



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

March 2019

CHEMICAL ASSESSMENTS

Status of EPA's Efforts
to Produce
Assessments and
Implement the Toxic
Substances Control
Act

GAO Highlights

Highlights of [GAO-19-270](#), a report to the Ranking Member, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

EPA is responsible for reviewing chemicals in commerce and those entering the marketplace. Currently there are more than 40,000 active chemical substances in commerce, with more submitted to EPA for review annually. EPA's IRIS database contains the agency's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment. EPA's IRIS Program, which produces toxicity assessments, has been criticized in the past for timeliness and transparency issues. In response, the IRIS Program committed to making program improvements starting in 2011, which the National Academy of Sciences (NAS) recently commended. TSCA as amended in 2016 provides EPA with additional authority to review both existing and new chemicals and to regulate those that EPA determines pose unreasonable risks to human health or the environment.

This report describes (1) the extent to which the IRIS Program has addressed identified challenges and made progress toward producing chemical assessments; and (2) the extent to which EPA has demonstrated progress implementing TSCA. GAO reviewed NAS and EPA documents and interviewed officials from EPA and representatives from two environmental and two industry stakeholder organizations.

What GAO Recommends

GAO made recommendations previously to improve the IRIS Program and TSCA implementation. EPA provided comments, which GAO incorporated as appropriate.

View [GAO-19-270](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

March 2019

CHEMICAL ASSESSMENTS

Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act

What GAO Found

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program, which prepares human health toxicity assessments of chemicals, has made progress addressing historical timeliness and transparency challenges in the assessment process. Efforts to address timeliness include employing project management principles and specialized software to better plan assessments and utilize staff. To address the need for greater transparency in how the program conducts assessments, IRIS officials and the IRIS Program have implemented systematic review, which provides a structured and transparent process for identifying relevant studies, reviewing their methodological strengths and weaknesses, and integrating these studies as part of a weight of evidence analysis.

Since the process improvements were implemented, the program made progress toward producing chemical assessments through May 2018. In June 2018, the EPA Administrator's office told IRIS officials that they could not release any IRIS-associated documentation without a formal request from EPA program office leadership. In August 2018, according to IRIS officials, program office leadership was asked to reconfirm which ongoing chemical assessments their offices needed. In late October 2018, these offices were asked to limit their chemical requests further, to the top three or four assessments. At the same time—4 months after IRIS assessments were stopped from being released—28 of approximately 30 IRIS staff were directed to support implementation of the Toxic Substances Control Act of 1976 (TSCA), as amended, with 25 to 50 percent of their time, according to officials. Then on December 19, 2018, the Office of Research and Development released its IRIS Program Outlook, which provided an updated list of 13 assessments. Eleven of the 13 chemicals on the IRIS Program Outlook were requested by two EPA program offices. A memorandum issued earlier in December, gave no indication of when additional assessments could be requested or what the IRIS Program's workflow would be in the near term.

EPA has demonstrated progress implementing TSCA, which was amended in June 2016, by responding to statutory deadlines. For example, EPA finalized rules detailing the general processes for prioritizing and evaluating chemicals, known as the Framework Rules, but three of the four rules have been challenged in court. Environmental organizations have argued, among other things, that TSCA requires EPA to consider all conditions of use in prioritizing and evaluating chemicals, rather than excluding, for example, uses that EPA believes are "legacy uses," for which a chemical is no longer marketed. EPA argued that TSCA grants it discretion to determine what constitutes a chemical's conditions of use. Amendments to TSCA in 2016 increased EPA's responsibility for regulating chemicals and in turn, its workload. As such, EPA is required to prioritize and evaluate existing chemicals by various deadlines over an extended period and to make a regulatory determination on all new chemicals. Senior management told GAO that they were confident that ongoing hiring and reorganization would better position the office that implements TSCA.

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Abbreviations

EPA	Environmental Protection Agency
ETBE	ethyl tertiary butyl ether
FTE	full-time equivalent
IRIS	Integrated Risk Information System
Lautenberg Act	Frank R. Lautenberg Chemical Safety for the 21 st Century Act
NAS	National Academy of Sciences
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PFAS	per- and polyfluoroalkyl substance
PFBA	perfluorobutanoic acid
PFBS	perfluorobutane sulfonic acid
PFDA	perfluorodecanoic acid
PFHxA	perfluorohexanoic acid
PFHxS	perfluorohexane sulfonic
PFNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonate
RDX	hexahydro-1,3,5-trinitro-1,3,5-triazine
SAB	Science Advisory Board
TBA	tert-butyl alcohol
TSCA	Toxic Substances Control Act

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March 4, 2019

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

Dear Senator Carper:

The Environmental Protection Agency (EPA) is responsible for reviewing the environmental and health effects of chemicals in commerce and chemicals that have yet to enter commerce. Currently more than 40,000 active chemical substances exist in commerce in the United States, with more new chemicals submitted to EPA for review every year.¹ Since June 22, 2016, companies have manufactured more than 550 new chemical substances that EPA approved for commerce. While chemicals contribute to virtually every aspect of modern life, exposures to 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 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. Several program and regional offices at EPA use these chemical assessments in their statutorily mandated risk management work.

The Toxic Substances Control Act of 1976 (TSCA) provides EPA with the authority to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals), obtain more information on the effects of chemicals on human health and the environment, and regulate those that EPA determines pose unreasonable risks to human health or the environment. In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), which amended TSCA to expand EPA's authority and responsibility related to regulating toxic chemicals, and established

¹EPA defines "active substance" to generally include, among other things, chemical substances added to the Toxic Substances Control Act of 1976 (TSCA) Inventory on or after June 21, 2006. 40 C.F.R. § 710.23. According to EPA's TSCA Inventory, last updated on February 19, 2019, there were 40,655 active chemical substances.

specific deadlines to promulgate new rules, conduct risk evaluations for existing chemicals, and review and make determinations for new chemical submissions, among other responsibilities.

The National Academy of Sciences (NAS) and we have made recommendations on many topics related to IRIS.² As part of EPA's response to NAS's and our recommendations, the IRIS Program began making changes designed to increase transparency about the program's processes and methodologies, increase the use of a systematic review process,³ and modernize information collection. In addition, we previously recommended that EPA develop an agency-wide chemical management strategy to address the unmet needs of EPA program offices and regions.⁴ In 2009, we also 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 are in most need of transformation.⁵ This area was added to the High-Risk List as a government program in need of broad-based transformation. While several areas of EPA carry out chemical risk assessments, this report focuses on the IRIS Program and EPA's implementation of 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). See Related GAO Products at the end of this report.

³Systematic review provides a structured and transparent process for identifying relevant studies, reviewing their methodological strengths and weaknesses, and integrating these studies as part of a weight of evidence analysis.

⁴[GAO-13-369](#). EPA partially agreed with this recommendation, and as of January 2019, it remained open.

⁵GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009). We added the area because in 2009, actions were needed to streamline and increase the transparency of IRIS and to enhance EPA's ability under TSCA to obtain health and safety information from the chemical industry. This high-risk area has evolved since 2009; for more information, see [GAO-17-317](#). GAO has previously made recommendations aimed at improving the IRIS Program and TSCA implementation.

You asked us to examine EPA’s chemical management strategies. This report describes (1) the extent to which the IRIS Program has addressed identified challenges and made progress toward producing chemical assessments and (2) the extent to which EPA has demonstrated progress, if at all, implementing TSCA, and the key challenges that remain.

To describe the extent to which the IRIS Program has addressed identified challenges and made progress toward producing chemical assessments, we interviewed IRIS officials, including leadership and staff, and leadership in EPA’s National Center for Environmental Assessment, which manages the IRIS Program. We also interviewed the leadership (as of September 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 have both been involved in chemical regulatory policy and worked with or followed the IRIS Program for the past several years, including providing comments to the IRIS Program in response to a *Federal Register* notice. We identified these individuals from our prior work with the IRIS Program. In addition, we obtained program documentation from 2012 through 2019 from IRIS officials and through our own searches of EPA’s website on changes to IRIS Program management practices, use of new tools and techniques, and timelines for the development of chemical assessments. We reviewed applicable EPA guidelines and program management practices, including the lean management system being implemented at EPA.⁶ We also compared EPA’s actions to establish priorities with federal standards for internal control.⁷

To describe the extent to which EPA has demonstrated progress, if at all, implementing TSCA, and the key challenges that remain, we interviewed EPA officials in the Office of Chemical Safety and Pollution Prevention

⁶Lean management was developed in the private sector to improve manufacturing processes, but government has adopted several principles. According to EPA’s website, EPA is initiating the application of lean management principles to “identify and eliminate waste . . . 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.”

⁷GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

(OCSPP), the EPA office with primary responsibility for implementing TSCA, including staff in the Office of Pollution and Prevention's (OPPT) Chemical Control Division—responsible for risk management—and staff in the Risk Assessment Division—responsible for risk assessment. In the Risk Assessment Division, we interviewed five technical teams—working groups organized by discipline that bring together experts from across OPPT branches. To gain perspective from outside stakeholder organizations with interests in EPA's chemical management strategies, in addition to the two stakeholder organizations we identified above, we also interviewed additional representatives from one environmental stakeholder organization that have followed EPA's implementation of TSCA and one industry stakeholder organization that represents companies affected by changes to TSCA. Our interviews with stakeholder organizations were designed to collect anecdotal information rather than findings that could be generalized across all possible stakeholder organizations. We obtained and reviewed documentation from OCSPP related to its recent activity responding to TSCA's requirements and conducted our own searches of the *Federal Register* and EPA's website to ascertain OCSPP's progress in responding to deadlines. We also reviewed documentation on previous and proposed budgets and human resources associated with OPPT and EPA's cost estimates for TSCA implementation.

