United States Government Accountability Office

Report to Congressional Committees

February 2023

EPA CHEMICAL REVIEWS

Workforce Planning Gaps Contributed to Missed Deadlines

GAO-23-105728

GAO Highlights

Highlights of GAO-23-105728, a report to congressional committees

February 2023

EPA CHEMICAL REVIEWS

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Why GAO Did This Study

Thousands of chemical substances play an important role in modern life and commerce, but can also present serious risks to human health and the environment. In 2016, Congress amended TSCA to establish new deadlines for reviewing chemicals already in commerce, including an initial set of 10 existing chemicals. It also provided that EPA make a formal determination before new chemicals can be manufactured.

GAO was asked to review EPA's implementation of its chemical review responsibilities under TSCA. This report evaluates the extent to which (1) EPA met selected TSCA deadlines for reviewing existing and new chemicals since June 2016, and (2) EPA engaged in workforce planning for implementing its chemical review responsibilities. GAO reviewed relevant laws, regulations, and workforce planning documents, and collected EPA data on new chemical review times and its workforce. GAO also interviewed EPA officials and representatives from industry and environmental health stakeholder organizations.

What GAO Recommends

GAO recommends that EPA develop a process and timeline to fully align its workforce planning efforts for implementing its TSCA chemical review responsibilities with workforce planning principles. EPA agreed with our recommendation but indicated that insufficiency of resources is the primary factor, among others we noted, for missed deadlines.

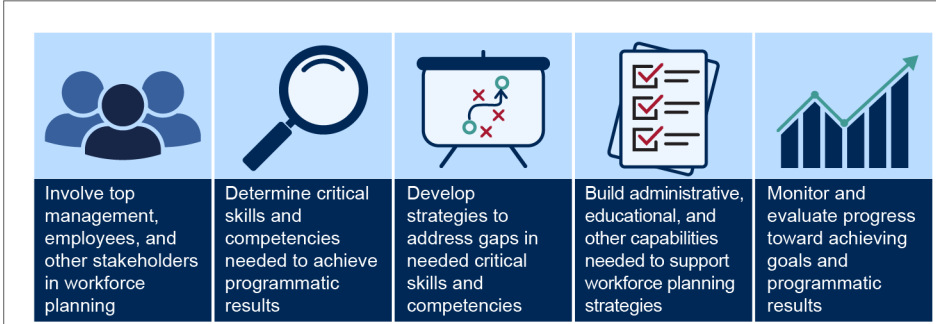
View GAO-23-105728. For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

What GAO Found

Since 2016, the Environmental Protection Agency (EPA) has missed most deadlines for reviewing existing and new chemicals under the Toxic Substances Control Act (TSCA), as amended. Once prioritized, existing chemicals are reviewed in two main phases —risk evaluation and risk management—and TSCA established specific deadlines for each phase. GAO found that EPA completed the first risk evaluation step (i.e., scoping) for the initial 10 existing chemical reviews on time. However, EPA missed all but one subsequent risk evaluation and risk management deadlines for these chemicals. Additionally, TSCA as amended provides that a person may only manufacture a new chemical if such person submits information to EPA and the agency makes an affirmative determination on the risk of injury to health or the environment. However, GAO found that among those pre-manufacture reviews that EPA completed from 2017 through 2022, the agency typically completed the reviews within the 90-day TSCA review period less than 10 percent of the time. EPA missed the chemical review deadlines due in part to several contributing factors and is implementing some related improvements (e.g., modernizing information systems). However, according to EPA, resource constraints, including insufficient staff capacity, remain the primary reason for missed chemical review deadlines.

EPA has engaged in some initial workforce planning activities for its chemical review responsibilities, but significant workforce planning gaps contribute to missed chemical review deadlines. For example, in March 2021, EPA conducted a skills gap assessment, which included hiring targets for mission-critical occupations. However, EPA officials told GAO the assessment no longer reflects current workforce needs, and that EPA has not created a strategic workforce plan to develop long-term strategies for recruiting, developing, and retaining staff. GAO has identified five principles with which federal agencies' strategic workforce planning efforts should align (see figure). EPA officials told GAO that while they agree that these principles are relevant and reasonable for its TSCA workforce planning efforts, they have not developed a process or timeline to fully align such efforts with these principles. Without doing so, EPA will likely continue to struggle to recruit, develop, and retain the workforce it needs to meet TSCA deadlines for completing existing and new chemical reviews.

Figure: GAO's Five Key Strategic Workforce Planning Principles



Source: GAO. | GAO-23-105728

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Abbreviations

1-BP	1-bromopropane
BBP	butyl benzyl phthalate
D4	octamethylcyclotetrasiloxane
DBP	dibutyl phthalate
DEHP	di-ethylhexyl phthalate
DIBP	diisobutyl phthalate
DIDP	diisodecyl phthalate
DINP	di-isononyl phthalate
EPA	Environmental Protection Agency
FTE	full-time equivalent
FY	fiscal year
HBCD	cyclic aliphatic bromide cluster
HHCB	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran
LoREX	low release and low exposure
LVE	low volume exemption
MCAN	microbial commercial activity notice
NMP	N-Methylpyrrolidone
OCSPP	Office of Chemical Safety and Pollution Prevention
OIG	Office of Inspector General
OPPT	Office of Pollution Prevention and Toxics
OTNE	octahydro-tetramethyl-naphthalenyl-ethanone
PMN	pre-manufacture notice
PPE	personal protective equipment
PV29	C.I. pigment violet 29
SNUN	significant new use notice
TBBPA	4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol]
TCE	trichlorethylene
TCEP	tris(2-chloroethyl) phosphate
TPP	phosphoric acid, triphenyl ester
TSCA	Toxic Substances Control Act

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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February 17, 2023

The Honorable Thomas R. Carper
Chairman
The Honorable Shelley Moore Capito
Ranking Member
Committee on Environment and Public Works
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

More than 86,000 chemicals are publicly listed for a broad range of potential uses, such as solvents, coatings, electronics, computer chips, fuels, and motor vehicle components.[1] These chemicals play important roles in modern life and commerce, but most have not been evaluated to determine whether they pose serious risks to human health and the environment. Susceptible subpopulations such as workers and communities near industrial facilities—often referred to as "fenceline" communities—may face greater exposure and risk. The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) in 2016, authorizes the Environmental Protection Agency (EPA) to assess and regulate chemical risks for chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals).[2]

[1]EPA maintains an inventory of chemical substances manufactured or processed in the United States for nonexempt commercial purposes under the Toxic Substances Control Act (TSCA) and generally publishes updates to the list about every 6 months. The most recent update, in February 2022, included 86,631 chemicals, of which 42,039 are active substances. According to EPA officials, the February 2022 update was the only posted update in 2022 because of parallel efforts to declassify large numbers of confidential chemicals on the inventory. Officials told us that the next update is expected to be published in spring 2023.

[2]Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. § 2601 et seq.). TSCA was substantially amended in 2016 by the Lautenberg Act. Pub. L. No. 114-182, 130 Stat. 448 (2016).

