



Testimony

Before Subcommittees on Investigations
and Oversight and Environment,
Committee on Science, Space, and
Technology, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. ET
Wednesday, March, 27, 2019

CHEMICAL ASSESSMENTS

Overview of EPA's Efforts to Produce Assessments

Statement of J. Alfredo Gómez, Director,
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Accessible Version

Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees:

Thank you for the opportunity to be here today to discuss our recent report on the status of the Environmental Protection Agency's (EPA) efforts to produce assessments of the potential human health effects that may result from exposure to various chemicals in the environment. This is part of our body of work on the agency's efforts to address toxic chemicals.¹ EPA's ability to effectively implement its mission of protecting public health and the environment depends on its credible and timely assessments of the risks posed by chemicals. The agency's Integrated Risk Information System (IRIS) Program identifies and characterizes the health hazards of chemicals and produces chemical assessments that contain this information.

The National Academy of Sciences (NAS) and we have made recommendations on many topics related to IRIS.² In 2009, we added EPA's process for assessing and controlling toxic chemicals to our list of agencies and program areas that are high risk because of their vulnerabilities to fraud, waste, abuse, and mismanagement or that are in most need of transformation.³ This high-risk area has evolved since 2009, which we discuss in our two most recent high-risk reports.⁴

¹GAO, *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act*, [GAO-19-270](#) (Washington, D.C.: Mar. 4, 2019). While several areas of EPA carry out chemical risk assessments, this report focused on the IRIS Program and EPA's implementation of the Toxic Substances Control Act (TSCA), as amended.

²National 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). 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 *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, [GAO-17-317](#) (Washington, D.C.: Feb. 15, 2017).

³GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009). This area was added to the High Risk List as a government program in need of broad-based transformation.

⁴GAO, *High-Risk Series: Substantial Efforts needed to Achieve Greater Progress on High-Risk Areas*, [GAO-19-157SP](#) (Washington, D.C.: March 2019) and [GAO-17-317](#).

My statement today discusses the extent to which the IRIS Program has made progress in (1) addressing identified challenges and (2) producing chemical assessments. This statement summarizes our March 2019 report on EPA's efforts to produce IRIS assessments.⁵ We reviewed program documentation from 2012 through 2019 and applicable EPA guidelines and program management practices. We interviewed IRIS officials, the leadership (as of October 2018) in EPA's Office of Research and Development (ORD), and officials from EPA program and regional offices that request or use IRIS assessments on a regular basis. We interviewed representatives from an environmental stakeholder organization and an industry stakeholder organization that both have been involved in chemical regulatory policy and worked with or followed the IRIS Program for the past several years. Our March 2019 report contains a detailed overview of our scope and methodology.

We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

EPA uses risk assessments to provide information on potential health or ecological risks.⁶ A number of program and regional offices at EPA prepare chemical risk assessments, and these risk assessments 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. In preparing risk management decisions, some EPA program and regional offices rely in part on chemical assessments that the IRIS Program prepares. IRIS assessments generally include hazard identification and dose-response assessment. Hazard identification identifies credible health hazards

⁵[GAO-19-270](#).