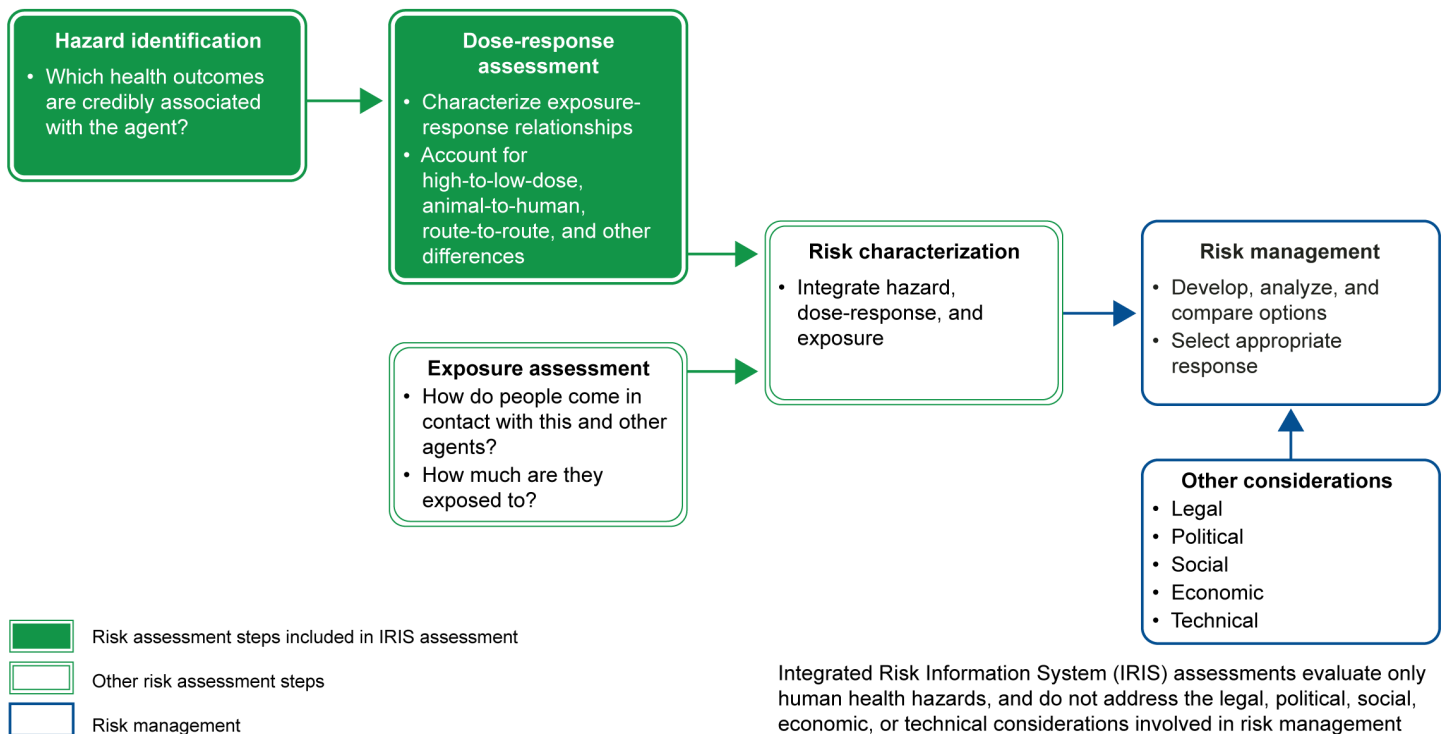
We conducted this performance audit from March 2018 to March 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based 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

Risk Assessment and Risk Management at EPA

According to EPA, risk assessments provide information on potential health or ecological risks.⁸ Information from risk assessments, in combination with other information, provides the basis for risk management actions, as illustrated in the risk assessment model in figure 1.

Figure 1: Risk Assessment Process Used by the Environmental Protection Agency (EPA)



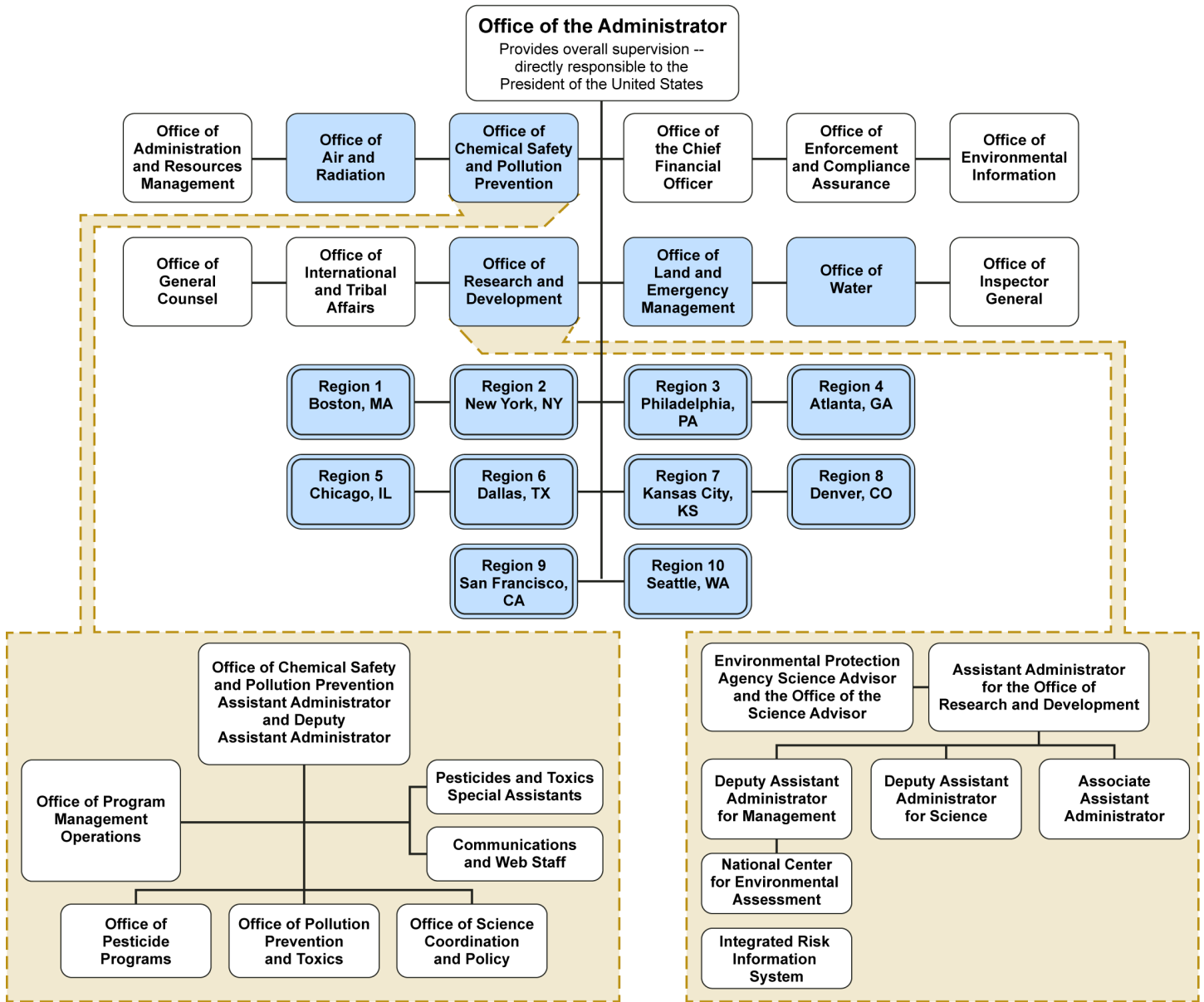
Source: EPA. | GAO-19-270

⁸Environmental Protection Agency, Risk Characterization Handbook (Washington, D.C.: December 2000), January 7, 2019, https://www.epa.gov/sites/production/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf.

EPA may also consider scientific and economic factors; court decisions; and social, technological, and political factors during the risk management process.

A number of program and regional offices at EPA prepare chemical risk assessments. These risk assessments in turn provide the foundation for EPA's risk management decisions, such as whether EPA should establish air and water quality standards to protect the public from exposure to toxic chemicals. To prepare these risk assessments, some EPA program and regional offices often rely in part on chemical assessments that the IRIS Program, as part of ORD, prepares. IRIS assessments generally include the first two steps of the risk assessment process seen in green in figure 1: (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 through this quantitative relationship. These toxicity values are combined with exposure assessments (produced by other offices within EPA) to produce a risk assessment. OCSPP, which oversees TSCA implementation, also prepares chemical risk assessments, though it does not generally rely on IRIS toxicity values. OCSPP's risk evaluations provide the foundation for a risk management action under TSCA if a use is found to present unreasonable risk of injury to human health or the environment. Risk management actions under TSCA can include but are not limited to restrictions or bans on a chemical or a condition of use, limitations on processing or manufacture, or changes to product labeling. Figure 2 shows EPA's organizational structure, including the program and regional offices that prepare chemical risk assessments.

Figure 2: Environmental Protection Agency's (EPA) Organizational Structure



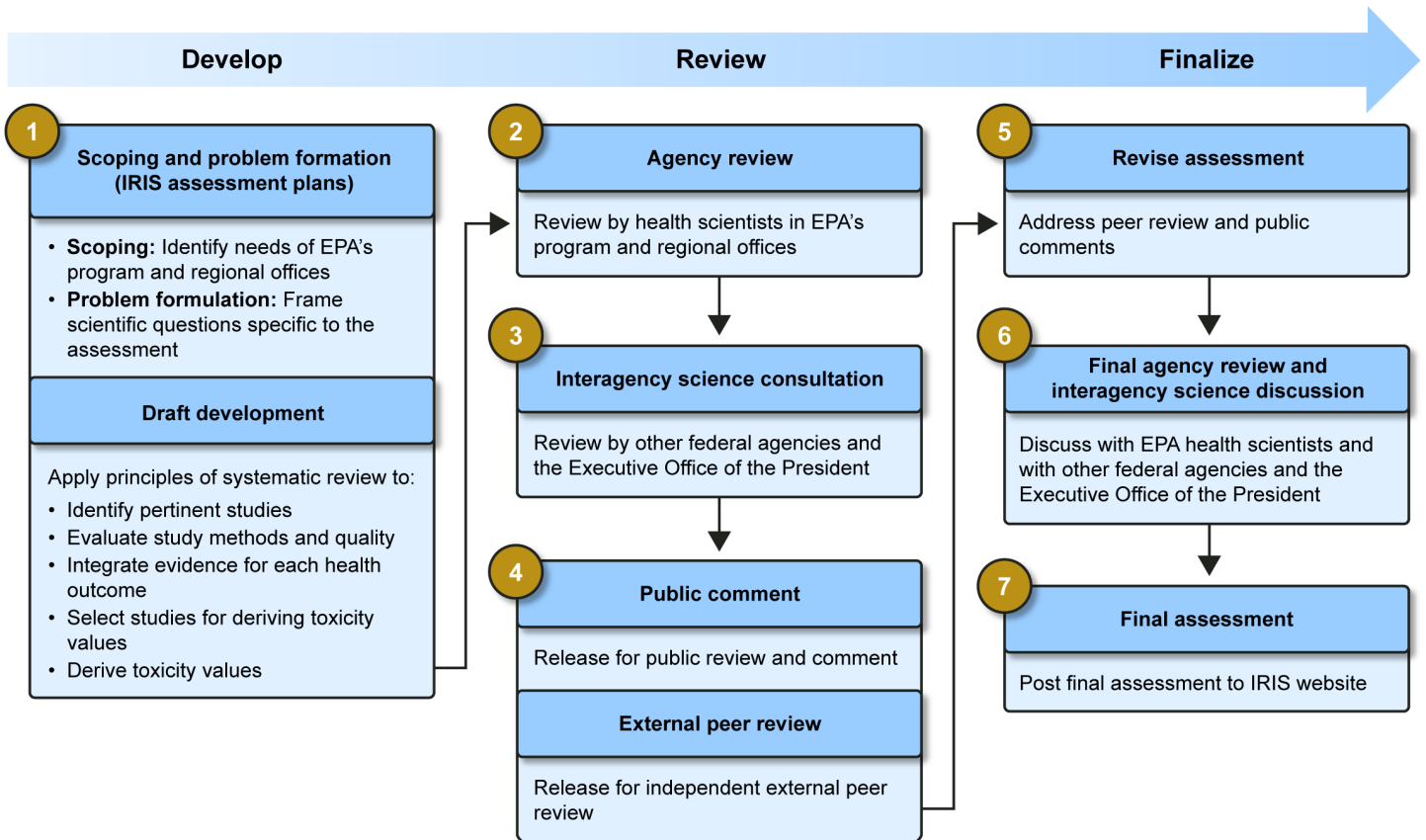
EPA offices that conduct risk assessments

Source: GAO analysis of EPA information. | GAO-19-270

EPA's IRIS Program and 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 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 3.

