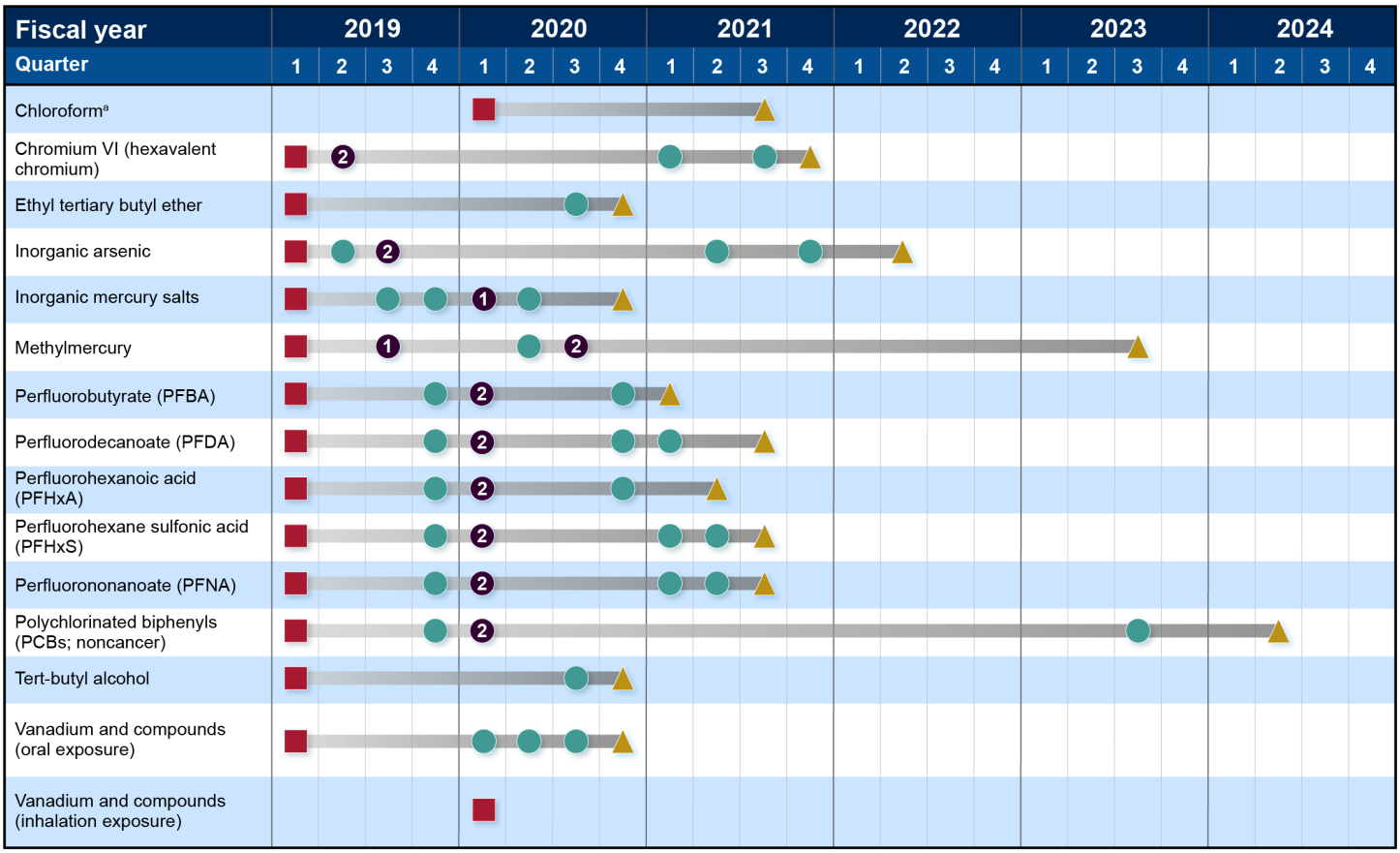
In all six IRIS Program Outlook documents released since December 2018, the time line for each of the included chemicals shows a delay of one quarter or more into the future (see fig. 3). The majority of these chemicals remain at the step they were at in December 2018. For example:

- Chromium VI (hexavalent chromium): in the December 2018 Program Outlook, chromium VI was projected to reach external peer review (step 4) in the third quarter of fiscal year 2020. That milestone was delayed in most subsequent Outlooks and, as of June 2020, the chromium VI assessment is projected to be ready for external peer review in the first quarter of fiscal year 2022.
- Inorganic arsenic: in the December 2018 Program Outlook, inorganic arsenic was projected to reach public comment draft (a portion of step 4) in the second quarter of fiscal year 2020. That milestone was delayed in most subsequent Outlooks and, as of June 2020, the inorganic arsenic assessment is projected to be ready for a public comment draft to be released in the second quarter of fiscal year 2022.
- Polychlorinated biphenyls (PCBs; noncancer): in the December 2018 Program Outlook, the PCBs assessment was projected to reach public comment draft (a portion of step 4) in the first quarter of fiscal year 2021. That milestone was delayed in most subsequent Outlooks and, as of June 2020, assessment for PCBs is projected to be ready

for a public comment draft to be released in the second quarter of fiscal year 2024.

Most other assessments in development have experienced similar delays. See figure 3 for a list of all ongoing assessments and their anticipated assessment time lines.

Figure 3: Anticipated Assessment Time Lines by Fiscal Quarter According to IRIS Program Outlooks for All Chemicals Currently under Assessment, 2019-2024



Source: GAO analysis of Environmental Protection Agency data. | GAO-21-156

Text of Figure 3: Anticipated Assessment Time Lines by Fiscal Quarter According to IRIS Program Outlooks for All Chemicals Currently under Assessment, 2019-2024

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
Chloroform (inhalation)	June 2020 (FY2020 Q3)	Step 1: IRIS Assessment Plan	Released September 18, 2017. Public Meeting on September 27, 2017
		Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	February 2020 (FY2020 Q2)	Step 1: IRIS Assessment Plan	Released September 18, 2017. Public Meeting on September 27, 2017
		Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released September 18, 2017
		Step 1: Systematic Review Protocol	Released January 31, 2018
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Chromium VI	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q1
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY22 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY22 - Q1
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	Released March 15, 2019. Public Science Meeting April 24, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q3
		Step 1: Systematic Review Protocol	FY19 - Q2
		Step 4: Public Comment Draft	FY20 - Q1

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	December 2018 (FY2019 Q1)	Step 4: External Peer Review	FY20 - Q3
Ethyl tertiary butyl ether	June 2020 (FY2020 Q3)	Step 7: Final	FY20 - Q4
	February 2020 (FY2020 Q2)	Step 7: Final	FY20 - Q4
	December 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	October 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	April 2019 (FY2019 Q3)	Step 7: Final	FY20 - Q3
	December 2018 (FY2019 Q1)	Step 7: Final	TBD
Inorganic Arsenic	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released May 28, 2019. NAS review meeting July 16, 2019
		Step 4: Public Comment Draft	FY22 - Q2
		Step 4: External Peer Review	FY22 - Q4
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released May 28, 2019. NAS review meeting July 16, 2019
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q2
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released May 28, 2019. NAS review meeting July 16, 2019
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY21 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released May 28, 2019. NAS review meeting July 16, 2019
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY21 - Q4

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q3 (anticipated May 17, 2018, NAS review July 16, 2019)
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q2
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	FY19 - Q2
		Step 4: Public Comment Draft	FY20 - Q2
		Step 4: External Peer Review	FY21 - Q1
Inorganic Mercury Salts	June 2020 (FY2020 Q3)	Step 1: IRIS Assessment Plan	Released October 8, 2019. Public Science Meeting December 5, 2019
		Step 1: Systematic Review Protocol	FY20 - Q4
		Step 4: Public Comment Draft	FY22 - Q1
		Step 4: External Peer Review	FY22 - Q3
	February 2020 (FY2020 Q2)	Step 1: IRIS Assessment Plan	Released October 8, 2019. Public Science Meeting December 5, 2019
		Step 1: Systematic Review Protocol	FY20 - Q4
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released October 8, 2019. Public Science Meeting December 5, 2019
		Step 1: Systematic Review Protocol	FY20 - Q2
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q1
	October 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released October 8, 2019. Public Science Meeting December 5, 2019
		Step 1: Systematic Review Protocol	FY20 - Q2
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q1
	April 2019 (FY2019 Q3)	Step 1: IRIS Assessment Plan	FY19 - Q4
		Step 1: Systematic Review Protocol	FY20 - Q2
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY22 - Q1
	December 2018 (FY2019 Q1)	Step 1: IRIS Assessment Plan	FY19 - Q3
		Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY21 - Q4
		Step 4: External Peer Review	FY22 - Q2
Methylmercury		Step 1: IRIS Assessment Plan	Released April 4, 2019. Public Science Meeting May 15, 2019
		Step 1: Systematic Review Protocol	Released May 26 2020