The Lautenberg Act expanded EPA's authority and responsibility to regulate toxic chemicals, in response to concerns about the pace of the agency's work under TSCA and EPA's ability to effectively use its existing authority, according to a committee report accompanying the act.[3] The 2016 amendments established deadlines for conducting risk evaluations and initiating risk management actions for existing chemicals and directed EPA to make formal determinations on all new chemicals before they can be manufactured.

You asked us to review EPA's implementation of its chemical review responsibilities. This report evaluates the extent to which (1) EPA met selected TSCA deadlines for reviewing existing and new chemicals since June 2016, and (2) EPA engaged in workforce planning for implementing its chemical review responsibilities.

To address the first objective, we examined selected provisions of TSCA, as amended by the Lautenberg Act, related to EPA's chemical review responsibilities. Specifically, we reviewed laws and regulations to identify relevant deadlines for EPA's review of existing and new chemicals. We determined EPA's review times for existing chemicals by analyzing relevant EPA documents, such as rules and notices. We collected and assessed New Chemicals Review system data from EPA to determine its review times and determinations for new chemical reviews. We compared EPA's review times to the selected TSCA deadlines to evaluate the extent to which the agency met the deadlines. We reviewed relevant EPA documentation and interviewed knowledgeable EPA officials about the data, and we determined the data were sufficiently reliable for purposes of describing changes from June 22, 2016, through May 16, 2022, the most recent information available for our review.

To corroborate TSCA chemical review implementation progress and identify associated challenges, we interviewed officials from EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and representatives from two industry and two environmental health stakeholder organizations identified mostly from our prior work, given that work's similar focus on EPA chemical reviews.[4] Our interviews with

[3]H.R. REP. NO. 114-176, at 12-13 (2015).

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

stakeholder organizations collected illustrative examples that are not generalizable across all stakeholder organizations.

To address the second objective, we identified principles from prior GAO work that federal agencies' strategic workforce planning should address, such as determining critical skills needed to achieve programmatic results and developing strategies to address identified skills gaps.[5] To identify EPA's workforce planning processes, we reviewed relevant EPA planning and budgetary documents. We also interviewed officials from OCSPP's Office of Program Support and representatives from stakeholder organizations. We then compared EPA's workforce planning processes to workforce planning principles.

We collected and analyzed workforce data from EPA on its full-time equivalents (FTEs) for the Office of Pollution Prevention and Toxics (OPPT), which is responsible for TSCA-related activities, for fiscal year 2022.[6] Additionally, we collected TSCA-related workforce counts for onboard staff, hires, and departures from the end of fiscal year 2021 through fiscal year 2022, by mission-critical occupation. EPA could not provide consistent counts for fiscal years prior to 2021 due to a reorganization of OCSPP in October 2020. We interviewed knowledgeable agency officials about the data. We determined that the FTE and workforce count data were sufficiently reliable for purposes of generally understanding EPA's workforce recently available to conduct chemical reviews under TSCA. EPA FTE data do not precisely match activities related solely to EPA's chemical review responsibilities under TSCA.[7] Because they do cover EPA's staff recently available to conduct chemical reviews under TSCA, we determined that the FTE and workforce count data were sufficiently reliable for our purposes.

We conducted this performance audit from January 2022 to February 2023 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

[5]GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, GAO-04-39 (Washington, D.C.: Dec. 11, 2003).

[6]According to the Office of Management and Budget, FTE employment is the basic measure of the levels of employment used in the budget. It is the total number of hours worked (or to be worked) divided by the number of compensable hours applicable to each fiscal year. See the Office of Management and Budget, *Circular No. A-11: Preparation, Submission, and Execution of the Budget* (Washington, D.C.: Aug. 15, 2022).

[7]Additionally, according to EPA, some of the FTEs supporting TSCA are not in OPPT and therefore are not included in our FTE counts. For example, the Office of Program Support provides information technology system support and related project management.

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

Within EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), the Office of Pollution Prevention and Toxics (OPPT) manages EPA activities under TSCA. Several divisions within OPPT have chemical review-related responsibilities, notably its Existing Chemicals Risk Assessment Division; Existing Chemicals Risk Management Division; Data Gathering and Analysis Division; and New Chemicals Division. OPPT's Project Management and Operations Division supports the stakeholder transparency and information technology needs of the office's chemical review responsibilities. OCSPP's Office of Program Support is responsible for supporting the office's administrative programs, including workforce planning.[8]

Existing Chemicals

This report discusses three groups of reviews of existing chemicals under TSCA.[9] These are:

- **Initial 10 chemical substances.** As required by TSCA, EPA initiated risk evaluations in December 2016 on an initial set of 10 chemical substances drawn from the 2014 update of the TSCA Work Plan. These included asbestos and methylene chloride.
- **Subsequent 20 high-priority chemical substances.** As required by TSCA, EPA initiated risk evaluations in December 2019 on a subsequent set of 20 high-priority chemical substances.[10]

[8]OCSPP also includes the Office of Pesticide Programs, which does not have TSCA-related responsibilities. In October 2020, EPA reorganized OPPT by creating separate risk evaluation, data gathering, and risk management divisions for existing chemicals and by establishing a single division responsible for risk assessment and risk management of new chemicals.

[9]For purposes of this report, we use the term "existing chemical reviews" to include EPA's risk evaluation and risk management activities for existing chemicals under TSCA. 15 U.S.C. § 2605.

[10]In designating high-priority substances, TSCA requires that EPA select at least half from the chemical substances listed in the 2014 update of the TSCA Work Plan; however, all chemicals in the TSCA inventory are subject to EPA's prioritization screening process. The subsequent 20 high-priority substances designated by EPA on which risk evaluations were initiated include a variety of solvents, phthalates, flame retardants, fragrance additives, and other chemicals.

- **Manufacturer-requested risk evaluations.** At the request of one or more manufacturers as provided under TSCA, EPA initiated risk evaluations of other existing chemical substances.[11]