Figure 3: Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Chemical Assessment Development Process



Source: EPA. | GAO-19-270

The first step in the assessment development process is developing a draft assessment. This begins with IRIS Program staff determining the scope and initial problem formulation of an assessment in consultation with EPA program and regional offices. This information is documented in an IRIS Assessment Plan and 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 IRIS will use to conduct the assessment. During 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. 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. 3), the draft assessment goes through internal agency and interagency review, public comment, and peer review, as shown in steps 2 through 4 in figure 3. After making revisions to address comments received (step 5), the assessment goes through another round of internal and interagency review (steps 6a and 6b), and then the program finalizes and posts the assessment to the IRIS website.⁹

According to IRIS officials, in order to prepare IRIS assessments, a group of staff with specialized skills are required. On any given assessment, approximately a dozen staff drawn from several different backgrounds (e.g., toxicologists and epidemiologists) work on each assessment. While some of the assessment preparation—that is, setting up database searches and performing initial search screenings—can be performed by any staff, other parts of assessment development require that the staff have specific expertise.

The IRIS assessment development process—and the associated implementation of systematic review processes—has continued to evolve since 2011, primarily as a result of NAS recommendations made in two reports issued in 2011 and 2014. The 2011 report was a NAS peer review of the IRIS assessment of formaldehyde.¹⁰ In that report, NAS recommended several changes to the formaldehyde assessment and also offered recommendations more generally about the IRIS assessment development process. For example, NAS recommended methods for identifying evidence to be included in IRIS assessments; assessing and weighting that evidence in preparing the assessment; selecting studies that are used for calculating toxicity; and documenting how those toxicity

⁹The IRIS Program has not changed the process steps presented in figure 3 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.

¹⁰Formaldehyde—one of the most widely produced chemicals in the world—is used in many products, including disinfectants, pressed-wood, and clothing and other textiles. Exposure to this chemical, which has been linked to adverse health effects for more than 30 years, typically occurs through inhalation and dermal (skin) contact.

calculations are carried out. A House appropriations committee report for fiscal year 2015 directed EPA to implement the 2011 report's recommendations and NAS to review the changes that EPA was making (or proposing to make). In its review, NAS made additional recommendations to the program. In April 2018, NAS released a report on the IRIS Program's responses to the 2014 recommendations.¹¹

IRIS assessments are one potential source of information for risk assessors in OCSPP who conduct risk evaluations informing risk management activities under TSCA. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to human health or the environment.

EPA's Evaluation and Management of Chemicals under TSCA

TSCA authorizes EPA to evaluate and, if appropriate, regulate existing chemicals and new chemicals. TSCA generally covers chemicals manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States. If EPA finds that any of these activities with respect to a specific chemical presents an unreasonable risk of injury to health or the environment, EPA must issue regulations that can, among other things, restrict or prohibit these activities.¹²

TSCA also specifies the information obtained from chemical companies that EPA must publicly disclose and the circumstances under which chemical companies can claim certain information, such as data about chemical processes, as confidential business information. EPA's OPPT within the Office of Chemical Safety and Pollution Prevention manages risk assessment and risk management strategies for chemicals under TSCA. According to EPA officials, OPPT's Risk Assessment Division

¹¹NAS made 38 specific recommendations to the IRIS Program about processes in its 2014 report and provided an update on the program's progress in implementing them in its 2018 IRIS Program evaluation. See Appendix E in National Academies of Sciences, Engineering, and Medicine *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation* (National Academies Press, Washington, D.C., 2018).

¹²The "unreasonable risk of injury" standard differs from those under other environmental laws, such as those under the Clean Air Act and Clean Water Act, which require EPA to limit pollutant emissions to levels that are technologically achievable. See 42 U.S.C. § 7412(d)(2) (EPA must establish Clean Air Act standards that require the maximum degree of reduction in emissions of the hazardous air pollutants achievable for new or existing sources in the category or subcategory to which such emission standard applies); 33 U.S.C. § 1314(b) (EPA must establish technology-based effluent limitation guidelines under the Clean Water Act).

uses a number of different streams of information—including IRIS assessments—to prepare chemical risk assessments in order to make determinations about the safety of chemicals, and the Chemical Control Division uses those risk assessments to prepare risk management plans for chemicals.

Prior to 2016, environmental and industry stakeholder organizations expressed concern that public confidence was decreasing regarding the safe use of chemicals in commerce and that federal oversight should be strengthened. For example, according to an American Bar Association new TSCA guide,¹³ the desire for reform was driven by a proliferation of state-based chemical initiatives threatening to disturb interstate commercial transactions and by a continuing erosion of public confidence in TSCA's ability to protect human health and the environment from unreasonable risks presented by chemicals. In addition, according to a statement from the Environmental Defense Fund, federal oversight could not keep pace with science or rapidly expanding production and use of chemicals.

In June 2016, Congress passed the Lautenberg Act, which amended TSCA in several ways. Table 1 summarizes some of the major changes in the act, along with the purpose and application of TSCA's major sections.

¹³Lynn Bergeson and Charles Auer, *New TSCA: A Guide to the Lautenberg Chemical Safety Act and Its Implementation* (American Bar Association, 2017), xvii-xviii.

Table 1: Selected Provisions of the Toxic Substances Control Act (TSCA) and Changes based on the Frank R. Lautenberg Chemical Safety for the 21st Century Act

Section of TSCA	Topic	Lautenberg Act changes
4 - Chemical testing	Authorizes the Environmental Protection Agency (EPA) to issue regulations requiring companies to test chemicals to develop information with respect to their health and environmental effects if EPA finds that the chemical may present an unreasonable risk.	Authorizes EPA to require chemical testing for certain purposes by order or consent agreement in addition to by rule, without a prior finding of risk.
5 - New chemical substance and significant new use notices	Requires manufacturers to provide notice for new chemical substances and significant new uses. Under the original law, manufacture could generally occur 90 days after submission.	Requires EPA to make a determination within 90 days of application submission as to whether regulatory action is warranted before a new chemical, or a chemical for a use that is a significant new use, can be manufactured or processed.
6 - Chemical regulation	Authorizes EPA to regulate chemicals by, among other things, banning or restricting their manufacture.	Requires EPA to establish by rule a new risk-based process for prioritizing, evaluating, and regulating chemical risks and establishes relevant deadlines.
8 - Reporting and retention of chemical information (TSCA Inventory)	Directs EPA to promulgate rules regarding recordkeeping and reporting of certain chemical information, such as on exposure and environmental and health effects.	Establishes a process under which EPA is to require chemical manufacturers to update EPA regarding which chemicals on the TSCA Inventory were manufactured or processed during the 10-year period before the enactment of the Lautenberg Act (from June 2006 through June 2016) and, as appropriate, substantiate claims of confidentiality regarding chemical identity pursuant to section 14.
14 - Confidentiality and disclosure of information	Sets forth the circumstances under which the disclosure of information provided to or obtained by EPA under TSCA is required, permitted, or prohibited.	Establishes new substantiation requirements for confidentiality claims regarding a specific chemical identity and new circumstances under which information is to be disclosed, including in certain situations to states and human health or environmental professionals.
18 - Preemption of state requirements	Describes the circumstances where states are prohibited from establishing and enforcing chemical regulations.	Defines the types of state actions that are and are not generally preempted by TSCA, and authorizes EPA to grant waivers under certain circumstances.
26 - Administration of TSCA, including fees	Authorizes EPA to collect fees for submission of certain information.	Establishes a TSCA Service Fee fund under which fees assessed by EPA for submission of notices and other information under section 5 and for risk evaluation are to be deposited. Provides that EPA can retain and use the fees collected for certain specified purposes. Requires EPA, in carrying out sections 4, 5, and 6, to use scientific information and methods in a manner consistent with the best available science.

Source: GAO analysis of TSCA and the Lautenberg Act. | GAO-19-270

Since passage of the Lautenberg Act, several areas of disagreement have arisen among stakeholders regarding the implementation of various aspects of the act. One of the main points of ongoing discussion centers on what conditions of use EPA must consider in a chemical risk evaluation under TSCA. EPA and some stakeholders also disagree on other areas such as the methodologies EPA uses in its systematic review approach, the extent to which companies' data are exempt from disclosure, and the extent to which the fees rule accurately reflects EPA's costs for implementing TSCA. Some of these issues have resulted in litigation.

The IRIS Program Has Made Progress in Addressing Identified Process Challenges, but EPA Leadership Deliberations Delayed Progress on Producing Assessments

The IRIS Program has addressed many process challenges, such as by making changes to address the length of time it takes to develop chemical assessments and to increase transparency, but EPA has not made progress toward producing chemical assessments. 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 IRIS Program Has Made Progress in Addressing Identified Challenges

The IRIS Program in 2011 began making changes to address identified challenges, particularly the length of time the program took to produce assessments and the level of transparency in how the program prepared assessments. The program has made some progress since the beginning of 2017 toward producing assessments and is ready to release assessment-related documents. These changes were made in response to program implementation challenges identified by governmental,

The IRIS Program Has Made Changes to Address Timeliness

industry, academic, and non-governmental stakeholders in recent years.¹⁴ For example, in its 2011 report, NAS identified timeliness and transparency as issues.¹⁵ In our review of the 2011 and 2014 NAS reports and other documentation as well as our interviews with IRIS officials and leadership and officials in program and regional offices that use IRIS assessments, 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.

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 2011.¹⁶ Program and regional offices that use IRIS assessments understand this, and 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.