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	June 2020 (FY2020 Q3)	Step 4: Public Comment Draft	FY23 - Q3
		Step 4: External Peer Review	FY24 - Q1
	February 2020 (FY2020 Q2)	Step 1: IRIS Assessment Plan	Released April 4, 2019. Public Science Meeting May 15, 2019
		Step 1: Systematic Review Protocol	FY20 - Q3
		Step 4: Public Comment Draft	FY22 - Q4
		Step 4: External Peer Review	FY23 - Q3
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released April 4, 2019. Public Science Meeting May 15, 2019
		Step 1: Systematic Review Protocol	FY20 - Q2
		Step 4: Public Comment Draft	FY22 - Q2
		Step 4: External Peer Review	FY24 - Q4
	October 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	Released April 4, 2019. Public Science Meeting May 15, 2019
		Step 1: Systematic Review Protocol	FY20 - Q2
		Step 4: Public Comment Draft	FY22 - Q2
		Step 4: External Peer Review	FY24 - Q4
	April 2019 (FY2019 Q3)	Step 1: IRIS Assessment Plan	FY19 - Q3 (anrticipated release April 4, 2019. Anticipated Public Science Meeting May 15, 2019)
		Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY22 - Q1
		Step 4: External Peer Review	FY22 - Q1
	December 2018 (FY2019 Q1)	Step 1: IRIS Assessment Plan	FY19 - Q1
		Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY22 - Q1
Perfluorobutyrate (PFBA)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q2
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
		Step 1: Systematic Review Protocol	FY20 - Q1

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	October 2019 (FY2020 Q1)	Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY20 - Q3
		Step 4: External Peer Review	FY21 - Q1
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Perfluorodecanoate (PFDA)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q3
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q2
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released November 8, 2019
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY20 - Q3
		Step 4: External Peer Review	FY21 - Q1
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Perfluorohexanoic acid (PFHxA)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY21 - Q3
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q1
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY20 - Q3
		Step 4: External Peer Review	FY21 - Q1
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Perfluorohexane sulfonic acid (PFHxS)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q3
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY21 - Q3
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q4
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q2
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Perfluorononanoate (PFNA)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q3
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q2
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	Released on November 8, 2019
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q4

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q4
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY20 - Q4
		Step 4: External Peer Review	FY21 - Q2
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Polychlorinated biphenyls (PCBs; noncancer)	June 2020 (FY2020 Q3)	Step 1: Systematic Review Protocol	Released on December 19, 2019
		Step 4: Public Comment Draft	FY24 - Q2
		Step 4: External Peer Review	FY24 - Q4
	February 2020 (FY2020 Q2)	Step 1: Systematic Review Protocol	Released on December 19, 2019
		Step 4: Public Comment Draft	FY23 - Q3
		Step 4: External Peer Review	FY23 - Q4
	December 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY22 - Q4
		Step 4: External Peer Review	FY22 - Q4
	October 2019 (FY2020 Q1)	Step 1: Systematic Review Protocol	FY20 - Q1
		Step 4: Public Comment Draft	FY22 - Q3
		Step 4: External Peer Review	FY22 - Q4
	April 2019 (FY2019 Q3)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY22 - Q2
		Step 4: External Peer Review	FY22 - Q4
	December 2018 (FY2019 Q1)	Step 1: Systematic Review Protocol	FY19 - Q4
		Step 4: Public Comment Draft	FY21 - Q1
		Step 4: External Peer Review	FY21 - Q2
Tert-butyl alcohol	June 2020 (FY2020 Q3)	Step 7: Final	FY20 - Q4
	February 2020 (FY2020 Q2)	Step 7: Final	FY20 - Q4
	December 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	October 2019 (FY2020 Q1)	Step 7: Final	FY20 - Q3
	April 2019 (FY2019 Q3)	Step 7: Final	FY20 - Q4
	December 2018 (FY2019 Q1)	Step 7: Final	TBD
Vanadium and Compounds (Oral exposure)	June 2020 (FY2020 Q3)	Step 1: IRIS Assessment Plan	FY20 - Q4
		Step 1: Systematic Review Protocol	FY21 - Q1
		Step 4: Public Comment Draft	FY22 - Q1
		Step 4: External Peer Review	FY22 - Q2
	February 2020 (FY2020 Q2)	Step 1: IRIS Assessment Plan	FY20 - Q3
		Step 1: Systematic Review Protocol	FY20 - Q4
		Step 4: Public Comment Draft	FY21 - Q3
		Step 4: External Peer Review	FY21 - Q4
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	FY20 - Q2
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
	October 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	FY20 - Q2
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
	April 2019 (FY2019 Q3)	Step 1: IRIS Assessment Plan	FY20 - Q1
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
	December 2018 (FY2019 Q1)	Step 1: IRIS Assessment Plan	TBD
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
Vanadium and Compounds (inhalation exposure)	June 2020 (FY2020 Q3)	Step 1: IRIS Assessment Plan	TBD
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD

Chemical	Outlook Date	Next Anticipated Public Step(s)	Projected Fiscal Year Quarter
	February 2020 (FY2020 Q2)	Step 1: IRIS Assessment Plan	TBD
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD
	December 2019 (FY2020 Q1)	Step 1: IRIS Assessment Plan	TBD
		Step 1: Systematic Review Protocol	TBD
		Step 4: Public Comment Draft	TBD
		Step 4: External Peer Review	TBD

Note: This information is from the June 2020 IRIS Program Outlook. In October 2020 EPA's IRIS Program released another Program Outlook but did not provide it to GAO until after analysis on this review was completed; therefore, it was not included in this report.

[a]The chloroform assessment was suspended in 2018 and restarted in 2019.

When asked about delays, representatives from EPA's OCIR stated in a written document that: "Changes that occur [in IRIS Program Outlooks] are typically the result of the scientific complexities of each assessment and availability of staff with the appropriate expertise to address those complexities. Generally, single quarter shifts [in projected next steps for assessments in development] are the result of cascading changes to review, revision, and posting timelines of assessment products." Officials in ORD and IRIS did not further clarify or explain the causes of repeated delays, what constitutes a scientific complexity, why program staff levels were not adjusted to accommodate the needed capacity of the program, or why there has not been a change to their forecasting of next steps despite 2 years of regular quarterly delays.

The IRIS Program has publicly released nine supporting documents for ongoing assessments since December 2018. These documents include IRIS Assessment Plans and Systematic Review Protocols, which present methods for conducting the systematic review of scientific literature and dose-response analysis to the public. EPA also held multiple public events and events with the NAS to discuss the assessments in development, allow for public comment on Assessment Plans, and other public science meetings for the IRIS Program. (See table 2.)