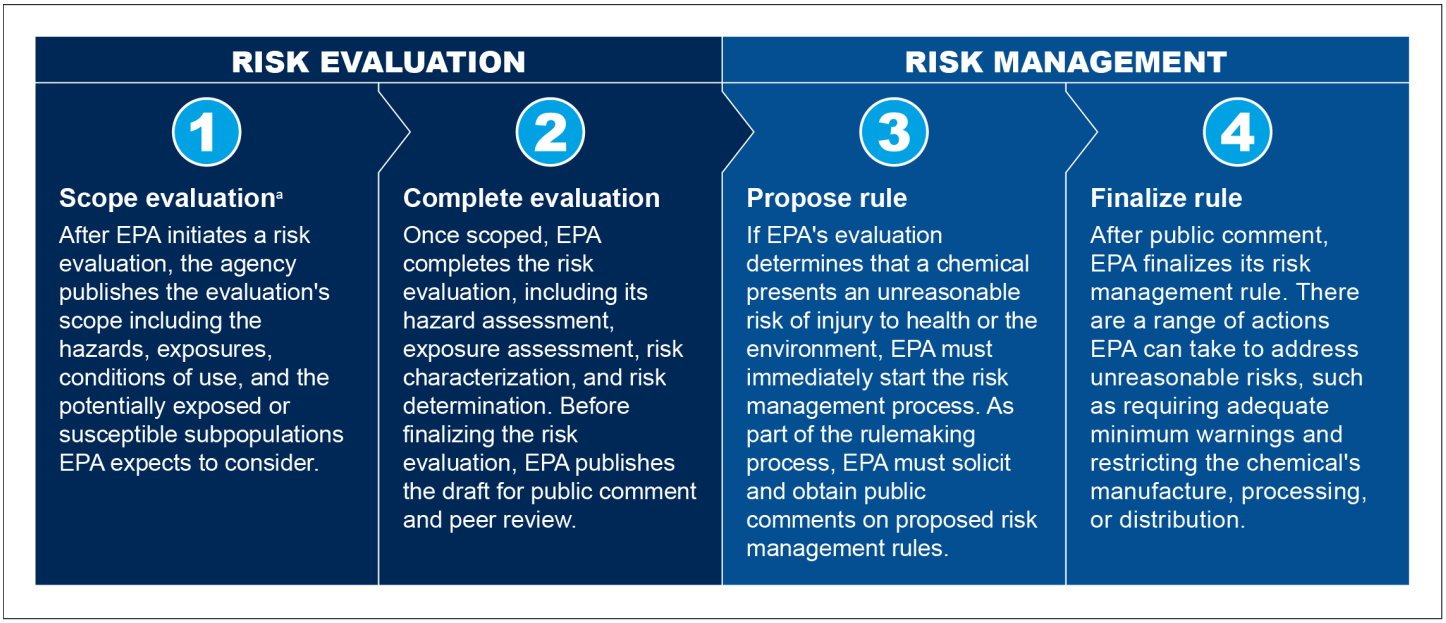
Prioritization is the risk-based screening process for designating existing chemicals for risk evaluation under TSCA. Specifically, EPA uses the prioritization process to designate a chemical substance as either high priority for risk evaluation, or low priority for which risk evaluation is not warranted at the time.[12]

After prioritization, existing chemical reviews involve two main phases: risk evaluation and risk management. Each phase consists of various required steps, including scoping and completing the risk evaluation, as well as proposing and finalizing rules to address unreasonable risks of injury to health or the environment (see fig. 1). For example, scoping is a critical step in EPA's risk evaluation process, since it includes the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider. Before publishing the final scope, EPA publishes the draft scope for public comment.

[11]As of September 1, 2022, EPA had initiated manufacturer-requested risk evaluations of three chemical substances: diisodecyl phthalate (DIDP) (1,2-benzene-dicarboxylic acid, 1,2- diisodecyl ester); di-isononyl phthalate (DINP) (1,2-benzenedicarboxylic acid, 1,2-isononyl ester); and octamethylcyclotetrasiloxane (D4). Manufacturers have also requested that EPA conduct a risk evaluation of octahydro-tetramethyl-naphthalenyl-ethanone (OTNE). After finding the request to be "facially complete" under EPA regulations in December 2020, EPA issued a notice of receipt of the request for risk evaluation and solicitation of public comments in Feb. 2021. 86 Fed. Reg. 10,267 (Feb. 19, 2021). The public comment period, which was extended, closed on May 5, 2021. As of December 2022, EPA has not granted the request.

[12]In February 2020, EPA designated 20 chemical substances as "low priority." TSCA requires that upon completion of a risk evaluation (other than those requested by a manufacturer), EPA must designate at least one additional high-priority chemical to take its place, thus ensuring that the EPA's risk evaluation queue always remains full. *See* 15 U.S.C. § 2605(b)(3)(C).

Figure 1: Environmental Protection Agency's (EPA) Risk Evaluation and Risk Management Phases for Existing Chemical Reviews

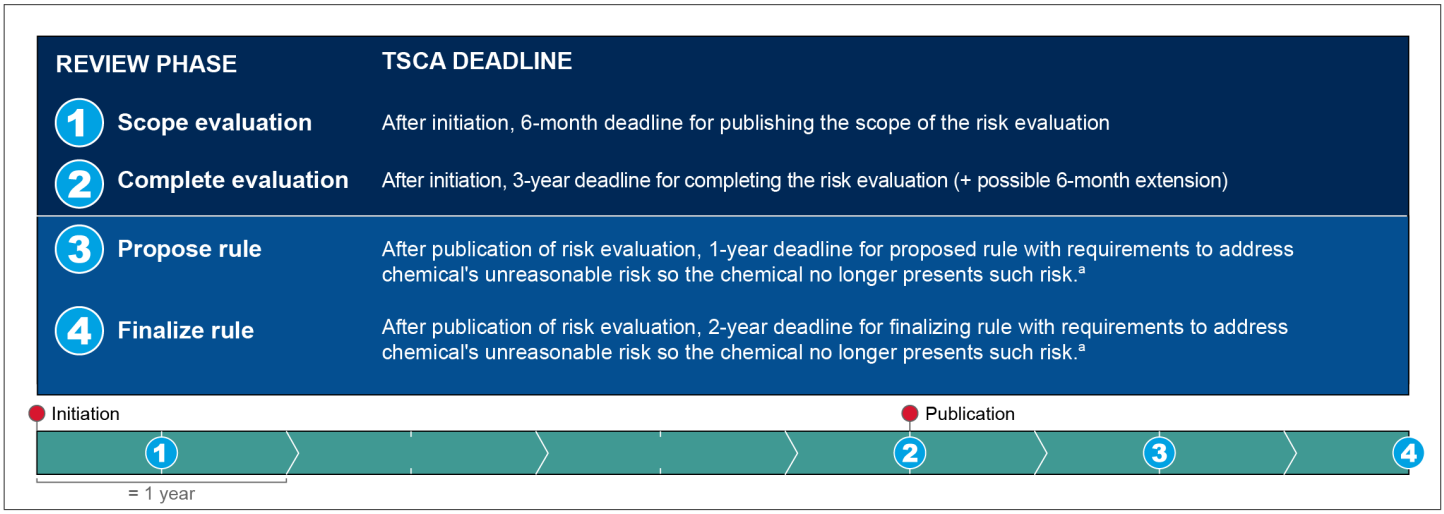


Source: GAO. | GAO-23-105728

[a]Before initiating the formal risk evaluation process, EPA conducts a prioritization process. Prioritization is the risk-based screening process for designated existing chemicals for risk evaluation under TSCA. EPA uses the prioritization process to designate a chemical substance as either high priority for further risk evaluation, or low priority for which risk evaluation is not warranted at the time.

TSCA established specific statutory deadlines for certain steps of EPA's risk evaluation and risk management phases (see fig. 2). For example, after EPA initiates a risk evaluation, it must publish the evaluation's scope within 6 months.

Figure 2: Selected Deadlines for Environmental Protection Agency (EPA) Review of Existing Chemicals under the Toxic Substances Control Act (TSCA)



Source: GAO. | GAO-23-105728

[a]By statute, EPA may extend the deadlines for the publication of a proposed or final rule for not more than 2 years, as long as the aggregate length of such extensions, as well as any extension to the 3-year risk evaluation deadline, does not exceed 2 years, subject to certain additional conditions. 15 U.S.C. § 2605(c)(1)(C). According to EPA officials, the agency has not exercised this extension authority for any existing chemical reviews.