To address the length of time it takes to produce assessments, the IRIS Program is (1) employing project management principles and specialized software that enable the program to better plan assessment schedules and utilize staff to make the systematic review process more efficient; (2) focusing on better scoping assessments to create timely, fit-for-purpose

¹⁴National 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* (National Academies Press, Washington, D.C., 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).

¹⁵Subsequent NAS reports re-iterated these recommendations but also commended the program for the progress it made in implementing changes in response to recommendations. See NAS's *Review of EPA's Integrated Risk Information System (IRIS) Process and Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*.

¹⁶[GAO-12-42](#).

products that address specific agency needs;¹⁷ and (3) streamlining the peer review process as much as possible.

The Program Has Adopted Project Management Principles and New Software

The first way in which the IRIS Program is addressing the length of time it takes to produce assessments is by 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. For example, IRIS officials said that as part of an EPA-wide initiative, they began incorporating lean management techniques, which aim to improve efficiency and effectiveness by reducing unnecessary process steps and waiting time. Additionally, IRIS officials said that they have begun using a staffing model that trains staff to be proficient in all phases of the systematic review process (i.e., screening, data extraction, study evaluation, and evidence synthesis). This modularity will make it easier for staff to work across teams and on multiple projects, assisting with systematic review needs while also contributing in their areas of expertise, according to IRIS Program officials. In addition, the IRIS Program began using both project management software and business intelligence and visualization software in 2017. IRIS Program leadership is using this software to generate resource allocation reports showing staff assignments, enabling leadership to better manage staff workloads.

According to IRIS officials, the recent adoption of specialized systematic review software also enables program staff to perform more literature searches faster, and the ability to filter search results allows staff to find more quickly the most relevant information for an assessment. Use of software tools with machine-learning capabilities facilitate program staff's ability to screen studies for relevance more quickly compared to approaches used before 2017. Prior to the adoption of these specialized software tools, much of the development of an assessment was manual (i.e., using a spreadsheet). For example, for one assessment developed manually, contactors working on an IRIS assessment took over 200 hours to screen and catalog 1,200 epidemiological studies, including carrying out quality assurance checks. By comparison, using machine-learning

¹⁷Fit-for-purpose assessments are more limited in scope and targeted to a specific requester's need, rather than encompassing all possible information about a chemical.

tools, EPA staff were able to screen almost 5,500 articles in about 30 hours. With the new tools, quality assurance was embedded into the workflow by having two independent reviewers and a software-facilitated process track and resolve screening conflicts.

Additionally, an official from EPA's National Health and Environmental Effects Research Laboratory said that the laboratory uses a similar screening process. The laboratory worked with the IRIS Program to identify similar constructs in their processes and used each other's results to make changes and validate tools used by both. According to IRIS officials, as a result, the use of these tools has created more efficient workflow processes, leading to considerable cost and time savings. The incorporation of systematic review software tools has greatly helped the program more efficiently carry out tasks like screening literature, evaluating study quality, extracting data, and developing visualizations, according to IRIS Program officials we interviewed. Most importantly, the software tools allow multiple staff members to work on tasks simultaneously, rather than one at a time, facilitating concurrent completion of key assessment pieces.

The Program Tailors Assessments to Program and Regional Office Needs

The second way in which the IRIS Program is reducing the length of time it takes to produce assessments is by tailoring them to program and regional office needs, called fit-for-purpose assessments. According to IRIS officials, part of the reason assessments historically were time-consuming was because the program tried to synthesize and present all possible information on the human health effects of a particular chemical, including multiple exposure pathways (e.g., inhalation, ingestion, or dermal) and reference doses, reference concentrations, and cancerous and non-cancerous effects.¹⁸ This required large amounts of data

¹⁸According to IRIS Program information, reference concentrations are an estimate of a continuous inhalation exposure to the human population that is likely to be without an appreciable risk of harmful effects during a lifetime. Reference doses are an estimate of a daily oral exposure to the human population that is likely to be without an appreciable risk of harmful effects during a lifetime. Cancer descriptors characterize a chemical as: "carcinogenic to humans," "likely to be carcinogenic to humans," "suggestive evidence of carcinogenic potential," "inadequate information to assess carcinogenic potential," or "not likely to be carcinogenic to humans." While the TSCA program makes use of some of the information contained in IRIS assessments, it generally does not use these IRIS endpoint values.

extraction and was very time intensive. Beginning in early 2017, the program began implementing the fit-for-purpose approach to producing 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 needed to search for information, synthesize it and draft, review, and issue an assessment. For example, if the Office of Air and Radiation needed a chemical assessment that examined only inhalation exposures, the IRIS Program could limit its assessment to a single exposure pathway, which would reduce the amount of data that staff review and extract and, with less text to draft and less complex peer reviews, allow the assessment to more quickly move through the process.

IRIS officials said that if offices make subsequent requests for other effects or exposure pathways, the IRIS Program can update the original assessment. IRIS officials said that they expect time savings as a result of moving to the fit-for-purpose model. As of November 1, 2018, the IRIS Program had produced two fit-for-purpose assessments: a request for correction on chloroprene and an update of the assessment on acrolein. An assessment on perfluorobutane sulfonic acid (PFBS) was also released for public comment following peer review.¹⁹ PFBS are a member of a class of man-made chemicals known as per- and polyfluoroalkyl substances (PFAS)—a groups that also includes perfluorooctane sulfonate acid (PFOS), perfluorooctanoic acid (PFOA), GenX, and many others. In addition, since 2017, the IRIS Program released scoping and problem formulation materials for six IRIS chemical assessments

¹⁹The chloroprene correction took approximately 7 months to complete, and the update of the acrolein assessment took approximately 4 months to produce and will be ready to be released for review pending the results of EPA leadership deliberations. The assessment on PFBS took approximately 9 months to produce and was ready to be released for public comment as of October 2018. Chloroprene is a flammable liquid used to make rubber; acrolein is a liquid used as a pesticide and to make other chemicals, and PFBS is a compound used to make various consumer products.

(nitrates/nitrites, chloroform, ethylbenzene, uranium, ammonia, and naphthalene).²⁰

Additionally, the program is examining ways to assist program and regional offices with information that may not necessitate developing a full assessment. For example, the Office of Air and Radiation was doing work using a toxicity value for acrolein that the California Environmental Protection Agency prepared in 2008, because that value was more recent than the value in the IRIS database. However, a large number of studies on acrolein had been released since 2008, so the IRIS Program searched approximately 10,000 new studies and concluded that the study used by California Environmental Protection Agency in 2008 was still the most appropriate study for chronic toxicity value derivation. In addition, IRIS staff developed an updated draft reference concentration for acrolein based on this study. The screening and update process took approximately 4 months, demonstrating how the IRIS Program's use of new tools and a targeted scope resulted in more timely attention to program office needs.

The Program Is Streamlining the Peer Review Process

The third way the IRIS Program is addressing the length of time it takes to produce assessments is by streamlining the peer review process as much as possible without compromising the quality of the review. 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 (SAB) or a NAS panel, though IRIS leadership determines the most appropriate method of peer review based on Office of Management and Budget and EPA Peer Review Handbook guidelines. While the contractor-led letter or panel reviews are no less robust than full SAB or NAS panel reviews, the contractor-led reviews are usually smaller and completed in less time because they are reviewing smaller, less complex IRIS assessments. The time savings occur because the reviewers do not typically meet in person, or may meet only

²⁰Nitrates/nitrites are naturally occurring ionic species used in inorganic fertilizers. Chloroform is a colorless liquid used to make other chemicals. Ethylbenzene is a colorless, flammable liquid found in natural products and manufactured products such as ink, insecticides, and paints. Uranium is a naturally occurring and radioactive substance. Ammonia is a colorless gas used in cleaning products and fertilizers. Naphthalene is a white solid used in the manufacture of plastics, moth repellents, and toilet deodorant blocks.

once, typically taking a few months to complete their reviews. In contrast, SAB and NAS panels involve larger numbers of people who meet multiple times, review longer and more complex assessments, and must reach consensus on their reviews. As a result, SAB and NAS peer reviews can take more than a year to complete. 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. IRIS Program officials said they also hope that other changes they recently implemented—primarily, increased transparency and systematic review—will help speed up the peer review process by producing a higher-quality overall draft.

The IRIS Program Has Made Changes to Address Lack of Transparency

Another major category of NAS recommendations that the IRIS Program has addressed is the need for greater transparency in how the program conducts assessments. For example, one industry representative expressed concern in August 2018 about transparency before the program began making changes, describing the IRIS Program as a “black box” because “no one knew how the program created its methodologies, weighted evidence, or produced assessments.” In response, the IRIS Program has in the past several years (1) implemented systematic review, which provides a structured and transparent process for identifying relevant studies, reviewing their methodological strengths and weaknesses, and integrating these studies as part of a weight of evidence analysis, and (2) increased outreach efforts with stakeholders and the public, both in terms of the frequency and the depth of content about assessment preparation.

The Program Began Implementing Systematic Review as a Basis of Its Assessments

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. A systematic review is a structured and documented process for transparent literature review. It is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent. 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 is working with technical experts to increase the applications of machine learning for carrying out systematic review.

Additionally, new software allows the IRIS Program to save and publish its search strings and to indicate why it selected certain studies over others for review and inclusion. The software also allows multiple staff to check searches and concur or not-concur with the initial assessment about including a scientific article in the draft assessment. IRIS officials told us that the transparency associated with systematic review and clearer explanation of methodologies in assessments (as well as releasing subsidiary documents, such as IRIS Assessment Plans and Assessment Protocols) will improve stakeholders' understanding of how the program arrives at its conclusions.

The Program Has Made Changes to Communication Frequency and Type

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. This allows EPA program and regional offices to know when to expect assessments, as well as what those assessments will cover. To prepare the 2015 Multi-Year Agenda, the IRIS Program solicited requests from EPA program and regional offices about which chemical assessments they needed; these requests were released in December 2015.²¹ When new leadership joined the IRIS Program in early 2017, the new officials began reaching out to individual program and regional offices to re-confirm 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. Based on these conversations with program and regional office staff, the IRIS Program made some chemical assessments higher priority and removed others from the program's workflow, consistent with stated needs.

In May 2018, the IRIS Program prepared a statement for posting on the IRIS website outlining these changes to the program's workflow and an updated list of assessments that were being developed with anticipated

²¹The IRIS Multi-Year Agenda identifies the top priority chemical assessments for which the IRIS Program will develop assessments in the next few years.

completion time frames. However, EPA leadership in ORD—the office that oversees the IRIS Program—did not approve this statement for release because current EPA leadership in program and regional offices had not formally requested these assessments. Nevertheless, officials from program and regional offices that use IRIS assessments told us that they received clear communication from the IRIS Program about priorities and timelines for individual assessments. According to these officials, some of this communication took place when IRIS Program leadership reached out to program and regional office officials to confirm their needs, and some took place during monthly telephone calls the IRIS Program held to update stakeholders on assessment development timelines. Program and regional office officials told us that they appreciated the IRIS Program’s recent efforts to understand program and regional office needs and timelines; communicate the status of assessments more frequently; and find ways to assist program offices that may not require developing a full assessment, such as assessment updates or literature reviews.