Table 2: Time Line of Document Releases and IRIS-Related Events, 2019-2020

Year	Date of release/ agency action	Agency action/event
2020	August 19, 2020	Integrated Risk Information System (IRIS) public science meeting - vanadium and compounds (oral exposure)
	July 28, 2020	Release of updated Draft Systematic Review Protocol - perfluorobutyrate (PFBA), perfluorodecanoate (PFDA), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorononanoate (PFNA). Collectively known as PFAS.
	July 24, 2020	Release of Draft IRIS Assessment Plan - vanadium and compounds (oral exposure)
	May 28, 2020	Release of Draft Systematic Review Protocol - methylmercury
2019	December 19, 2019	Release of Draft Systematic Review Protocol – polychlorinated biphenyls (PCBs; noncancer)
	December 18, 2019	Chloroform added to IRIS Program Outlook
	December 18, 2019	Vanadium and compounds (inhalation exposure) added to IRIS Program Outlook
	December 5, 2019	IRIS public science meeting - mercury salts
	November 8, 2019	Release of Draft Systematic Review Protocol - PFBA, PFHxA, PFHxS, PFNA, and PFDA. Collectively known as PFAS.
	October 8, 2019	Release of Draft IRIS Assessment Plan - inorganic mercury salts
	July 16, 2019	National Academy of Sciences (NAS) public science meeting - inorganic arsenic
	June 3-4, 2019	NAS public science workshop - review of IRIS Program's Systematic Review Protocols
	May 28, 2019	Release of draft problem formulation and Systematic Review Protocol - inorganic arsenic
	May 15, 2019	IRIS public science meeting (webinar) - methylmercury
	April 24, 2019	IRIS public science meeting – chromium VI (hexavalent chromium)
	April 4, 2019	Release of Draft IRIS Assessment Plan – methylmercury
	March 15, 2019	Release of Draft Systematic Review Protocol – Chromium VI (hexavalent chromium)

Key of color meaning
Addition to Program Outlook
IRIS-related event
Release of document

Source: GAO analysis of Environmental Protection Agency (EPA) information. | GAO-21-156

The IRIS Program Has Taken Some Actions to Make the Assessment Process More Transparent, but the Need for Greater Transparency Remains

The IRIS Program has taken some actions to increase transparency throughout its assessment process, including regular communication with program and regional offices about assessment progress and releasing assessment documents for public comment. However, assessments still face years-long delays with no public explanation. ORD has only recently

released the IRIS Handbook—the overarching document to codify and communicate the IRIS assessment process to the public—for peer review and offered limited explanation on delays in getting the document to this stage.

Previous NAS reports on the IRIS Program recommended increasing the transparency of the IRIS assessment process, including how the Program develops its assessment time lines.[18] The IRIS Program made changes to the assessment process to address these recommendations. According to EPA officials, these include releasing supporting assessment documentation earlier in the process, updating their website more frequently with some information on assessment progress, and holding more frequent meetings with program and regional office staff. But officials from one EPA office told us that these measures, such as earlier engagement with the public and increased thoroughness of review, have resulted in longer assessment time lines. Other offices praised the transparency efforts and stated that the implementation of Systematic Review and the public release of Systematic Review Protocols have increased the understanding of how assessments are produced and what sources of toxicity information are used to develop assessments.

Although communication and transparency efforts have increased, the public has limited information about where assessments are in the IRIS process, especially because several steps in the process are not announced publicly. Additionally, when assessment time lines are delayed, EPA does not publicly provide reasons or explanations. As we noted previously, between November and December 2018, seven chemical assessments were suspended, and eight were discontinued; EPA provided only limited explanation. According to a representative from OCIR, the IRIS Program does not announce the advancement of assessments to nonpublic steps like agency review, interagency science consultation, and final agency review (steps 2, 3, and 6 in fig. 2) on the IRIS website. For example, tert-butyl alcohol (TBA) and ethyl tertiary butyl ether (ETBE) have been listed at step 5 (revising the assessment based on public comment and external peer review) on the IRIS website since

[18]National Research Council of the National Academies, *Review of EPA's Draft IRIS Assessment of Formaldehyde* (Washington, D.C.: National Academies Press, 2011); *Review of EPA's Integrated Risk Information System (IRIS).Process* (Washington, D.C.: National Academies Press, 2014); and *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (Washington, D.C.: National Academies Press, 2018).

December of 2018, despite advancing to step 6 (final agency and interagency review) in fiscal year 2020.[19]

Additionally, ORD has only recently released the IRIS Handbook for peer review, which has been in development since at least 2013.[20] The IRIS Handbook is supposed to provide standardized operating procedures for the development of IRIS assessments to promote consistency across assessments and to help inform EPA offices, EPA scientists, industry groups, and the public of how IRIS assessments are developed. In written correspondence from OCIR dated September 4, 2020, we were told the IRIS Handbook was currently under review by the Office of the Assistant Administrator in ORD and would be ready for release for public comment, followed by external peer review, sometime in the first quarter of fiscal year 2021. A representative from OCIR stated that the delay in releasing the IRIS Handbook was due to the complexities of cross-agency comment and collaboration. The Handbook was made available for peer review on November 30, 2020 and we did not have the opportunity to review it for this report.

Leading program management practices and *Standards for Internal Control in the Federal Government* state that agency management should internally and externally communicate the necessary, quality information to achieve the entity's objectives.[21] The information should be communicated down, across, up, and around reporting lines to all levels of the agency, as well as to and from external parties (including regulators, external auditors, government entities, and the general public) using established, open reporting lines. If EPA were providing clear communication about where assessments are in the development

[19]On July 23, 2020, TBA was released for step 6 (final agency and interagency review). On August 4, 2020, ETBE was released for step 6 (final agency and interagency review). In written correspondence with agency officials, EPA told us that these chemicals, TBA and ETBE, completed reviews by the Science Advisory Board (SAB) in February 2019 and were scheduled for release in quarter four of fiscal year 2020. Representatives from ORD told us that reviews are posted on their web page but, unlike other assessment-related documentation, the SAB's reports for these chemicals are neither listed on the IRIS Program website's list of recent additions nor are they listed in the IRIS Program Outlooks.

[20]In our March 2019 report, GAO-19-270, we reported that as of November 2018, the IRIS Handbook was nearing completion of EPA's internal review process and was being prepared for public release. The Handbook was reviewed by NAS in 2014 and again in 2018. NAS's 2018 report praised EPA for progress made on the development of the Handbook

[21]GAO-14-704G.

process, stakeholders might be able to set expectations for receiving the completed assessment. However, because EPA does not address where assessments are in the development process, stakeholders remain unaware of when to expect completed assessments.

During our interviews with two relevant stakeholder groups, representatives from both a chemical industry group and an environmental advocacy organization stated that the IRIS Program would benefit from greater transparency throughout the chemical assessment process. Representatives from the industry group told us that in their view, not enough is being done to show how newly implemented changes to the Program are shortening assessment timelines. The delay in publishing the IRIS Handbook was further preventing industry groups and the public from seeing how IRIS's process has changed, as there is no overarching document available that defines how IRIS assessments are produced. Representatives from an environmental advocacy organization voiced similar concerns that delays in assessment time lines lack public explanation and, due to the absence of publicly available information on the assessment process, there is limited understanding of how the program operates and why years-long delays occur. Representatives from this environmental advocacy organization group also stated that while IRIS is the gold standard for chemical assessments, the IRIS Program needs to release assessments more expeditiously. Representatives from a chemical industry group added that the lack of transparency in terms of time lines and explanations for delays is frustrating.

Recent Actions to Manage the IRIS Program Were Implemented without Sufficient Guidance or Criteria and Have Not Helped IRIS Meet User Needs

In mid-2018, ORD instituted a new annual survey process to solicit nominations for chemical assessments conducted by the IRIS Program but did so without sufficient guidance or criteria, which is inconsistent with leading practices for program management and quality information. In addition, the strategic plan ORD developed in 2020 does not include information on resources and implementation steps; without such information, it is difficult for ORD to plan to meet IRIS Program user needs.

ORD Instituted Its Process for Soliciting Nominations for IRIS Assessments without Providing Sufficient Criteria or Information

ORD instituted a new process for soliciting nominations for IRIS assessments without issuing criteria stating how they select chemical nominations for assessment or providing information about how they prioritize the IRIS Program's work to inform program and regional office officials during the process. Additionally, program office Assistant Administrators and Regional Administrators did not issue guidance or criteria for their respective offices to inform the selection of chemicals for submission to ORD. Further, ORD has not assessed whether the new nomination process has produced quality information that can be used to evaluate whether the IRIS Program is meeting its users' needs.

ORD Did Not Issue Criteria about How They Select Chemical Nominations or Information About How ORD Prioritizes the IRIS Program's Assessment Work

When ORD introduced its new survey process for nominating chemicals for assessment in 2018, it did not provide program and regional offices with criteria stating how nominations would be selected for inclusion in IRIS's list of assessments in development nor information about how the IRIS Program's work is prioritized.[22] Information about ORD's selection criteria and prioritization decisions would have helped EPA program and regional offices better determine what chemicals to nominate for assessment.