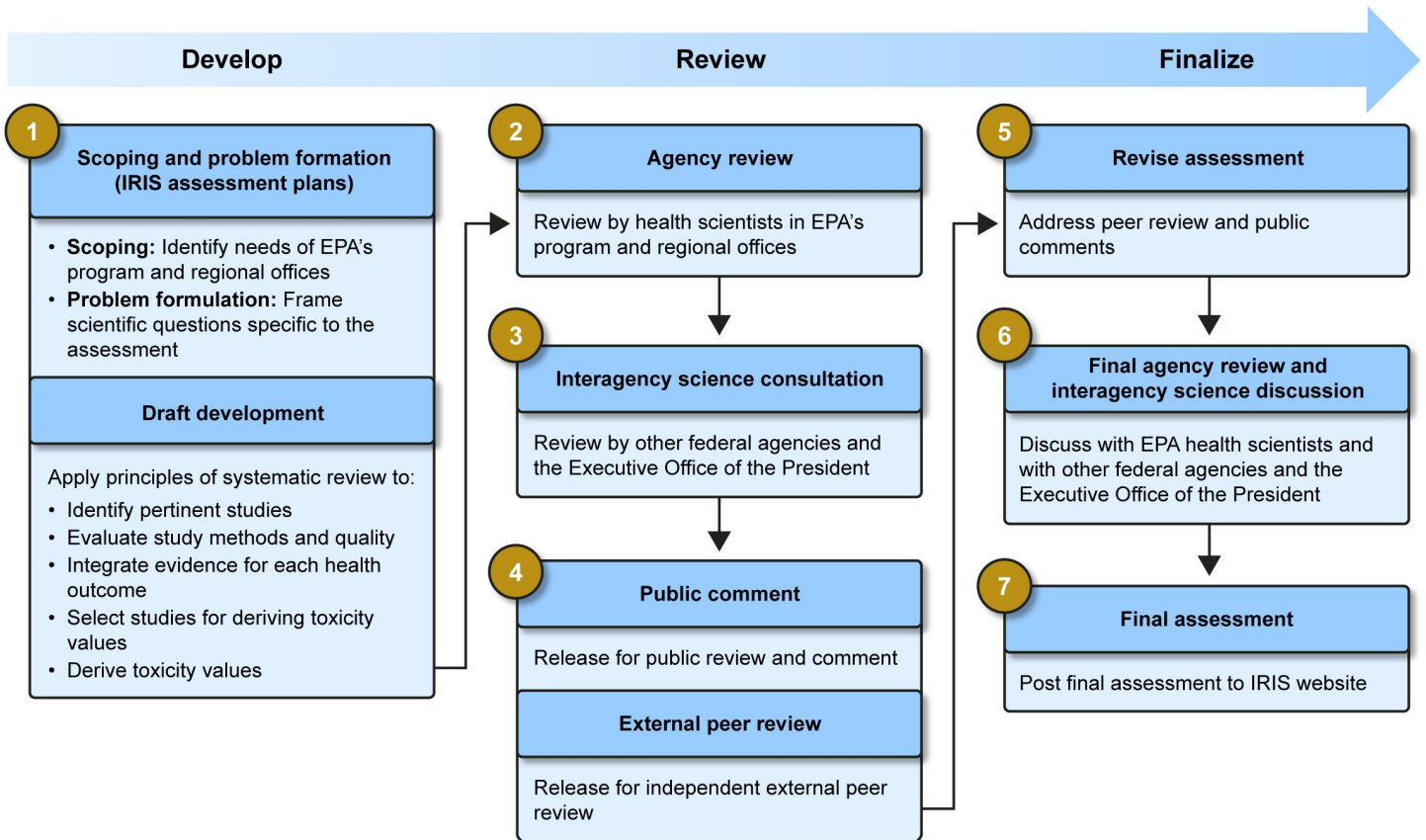
⁶Environmental Protection Agency, *Risk Characterization Handbook* (Washington, D.C.: December 2000), accessed January 7, 2019, https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

associated with exposures to a chemical, and dose-response assessment characterizes the quantitative relationship between chemical exposure and each credible health hazard. The IRIS Program derives toxicity values through this quantitative relationship. These toxicity values are combined with exposure assessments, produced by other offices within EPA, to produce a risk assessment.

EPA created the IRIS Program in 1985 to help develop consensus opinions within the agency about the health effects from lifetime exposure to chemicals. The IRIS database of chemical assessments contains EPA's scientific positions on these health effects, and, as of November 2018, it included information on 510 chemicals. Based on our body of work on the IRIS Program, the program's importance has increased over time as EPA program offices and regions 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.

The IRIS Program uses a seven-step process to produce chemical assessments, as shown in figure 1.