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 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. IRIS officials also said that they created templates for several parts of the assessment process, including the IRIS Assessment Plans and assessment protocols, which help maintain consistency throughout assessment development and from one assessment to the next.

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 9 different chemical assessments and released the template for assessment protocols for agency review. The IRIS Program also produced a report to Congress on the program’s work in January 2018 and took part in a NAS

review of the program in February 2018. The NAS review, which offered a third-party assessment of the program's efforts, provided a supportive assessment of ongoing transformations aimed at ensuring data quality, new systematic approaches for data analysis and expanded stakeholder engagement efforts, and increased the efficiency of assessments. According to the report, NAS reviewers were impressed with the changes being instituted in the IRIS Program since 2014, including substantive reforms by new IRIS Program leadership, such as the development, implementation, and use of systematic review methods to conduct IRIS assessments. In addition, as of August 2018, the final IRIS assessment of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) was issued.²² In early November 2018, IRIS officials told us that the agency had almost completed internal review of the handbook, which was being prepared for public release. In December 2018, the IRIS Program and OPPT participated in a NAS workshop that informed the systematic review of mechanistic evidence.²³

Budget Cuts May Impact the Program's Ability to Expand Assessment Development

The IRIS Program has made important changes aimed at producing more timely and transparent assessments, but IRIS officials told us that proposed budget cuts have caused them concern about whether they will have sufficient resources to expand assessment work in the future. The human health risk assessment area, of which IRIS's budget makes up approximately half, has been funded at about \$38 million annually since fiscal year 2013 based on our review of EPA budget documents. However, the President's budget request for human health risk assessment work in fiscal years 2018 and 2019 was \$22.5 million and \$22.2 million, respectively. This represents a cut of approximately \$17 million from previous budget levels dating back to fiscal year 2013. The IRIS Program budget would drop approximately 40 percent from \$20.8 million to approximately \$12 million if these cuts were enacted. Congress did not support these reductions. Specifically, according to the joint explanatory statements accompanying the Consolidated Appropriations Act, 2018, and Consolidated Appropriations Act, 2019, Congress had agreed to continue providing funding at fiscal year 2017 enacted levels. Cuts to the program could impact EPA's regulatory work: Officials in

²²RDX is a highly powerful explosive used by the U.S. military in thousands of munitions.

²³On December 10 and 11, 2018 the National Academies of Sciences, Engineering, and Medicine held a workshop on current state-of-the-art in performing systematic reviews of mechanistic data to support chemical assessments. <http://dels.nas.edu/Upcoming-Workshop/Strategies-Tools-Conducting-Systematic/AUTO-5-32-82-N>.

almost all of the program and regional offices that use IRIS assessments told us that they rely on IRIS assessments to do their work—it is the first place they look for chemical toxicity values, and if the IRIS Program is unable to produce assessments, their offices would be challenged to meet statutory deadlines and there would be a generally negative effect on public health.

IRIS Program Progress toward Producing Assessments Was Delayed by EPA Leadership Deliberations about Priorities

The IRIS Program made progress developing assessments and producing assessment documentation (e.g., IRIS Assessment Plans and protocols) in early 2018. However, 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.²⁴ At the request of the Administrator, IRIS officials prepared a survey of program and regional offices, asking them to re-confirm their needs for 20 assessments that were in development.²⁵ 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 re-confirmations were consistent with the priorities of EPA program office leadership.²⁶ While survey responses were being compiled, EPA leadership in ORD instructed the IRIS Program not to publically 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

²⁴This included any associated parts of an assessment, such as Assessment Plans or protocols. For 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, but the public meeting to discuss the naphthalene IRIS Assessment Plan that was scheduled for August 23, 2018, was postponed the day before that meeting with no explanation and no makeup date.

²⁵The 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.

²⁶Regional offices were told that their submissions would be included as part of a program office request.

comment, or peer review was unable to proceed through the IRIS assessment development process.

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 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. And since neither the program and regional offices nor the IRIS Program had information from the Administrator's office about what the prioritization was meant to achieve, the IRIS Program was unable to provide guidance about what chemicals might be considered a priority, or how many they might be able to continue work on.

When EPA leadership's deliberations about the program's priorities were completed, a memorandum was issued 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 an outlook of program activities, which included two additional assessments that were not included in the memorandum. These 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 and had not been issued were not included in the December 2018 Outlook. The four

assessments were: acrylonitrile, n-Butyl alcohol, formaldehyde,²⁷ and polycyclic aromatic hydrocarbon (PAH). The assessment of formaldehyde was, according to the “IRIS Assessments in Development” website, at Step 4 of the IRIS process (an assessment is drafted and was ready to be released for public comment and external peer review). 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.²⁸ 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.

As of December 19, 2018, the status of the 13 assessments in the December 2018 Outlook was:

- **External peer review:** ETBE and TBA.²⁹
- **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).³⁰

²⁷As 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 used in many household products, including paper, pharmaceuticals, and leather goods. [GAO-08-440](#).

²⁸[GAO-08-440](#).

²⁹As of February 27, 2019, the external peer review reports for ETBE and TBA were publicly released. [https://yosemite.epa.gov/sab/sabproduct.nsf/1BC795C095943F25852583AE00659299/\\$FILE/EPA-SAB-19-001%20.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/1BC795C095943F25852583AE00659299/$FILE/EPA-SAB-19-001%20.pdf).

³⁰PFNA, 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.

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- **Scoping and Problem Formulation:** mercury salts; methylmercury; vanadium and compounds.³¹

According to IRIS officials, the IRIS Program was unable to release any work since June 2018, while it was waiting for feedback from the Administrator's office regarding whether its assessment workflow was consistent with agency priorities. IRIS officials told us that staff continued whatever draft development work that they could do internally, but several IRIS staff have been working increasingly for OPPT to support its work preparing risk evaluations under TSCA. ORD reported to us that in September 2018—3 months after IRIS assessments were stopped from being released because of ongoing EPA leadership deliberations—5 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 noted above, TSCA establishes a regulatory standard that generally differs from those under other environmental laws, so the TSCA assessments will not necessarily be relevant to other EPA programs that have relied on IRIS endpoint values in making their regulatory decisions.

³¹For more information on the assessments released in the IRIS 2018 IRIS Program Outlook, see: <https://www.epa.gov/iris/iris-program-outlook>.

EPA Has Demonstrated Progress Implementing TSCA by Responding to TSCA Statutory Deadlines through the End of Fiscal Year 2018, but Key Challenges Remain

EPA has demonstrated progress implementing TSCA by responding to TSCA's statutory deadlines through the end of fiscal year 2018, including promulgating rules, developing guidance, and releasing reports.³² However, EPA faces key challenges to its ability to implement TSCA, such as managing the risks posed by ongoing litigation, ensuring appropriate resources, developing guidance to ensure consistency, and ensuring that the new chemicals review process is efficient and predictable.

EPA Responded to TSCA Statutory Deadlines

EPA has responded to initial statutory deadlines under TSCA, as amended by the Lautenberg Act, including requirements to promulgate new rules, develop guidance, and release reports. For example, EPA

- began 10 risk evaluations drawn from the 2014 update of the TSCA Work Plan within 180 days of enactment of the Lautenberg Act (§ 6(b)(2)(A));
- submitted an initial report to Congress estimating capacity for and resources needed to complete required risk evaluations within 6 months of enactment (§ 26(m)(1));
- carried out and published in the *Federal Register* an inventory of mercury supply, use, and trade in the United States by April 1, 2017.³³ (§ 8(b)(10)(B));
- developed guidance to assist interested persons in developing and submitting draft risk evaluations within 1 year of enactment (§ 26(l)(5)); and
- developed a plan for using alternative test methods to reduce use of vertebrate animal testing within 2 years of enactment (§ 4(h)(2)(A)).

³²As we discuss below, several aspects of EPA's implementation of TSCA are in litigation. GAO does not typically express an opinion in disputes pending before a court.

³³EPA must also do this every 3 years thereafter.

In addition, in four areas in which Congress required EPA to establish processes and structures for TSCA, EPA finalized four rules detailing the general processes for prioritizing and evaluating chemicals under TSCA, known together as the Framework Rules. EPA responded to the 1-year deadlines to establish three of the four Framework Rules.³⁴ These three rules are

- **the risk prioritization rule**, which explains EPA's process for prioritizing existing chemicals for risk evaluation;
- **the risk evaluation process rule**, which explains EPA's process for conducting risk evaluations on existing chemicals; and
- **the inventory notification rule**, which requires manufacturers and processors of chemical substances to report which chemicals are currently in commerce.

The fourth Framework Rule EPA issued, which had no issuance deadline, implements a Lautenberg Act provision authorizing EPA to collect fees for carrying out a number of different activities under TSCA, including collecting fees from manufacturers and processors that submit new chemicals or submit chemicals for significant new uses to EPA for review.

Though EPA responded to all of the statutory deadlines, some environmental and industry stakeholder organizations we interviewed told us that they do not believe this is a complete measure of how well EPA is implementing TSCA. Representatives from one environmental stakeholder organization told us in July 2018 that it is still too early to assess how well EPA is implementing TSCA because none of the existing chemical risk evaluations ongoing under the new process have been released; the wording in the new rules and documentation is unclear; and the risk prioritization rule, the risk evaluation rule, and the inventory reset rule have been challenged in court. However, in January 2019 they told us that they were too optimistic in their assessment of TSCA implementation and believe EPA is falling behind in its progress. As of December 2018, representatives from another environmental stakeholder group told us that, while EPA has met a number of major statutory deadlines, the agency's rules and other actions do not reflect the best available science and are contrary to both the letter and intent of the new

³⁴The risk prioritization rule, risk evaluation rule, and inventory notification rule were finalized June 22, 2017. The fees rule was finalized on September 27, 2018.

TSCA Act. However, in January 2019 an industry stakeholder organization noted that the 2016 amendments to TSCA are generally being implemented effectively and efficiently as Congress envisioned, and the agency continues to meet important deadlines required by the law. In addition, they also told us that EPA’s TSCA program is also utilizing the best available science and a weight of the evidence approach to make high quality chemical management decisions. Representatives from industry stakeholder organizations we interviewed told us they believe the rules are consistent with TSCA, but that EPA is not consistently meeting the 90-day deadline to make determinations on new chemicals or the 30-day deadline to make determinations on low-volume exemptions.³⁵

EPA Faces Challenges Implementing TSCA

EPA faces challenges with its ability to implement TSCA, such as managing the risk posed by ongoing litigation, ensuring appropriate resources, developing guidance documents to ensure consistency, and ensuring that the new chemicals review process is efficient and predictable.