New Chemicals

TSCA generally requires any person who plans to manufacture (including produce and import) or process a new chemical substance for a non-exempt commercial purpose to submit a pre-manufacture notice to EPA for review of potential unreasonable risks to human health and the environment before initiating the activity.[13] Under TSCA prior to the Lautenberg Act amendments, a person could manufacture a new chemical 90 days after submitting a pre-manufacture notice unless EPA made a determination of unreasonable risk and took action to protect against such risk.

As amended in 2016, TSCA provides that a person may only manufacture new chemicals if, in addition to submitting a pre-manufacture notice, EPA

[13]In addition, if EPA determines that a use of a chemical substance is a significant new use, TSCA requires persons to submit a significant new use notice to EPA at least 90 days before manufacturing or processing the chemical substance for that use. Some new chemical substances are not subject to pre-manufacture notice reporting. These substances are either (1) excluded from TSCA reporting or (2) exempt from all or part of this reporting because EPA has determined that they do not warrant review or require only a short review, such as Low Volume Exemptions and Low Release/Low Exposure Exemptions.

makes an affirmative determination on the risk of injury to health or the environment of the new chemical and takes any subsequent required actions to mitigate the risk after such a determination.[14] EPA's actions may include, for example, limiting the amount of the substance that may be manufactured, processed, or distributed. According to EPA, TSCA's requirement after the 2016 amendments to make a formal determination on each submission before the chemical can be manufactured or processed has significantly increased EPA's new chemical review responsibilities. According to EPA, the agency made formal determinations for about 20 percent of submissions prior to the amendments in 2016.

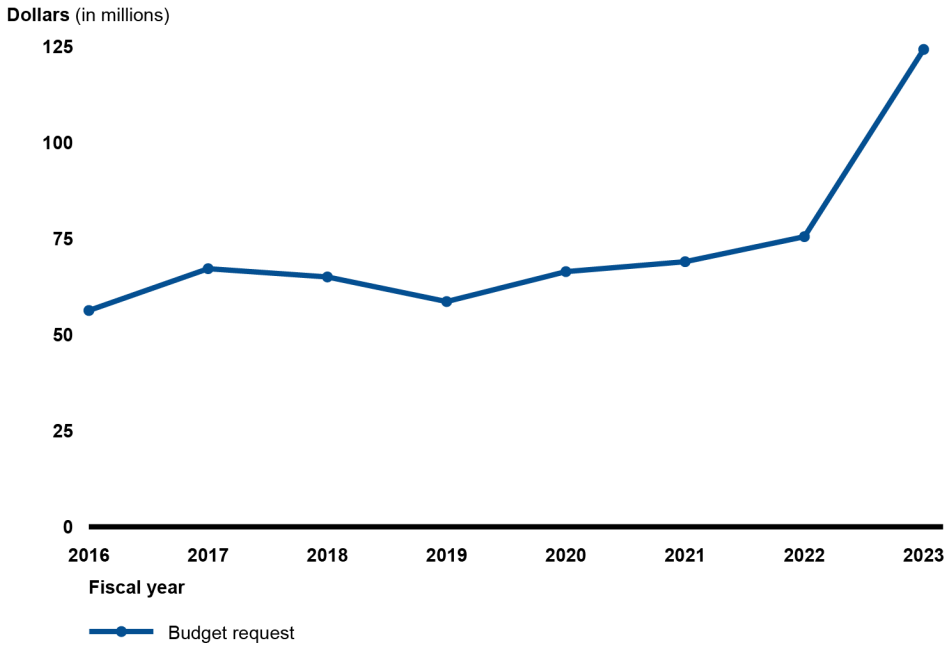
Budget Request

EPA's budget request to implement its TSCA responsibilities remained relatively level from fiscal year 2016 through fiscal year 2022, but notably increased in fiscal year 2023 (see fig. 3). In its request for fiscal year 2023, EPA stated that the agency needs a substantial increase in scientific expertise and financial resources to ensure it can achieve TSCA statutory requirements.[15] EPA noted, however, that appropriations for its TSCA program remained relatively level for the first six years after the 2016 amendments, despite this significant increase in responsibility.

[14]Under TSCA, the applicable review period for EPA's determination and any subsequent required actions is generally 90 days. *See* 15 U.S.C. § 2604(*i*)(3). TSCA further provides that EPA may for good cause extend the review period for additional periods (not to exceed 90 days in the aggregate). 15 U.S.C. § 2604(c). By statute, such an extension and the reasons for it are to be published in the *Federal Register* and constitute a final agency action subject to judicial review. *Id.* According to EPA, the agency has used this extension authority only once since 2016, as a result of the partial government shutdown due to a lapse in funding in February 2019.

[15]TSCA, as amended, requires EPA to publish an annual plan that, among other things, identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion. 15 U.S.C. § 2625(n)(2). The 2016 amendments to TSCA also provided EPA with expanded authority to collect fees from chemical manufacturers and importers to help defray up to 25 percent of the costs associated with overall TSCA implementation efforts, and authorized EPA to establish a fee structure by rule. EPA finalized the Fees for the Administration of TSCA rule in October 2018. *See* 83 Fed. Reg. 52,694 (Oct. 17, 2018). However, according to EPA, the rule resulted in the agency collecting only about 13 percent of the "artificially low baseline cost estimate" for the program. EPA issued a proposed rule in January 2021 to revise its 2018 fee rule, and in November 2022, the agency issued a Supplemental Notice of Proposed Rulemaking to modify and supplement the 2021 proposal. *See* 87 Fed. Reg. 68,647 (Nov. 16, 2022) (modifying and supplementing 86 Fed. Reg. 1890 (Jan. 11, 2021)). The 2022 supplemental proposed rule would, among other things, change the TSCA fee amounts and the estimate of EPA's total costs for administering TSCA. 87 Fed. Reg. at 68,647, 68,648.

Figure 3: Budget Request Information for the Environmental Protection Agency's "Toxic Substances: Chemical Risk Review and Reduction" Program Project, Fiscal Years 2016–2023



Source: GAO analysis of EPA annual budget justification documents. | GAO-23-105728

In March 2019, we reported that EPA faced challenges implementing TSCA, such as ensuring that the new chemical review process was efficient and predictable and that EPA had sufficient resources.[16] At the time, EPA officials likened implementing the TSCA amendments to "building an airplane as they fly it," since they had to create guidance and processes while simultaneously applying them to chemical evaluations.

Since 2009, we have also included EPA's processes for assessing and controlling toxic chemicals on our High Risk List as a government program in need of broad-based transformation. In our 2021 update, we reported that EPA neither met initial statutory deadlines for completing chemical risk evaluations nor completed workforce planning to ensure it has the resources and plans in place to implement TSCA.[17]

[16]GAO, *Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act*, GAO-19-270 (Washington, D.C.: Mar. 4, 2019).