Figure 1: Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS) Chemical Assessment Development Process



Source: EPA. | GAO-19-454T

Text of Figure 1: Environmental Protection Agency’s (EPA) Integrated Risk Information System (IRIS) Chemical Assessment Development Process

1) Develop

a) Scoping and problem formation (IRIS assessment plans)

- i) Scoping: Identify needs of EPA’s program and regional offices
- ii) Problem formulation: Frame scientific questions specific to the assessment

b) Draft development

- i) Apply principles of systematic review to:
 - ii) Identify pertinent studies
 - iii) Evaluate study methods and quality
 - iv) Integrate evidence for each health outcome
 - v) Select studies for deriving toxicity values
 - vi) Derive toxicity values
- 2) Review
- a) Agency review
 - i) Review by health scientists in EPA's program and regional offices
 - b) Interagency science consultation
 - i) Review by other federal agencies and the Executive Office of the President
 - c) Public comment
 - i) Release for public review and comment
 - d) External peer review
 - i) Release for independent external peer review
- 3) Finalize
- a) Revise assessment
 - i) Address peer review and public comments
 - b) Final agency review and interagency science discussion
 - i) Discuss with EPA health scientists and with other federal agencies and the Executive Office of the President
 - c) Final assessment
 - i) Post final assessment to IRIS website

The first step in the assessment development process includes a wide range of efforts by program staff, such as determining the scope and initial problem formulation of an assessment in consultation with EPA program and regional offices; obtaining agency and public feedback on the result, called the IRIS Assessment Plan; selecting and extracting relevant data; analyzing and integrating the evidence into a draft assessment; and deriving chemical toxicity values. After these efforts, depicted in step 1 of figure 1, the draft assessment goes through internal agency and interagency review, public comment, and peer review as shown in steps 2 through 4. After staff make revisions to address comments received (step 5), the draft assessment goes through another round of internal and interagency review, and then the program finalizes and posts the assessment to the IRIS website.⁷

The IRIS Program Has Made Progress in Addressing Identified Process Challenges

As detailed in our report, the IRIS Program has made progress toward addressing process challenges related to timeliness and transparency that governmental, industry, academic, and non-governmental stakeholders identified in recent years.⁸ In our report, we identified the key actions the IRIS Program has taken to address lack of timeliness in producing assessments and lack of transparency in how it produces assessments.

⁷The IRIS Program has not changed the process steps since 2013, but the types of documents produced during step 1 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.

⁸National 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); *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (Washington, D.C.: National Academies Press, 2018). GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, [GAO-08-440](#) (Washington, D.C.: Mar. 7, 2008); *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program*, [GAO-12-42](#) (Washington, D.C.: Dec. 9, 2011); [GAO-13-369](#); and [GAO-17-317](#). *Making EPA Great Again, Before the H.R. Comm. On Science, Space, and Technology*, 115th Cong. (2017) (Statement of Kimberly W. White, Ph.D., American Chemistry Council).

The IRIS Program Has Made Changes to Address Timeliness

As discussed in our report, developing IRIS assessments has historically been a lengthy process. Because of the rigor of the IRIS process and the amount of literature that program staff must search and consider, producing an assessment typically takes several years, as we found in December 2011.⁹ For our March 2019 report, officials from several program and regional offices told us that despite the length of time it takes for the IRIS Program to complete its assessments, they prefer these assessments as sources of information over other agencies' toxicity assessments.

The IRIS Program is striving to address the length of time it takes to produce assessments in three key ways. First, IRIS is utilizing project management principles and new software that enable the program to better plan assessment schedules and utilize staff. IRIS officials said that by using these tools, IRIS staff are able to view project tasks, timelines, and milestones to manage their individual tasks and assessment work. Additionally, according to IRIS officials, the recent adoption of specialized systematic review software also enables program staff to more quickly perform literature searches and to efficiently filter search results to the most relevant information for an assessment.

Second, the IRIS Program is tailoring assessments to program and regional office needs, called fit-for-purpose assessments. IRIS officials said the idea is that instead of producing a wide-ranging assessment, the program can produce assessments that are more limited in scope and targeted to specific program and regional office needs, reducing the amount of time IRIS staff need to search for information; synthesize it; and draft, review, and issue an assessment. The program began employing this model in 2017.