[22]IRIS's process for soliciting requests for chemical assessments from EPA program and regional offices changed in 2018. Prior to mid-2018, the IRIS Program typically solicited requests for assessments every 2 to 3 years; through surveys of program and regional offices; and through more frequent, informal communication with program and regional office staff, which provided status updates on office needs based on upcoming regulatory decisions and the priorities of Assistant Administrators. Program and regional office staff sent nominations to IRIS Program staff, who prioritized them using the IRIS Program's criteria that were publicly available as part of its Multi-Year Agenda. After mid-2018, ORD sent a new survey to program office Assistant Administrators and regional office Administrators, requesting nominations for new, high-priority chemical assessments. The Assistant Administrators were required to support each individual chemical nomination from their office, and regional offices were required to submit their nominations to program offices, who submitted nominations back to the Assistant Administrator in ORD. Officials in ORD then determined which nominations to add to the IRIS Program's list of assessments in development.

In response to the August 2018 survey, most program and regional offices submitted nominations totaling more than 50 chemicals for assessment. Because of changes to the nomination process that required regional offices to submit their nominations through program offices, officials from two regional offices indicated that there was initial confusion about how to submit nominations; they indicated that they never received explicit instructions from ORD. In fact, documentary evidence from EPA indicated that ORD's senior leadership had not communicated to program and regional offices how nominations were to be coordinated and submitted to ORD, even after the survey was released.

In October 2018, when officials in ORD requested that offices resubmit only their high priorities, two offices responded and submitted a reduced number of nominations–generally three or four per office. But neither during the original survey nor during the request for only high priorities did ORD provide criteria to offices explaining how they were weighting various factors in determining which nominations would be added to the IRIS Program's list of assessments in development. In addition, ORD did not provide information to program and regional offices about how IRIS resources would affect the number of assessments the IRIS Program could do nor how the IRIS Program would prioritize which assessments it would conduct.

In December 2018, the IRIS Program released a Program Outlook that listed the 11 chemicals that had been selected for assessment.[23] There was no public explanation from the IRIS Program or ORD of how those chemicals were chosen from among the nominations they had received, though EPA officials said in September 2020 that the 11 chemicals in the December 2018 Program Outlook constituted all of the high-priority nominations they had received from program offices in October 2018. However, according to an EPA official in March 2019, the high-priority nominations from at least one program office were not included in the December 2018 Program Outlook.

In September 2019, ORD sent another annual survey to program and regional offices, but this one only requested nominations for high-priority chemical assessments. The survey provided no information about the IRIS Program's capacity or how ORD was prioritizing the IRIS Program's assessments in development. Without such information, it was difficult for

[23]ORD's initial memo listed 11 chemicals; later in December 2018, two more chemicals, TBA and ETBE, were added as they were already in peer review, bringing the total number of assessments in development to 13, as of December 2018.

program and regional offices to determine how ORD viewed their high-priority needs. Representatives from an industry stakeholder organization told us that having a better sense of ORD's criteria for selecting chemicals for assessment and prioritization would also help the public understand how ORD defines its priorities.

Leading program management practices and *Standards for Internal Control in the Federal Government* state that agency management should internally communicate the necessary, quality information to achieve the entity's objectives.[24] According to these standards, quality information should be communicated down, across, up, and around reporting lines to all levels of the entity. Without clear communication and quality information about how ORD and the IRIS Program address the following aspects of selecting nominations for assessment, offices cannot make informed judgments about whether and which chemicals to consider submitting. These aspects include: (1) defining what makes an assessment high priority, (2) criteria for determining which nominations are selected to add to the list of assessments in development, (3) how ORD and IRIS prioritize assessment work, and (4) the IRIS Program's capacity to undertake work at any given time. The IRIS Program is EPA's preferred source of information for identifying and characterizing the health hazards of chemicals found in the environment and is relied upon for toxicity values that underpin risk evaluations produced by EPA offices. Issuing criteria for how ORD selects nominations for assessment and prioritizes the IRIS Program's work would enable program and regional offices to better utilize the nomination process to communicate needs that the IRIS Program can meet.

Program Office Assistant Administrators and Regional Administrators Did Not Issue Guidance or Criteria for Selecting Chemicals for Nomination

Another major change in EPA's process for nominating chemicals for assessment was a requirement that each nomination submitted to ORD be approved by the head of each program office—the Assistant Administrator. However, program and regional office staff did not receive guidance from their respective Assistant Administrators about how to select chemicals for nomination or criteria explaining how Assistant

[24]GAO-14-704G.

Administrators would determine which of their nominations to support and which they may choose not to support.

According to officials from every program and regional office, they were not given explicit criteria for choosing chemicals to nominate—such as how nominations fit in with office priorities set by their Assistant Administrator. Instead, staff from each program office decided how many and which chemicals to nominate based on their own professional judgment; this included some program office officials determining how to prioritize nominations from regional offices. Officials from one program office said that, when asked to determine their highest-priority chemicals, it was an arbitrary decision. Regional offices were also required to fill in the same template as program offices to nominate a chemical for assessment—providing scope and regulatory justifications—and had to have nominations approved by Regional Administrators before they were sent to program offices, where they needed to be approved again by program office Assistant Administrators in order to be sent to ORD. Officials from one region said that they were unsure if their nominations were sent to ORD from program offices, since they did not receive any direct communication in response to their submissions.

Requiring regulatory justifications for all chemical nominations submitted from program and regional offices was in keeping with past nomination practices. However, in 2018 and 2019, no documentation or justification was required when Assistant Administrators chose not to support a specific nomination, or submit any nominations on behalf of their office. For instance, in 2019, the EPA Chief of Staff—who approved nominations for the Office of Children's Health Protection (OCHP)—declined to submit OCHP staff's nominations to ORD, stating that OCHP did not have a regulatory justification for needing chemical assessments. OCHP officials concurred, noting that despite not having direct regulatory needs for IRIS assessments, they previously nominated chemicals for assessment where there were specific children's health concerns. However, OCHP officials were not able to make nominations under the new survey process. Additionally, in 2019, a regional office sent nominations for new chemical assessments to four program offices, but the program offices did not send those nominations to ORD; no reason was given by the respective Assistant Administrators. Being able to set an office's priorities is an Assistant Administrator's prerogative. But an Assistant Administrator's reasons for supporting, or declining to support, chemical nominations should be transparent to ensure that the decisions are consistent with the office's work and mission. Additionally, understanding why specific nominations may not be supported at one time can help staff

understand if a chemical should be considered for nomination in the future.

Leading program management practices and *Standards for Internal Control in the Federal Government* state that agency management should internally communicate the necessary, quality information to achieve the entity's objectives.[25] Without information about how individual program offices determined which chemicals to nominate and which regional office nominations to convey to ORD, it is difficult to know whether nominations represented the most appropriate assessment needs. Additionally, without insight into the process for determining and approving nominations, ORD cannot gain a fuller understanding of each office's priorities—both how they are determined and specifically what they are.

Although the Response Rate to ORD's Survey Has Declined, EPA Has Not Assessed Whether the Results Reflect Quality Information

ORD issued two iterations of the survey, in 2018 and 2019.[26] The number of offices that responded to the survey in 2019 declined by 57 percent, raising questions about whether the survey was generating quality information. OCIR did not indicate whether the agency has conducted a systematic assessment of the survey to determine if it is generating quality information.

In response to the August 2018 survey, 14 of 16 program and regional offices submitted nominations for more than 50 chemical assessments. But in September 2019, only six offices responded to the survey. One regional office submitted 26 nominations to program offices, but only one of those nominations was sent to ORD by a program office. One program office submitted nominations for three new assessments; two of these chemicals were added to the IRIS Program Outlook in December 2019. Three regional and program offices responded to the survey by confirming their needs from 2018.

Officials from six offices explained that they did not submit a response to the 2019 survey because their priority needs had not changed between

[25]GAO-14-704G.