[17]GAO, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas*, GAO-21-119SP (Washington, D.C.: Mar. 2, 2021).

EPA Missed Most TSCA Deadlines for Reviewing Existing and New Chemicals, but Identified Some Planned Improvement Steps

For existing chemicals, EPA completed the first risk evaluation step (i.e., scoping) for an initial set of 10 chemical reviews on time; however, it missed all but one of the subsequent risk evaluation and risk management deadlines. Among those pre-manufacture reviews that EPA completed from 2017 through 2022, the agency typically completed the reviews within the 90-day TSCA review period less than 10 percent of the time. According to EPA officials, the agency missed these deadlines primarily due to resource constraints, including insufficient capacity in mission-critical occupations needed to complete the reviews, but has taken some steps to improve.

EPA Published Some of the Initial 10 Existing Chemical Review Documents on Time, but Missed Almost All Subsequent Review Deadlines

Missed Deadlines for the Initial 10 Existing Chemical Risk Evaluations

EPA initiated and published the scope of the initial 10 existing chemical risk evaluations on time. However, it missed all but one of the subsequent review deadlines for all three groups of existing chemical evaluations.[18] Specifically, EPA met TSCA's deadline to publish the scope of the initial 10 existing chemical reviews in June 2017. Before publishing the final scope, EPA publishes the draft scope for public comment. However, EPA missed the June 2020 deadline (as extended by 6 months) for completing the risk evaluations of nine of the initial 10 existing chemicals. EPA missed TSCA deadlines for completing the evaluations by time periods ranging from 2 months for 1-bromopropane to 7 months for C.I. pigment violet 29 (PV29) and 1,4-dioxane. We discuss factors that contributed to EPA missing these deadlines below.

Additionally, EPA proposed risk management rules for one existing chemical substance (asbestos, part 1), but did so 4 months after the

[18]The statutory deadline for EPA to publish the scope of the risk evaluations was June 19, 2017. EPA filed the scoping documents in the *Federal Register* on June 20, 2017. Additionally, the statutory deadline for EPA to complete the risk evaluation for methylene chloride was June 19, 2020. EPA filed the completed evaluation in the *Federal Register* on June 23, 2020. Although EPA completed these steps shortly after the TSCA deadlines, for purposes of our analysis, we considered EPA to have "met" these deadlines.

deadline.[19] Moreover, EPA has not yet issued proposed rules for the remaining existing chemical substances.[20] EPA officials noted that they have made progress in identifying and analyzing risk management options and completing other necessary reviews for five additional existing chemical substances in preparation for the development of proposed rules for those chemicals.[21] (See appendix I for more information on EPA's performance in meeting TSCA deadlines for the initial 10 existing chemical reviews.)

Missed Deadlines for the Subsequent 20 and Manufacturer-Requested Existing Chemical Risk Evaluations

EPA also missed the TSCA deadline for publishing the scope of the subsequent 20 high-priority existing chemical substances as well as manufacturer-requested risk evaluations. For example, EPA published the scope of the subsequent 20 high-priority chemical substances in August 2020—two months after the TSCA deadline. Moreover, EPA officials told us that, as a result of insufficient resources provided through the budget process, they do not expect to meet the future deadlines for these evaluations. Representatives from an environmental health stakeholder organization we interviewed told us such delays prolong the potential risk these chemicals pose to human health and the environment by remaining in commerce without risk management rules in place.

Re-opening and Revising Completed Risk Evaluations Contributed to Missed Deadlines

OPPT officials told us that re-opening and revising, as appropriate, completed risk evaluations on the initial 10 chemical substances contributed to missed deadlines for existing chemical risk management rules. They noted that if EPA had not taken these steps, not only would its risk evaluations and associated risk management actions have been less protective, the agency could also have assumed future litigation risk that could have resulted in additional delays. In June 2021, EPA announced the following planned approaches to risk evaluations intended to align more closely with TSCA legal requirements:

[19]Specifically, in April 2022, EPA published a proposed rule to address the unreasonable risk of injury to health it identified from certain asbestos uses (Asbestos, Part 1: Chrysotile Asbestos). 87 Fed. Reg. 21,706 (Apr. 12, 2022). EPA published the final risk evaluation for Asbestos, Part 1, in December 2020, 4 months later than the statutory 1-year deadline for proposed rules.

[20]As noted previously, by statute, EPA is to propose a rule in the *Federal Register* not later than 1 year after, and publish a final rule not later than 2 years after, the publication of the final risk evaluation for a chemical. EPA may extend the deadlines for the publication of a proposed or final rule for not more than 2 years, as long as the aggregate length of such extensions, as well as any extension to the 3-year risk evaluation deadline, does not exceed 2 years, subject to certain limitations. 15 U.S.C. § 2605(c)(1).

[21]In November 2022, EPA submitted to the Office of Management and Budget for interagency review the proposed rule for methylene chloride, and EPA expects to submit additional proposed rules in the coming months, according to EPA officials.

- **Exposure pathways and fenceline community exposure.** In the final risk evaluations for some of the initial 10 chemical substances, EPA noted that it did not assess all air, water, or disposal exposures to the general population because other EPA-administered statutes such as the Clean Air Act already regulated, or could in the future regulate, these exposure pathways. However, according to EPA, excluding these pathways also resulted in a failure to consistently and comprehensively assess risks to both the general population and to potentially exposed or susceptible subpopulations, including communities near industrial facilities (i.e., fenceline communities). Thus, EPA developed a screening-level approach to conduct ambient air and surface water fenceline exposure assessments to understand risks associated with fenceline exposures for certain conditions of use and pathways for some of the first 10 chemicals.[22]
- **Personal protective equipment (PPE).** In its final risk evaluations, EPA generally assumed that workers were always provided, and used, PPE appropriately. However, EPA stated that some workers are not covered by applicable Occupational Safety and Health Administration standards (e.g., self-employed individuals), some employers are out of compliance with the standards, and the standards may be inadequate for ensuring worker protection. EPA is no longer assuming that workers always use PPE in occupational settings, which has resulted in changes to some of the conclusions about unreasonable risk associated with some conditions of use for eight of the initial 10 chemical substances.[23] The statutory definition of "potentially exposed or susceptible subpopulations" specifically identifies workers as an example of such subpopulations, and TSCA requires EPA to develop risk evaluations for conditions of use that include risks to such subpopulations. According to EPA officials, assuming that all workers always have access to and appropriately use PPE not only does not ensure that all workers are protected, but also adds litigation vulnerability for the agency.
- **Whole chemical approach.** In its final risk evaluations, EPA made separate unreasonable risk determinations for every condition of use of a chemical. EPA is withdrawing the previously issued orders for those conditions of use for which no unreasonable risk was found for

[22]According to EPA, the 6 existing chemicals are methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, n-methylpyrrolidone (NMP), and 1-bromopropane.

[23]According to EPA, the eight existing chemicals are methylene chloride, 1-bromopropane, cyclic aliphatic bromide cluster (HBCD), NMP, perchloroethylene, PV29, trichloroethylene (TCE), and carbon tetrachloride.

the risk evaluations for the initial 10 chemical substances. According to EPA, it is also issuing a single revised unreasonable risk determination for each of these chemicals as a "whole chemical substance."