Third, the IRIS Program is streamlining the peer review process as much as possible. EPA guidelines require peer review of all IRIS assessments. Smaller, less complex assessments may be peer reviewed through a contractor-led letter review or panel; more complex assessments are usually reviewed by a full Scientific Advisory Board or a NAS panel, though IRIS leadership determines the most appropriate method of peer

⁹[GAO-12-42](#).

review based on Office of Management and Budget and EPA Peer Review Handbook guidelines. IRIS officials said that as they try to produce more fit-for-purpose assessments that are smaller in scope, they plan to utilize letter reviews, as appropriate, to streamline the peer review process.

The IRIS Program Has Made Changes to Address Lack of Transparency

As detailed in our report, another major category of NAS recommendations that the IRIS Program has addressed is the need for greater transparency in how the program conducts assessments. In response, the IRIS Program has in the past several years implemented systematic review and increased outreach efforts with stakeholders and the public.

The IRIS Program began addressing the need for greater transparency by implementing systematic review as a basis for every assessment and has been doing so for several years. By using systematic review, the IRIS Program can demonstrate that it considered all available literature in forming conclusions and deriving toxicity values. Utilizing the new software tools described above allows program staff to search more widely than before and to identify the most relevant results faster and more accurately.

The IRIS Program also furthered transparency by increasing the frequency, structure, and content of communications with EPA program and regional offices about overall program priorities and individual assessments. When new leadership joined the IRIS Program in early 2017, they began reaching out to individual program and regional offices to reconfirm their needs and priorities. IRIS officials said this effort was in part to ensure that the IRIS Program was delivering what the program offices needed, as well as to help the IRIS Program keep its priorities up to date and ensure that resources (primarily staff) were aligned with EPA-wide priorities.

Since 2013, the IRIS Program has released preliminary assessment materials—including IRIS Assessment Plans and assessment protocols—so that EPA and interagency stakeholders and the public could be aware of scoping and problem formulation for each assessment. Since 2017, according to EPA, these documents have had a new structure and better demonstrate the application of systematic review, and they continue to

convey EPA's need for each assessment and frame questions specific to each assessment. Officials in several program and regional offices that use IRIS assessments told us that the release of IRIS Assessment Plans and protocols was very helpful because it allowed them to offer early input to the IRIS Program about the scope of an assessment, when it could affect the direction of the assessment.

EPA Leadership Deliberations Delayed Progress on Producing Assessments

EPA made progress in early 2018 on assessments in development. However, the release of documents related to IRIS assessments was delayed for nearly 6 months because EPA leadership instructed the IRIS Program not to release any assessment documentation pending the outcome of EPA leadership deliberations concerning IRIS Program priorities.

The Program Made Progress in Early 2018 on Assessments in Development

During calendar year 2018, the IRIS Program planned to release documents or hold meetings for 15 of the 23 ongoing chemical assessments in development, as well as for the IRIS Handbook and a template for assessment protocols. From January through May 2018, the IRIS Program met each of its internal deadlines for work on nine different chemical assessments and released the template for assessment protocols for agency review.

IRIS Program Assessment Production Was Delayed by EPA Leadership Deliberations about Priorities

As we described in our report, EPA leadership deliberations about the program's priorities that took place from June through December 2018 delayed the program's assessment production. IRIS officials told us that in early June 2018, EPA leadership in ORD informed them that the IRIS Program could not release an assessment without a formal request for

that assessment from the current leadership of a program office.¹⁰ At the request of the EPA Administrator, IRIS officials prepared a survey of program and regional offices, asking them to reconfirm their needs for 20 assessments that were in development.¹¹ This survey was sent by memorandum in August 2018. Program office responses were to be signed by the Assistant Administrator of each program office to ensure that the reconfirmations were consistent with the priorities of EPA program office leadership.¹² While survey responses were being compiled, EPA leadership in ORD instructed the IRIS Program not to publicly release any assessment documentation. As a result, any assessment or subsidiary assessment document (e.g., an IRIS Assessment Plan or protocol) that was ready for agency review, public comment, or peer review was unable to proceed through the IRIS assessment development process.