[26]ORD sent out a third survey, for nominations for fiscal year 2021, on September 30, 2020. However, ORD did not provide us with a copy of that survey memorandum until November 23, 2020, and we were unable to examine the survey memorandum or any results it generated in time for inclusion in this report.

2018 and 2019; some of these officials said that they just needed the assessments that the IRIS Program was already working on. In addition, officials from one program office told us that the survey compilation process was burdensome, as they had to compile nominations from numerous regional offices. Although the IRIS Program had not produced any final assessments between August 2018 and September 2020, officials in ORD told us that they were preparing to send another survey for fiscal year 2021 nominations.

Since regional offices were required to submit nominations through program offices, rather than directly to ORD, it is unclear whether the information generated by the survey accurately reflects assessment needs in the agency, in terms of either volume (number of offices requesting a chemical) or priority (whether it was a high priority for multiple offices). For example, under the new survey process, ORD sees only the nominations for a chemical from the individual program office that coordinated the nomination. ORD would not be aware of how many regional offices had nominated the chemical for assessment or how high a priority the chemical was for any individual regional office that had nominated it.

Leading program management practices and *Standards for Internal Control in the Federal Government* state that agency management should monitor and evaluate program activities. Specifically, both the management practices and standards for internal control indicate that management should periodically evaluate program activities in order to ascertain the effectiveness of ongoing activities.[27] The decline in participation and the reasons articulated by officials for why they did not participate should be part of a systematic assessment of the survey process to see if it is soliciting actual user needs. Without evaluating the quality of the information produced by the survey, ORD cannot know if the survey is achieving its intended purpose and whether ORD has the information necessary to evaluate the extent to which the IRIS Program is meeting its users' needs.

ORD's Strategic Plan for IRIS Does Not Include Information about Resources and Implementation Steps

ORD does not have a strategic plan that includes resource information or detailed implementation steps for the IRIS Program, raising questions

[27]GAO-14-704G.

about whether the IRIS Program can meet user needs that may or may not be identified by the survey process.

In response to our questions about whether the IRIS Program had developed a strategic plan, ORD provided us with a draft of the Strategic Research Action Plan for the Health and Environmental Risk Assessment (HERA) National Research Area, of which IRIS is a part.[28] While not an agency-wide strategy, as we recommended in May 2013,[29] the HERA strategic plan calls for coordinating the work of several ORD programs that produce chemical assessments—IRIS, Provisional Peer Reviewed Toxicity Values, and Integrated Science Assessments—to meet EPA user needs for chemical information. Planning for such coordination of the various assessments produced by ORD is encouraging and indicates that ORD's overall knowledge of the universe of user needs is wider than just what is requested of IRIS. However, in a review of the draft strategic plan released in August 2020, the Board of Scientific Counselors[30] stated that it was difficult to determine how the goals outlined in the plan would be accomplished through specific research projects and deliverables and noted that the plan did not include a detailed implementation strategy or metrics to define progress in the draft strategic plan.

Additionally, there was no mention in the HERA strategic plan of the resources needed – by IRIS or any other ORD assessment program – to produce assessments to meet user needs. For example, in 2018, ORD received nominations for more than 50 chemical assessments from program and regional offices, including high-priority chemicals like per- and polyfluoroalkyl substances (PFAS). IRIS staff were also supporting the Office of Chemical Safety and Pollution Prevention, including supporting the Office of Pollution Prevention and Toxics implementation of TSCA, the Office of Pesticide Programs, and the Office of Science Coordination and Policy. Although the demand for IRIS assessments and expertise was similar to demand levels from previous years, EPA's congressional budget justification for fiscal year 2021 proposed cuts of 34 percent to the budget for HERA activities (cuts of $12.7 million dollars and a loss of 43 full-time employees), of which IRIS's budget makes up

[28]EPA, *Draft Health and Environmental Risk Assessment National Research Programs Strategic Research Action Plan, 2019-2022.* (Washington, D.C.: April 2020).

[29]GAO-13-369.

[30]The Board of Scientific Counselors is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs.

approximately half. These suggested cuts continue a pattern that began in fiscal year 2018. However, to date, Congress has not enacted these cuts.

The HERA strategic plan indicated that ORD's assessment production programs were coordinating their work, but the plan did not provide details about how coordination was being carried out with other EPA offices or programs that produce chemical assessments. In addition, the plan did not describe how ORD was building partnerships with other federal research agencies to fill gaps in assessment production capacity.

Lastly, the HERA strategic plan is inconsistent with leading practices for strategic planning, including the Government Performance and Results Act of 1993 (GPRA), as amended.[31] GPRA establishes requirements for agency-level strategic plans and states that plans should address strategies and resources to achieve goals and objectives, how external factors could affect achieving goals and objectives, interagency collaboration to achieve goals and objectives, and how program evaluations help shape the plan. We have previously reported that GPRA's requirements, including those for strategic plans, can serve as leading practices at lower organizational levels within federal agencies, such as individual divisions, programs, or initiatives—in this case, EPA's ORD.[32] Developing a strategic plan that includes information on the IRIS budget and workforce necessary to complete assessments is important; furthermore, a plan that establishes how IRIS works in relation to other EPA chemical assessment activities would ensure that IRIS is better able to identify and meet user needs within EPA. By doing so, the IRIS Program can remain an important source of chemical toxicity information for other federal agencies as well as state and local health agencies and international health organizations.

[31]Pub. L. No. 103-62, 107 Stat. 285, as amended by the GPRA Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866 (2011).

[32]For example, see *Coast Guard: Actions Needed to Enhance Performance Information Transparency and Monitoring, GAO-18-13* (Washington, D.C.: Oct. 27, 2017); *Motor Carriers: Better Information Needed to Assess Effectiveness and Efficiency of Safety Interventions*, GAO-17-49, (Washington, D.C.: Oct. 27, 2016); and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

Conclusions

EPA's ability to effectively fulfill its mission of protecting public health and the environment depends on understanding the universe of chemicals in or considered for commerce and producing timely assessments of the risks posed by those chemicals. EPA's IRIS Program has made strides in updating its assessment development process in response to recommendations from the National Academy of Sciences and GAO; for example, by implementing systematic review processes and increasing communications with program and regional offices.

We have made several recommendations to EPA regarding the IRIS Program since 2008, including a recommendation in 2008 to ensure that any revision to the IRIS draft development process periodically assesses the level of resources that should be dedicated to the program to meet user needs and maintain a viable IRIS database. We also recommended in 2011 that ORD examine stated time frames for each type of IRIS assessment and ensure that the time frames are realistic and provide greater predictability to stakeholders.

In examining the IRIS Program's progress on producing assessments since 2018, we found that although the IRIS draft development process has improved, especially in communication and transparency efforts, the Program still does not publicly release updated information about where assessments are in every step of the draft development process. And, when assessments are delayed, no public explanations are given. Communicating where a draft assessment is at every step of the process, and explaining why delays occur, may help EPA offices and other stakeholders find solutions for delays if they are aware of the underlying causes.

We also found that quality information was not available to facilitate decision-making at multiple levels of EPA. The Assistant Administrators of program and regional offices did not issue any criteria or information to guide their staff as they selected chemicals to nominate for assessment. Providing criteria and information to program and regional office staff would help them plan their chemical nominations to align with their own office's goals as well as facilitate understanding about how their needs are prioritized by ORD.

Furthermore, we found that ORD's survey was not supported by quality information—particularly explicit criteria on how ORD selected chemical

nominations for inclusion in the IRIS Program's list of assessments in development and information about how the IRIS Program's work was prioritized. Providing that information to program and regional offices would have communicated how their nominations are selected and prioritized, allowing them to better utilize the nomination process to communicate needs that the IRIS Program can meet.

Additionally, based on the reasons offices gave for not responding to the 2019 survey, the survey may not be generating quality information. Without quality information about program and regional office needs, ORD's ability to understand the true scope and scale of need for an assessment is limited, as is its opportunity to have foresight into how and why offices select certain chemicals to nominate for chemical assessments and not others.

Finally, ORD has not created a strategic plan with resource information and clear implementation steps that could inform EPA program and regional offices, and the public, about the IRIS Program's ability to meet user needs. Developing a strategic plan that includes information on the IRIS budget and workforce necessary to complete assessments and that establishes how IRIS works in relation to other EPA chemical assessment activities would ensure that IRIS is better able to identify and meet user needs within EPA.