According to EPA, these changes are intended to help the agency fully uphold its mission to protect human health and the environment, follow the statutory requirements to determine whether a chemical substance poses an unreasonable risk, and potentially limit future timely and costly litigation.

Industry and environmental health stakeholder organizations we interviewed shared differing perspectives on the merits of EPA's announced policy changes for existing chemical reviews. Representatives from an industry stakeholder organization we met with reported that the policy changes fail to adequately consider the existence, applicability, and jurisdiction of other federal laws and make incorrect assumptions about worker protections and workplace environments. They also reported that the changes were developed without sufficient on-staff expertise or interagency consultation in relevant scientific and technical fields, particularly with respect to industrial hygiene.[24] They noted that the changes sidestep the best available science requirements of the statute, and risk misleading and confusing the regulated community and the public.[25]

However, representatives from an environmental health stakeholder organization we interviewed told us that unlike most other environmental laws, TSCA obligates EPA to evaluate a chemical's risk throughout its life cycle—from manufacturing through disposal. They noted that TSCA also requires EPA to determine whether a chemical presents an unreasonable risk, without consideration of costs or other nonrisk factors, and to regulate the chemical to the extent necessary so that it no longer presents an unreasonable risk. They supported EPA's decision to revisit the assumption that workers always use appropriate PPE for the specific occupational setting, because the assumption represented a broad generalization based on limited data. Moreover, they noted that the

[24]According to EPA, OPPT currently has a small number of industrial hygienists on staff and is recruiting and hiring new employees into critical science and regulatory positions, including for industrial hygienists.

[25]EPA is required to meet the scientific standards in TSCA for best available science, utilizing a weight-of-scientific-evidence approach when conducting risk evaluations.15 U.S.C. § 2625(h), (i).

Occupational Safety and Health Administration's Permissible Exposure Limit worker safety standards are outdated and not protective.[26]

Court Orders and Other Review Requirements Also Contributed to Missed Deadlines

OPPT officials told us that other factors contributed to missing TSCA deadlines for existing chemicals, such as:

- **Supplemental evaluation after court decision.** As noted previously, EPA designated asbestos as one of the initial 10 chemicals to undergo risk evaluations after the 2016 amendments to TSCA. EPA initially focused the risk evaluation for asbestos on chrysotile asbestos, the only asbestos fiber type that is currently imported, processed, or distributed in the U.S. During the development of the draft risk evaluation, a November 2019 court decision held that EPA's risk evaluation procedural rule should not have excluded legacy uses or associated disposals from the definition of conditions of use.[27] Following the 2019 decision, EPA determined that it would issue the risk evaluation for asbestos in two parts. EPA continued development of the risk evaluation for chrysotile asbestos, the "part 1" risk evaluation, in order to move more expeditiously into risk management, while also initiating a "part 2" risk evaluation for asbestos to address legacy uses and associated disposals.[28] According to EPA, because of the timing of the court decision, the agency did not initiate the part 2

[26]The Occupational Safety and Health Administration recognizes that many of its permissible exposure limits are outdated and inadequate for ensuring protection of worker health. Most of its permissible exposure limits were issued shortly after adoption of the Occupational Safety and Health Act in 1970, and have not been updated since that time. See www.osha.gov/annotated-pels.

[27]*Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). With regard to risk evaluations, TSCA, as amended, provides that EPA is to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, *under the conditions of use*" (emphasis added). 15 U.S.C. § 2605(b)(4)(A). TSCA defines "conditions of use" as the circumstances, as determined by EPA, 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). While EPA's risk evaluation procedural rule used the same definition of "conditions of use" as the statute, in the preamble to the final rule, EPA stated that several categories of uses and activities were excluded from the definition of "conditions of use." 82 Fed. Reg. 33,726, 33,729 (July 20, 2017). The court in *Safer Chemicals, Healthy Families* found that EPA's exclusion of two of those categories, legacy uses and associated disposals, was contrary to TSCA's definition of "conditions of use," although EPA's exclusion of legacy disposals was not contrary to TSCA's definition of "conditions of use." *See* 943 F.3d at 421.

[28]EPA issued the final part 1 risk evaluation for asbestos in January 2021. *See* 86 Fed. Reg. 89 (Jan. 4, 2021).

risk evaluation with sufficient time to meet the TSCA risk evaluation deadline for asbestos as one of the initial 10 chemicals. Nevertheless, under a consent decree in a separate case, EPA is required to publish the final part 2 risk evaluation for asbestos by December 1, 2024.[29]

- **Other review requirements.** OPPT officials told us that other laws (e.g., the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act) and executive orders (e.g., E.O. 12866) require EPA to conduct additional analyses and consultations that are incompatible, absent significant additional resources, with meeting TSCA risk management deadlines. In addition, they noted that without sufficient resources it can be challenging to fully conform to the practices described in EPA's Action Development Process—a series of steps the agency follows when it develops actions such as regulations and policy statements—and comply with statutory deadlines for rulemaking.[30]

Process and Policy Improvements to Address Missed Deadlines

OPPT officials told us they plan to identify and implement process and policy improvements to help the agency meet future TSCA statutory deadlines for existing chemical reviews. Specifically, based on an ongoing and iterative review of lessons learned from the initial 10 existing chemical reviews, OPPT officials told us they plan to begin the internal agency rulemaking process earlier and develop templates that enable staff to conduct existing chemical evaluations more consistently. In addition, EPA plans to improve some chemical risk evaluation processes. For example, OCSPP officials told us they are developing approaches to help ensure objectivity in the review and selection of scientific studies used to inform chemical risk evaluations. In April 2022, OPPT obtained external peer review of a draft TSCA Systematic Review Protocol intended to strengthen its approach and help ensure that the agency has the best tools under TSCA to protect human health and the environment. EPA officials noted that even if the agency implements these improvements, without additional resources, EPA will not meet its statutory obligations for existing chemical reviews.

[29]EPA finalized the scope for the part 2 risk evaluation for asbestos in June 2022. *See* 87 Fed. Reg. 38,746 (June 29, 2022).

[30]Officials noted they have sought to take advantage of flexibilities afforded under the Action Development Process by seeking expedited review times where possible and identifying steps which can be waived or modified (e.g., streamlining the Early Guidance process). For additional information about EPA's Action Development Process, see GAO, *Environmental Regulation: EPA Should Improve Adherence to Guidance for Selected Elements of Regulatory Impact Analyses*, GAO-14-519 (Washington, D.C.: July 18, 2014).