According to documents we reviewed, by mid-September 2018, several program offices had submitted responses to the survey to ORD. Three program offices confirmed their needs for the majority of chemicals on the survey list: the Office of Water confirmed needs for 15 of 20, the Office of Land and Emergency Management confirmed needs for all 20 chemicals, and the Office of Children's Health Protection confirmed needs for 18 of 20 chemicals. The Office of Policy also emailed ORD to add its concurrence with the list of ongoing assessments. The Office of Chemical Safety and Pollution Prevention did not confirm needs for any of the 20 chemicals but did nominate nine new chemicals. The Office of Air and Radiation did not submit a reply to ORD.

In late October 2018, prior to releasing results of the initial program and regional office survey, EPA leadership in ORD made a second request of

¹⁰For example, IRIS officials said that the IRIS Assessment Plan for naphthalene had been ready for release since May 25, 2018, but EPA leadership in ORD refused to sign off on the release because no other EPA leadership in program offices had formally requested the assessment. The IRIS Assessment Plan for naphthalene was eventually released for public comment on July 5, 2018. Additionally, a May 2018 statement prepared by the program outlining changes to the program's workflow and an updated list of assessments in development was not approved by EPA leadership in ORD for posting to the IRIS website because current EPA leadership in program and regional offices had not formally requested these assessments.

¹¹The survey did not include two assessments, ethyl tertiary butyl ether (ETBE) and tert-butyl alcohol (TBA), because they were out for public comment and external peer review.

¹²Regional offices were told that their submissions would be included as part of a program office request.

program offices for a prioritized list of assessments. According to officials from the IRIS office, who were queried for advice by officials from some program offices, ORD's second request was made verbally at a meeting and included direction to the program offices to limit their requests to no more than three to four chemicals. ORD's request did not provide information on the basis for selecting priorities or the reason for the limit of three or four chemical assessments from the original survey submissions. The calls for advice from program office officials represented the first time the IRIS Program heard about the requests for a prioritized list, according to IRIS program officials. Furthermore, since neither the program and regional offices nor the IRIS Program had information from the EPA Administrator's office about what the prioritization was meant to achieve, the IRIS Program was unable to provide guidance about which chemicals might be considered a priority or how many the program might be able to continue work on.

When EPA leadership completed its deliberations about the program's priorities, it issued a memorandum on December 4, 2018, that listed 11 chemical assessments that the IRIS Program would develop. This was a reduction of the program's workflow from 22 assessments, but the memorandum announcing the reduced workflow gave no reason for the reduction. The memorandum accompanying the list of 11 chemicals gave no indication of when more assessments could be requested or if IRIS's workflow would remain at 11 chemicals for the foreseeable future. According to the memorandum, the 11 chemicals were requested by two EPA program offices (the Office of Water and the Office of Land and Emergency Management). We received this memorandum at the end of our review and did not have the opportunity to review the prioritization process that led to its drafting.

Two weeks after the issuance of the memorandum, the IRIS Program publicly issued a program outlook, which included two additional assessments that were not included in the memorandum for a total of 13 assessments.¹³ The two assessments, ethyl tertiary butyl ether (ETBE) and tert-butyl alcohol (TBA), were not included in the memorandum because they were out for public comment and external peer review. Furthermore, four assessments that were in the later stages of development but had not yet been issued were not included in the 13

¹³For more information on the assessments released in the IRIS 2018 IRIS Program Outlook, see: <https://www.epa.gov/iris/iris-program-outlook>.

assessments listed in the December 2018 Outlook. The four assessments were: acrylonitrile, n-Butyl alcohol, formaldehyde,¹⁴ and polycyclic aromatic hydrocarbon. The absence of these four assessments from the December 2018 Outlook could create confusion for stakeholders interested in them. EPA provided no information on the status of these four assessments or whether it planned to discontinue working on them or restart them at another time. As we have previously reported, an overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is that once a delay in the assessment process occurs, work that has been completed can become outdated, necessitating rework throughout some or all of the assessment process.¹⁵ Thus, it remains to be seen when these assessments can be expected to move to the next step in the IRIS process or be completed. From June through December 2018, the IRIS Program was unable to release any work while it waited for feedback from the Administrator's office regarding whether its assessment workflow was consistent with agency priorities.