Three Rules Are Undergoing Litigation

Three of the four Framework Rules that EPA issued to implement TSCA have been challenged in court: the risk prioritization rule, the risk evaluation rule, and the inventory notification rule.

- **Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substance Control Act (risk prioritization rule).** In *Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency*, a collection of environmental and public health organizations challenged several aspects of EPA’s TSCA implementation, including the risk prioritization rule.³⁶ Specifically, the environmental organizations argue, among other things, that the plain language of TSCA requires EPA to consider all conditions of use in prioritizing chemicals for review under TSCA, rather than excluding, for example, uses that EPA believes are “legacy uses” for which a chemical is no

³⁵As we note below, the overall process can extend beyond the 90-day requirement.

³⁶*Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency*, Case No. 17-72260 (9th Cir.), filed August 10, 2017.

longer marketed.³⁷ EPA and chemical industry intervenors respond by arguing that TSCA grants EPA discretion to determine what conditions constitute a chemical's conditions of use and to generally exclude legacy activities—primarily historical activities that do not involve ongoing or prospective manufacturing, processing, or distribution in commerce of a chemical substance as a product.³⁸

- **Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (risk evaluation rule).** In *Safer Chemicals, Healthy Families v. U.S. Environmental Protection Agency*, the environmental organizations also contend that EPA's risk evaluation rule is contrary to TSCA, in part because, as noted above, the rule "impermissibly" excludes uses that the law requires EPA to include in its risk evaluations. EPA and industry intervenors responded by arguing that TSCA grants EPA discretion to determine what conditions constitute a chemical's conditions of use. The organizations also argued that the risk evaluation rule would deter public participation in the risk evaluation process by imposing criminal penalties on a member of the public who submits incomplete information to EPA but does not impose similar penalties on manufacturers.³⁹ In August 2018, the government moved to vacate the penalty regulation, and the environmental organizations consented to this motion.

³⁷Under TSCA, the process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), *the conditions of use or significant changes in the conditions of use of the chemical substance*, and the volume or significant changes in the volume of the chemical substance manufactured or processed." 15 U.S.C. § 2605(b)(1)(A) (emphasis added). TSCA defines "conditions of use" to mean the circumstances, as determined by [the EPA] Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. 15 U.S.C. § 2602(4).

³⁸An intervenor voluntarily enters a pending lawsuit because of a personal stake in it. *Black's Law Dictionary* (10th ed. 2014).

³⁹Submission to EPA of inaccurate, incomplete, or misleading information pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code." 40 C.F.R. § 702.31(d). The environmental organizations argued that because TSCA does not require members of the public to submit information to EPA, this regulation would have had the effect of penalizing voluntary information sharing, thus exceeding EPA's authority under TSCA as well as being unconstitutionally vague.

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- **Toxic Substances Control Act Inventory Notification (Active-Inactive) Requirements (inventory notification rule).** In *Environmental Defense Fund v. U.S. Environmental Protection Agency*,⁴⁰ an environmental organization challenged EPA's inventory notification rule, which EPA issued in response to a TSCA requirement that EPA identify which chemicals in the TSCA inventory are still in use and require substantiation of claims that chemical identities constitute confidential business information that can be withheld from public disclosure.⁴¹ The environmental organization argued, among other things, that the rule impermissibly allows any persons to assert confidentiality claims for any chemical they manufacture or process, rather than just the original claimant. EPA and industry intervenors responded in part by arguing that TSCA specifically allows any affected manufacturers to maintain an existing confidentiality claim for a specific chemical identity, which the industry intervenors assert constitutes critically important intellectual property.

OPPT officials told us they are trying to not anticipate the results of the litigation and, instead, address the outcome of each case as it is decided. They stated that they are staying aware of developments in ongoing litigation and are constantly considering potential outcomes but believe it would not be reasonable to prepare explicit resource plans for unknown future scenarios. If EPA loses any of these lawsuits, it may need to devote additional resources to implement the relevant provisions of TSCA. For example, if the suit involving the risk evaluation rule is successful, EPA may be forced to redo parts of its risk evaluations close to the December 2019 deadline to finalize these evaluations. EPA is required to complete its first 10 existing chemical evaluations not later than 3 years after the date on which it initiated the risk evaluations, which was December 2016. TSCA also allows for an extension of the risk evaluation deadlines for up to 6 months if the agency deems it necessary.

EPA Faces Challenges
Ensuring That It Has
Appropriate Resources

The Lautenberg Act greatly increased OPPT's workload. Prior to the enactment of the Lautenberg Act, EPA did not have deadlines for completing existing chemical evaluations. Under the Lautenberg Act, EPA must finalize 10 ongoing risk evaluations by December 2019, which

⁴⁰*Environmental Defense Fund v. U.S. Environmental Protection Agency*, No. 17-1201 (D.C. Cir), filed September 1, 2017.

⁴¹15 U.S.C. § 2607(b)(4).

represents a tight deadline, according to EPA officials.⁴² Furthermore, the law requires EPA to ensure that 20 risk evaluations are ongoing for high-priority substances 3-1/2 years after enactment and that at least 20 chemical substances have been designated as low-priority substances.⁴³ In addition, under TSCA prior to the Lautenberg Act, a new chemical could enter commerce after 90 days unless EPA took action to the contrary. Under the Lautenberg Act, EPA is required to make a determination on a new chemical before it can be manufactured—another source of increased workload.⁴⁴

Partially because of the increased workload, some OPPT officials told us that they have concerns about staff capacity within OPPT. Officials in both the Chemical Control Division (responsible for risk management) and the Risk Assessment Division (responsible for risk assessment) said that they do not have sufficient resources to do their work. This included staff from all five technical teams we interviewed in the Risk Assessment Division. Technical teams are working groups organized by discipline that bring together experts from across OPPT branches. The Risk Assessment Division is particularly affected by the heavy workload, according to OPPT officials and representatives from an industry

⁴²See 15 U.S.C. § 2605(b)(2)(A), (b)(4)(C), (b)(4)(G)(i). EPA may extend the deadline for a risk evaluation for not more than 6 months. 15 U.S.C. § 2605(b)(4)(G)(ii).

⁴³“The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.” 15 U.S.C. § 2605(b)(1)(B)(i). “The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.” 15 U.S.C. § 2605(b)(1)(B)(ii).

⁴⁴EPA must now make one of three determinations regarding a new chemical submission: (1) that the chemical under the conditions of use presents an unreasonable risk; (2)(a) that there is insufficient information available to make a judgment or that (b) in the absence of such information, the chemical may present an unreasonable risk, or (c) the chemical is or will be produced in substantial quantities that enter or may enter the environment or may cause substantial human exposure; or (3) that the chemical or use is not likely to present an unreasonable risk. 15 U.S.C. § 2604(a)(3). The law requires EPA to take further actions with respect to chemicals in the first two categories. See 15 U.S.C. § 2604(e), (f). EPA recently proposed to use significant new use rules under TSCA as an approach for managing reasonably foreseeable uses of chemicals without making one of the determinations listed above. 83 Fed. Reg. 52180 (Oct. 16, 2018).

stakeholder organization. The division must review all of the premanufacture notices for new chemicals and contribute to the first 10 existing chemical evaluations.⁴⁵ Officials from the Chemical Control Division told us that the Risk Assessment Division is struggling more because its work requires more technical employees. The officials said that EPA is hiring additional full-time equivalents (FTE), but it takes time to train new people, and this will initially increase workload. Officials told us that in July 2018, OPPT had about 300 FTEs and was authorized to hire 40 additional FTEs. As of October 2018, OPPT officials told us that they had hired or extended offers to 20 to 25 of that 40 and continued to hire more employees. OPPT officials told us that reaching an appropriate level of FTEs—including recruiting and retaining staff—is challenging. OPPT officials said they expect that the recently announced initiative to implement direct hiring authority for scientific and technical positions will have a positive impact on these efforts.

To address the staffing challenge, staff have also been reassigned from other parts of EPA to OPPT. For example, staff in the Safer Choice Program—an EPA program that helps consumers, businesses, and purchasers find products that perform and are safer for human health and the environment—were redeployed to the Chemical Control and the Risk Assessment Divisions. Representatives from both industry stakeholder organizations we interviewed told us that it can be difficult to work with recently reassigned staff who are not familiar with the chemicals they are working on. Representatives from an industry stakeholder organization told us that, in some cases, OPPT staff are ill-prepared to make decisions about a premanufacture notice. OPPT senior officials said there is always a learning curve for reassigned employees, but they do not put new people in positions to make decisions on premanufacture notices. They said that these decisions are never made by one person in a vacuum.

OPPT officials and staff told us that they are generally optimistic about an upcoming reorganization of OPPT that will separate assessment and management of new and existing chemicals programs and better align the structure of OPPT with the focus of TSCA's provisions. For example, the Chemical Control Division and the Risk Assessment Division currently each handle both new and existing chemicals, and the planned reorganization will divide the divisions into new and existing chemical

⁴⁵Anyone who plans to manufacture (including import) a new chemical substance for a nonexempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity. This notice is called a premanufacture notice.

divisions. However, staff told us that they have concerns about whether the new divisions will be adequately staffed, the timing of the reorganization, and their future placements.

Staff from multiple technical teams we interviewed in the Risk Assessment Division said that they are not sure if, after the reorganization, the new divisions will be adequately staffed. Staff from one technical team said there has been increased attrition in recent years, partially because of concerns about the upcoming reorganization. Staff from another technical team said that a large number of management positions are unfilled. Staff from multiple technical teams told us that it will take time after the reorganization to redistribute work and train staff. Staff from one team said the reorganization is ill-timed because there are currently too many other ongoing high-priority projects. Staff from multiple technical teams also told us that they are experiencing anxiety about their future placements and with whom they will work. In commenting on a draft of this report, EPA stated that the concerns raised by staff are likely common to any program undergoing change. OPPT officials said they submitted the reorganization proposal to EPA's Office of Mission Support—formerly the Office of Administration and Resources Management—in October 2018 and that it could take several more months as EPA management works out details with labor unions and addresses other issues. Officials said that they anticipate implementing the reorganization in early 2019.

OPPT senior officials said that now that OPPT has many new responsibilities and a heavier workload, they are taking steps to improve capacity by implementing the reorganization and hiring new staff. The officials said that though there will inevitably be growing pains, the changes are part of a larger plan specifically designed to better position OPPT to implement TSCA. Senior officials also told us that they have spent considerable time setting expectations for new and existing staff.