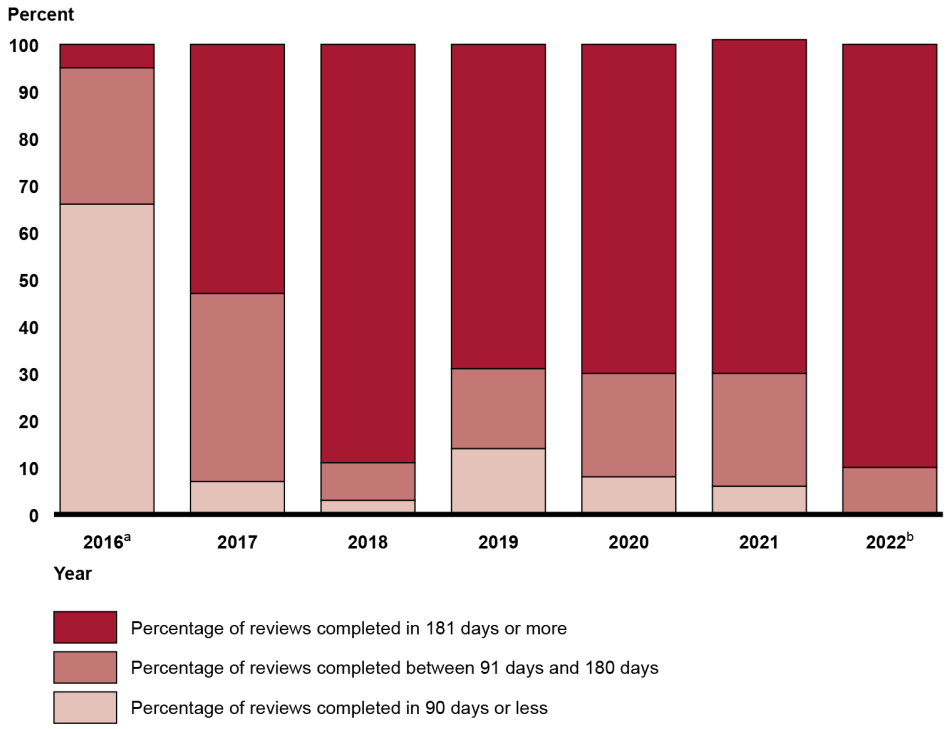
EPA Rarely Completed New Chemical Reviews by the TSCA Deadline, but Identified Some Steps to Improve Its Performance

Among those pre-manufacture reviews that EPA completed from 2017 through 2022, the agency typically completed the reviews within the 90-day TSCA review period less than 10 percent of the time.[31] (See fig. 4.) During that same time period, from 53 to 90 percent of such reviews were completed in 181 days or more. Moreover, some reviews remained under EPA review years after the agency received the submissions.[32] For example, 10 percent of new chemical pre-manufacture notice reviews of submissions EPA received in 2018 remained under EPA review in May 2022, according to the most recent information available for our review. As amended in 2016, TSCA provides that a person may only manufacture new chemicals if, in addition to submitting a pre-manufacture notice, EPA makes an affirmative determination on the risk of injury to health or the environment of the new chemical and takes any subsequent required actions to mitigate the risk after such a determination. Appendix II includes additional information about EPA's review times for new chemical reviews.

[31]According to OPPT officials, EPA's performance in completing pre-manufacture notice reviews within the TSCA 90-day review period appears better in 2016, because review times (as we report in figure 4) for that year reflect a limited period—June 22, 2016, through December 31, 2016 (192 days). Consequently, most review times we report will indicate that EPA completed reviews "in 90 days or less" or "between 91 days and 180 days" during that period. For EPA statistics prior to June 22, 2016, see "New Chemical Program Statistics Prior to June 22, 2016", https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemical-program-statistics. EPA also provides a general overview of its new chemicals workload, tracks the status of active cases currently under review, and illustrates general statistics for all new chemical submissions received since TSCA was amended in 2016. See "Statistics for the New Chemicals Review Program under TSCA", https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[32]EPA regulations provide that a person who submits a pre-manufacture notice may voluntarily suspend the running of the 90-day review period for a specified period of time. *See* 40 C.F.R. § 720.75(b). According to EPA officials, the agency does not consider itself to have missed the deadline for new chemical reviews within the statutory review period because it obtained voluntary suspensions in almost all cases. EPA analyzed its new chemical review data from June 22, 2016, to July 19, 2022, to determine any instances when it did not obtain voluntary suspensions. The agency found 22 instances where data entry errors likely resulted in final determination dates after the 90-day review period. For 20 of these instances, the difference was seven days or less. The greatest difference was 45 days.

Figure 4: Environmental Protection Agency (EPA) Review Times for New Chemical Pre-Manufacture Notices, June 2016 through May 2022



Source: EPA. | GAO-23-105728

Note: Counts are based on the calendar year in which EPA completed the review and reflect the calendar days between the date of receipt and the date of completion.

[a]Counts for 2016 include reviews from June 22, 2016, through December 31, 2016.

[b]Counts for 2022 include reviews from January 1, 2022, through May 16, 2022, which was the most recent information available for our review.

EPA Plans to Address Factors that Contribute to Missed Review Deadlines

OPPT officials told us the primary reason EPA missed new chemical review deadlines was the agency's lack of sufficient resources and expertise. According to EPA's October 2022 report to Congress on its capacity to implement TSCA, the agency continues to operate with significantly fewer resources than it needs to review new chemicals in the way Congress intended and will continue to struggle to quickly review the safety of new chemicals.[33] OPPT officials also identified factors that

[33]Environmental Protection Agency, *Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act* (Washington, D.C.: Oct. 2022). OCSPP estimates that the new chemicals program operates with 50 percent of the resources it needs to implement the program.

contribute to missed deadlines for new chemical reviews, along with planned or ongoing efforts to address them. These include the following:

- **Risk assessment revisions.** According to OPPT, when submissions involve the receipt of missing or late information, EPA commonly has to re-run new chemical review risk assessments. OPPT analyzed 94 reviews from 2019 to 2022 to identify the most common causes of this rework and found that an individual review may be reworked multiple times, adding months to the review period.[34] According to OPPT, when such delays are multiplied across hundreds of submissions each year, it compounds new chemical review delays and uses additional resources. In July 2022, EPA conducted an initial webinar for submitters to provide an in-depth look at common issues that cause rework. In October 2022, EPA hosted a subsequent webinar that provided examples of quantitative and qualitative data needed for an appropriate engineering assessment, clarifying common misconceptions and considerations EPA makes when evaluating data.
- **Guidance gaps.** OPPT officials told us that they lack sufficient financial and human resources to simultaneously complete new chemical reviews and develop comprehensive scientific and other guidance, which has contributed to delays and inconsistencies across reviews. For example, due to limited financial and human resources, EPA told us the agency has not updated its new chemicals procedural regulations to align with new requirements under TSCA, as amended, such as clarifying what data persons should include with their submissions. To clarify new chemicals notice requirements, in June 2018, OPPT updated its "Points to Consider" document to assist submitters in preparing pre-manufacture and other notices. According to EPA, it is developing a proposed rule, which it plans to publish in spring 2023, that seeks to increase the quality of information initially submitted in new chemicals notices and improve the agency's processes for the timely and effective completion of new chemical reviews.
- **Information technology challenges.** According to OPPT, the information technology system it uses to support its new chemical review program is unreliable, because it uses older security processes and technology. In September 2022, EPA awarded a new contract to modernize the system. Once modernized, new chemical review staff will be able to integrate data from different databases (e.g., historical

[34]According to EPA, the analysis included 94 unique cases originally submitted from fiscal year 2019 to fiscal year 2022 that required revisions to EPA's engineering assessment due to submission of additional information.

data sources, scientific literature, and public information) and better document the results of their analysis and decisions.