Recommendations for Executive Action

We are making the following five recommendations to the Administrator of the Environmental Protection Agency:

The Administrator should direct the Assistant Administrator of the Office of Research and Development to provide more information publicly about where chemical assessments are in the development process, including internal and external steps in the process, and changes to assessment milestones. (Recommendation 1)

The Administrator should direct the Assistant Administrators of program offices and Regional Administrators to develop and make available guidance for chemical assessment nominations. Such guidance could include information such as how to select chemicals for IRIS assessment nomination or for high priority needs, criteria explaining how Assistant and Regional Administrators determine which nominations to support and

which they may choose not to support, and how to document these decisions. (Recommendation 2)

The Administrator should direct the Assistant Administrator of the Office of Research and Development to issue criteria for how chemical assessment nominations are selected for inclusion in the IRIS Program's list of assessments in development and provide quality information about such topics as defining high-priority chemicals, prioritizing assessment work, and determining the IRIS Program's capacity to undertake work. (Recommendation 3)

The Administrator of EPA should direct the Office of Research and Development to continue evaluating the survey process used to solicit IRIS user needs and assess key elements, such as its purpose and timing, to facilitate the collection of quality information. (Recommendation 4)

The Administrator of EPA should include in ORD's strategic plan (or subsidiary strategic plans) identification of EPA's universe of chemical assessment needs; how the IRIS Program is being resourced to meet user needs; and specific implementation steps that indicate how IRIS will achieve the plan's objectives, such as specific metrics to define progress in meeting user needs. (Recommendation 5)

Agency Comments and our Evaluation

We provided a draft of this report to the U.S. Environmental Protection Agency (EPA) for its review and comment. EPA provided written comments, which are summarized below and reproduced in appendix I. EPA also provided technical comments, which we incorporated, as appropriate.

In its written comments, EPA stated that it agreed with certain aspects of our findings, conclusions, and recommendations and disagreed with other aspects. Specifically, EPA disagreed with three recommendations and partially agreed with two recommendations. EPA indicated that it has changed the survey nominations process since our review ended; they included a copy of the memorandum requesting new nominations that outlines the new process for nominating chemicals for an Integrated Risk Information System (IRIS) assessment.

Regarding the recommendations, EPA disagreed with the first, second, and fourth recommendations because it believes the agency has already taken the actions we recommended. Specifically, for our first recommendation—that the Office of Research and Development (ORD) should publicly provide more information about where the chemical assessments are in the development process—EPA stated that the agency already maintains a high level of transparency and that implementing the recommendation would create an additional reporting and management burden that would slow the development of assessments. We adjusted the language of the recommendation to clarify that more information is needed on the timing of nonpublic steps in the assessment process, not the reasons for assessment delays (though this information would always be helpful). As stated in the report, internal steps of the assessment (agency review, interagency science consultation, revising the assessment based on peer review, and final agency review—steps 2, 3, and 6) are not announced publicly, leaving the public without information to track their status. Stakeholders from an industry group and an environmental advocacy group told us that the IRIS Program would benefit from greater transparency throughout the chemical assessment process. The industry group expressed concern that not enough is being done to show how newly implemented changes to the program are shortening assessment time lines.

For our second recommendation—that agency program and regional office management should provide guidance to staff as they decide which chemicals to nominate—EPA provided GAO with information on changes made to the latest nominations process as articulated in a September 2020 memorandum that described the two-phase process for regional offices and National Program Managers. We have noted the memorandum's release in our report. We do not believe the memorandum addresses our recommendation. As we describe in our report, Assistant Administrators and Regional Administrators have not issued criteria or other information to guide their staff as they select chemicals to nominate for assessment. We continue to believe that providing such guidance to program and regional office staff would help them plan their chemical nominations to align with their office's goals as well as facilitate ORD's understanding about their office's current and future assessment needs.

For the fourth recommendation—that EPA should evaluate the survey process to ensure it generates quality information—EPA indicated that it already obtained useful feedback on ways to improve the clarity and transparency of its nominations process from program and regional office

senior leadership, as reflected in its September 2020 memorandum. We adjusted the language of the recommendation to acknowledge that EPA has started an evaluation process, but we believe that ongoing assessment of the annual survey process is warranted. As we state in our report, leading program management practices, as well as *Standards for Internal Control in the Federal Government*, state that agency management should monitor and evaluate program activities. Without evaluating the quality of the information produced by the survey, ORD cannot know if the survey is achieving its intended purpose and whether ORD has the information necessary to evaluate the extent to which the IRIS Program is meeting its users' needs.

EPA partially agreed with recommendations three and five and described actions the agency plans to take or has already started in response to these recommendations. For example, regarding the third recommendation—that ORD should issue criteria for how it determines which nominations for assessments it adds to the IRIS Program's ongoing work —EPA does not believe it merits immediate attention because agency officials stated that they have not rejected any formal nomination that has been submitted since initiating its new process in 2018. As we describe in our report, an understanding of the criteria used for prioritizing chemicals for assessment development can inform staff as they consider which chemicals to nominate. Regarding the fifth recommendation—that EPA include chemical assessment needs, how the program is being resourced, and other metrics, in its strategic plans—EPA indicated that it has already undertaken such actions. However, EPA has not identified the resources needed to address user needs. As we discuss in our report, a review of EPA's draft strategic plan, released by the Board of Scientific Counselors in August 2020, raised similar concerns. At that time, the Board of Scientific Counselors stated that it was difficult to determine how the goals outlined in the plan would be accomplished through specific research projects and deliverables. It further noted that the plan did not include a detailed implementation strategy or metrics to define progress in the draft strategic plan. Therefore, we continue to believe that ORD should include in a strategic plan information about the IRIS Program's resources and capacity.

As agreed with your offices, 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 of this report to the appropriate congressional committees, the EPA Administrator, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff 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 II.

J. Alfredo Gómez
Director, Natural Resources and Environment

List of Requesters

The Honorable Thomas Carper
Ranking Member
Committee on Environment and Public Works
United States Senate

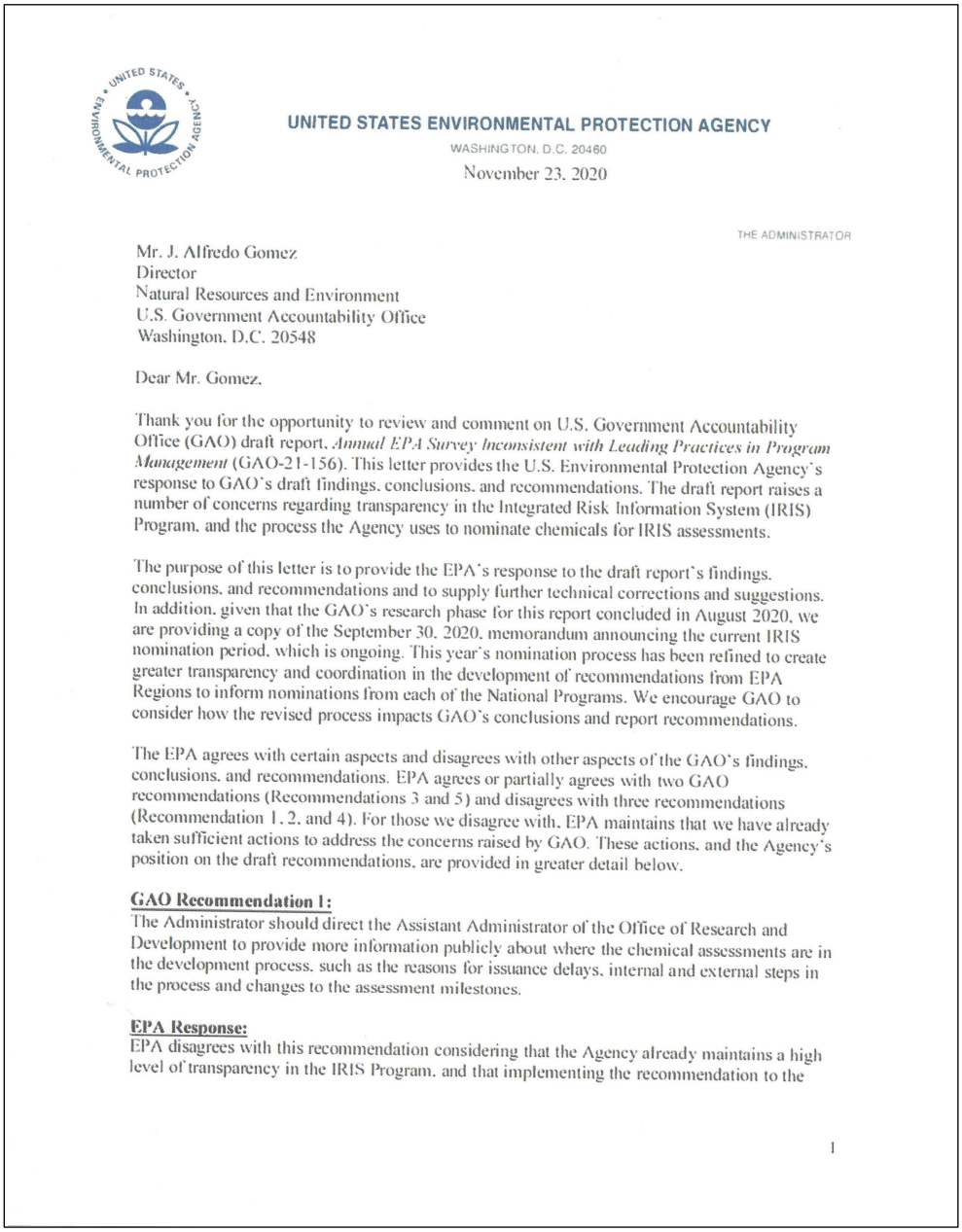
The Honorable Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology
House of Representatives