In tandem with the major changes that increased EPA's workload, the 2016 amendments to TSCA authorize EPA to establish fees to defray a portion of the costs of administering TSCA sections 4, 5, and 6 and collecting, processing, reviewing, providing access to, and protecting information about chemical substances from disclosure, as appropriate, under TSCA section 14.⁴⁶ Affected businesses began incurring fees

⁴⁶15 U.S.C. § 2625(b).

under the new rule as of October 1, 2018, but it is unclear whether the fees collected will be sufficient to support relevant parts of the program. OPPT officials told us that while they are uncertain how much the fees rule will generate the first year, they believe that over the course of a few years, the amount of money generated should stabilize. The first year is where officials are not sure how much they may receive. Officials expect to collect an average of \$20 million per year over the next 3 fiscal years. In fiscal year 2019, however, they expect to collect approximately \$7 million to \$8 million. According to EPA, the agency will be tracking its costs and use that information to adjust future fees, if appropriate. As required by law, EPA will evaluate and readjust, if necessary, the fees every 3 years.

EPA estimates the average yearly cost of TSCA implementation for fiscal years 2019 through 2021 to be \$80,178,000. EPA's fiscal year 2019 budget justification shows \$57,973,700 allocated to TSCA implementation. However, EPA does not expect a budget shortfall in fiscal year 2019 because, according to officials, they (1) have funds available from 2018 to support fiscal year 2019 needs, (2) receive support from other EPA offices like the Office of General Counsel and the Office of Research and Development, (3) expect fiscal year 2019 costs to be lower than the 3-year average described in the fees rule, and (4) expect some indirect costs to be covered by non-TSCA budget categories.⁴⁷

EPA Faces Challenges Developing Guidance to Ensure Consistency

EPA also faces challenges in developing guidance to ensure consistency in implementing the law. OPPT officials said that, given the tight timelines that TSCA requires, they have not yet created all the necessary guidance for staff implementing the law. Officials likened it to building an airplane as they fly it, as they must create guidance and processes, while simultaneously applying them to chemical evaluations. Staff from four of five technical teams we interviewed are either currently updating their guidance, still developing their guidance, or have never developed guidance before. Staff from two teams told us that they are developing the guidance as they apply it to their work. OPPT officials told us that they are using some guidance that was in place before the Lautenberg Act was enacted, though they are working on updates.

⁴⁷In commenting on a draft of this report, EPA noted that the current budget situation is helped by the fact that EPA will only be conducting 10 risk evaluations instead of the 20 required in later years.

EPA Faces Challenges
Ensuring That the New
Chemicals Review Process Is
Efficient and Predictable

Representatives we interviewed from industry stakeholder organizations said they want EPA to be clear about its standards for the new chemicals program and how they are defining terms in TSCA. Representatives from one industry stakeholder organization suggested that EPA should establish some definitions and develop guidance on how to apply those definitions, in order to help both chemical manufacturers and reviewers within OPPT. In June 2018, EPA released “Points to Consider When Preparing TSCA New Chemical Notifications,” guidance that representatives from industry stakeholder organizations said is helpful, but they are still not sure how EPA is using information like the Points to Consider guidance in its evaluations and against what standard EPA’s reviewers are reviewing and assessing a chemical. Representatives we interviewed from industry stakeholder organizations said that decisions on new chemical reviews depend on individual reviewers because EPA has not provided the reviewers with guidance that ensures consistency.⁴⁸ OPPT officials also said consistency is a challenge in conducting risk assessments. Representatives we interviewed from environmental stakeholder organizations did not mention consistency as an area of challenge.

Representatives from both industry stakeholder organization we interviewed also told us that the new chemicals program is too slow and unpredictable, which can negatively affect innovation. For example, representatives from one company told us in comments they provided through an industry stakeholder organization we interviewed that it submitted a premanufacture notice for a substance that would decrease the potential for worker and environmental exposure while providing improved product performance. The approval process extended to nearly 550 days compared to the 90 days it typically took to obtain approval prior to TSCA’s amendment. EPA can request extensions, and submitters can voluntarily suspend the review process; therefore, the overall process can extend beyond the 90-day requirement. For example, in the new chemical review process, EPA first makes an initial determination. If a company does not like this initial determination, it can request more time to provide additional data or develop new data in an effort to get a positive final determination. A company withdraws its submission prior to a final EPA determination if it is clear the determination will not be favorable and the

⁴⁸In commenting on our draft report, EPA noted that OPPT officials add that the decision-making process involves multiple layers of management officials and peer committees that are designed to promote consistency across decisions.

chemical will be regulated.⁴⁹ EPA officials said the agency does not violate the mandated timelines because submitters agree to voluntarily suspend the review process. However, representatives from one industry stakeholder organization told us that as of December 2018, with the passage of time and greater familiarity with Lautenberg, OPPT's decision making process has improved and is more predictable.

EPA officials said that historically, even among new chemicals for which EPA completed review, 57 percent actually entered commerce. Officials said that in the past companies submitted new chemicals just to see what determinations EPA would make. Going forward, as of October 2018, officials said they expect larger fees will result in some companies choosing to be more selective in the chemicals they submit to the program. In addition, EPA officials told us that after OPPT's reorganization, a more devoted team will focus on pre-notice meetings with companies. Officials said this should reduce some of the back and forth with submitters, thereby improving timelines.

Representatives we interviewed from industry stakeholder organizations also told us that delays motivate companies to introduce chemicals first in foreign markets. For example, one company told us through comments it provided through an industry stakeholder organization we interviewed that it developed a new technology in the United States, but because of the lengthy delays experienced with new chemicals reviewed under TSCA, they will neither register nor commercialize the product in the United States at this time. Rather, the company has decided to pursue commercialization in Europe, which will enable the company to deliver the benefits of this new technology to their customers in the European market sooner than is possible in the United States.⁵⁰

Agency Comments

We provided a draft of this report to EPA for its review and comment. We received written comments from EPA that are reproduced in appendix I and summarized below.

⁴⁹In commenting on our draft report, EPA noted that since 1979 to June 2016 about 3% of submissions were withdrawn. From June 2016 to present about 9% of submissions were withdrawn.

⁵⁰Foreign programs for assessing and managing chemicals operate within different institutional structures.

In its written comments, EPA stated that while the draft comprehensively describes the challenges facing the TSCA and IRIS programs, it does not appropriately address EPA's extensive progress in implementing TSCA, and EPA recommended that our final report include information regarding its accomplishments under the new law. Specifically, we report on the steps EPA has taken to respond to the requirements of the law because in many instances, whether EPA's response is legally sufficient is in litigation, and GAO does not typically express a view on legal or factual matters in dispute before a court. We have updated our report with additional examples, which the agency provided in its comments, of steps it has taken to implement TSCA.

In addition, EPA requested that we consider its progress made in addressing and controlling toxic chemicals with respect to the five criteria for removal from our high-risk list. The application of the high-risk criteria was not within the scope of this report. Our forthcoming 2019 high-risk update will address actions taken by agencies on the list, including EPA, since the last update in 2017. EPA said that to monitor progress, it had put into place a rigorous program; as a regular practice, EPA stated that Deputy Assistant Administrators from the Office of Chemical Safety and Pollution Prevention conduct monthly Business Review meetings with the Office Directors, Deputy Office Directors, lead region representatives, and other key staff. EPA stated that during these meetings they discuss their organizations' operations and performance, including TSCA implementation status, using performance charts to track progress on mission measures, identify and update countermeasures, and resolve problems. However, over the year that we conducted our review, EPA officials did not mention conducting such meetings and did not provide documentation that such meetings took place.

Further, in its written comments, EPA provided technical comments on the draft report, which we address as appropriate. In one comment, EPA stated that instead of noting that the agency has successfully implemented many statutory requirements, the draft report stated that EPA responded to deadlines. We believe the report correctly characterizes steps EPA has taken to implement TSCA, and, as noted above, whether EPA's response is legally sufficient is in litigation, and GAO does not typically express a view on legal or factual matters in dispute before a court. In another case, the technical comments contradicted facts that we gathered during our review. For instance, while EPA stated that the draft report incorrectly noted that most of the IRIS staff had been working on TSCA activities, we provide further information to support our original statement; we replaced the term 'most' with

specific data on the number of IRIS staff and the percentage of their time that was devoted to TSCA activities.

Also in its technical comments, EPA stated that our analysis highlighted uncertainty resulting from the agency's recent activities to ensure IRIS Program efforts were aligned with the highest priorities of the agency. EPA acknowledged that this action did result in a delay but that in the long term, it would ensure that EPA's program and regional office priorities are being addressed and that each office is fully engaged in the development of IRIS assessments that will strengthen the agency's ability to address its mission for protecting human health and the environment. However, as we state in our report, prior to releasing results from the initial program and regional office survey, EPA leadership in ORD made a second request for a prioritized list of chemical assessments. According to officials from the IRIS office, who were queried for advice, the second request was made verbally at a meeting and did not provide the offices with information on the basis for selecting priorities or the reason for limiting the number of assessments to three or four chemicals. In addition, the ultimate priority list EPA issued in December 2018 reflected the priorities of two program offices and did not provide evidence that other EPA program offices had no interest in IRIS assessments. Because EPA did not identify the basis for program offices to select priorities or the reason for limiting the number of chemicals to assess, the process was not transparent, leaving room for uncertainty.

EPA also provided additional technical comments, which we have incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Administrator of the Environmental Protection Agency, 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 members have any questions about this report, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix II.

A handwritten signature in black ink that reads "Alfredo Gómez". The signature is written in a cursive style with a large, stylized "G" in the last name.

Sincerely yours,
J. Alfredo Gómez
Director, Natural Resources and Environment

Appendix I: Comments from the Environmental Protection Agency



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

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

FEB - 5 2019

Dear Mr. Gomez:

Thank you for the opportunity to comment on the Draft Report entitled "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act" (GAO-19-270) (Draft Report). We welcome continuing discussions with you and your staff regarding the accomplishments the U.S. Environmental Protection Agency (EPA) has achieved in implementing the new requirements under the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (Lautenberg Act) as well as our progress assessing chemicals through the Integrated Risk Information System (IRIS) program. We appreciate the time the U.S. Government Accountability Office (GAO) has spent assessing the intricacies of both the Toxic Substances Control Act (TSCA) and IRIS programs. Although GAO makes no recommendations for EPA in the Draft Report, GAO's review is helpful to the Agency as we continue our work to advance chemical safety and information transparency.

The Lautenberg Act was an extensive, comprehensive update to the 40-year old TSCA statute. Under Lautenberg, EPA is charged with developing and implementing a new TSCA program while achieving extremely aggressive timeframes. EPA has met each of its responsibilities associated with implementation of the new TSCA law in a timely manner with high quality products that are consistent with statutory obligations. EPA will continue to deliver demonstrated results under Lautenberg, while also boosting transparency, using the best available science and increasing public confidence in chemical safety.