The thirteen assessments that were included in the December 2018 Outlook and their statuses as of December 19, 2018 were:

- **External Peer review:** ETBE and TBA.
- **Draft Development:** arsenic, inorganic; chromium VI; polychlorinated biphenyls (PCBs; noncancer); perfluorononanoic acid (PFNA); perfluorobutanoic acid (PFBA); perfluorohexanoic acid (PFHxA); perfluorohexane sulfonate (PFHxS); and perfluorodecanoic acid (PFDA).¹⁶
- **Scoping and Problem Formulation:** Mercury salts; methylmercury; vanadium and compounds.

IRIS officials told us that staff continued whatever draft development work that they could do internally, but several IRIS staff had been working

¹⁴As we have previously reported, EPA began an IRIS assessment of formaldehyde in 1997 because the existing assessment was determined to be outdated. Formaldehyde is a colorless, flammable, strong-smelling gas used to manufacture building materials, such as pressed wood products, and is used in many household products, including paper, pharmaceuticals, and leather goods. See [GAO-08-440](#).

¹⁵[GAO-08-440](#).

¹⁶PFNA, PFBA, PFHxA, PFHxS and PFDA are members of a class of man-made chemicals known as PFAS—a groups that also includes PFOS, PFOA, GenX, and many others.

increasingly for a single office responsible for risk management—the Office of Pollution Prevention and Toxics (OPPT)—to support its work preparing risk evaluations under the Toxic Substances Control Act (TSCA), as amended.¹⁷ ORD reported to us that in September 2018—3 months after IRIS assessments were stopped from being released because of ongoing EPA leadership deliberations—five of approximately 30 IRIS staff were supporting OPPT with 25 to 50 percent of their time. In October 2018—4 months after IRIS assessments were stopped from being released—28 of approximately 30 IRIS staff were supporting OPPT with 25 to 50 percent of their time. According to IRIS officials, this was occurring primarily because OPPT has a significant amount of work to do to meet its statutory deadlines, and OPPT needed IRIS staff expertise to help meet those deadlines.

As we reported, EPA’s proposed budget cuts have caused IRIS officials concerns about whether they will have sufficient resources to expand assessment work in the future. For example, over the past 3 years, EPA’s budget justification for human health risk assessment work, of which IRIS’s budget makes up about half, was reduced to about \$22 million from its fiscal year 2017 budget of \$40.5 million. This led, in part to a decrease in the rating for leadership commitment for the IRIS Program from met in our February 2017 High-Risk Report to partially met in our March 2019 High-Risk Report.¹⁸ In February 2017, we reported that the EPA Administrator demonstrated leadership commitment to the IRIS Program by identifying action on toxics and chemical safety as one of her top seven priorities for the agency—priorities that included the IRIS Program. However, current EPA leadership has not made a similar statement and has proposed significant cuts to the program’s budget. Congress did not support these reductions.

Chairwomen Sherrill and Fletcher, Ranking Members Norman and Marshall, and Members of the Subcommittees, this completes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

¹⁷In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA to expand EPA’s authority and responsibility related to regulating toxic chemicals, and established specific deadlines to promulgate new rules, conduct risk evaluations for existing chemicals, and review and make determinations on new chemical submissions, among other responsibilities. For more information on EPA’s implementation of TSCA, see [GAO-19-270](#).

¹⁸[GAO-17-317](#) and [GAO-19-157SP](#).

GAO Contacts and Staff Acknowledgments

If you or your staff have any questions about information in this testimony or the related report, please contact J. Alfredo Gómez, Director, Natural Resources and Environment, at (202) 512-3841 or gomezj@gao.gov. Key contributors to this statement include Diane Raynes (Assistant Director), Summer Lingard-Smith (Analyst-in-Charge), and Alisa Carrigan. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony.

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