The Honorable Lizzie Fletcher
Chairwoman
Subcommittee on Energy
Committee on Science, Space, and Technology
House of Representatives

The Honorable Mikie Sherrill
Chairwoman
Subcommittee on Environment
Committee on Science, Space, and Technology
House of Representatives

The Honorable Bill Foster
Chairman
Subcommittee on Investigations and Oversight
Committee on Science, Space, and Technology
House of Representatives

Appendix I: Comments from the Environmental Protection Agency



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

November 23, 2020

THE ADMINISTRATOR

Mr. J. 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 U.S. Government Accountability Office (GAO) draft report, *Annual EPA Survey Inconsistent with Leading Practices in Program Management* (GAO-21-156). This letter provides the U.S. Environmental Protection Agency's response to GAO's draft findings, conclusions, and recommendations. The draft report raises a number of concerns regarding transparency in the Integrated Risk Information System (IRIS) Program, and the process the Agency uses to nominate chemicals for IRIS assessments.

The purpose of this letter is to provide the EPA's response to the draft report's findings, conclusions, and recommendations and to supply further technical corrections and suggestions. In addition, given that the GAO's research phase for this report concluded in August 2020, we are providing a copy of the September 30, 2020, memorandum announcing the current IRIS nomination period, which is ongoing. This year's nomination process has been refined to create greater transparency and coordination in the development of recommendations from EPA Regions to inform nominations from each of the National Programs. We encourage GAO to consider how the revised process impacts GAO's conclusions and report recommendations.

The EPA agrees with certain aspects and disagrees with other aspects of the GAO's findings, conclusions, and recommendations. EPA agrees or partially agrees with two GAO recommendations (Recommendations 3 and 5) and disagrees with three recommendations (Recommendation 1, 2, and 4). For those we disagree with, EPA maintains that we have already taken sufficient actions to address the concerns raised by GAO. These actions, and the Agency's position on the draft recommendations, are provided in greater detail below.

GAO Recommendation 1:
The Administrator should direct the Assistant Administrator of the Office of Research and Development to provide more information publicly about where the chemical assessments are in the development process, such as the reasons for issuance delays, internal and external steps in the process and changes to the assessment milestones.

EPA Response:
EPA disagrees with this recommendation considering that the Agency already maintains a high level of transparency in the IRIS Program, and that implementing the recommendation to the

1

extent described would create an additional reporting and management burden that would slow down the development of assessments.

In the draft report, GAO notes that there have been shifts in the timelines for assessments under development in the IRIS Program. These shifts are documented in the publicly available IRIS Program Outlook (https://www.epa.gov/iris/iris-program-outlook), which is updated at least three times a year. The majority of assessments currently in development are in Step 1, which includes preparation of IRIS assessment plans, assessment protocols, and draft assessments for Agency review. This is typically the longest step of the assessment development process and the most difficult timeframe to predict. While the IRIS Program has the relevant staff expertise to develop these assessments, every assessment requires thoughtful analysis of multiple, complex science issues, many of which are not readily apparent at the outset of initiating the assessment.

The IRIS Program recognizes the importance of timeliness and strives to minimize delays and develop assessments efficiently. GAO does not give sufficient weight to the complexity and uniqueness of each individual assessment, and that developing scientifically-acceptable approaches to address complex science topics is not a process that lends itself to the expectation that timelines will not change. This is one of the reasons why the IRIS Program outlook is updated several times a year. Similarly, shifts in the timing of expected milestones may occur after review and comment periods, when more information is provided which the IRIS Program must consider, evaluate, and then respond. The IRIS Program's ongoing practice of sharing updated timelines for assessments, including publicly indicating when assessment timelines shift, is a mark of transparency within the IRIS Program which GAO should consider.

In the course of the 7-step IRIS assessment development process, there are six opportunities to provide written or oral comment to the IRIS Program. Since 2013, the IRIS Program has interacted with more than 1,600 stakeholders at 20 different public science meetings and workshops. The IRIS website provides information on both finalized and ongoing assessments, including chemical-specific Web pages with specific points-of-contact for each assessment, relevant assessment documents, and a history of each chemical. The IRIS Program maintains an active website and outreach through a listserv (which reaches more than 10,000 individuals) to update anyone interested in programmatic activities, as well as makes use of *Federal Register* Notices and public dockets. Outside of the assessment development process, upon request, the IRIS Program also holds stakeholder meetings to discuss stakeholder concerns or general science issues. Summary minutes from these meetings are posted online for transparency (https://cfpub.epa.gov/ncea/iris2/events.cfm#stakeholderMeetings).

Moving forward, the IRIS Program will continue to conduct these activities to ensure programmatic transparency. It is unclear how providing the level of detail (e.g., timeframes for internal Agency review) and frequency of information that GAO is requesting would improve upon the already robust information sharing that the IRIS Program provides to the public. GAO's proposed actions impose an unreasonable program management burden that would likely hinder assessment development. We encourage GAO to compare the IRIS Program's practices with those of other federal assessment programs to gauge how well the IRIS Program compares in terms of transparency. Accordingly, EPA disagrees with this recommendation and requests removal of this recommendation in the final GAO report.

2

GAO Recommendation 2:
The Administrator should direct the Assistant Administrators of program and regional offices to develop and make available guidance for chemical assessment nominations. Such guidance could include information such as how to select chemicals for IRIS assessment nomination or for high priority needs; criteria explaining how Assistant Administrators determine which nominations to support and, which they may choose not to support; and how to document these decisions.

EPA Response:
EPA disagrees with this recommendation. EPA program and regional offices are the best sources to identify chemical priorities for their respective decision-making needs and should be provided flexibility in how to determine those priorities. As EPA detailed to GAO throughout the course of this audit, a one-size-fits-all approach to identifying assessment needs is not appropriate or practical.

While the priorities are driven by program and regional office needs, in discussion with Agency and EPA program and regional office leadership, this year's IRIS nomination process was revised to provide more opportunity for program and regional offices to gather information and coordinate on any potential nominations. Because GAO's review concluded in August 2020, more recent updates in the IRIS Program have not been included (e.g., the updated nomination process, release of the IRIS Handbook for public comment)[1]. Regions are now afforded specific time to compile their recommendations and share with the relevant National Program Manager (NPM). The NPMs are provided additional time to review any recommendations from the Regions, to be considered in conjunction with recommendations received from the relevant program or offices within the Office of the Administrator. After nominations are received by the Office of Research and Development (ORD), a meeting is scheduled to discuss nominations with the relevant Assistant Administrators and Region Administrators to ensure transparency and coordination, prior to briefing the EPA Administrator. These changes to the nomination process preserve the program and regional offices' ability to identify their unique assessment needs and to proceed through their own deliberative process, while creating a more transparent process and understanding within the entire Agency as to the resolution of all nominations.