GAO states the Draft Report describes: (1) the extent to which the IRIS program has addressed identified challenges and made progress toward producing chemical assessments; and (2) the extent to which EPA has demonstrated progress in implementing TSCA. While the Draft Report comprehensively describes the challenges facing the TSCA and IRIS programs, it does not appropriately acknowledge EPA's extensive progress in implementing TSCA. Importantly, as EPA's Lautenberg implementation directly ties in with GAO's High Risk List,¹ EPA recommends that GAO's Final Report include information regarding our accomplishments under the new law. For example, since 2016, EPA has issued more than 20 unique regulations and guidance documents, which provide the foundation for the transparent, consistent, and legally-sound

¹ https://www.gao.gov/highrisk/transforming_epa_and_toxic_chemicals/why_did_study#t=0

implementation of the new TSCA statute. Table A provides a list of each statutory requirement, EPA's activities to implement the requirements, and provides a weblink for public access to this critical work. EPA's response to the Draft Report documents the demonstrated progress that the TSCA program has achieved.

High Risk Assessment. As GAO reassesses EPA's progress in addressing and controlling toxic chemicals for its upcoming biennial High Risk Report, we ask GAO to consider these accomplishments with respect to the five criteria for removal from the High Risk List.

- **Leadership Commitment.** Demonstrated strong commitment and top leadership support.
- **Capacity.** Agency has the capacity (i.e., people and resources) to resolve the risk(s).
- **Corrective Action Plan.** A corrective action plan exists that defines the root cause, solutions, and provides for substantially completing corrective measures including steps necessary to implement solutions we recommended.
- **Monitoring.** A program has been instituted to monitor and independently validate the effectiveness and sustainability of corrective measures.
- **Demonstrated Progress.** Ability to demonstrate progress in implementing corrective measures and resolving the high-risk area.

In its last High Risk update², GAO concluded that EPA met the criteria for leadership commitment, but only partially met the criteria for capacity, having a corrective action plan, having a monitoring program, and demonstrating progress. We urge GAO to recognize the significant achievements³ that have taken place since the last update in both the TSCA and IRIS programs. We believe that the successful and timely completion of all statutorily-mandated activities under the new TSCA statute represents demonstrated progress in resolving the high-risk area. While EPA still faces challenges reaching optimal staffing levels, we are confident that the extraordinarily hard work of the approximately 250 employees that are dedicated to achieving these high quality and timely results demonstrates that we have met the criteria for having the capacity to do the work. With respect to having a corrective action plan, EPA is confident that the regulations that we have promulgated provide a transparent and public road map for the TSCA program's future activities and their associated milestones. To monitor progress, a rigorous program has been put into place by EPA. As a regular practice, the Office of Chemical Safety and Pollution Prevention (OCSPP) Deputy Assistant Administrators conduct monthly Business Review meetings with the Office Directors (ODs), Deputy Office Directors (DODs), lead region representatives, and other key staff. During these Business Reviews, office leaders discuss their organization's operations and performance, including TSCA implementation status, using performance charts to track progress on mission measures, identify and update countermeasures, and resolve problems. Since the 2017 GAO update, the incorporation and adoption of project management best practices into the IRIS program has bolstered its capacity to identify barriers to assessment development and optimize the management of project tasks and milestones. Recent

² https://www.gao.gov/highrisk/transforming_epa_and_toxic_chemicals/why_did_study#t=1

³ See <https://www.epa.gov/assessing-and-managing-chemicals-under-tscA/frank-r-lautenberg-chemical-safety-21st-century-act-5> for a comprehensive listing of all activities to date.

engagement across the Agency has identified the highest priority assessments, which will help ensure that IRIS program activities are meeting Agency needs.

Technical Comments on the Draft Report. While much work remains to be done, EPA is proud of our accomplishments in the TSCA program. We remain committed to continuing improvement of this program and will continue to develop and implement the most effective approaches possible given our current statutory and resource limitations. In EPA's attached Technical Comments, we address both the substance and tone of the Draft Report. For instance, instead of noting that EPA has successfully implemented many of statutory requirements, the Draft Report states that EPA "responded" to deadlines. Similarly, the Draft Report notes that "most" of the IRIS staff has been working on TSCA activities, which is not the case, as such our comments correct this. We proposed many of these changes previously to GAO in response to the Statement of Facts, and we appreciate the changes GAO has already made in response. In resubmitting these comments, we respectfully ask GAO to consider incorporating them in the final Report.

EPA appreciates the GAO's recognition of the IRIS program's progress in addressing challenges related to timeliness and transparency. We were pleased to see that the application of project management principles (and associated software applications) were recognized as leading to greater programmatic efficiencies. Similarly, we appreciate GAO's acknowledgement that the evolving preliminary materials released in the development of an IRIS assessment (assessment plans and protocols), have led to greater clarity for our partners in EPA's program and regional offices. GAO's analysis also highlighted uncertainty resulting from EPA's recent activities to ensure IRIS Program efforts are aligned with the highest priorities of the Agency. EPA's formal request for program priorities provided greater clarity for the IRIS Program and created awareness at all levels within the program and regional offices. While this action did result in a delay, in the long term, assuring that EPA's program and regional office priorities are being addressed and that each office is fully engaged in the development of IRIS assessments will strengthen the Agency's ability to address its mission of protecting human health and the environment.

EPA welcomes input from GAO on how to improve program management and operations. Again, we thank you for the opportunity to review the Draft Report. If you have any questions or concerns regarding our comments, we would be pleased to meet with you prior to GAO finalizing its report.

Sincerely,



Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety
and Pollution Prevention



Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator
Office of Research and Development

Table A

TSCA Statutory Requirement	EPA's Implementation Action
Day 1 – June 22, 2016	
New chemicals – implement all new requirements, including affirmative determinations	EPA is now required to Review and make an affirmative determination on all pre-manufacture notices (PMNs), Microbial Commercial Activity Notice (MCAN), and significant new use notices (SNUNs) before manufacturing can commence. To update the public on the changes EPA held two public meetings, December 14, 2016 , and December 6, 2017 , and has released additional information on the EPA review process.
Within the First 6 months – December 2016	
Propose TSCA Framework rules (prioritization, risk evaluation, and active/inactive inventory rules)	On January 13, 2016, EPA announced the proposed rules .
Publish list of first 10 chemicals for risk evaluation	On November 29, 2016 the first 10 chemicals were named for review under the new TSCA legislation
Publish annual reports on risk evaluations that identify the chemicals that will undergo risk evaluation in the coming year, their status and schedule, and the resources necessary to complete these activities.	2017 Annual Report
Determine whether “small business” definition warrants revision	On December 15, 2016, EPA issued a notice requesting public comment on whether revision to the current size standards for small manufacturers and processors, which are used in connection with reporting regulations under TSCA section 8(a), is warranted.
By the end of the First Year – June 2017	
Finalize TSCA Framework Rules	<ul style="list-style-type: none"> • Prioritization Process Rule - establishes a framework and criteria for identifying high-priority chemicals for EPA risk evaluations and low-priority chemicals. • Risk Evaluation Process Rule - establishes a framework for evaluating high priority chemicals to determine whether or not they present an unreasonable risk to health and/or the environment. • Inventory Rule - requires industry reporting of chemicals manufactured, imported, or processed in the U.S. over the past 10 years to identify which chemical substances on the TSCA Inventory are active in U.S. commerce.
Finalize scopes for the first 10 risk evaluations	The scope documents for the first 10 chemicals for risk evaluation describe the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that the Agency expects to consider. EPA also supplemented these scoping documents with problem formulation documents on each chemical that refine the scope of the risk evaluations.

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Publish Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations	EPA developed a guidance document to assist interested persons in developing and submitting draft risk evaluations to EPA. The guidance describes the science standards, data quality considerations, and the steps of the risk evaluation process that external parties should follow when developing draft TSCA risk evaluations.
Establish Science Advisory Committee on Chemicals	As required by section 9(a)(2) of the Federal Advisory Committee Act (FACA), EPA established the Science Advisory Committee on Chemicals (SACC). The purpose of the SACC is to provide independent advice and expert consultation, at the request of the EPA Administrator, with respect to the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures or approaches supporting implementation of TSCA.
Publish annual reports on risk evaluations that identify the chemicals that will undergo risk evaluation in the coming year, their status and schedule, and the resources necessary to complete these activities.	2017 Annual Report
Calendar Year 2018	
Section 26 Science Requirements	EPA released Application of Systematic Review in TSCA Risk Evaluations
Necessary policies, procedures and guidance for TSCA implementation (June 22, 2018)	<ul style="list-style-type: none"> • EPA's released 3 guidance documents outlining the circumstances under which TSCA allows the Agency to disclose confidential business information (CBI) and how state, tribal, and local governments; environmental, health, and medical professionals; and emergency responders can request disclosure. • EPA issued guidance, Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under the Toxic Substances Control Act, that allows EPA to share more information with the public about the structure of chemical substances while protecting the confidential elements of the substance's specific chemical identity. • EPA released a policy for assigning and applying unique identifiers for approved confidential business information (CBI) claims.
Strategic Plan for non-animal testing methodologies (June 22, 2018)	The Strategic Plan to Promote the Development and Implementation of Alternative Test Methods promotes the development and implementation of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing. The strategy contains components to identify, develop and integrate New Approach Methods (NAMs) for TSCA decisions; build confidence that the NAMs are scientifically reliable and relevant for TSCA decisions; and implement the reliable and relevant NAMs for TSCA decisions.
Mercury Reporting Rule (June 22, 2018)	The mercury reporting rule requires reporting from any person who manufactures (including imports) mercury or mercury-

Appendix I: Comments from the Environmental Protection Agency

	added products, or otherwise intentionally uses mercury in a manufacturing process. Information collected by the mercury inventory will be used to identify any manufacturing processes or products that intentionally add mercury; to recommend actions to achieve further reductions in mercury use; and to assist in its national reporting regarding implementation of the Minamata Convention on Mercury.
Final Rule for TSCA User Fees (September 2018)	The Fees Rule allows EPA to defray a portion of the costs (25%) for EPA to carry out its new responsibilities under TSCA by collecting fees from chemical manufacturers, including importers, and processors.
Publish annual reports on risk evaluations that identify the chemicals that will undergo risk evaluation in the coming year, their status and schedule, and the resources necessary to complete these activities.	2018 Annual Report

Appendix II: GAO Contacts and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Diane Raynes (Assistant Director), Summer Lingard-Smith (Analyst in Charge), Alisa Carrigan, Tara Congdon, Richard P. Johnson, Amber Sinclair, and William Tedrick made key contributions to this report. In addition Karen Howard, Dennis Mayo, Dan Royer, and Sara Sullivan made important contributions.

Related GAO Products

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

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.

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.

High-Risk Series: An Update. [GAO-09-271](#). Washington D.C: January 2009.

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

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