EPA recognizes that due to the timing of the audit and our annual nominations process, GAO did not have the details of the most recent nomination process in hand during this analysis of the IRIS Program. We have provided a copy of the latest nomination form accompanying this memorandum. As such, EPA requests GAO review their conclusions in light of the new memorandum and recommends removal of this recommendation from the final report.

GAO Recommendation 3:
The Administrator should direct the Assistant Administrator of the Office of Research and Development to issue criteria for how chemical assessment nominations are selected for inclusion in the IRIS Program's list of assessments in development and provide quality information about such topics as: defining high priority chemicals; prioritizing assessment work; and determining the IRIS Program's capacity to undertake it.

[1] The IRIS Handbook was released for public comment in November 2020. (https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=350086).

EPA Response:
EPA partially agrees with this recommendation but does not believe that it warrants immediate action to clarify how ORD, if it has limited capacity, would decide which nominated assessments to undertake for development. Chemicals are added to the IRIS Program assessment development process once they are submitted as a formal nomination by a National Program Manager (NPM). Each nomination submitted by an NPM contains the information needed for the IRIS Program to identify the chemical(s), scope of assessment, and regulatory need for a given assessment. Since the new nomination process was initiated (beginning August 2018), the IRIS Program has not rejected any formal nomination transmitted by the NPMs.

GAO Recommendation 4:
The Administrator of EPA should direct the Office of Research and Development to evaluate the survey process currently underway to solicit IRIS user needs, and assess key elements such as its purpose and timing, to facilitate the collection of quality information for ORD to use in assessing user needs for chemical assessments.

EPA Response:
EPA disagrees with this recommendation, given that ORD has already obtained feedback from program and regional office senior leadership on ways to improve the clarity and transparency of the IRIS assessment nomination process. This feedback from Agency leadership directly resulted in adjustments to the most recent IRIS nomination process (Attachment 2) and demonstrates that the Agency has already initiated action consistent with this recommendation. The Agency will continue to solicit feedback and discuss if changes are needed to the nomination process in future years.

GAO Recommendation 5:
The Administrator of EPA should include in ORD's strategic plan (or subsidiary strategic plans) identification of EPA's universe of chemical assessment needs, how the IRIS program is being resourced to meet user needs, and specific implementation steps that indicate how IRIS will achieve the plans, objectives, such as specific metrics to define progress meeting user needs.

EPA Response:
EPA partially agrees with this recommendation, in the context that the Agency has already taken actions to identify the universe of EPA's chemical assessment needs. ORD currently includes IRIS assessment products in its overall strategic metric, which surveys program and regional offices to evaluate the percentage of ORD products that meet users' needs. Another metric specific to the IRIS Program is unnecessary and would be duplicative.

Identifying the universe of EPA's chemical assessment needs is a broader Agency task and is not appropriate for limiting to ORD's Strategic Plan or the subsidiary Strategic Research Action Plans (StRAPs). EPA identifies its universe of assessment needs through programmatic activities housed in multiple offices within the Agency (e.g., chemical prioritization under TSCA on OCSPP/OPPT, pesticide registration and/or reviews through OCSPP/OPP, human health effects information developed within OW). Tasking ORD's Strategic Plan to capture and describe the totality of EPA's chemical assessment needs would fall outside the scope of a document intended to describe activities conducted within ORD. Similarly, requiring a level of detail and specificity

4

to the IRIS Program, in the context of all the work done in ORD, is not appropriate for the ORD Strategic Plan. Because the IRIS Program solicits nominations from program and regional offices annually, and the IRIS Program has not yet turned down any nominations, this is an indication that the IRIS Program is meeting the needs articulated by the NPMs.

As previously noted, IRIS Program assessment products fall under the Health and Environmental Risk Assessment (HERA) National Research Program. For the HERA program and the other five National Research Programs, our overarching measure for success from the ORD perspective is obtained through an ORD Survey to EPA program and regional offices with the metric of "increasing the percent of products that meet customer needs." For HERA, the products developed under Research areas 1 and 2, including IRIS, are assessments developed at the explicit request of the Agency. Assessments developed within the IRIS Program involve close engagement with partners from conception to completion, and engagement with the program and regional offices is continuous and built into HERA's structure. Because interaction and coordination with the program and regional offices is inherent to the development of assessments, and the assessment products are directly solicited by the NPMs, they are by definition meeting a need articulated by the program and regional offices, supplemented by the additional Survey parameters evaluating quality and timeliness.

Conclusion

In addition to the overarching responses described above, the draft report has been circulated to EPA offices who were engaged in this GAO activity, which included the Office of the Administrator (Office of Children's Health Protection, Office of Policy) and Regions. Extensive technical comments were identified, and an accompanying attachment (Attachment 1) provides these comments for GAO's consideration. These technical comments are vital to understanding the full extent of the Agency response and provide valuable context to our overarching responses to GAO's recommendations.

The toxicity assessments developed by the IRIS Program are highly technical, sophisticated scientific documents. The Agency is committed to advancing the IRIS Program emphasizing the development of quality and timely products to inform Agency-wide decision-making. EPA appreciates the opportunity to review and respond to the draft GAO report. We request that you include the entirety of this response, including all of the attachments, as an appendix to the GAO final report. If additional information is needed, please contact Susan Perkins at 202 564-8618.

Sincerely,

Andrew R. Wheeler

Enclosure: Attachment 1: Technical Comments for the Government Accountability Office (GAO) Draft Report *Annual EPA Survey Inconsistent with Leading Practices in Program Management*
Attachment 2: FY2021 Call for Nomination of Chemicals as a High Priority for an IRIS Assessment

5

Appendix II: 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 Raynes (Assistant Director); Summer Lingard-Smith (Analyst-in-Charge); Antoinette Capaccio, Alisa Carrigan: Evan Keir; Nacole King, Rich Johnson; Cindy Gilbert; John Delicath; Rebecca Parkhurst; and Sara Sullivan provided key contributions to this report.

Related GAO Products:

High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas. GAO-19-157P. Washington D.C.: March 6, 2019.

Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act. GAO-19-270. Washington, D.C.: March 4, 2019.

Chemical Innovation: Technologies to Make Processes and Products More Sustainable. GAO-18-307. Washington, D.C.: February 8, 2018.

High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others. GAO-17-317. Washington D.C: February 15, 2017.

Chemicals Management: Observations on Human Health Risk Assessment and Management by Selected Foreign Programs. GAO-16-111R. Washington, D.C.: October 9, 2015.

Chemical Assessments: Agencies Coordinate Activities, but Additional Action Could Enhance Efforts. GAO-14-763. Washington, D.C.: September 29, 2014.

Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation. GAO-13-696T. Washington, D.C.: June 13, 2013.

Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments. GAO-13-369. Washington, D.C.: May 10, 2013.

Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach. GAO-13-249. Washington, D.C.: March 22, 2013.

Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program. GAO-12-42. Washington, D.C.: December 9, 2011.

Related GAO Products:

High-Risk Series: An Update. GAO-09-271. Washington D.C: January 2009.

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

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through our website. Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. You can also subscribe to GAO's email updates to receive notification of newly posted products.

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, https://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on Facebook, Flickr, Twitter, and YouTube.
Subscribe to our RSS Feeds or Email Updates. Listen to our Podcasts.
Visit GAO on the web at https://www.gao.gov.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact FraudNet:

Website: https://www.gao.gov/fraudnet/fraudnet.htm

Automated answering system: (800) 424-5454 or (202) 512-7700

Congressional Relations

Orice Williams Brown, Managing Director, WilliamsO@gao.gov, (202) 512-4400,
U.S. Government Accountability Office, 441 G Street NW, Room 7125,
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548

Strategic Planning and External Liaison

Stephen J. Sanford, Acting Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548