Additionally, OPPT officials told us they are exploring other ways to streamline the new chemical review process. For example, in January 2022, EPA announced its biofuels initiative intended to standardize OPPT's review of new chemicals that could be used instead of other transportation fuels with higher emissions.[35] To streamline the process, OPPT formed a dedicated collaboration team that identified potential improvements, such as generating one report for biofuels pre-manufacture notices that combines the six different risk assessments that OPPT typically conducts. OPPT is expanding this approach to other chemical groups, and in October 2022 announced a new approach for mixed metal oxides, including Cathode Active Materials—a key component of electric vehicle batteries.

Industry and Environmental Health Stakeholder Organizations Offer Varying Views on EPA Missed Deadlines

Representatives from both industry stakeholder organizations we met with told us EPA delays in completing new chemical reviews hampered innovation. For example, they noted that EPA delays adversely impact research and development expenditures and prevent the availability of new and innovative chemistries to support important climate, sustainability, and infrastructure goals. Additionally, they stated that new chemicals are typically safer than the existing chemicals they will replace, so EPA review delays may prolong human health and environmental risk exposure to those existing chemicals.

Representatives from an environmental health stakeholder organization told us EPA could address delays if industry submitted more complete information with the initial new chemical review submission. They also stated that because the statute's intended purpose is to ensure a thorough risk evaluation before new chemicals enter commerce, EPA's performance should not be measured by the speed of these reviews.

EPA's Current Workforce Shortage Hinders Timely Completion of Existing and New Chemical Reviews

According to EPA officials, the agency missed TSCA deadlines primarily due to significant increases in its workload and resource constraints, particularly a workforce shortage within OPPT that continues to hinder timely completion of existing and new chemical reviews. In March 2019, we reported that OPPT faced challenges ensuring it had the appropriate

[35]See "EPA Announces Effort to Help Bring Climate-Friendly New Chemicals to Market to Reduce Greenhouse Gas Emissions", https://www.epa.gov/newsreleases/epa-announces-effort-help-bring-climate-friendly-new-chemicals-market-reduce.

FTE levels for reviewing existing and new chemicals.[36] Specifically, officials told us that in July 2018 OPPT had about 300 FTEs—a staffing level they described as insufficient for conducting existing and new chemical reviews by TSCA deadlines. EPA reported that, for fiscal year 2022, OPPT's workforce had increased to 305 FTEs—lower than the 374 FTEs EPA told us they estimated they would need in fiscal year 2022 to manage their TSCA workload.[37]

Moreover, EPA continues to have difficulty retaining and recruiting staff to conduct chemical reviews. According to OPPT officials, staff leaving OCSPP or the agency has contributed to delays in chemical reviews, and according to representatives from stakeholder organizations we met with, contributes to the loss of institutional knowledge that is important to completing timely and quality reviews. For example, representatives from industry stakeholder organizations told us the loss of expertise through staff attrition or reassignments delayed the processing of new chemical reviews and made review determinations less consistent. Appendix III provides further information on the number of staff in mission-critical and other occupations for reviewing new and existing chemicals since the end of fiscal year 2021.

OPPT's workforce challenges are particularly acute in its New Chemicals Division. In October 2021 and June 2022, OCSPP's Assistant Administrator testified that the lack of sufficient resources had an outsized impact on the new chemical program's ability to meet review deadlines under TSCA and, at the time of her 2022 testimony, the New Chemicals Division had two human health assessors, who are critical to completing

[36]GAO-19-270. According to the Office of Management and Budget, FTE employment is the basic measure of the levels of employment used in the Budget. It is the total number of hours worked (or to be worked) divided by the number of compensable hours applicable to each fiscal year.

[37]According to OPPT, contractors conduct some TSCA responsibilities for new and existing chemical reviews. For existing chemicals, contractor responsibilities include the initial review, summary, and integration of toxicity and other health data, according to OPPT. For new chemicals, according to OPPT, these responsibilities include drafting hazard identification, environmental fate, environmental release and exposure reports; calculating risk; and integrating information and data into the draft risk assessment reports. Officials noted that drafting rules, guidance documents, and policy development are examples of inherently governmental functions, which contractors cannot perform.

new chemical reviews.[38] Further, the Assistant Administrator stated that rebuilding the program's staff capacity was the office's highest personnel priority. For example, according to EPA, they are working to address staff shortages for new chemical reviews caused, in part, from a reorganization in October 2020, which resulted in approximately 15 percent of new chemical review staff permanently moving to work on existing chemical risk reviews. OPPT officials told us they had shifted several existing managers and staff with toxicology and other relevant experience to support new chemical reviews. In addition, the office anticipated hiring additional human health assessors to support new chemical risk assessments awaiting review, to a total of about 11 assessors.

Moreover, according to OPPT officials, these newly hired staff need substantial training and time to learn how to conduct new chemical reviews thoroughly and consistently which contributes to increased review times. OPPT officials told us that new hires may have to work with senior staff for a substantial amount of time before they are prepared to conduct reviews of chemicals on their own, and may continue to face challenges in understanding some aspects of the review process.

OPPT officials also told us the office faces challenges filling some mission-critical occupations in its divisions that review chemicals.[39] We asked OPPT to provide a list of vacant positions in August 2022. At that time, OPPT's list included several management positions (e.g., division director and deputy division director) and 20 staff positions in mission-critical occupations, such as toxicologists and biologists. EPA noted that some of these vacancies were new positions made possible by the spring 2022 enactment of the budget.

Over time, vacant positions have contributed to EPA relying on a limited number of staff to implement EPA's growing responsibilities under TSCA. Moreover, OPPT officials told us that the same limited staff work on multiple other tasks with competing priorities and deadlines. For example, scientists that conduct new chemical reviews are also responsible for

[38]For further information about the June 2022 testimony, see "Toxic Substances Control Act Amendments Implementation" at https://www.epw.senate.gov/public/index.cfm/2022/6/toxic-substances-control-act-amendments-implementation. For information about the October 2021 testimony, see "TSCA and Public Health: Fulfilling the Promise of the Lautenberg Act" at https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=114176.

[39]The Office of Personnel Management defines mission-critical occupations as occupations agencies consider core to carrying out their missions. Such occupations usually reflect the primary mission of the organization without which mission-critical work cannot be completed, the Office of Personnel Management's definition notes further.

reviewing scientific studies as well as developing relevant testing protocols, guidance documents, and training materials. OPPT officials told us they are working to address this challenge and have hired 26 new employees since May 2022. Appendix III provides hire and departure information for staff conducting new and existing chemical reviews since the end of fiscal year 2021.

EPA Engaged in Initial Workforce Planning, but Significant Gaps Contributed to Missed Deadlines for Chemical Reviews

EPA Has Conducted Some Initial Workforce Planning for TSCA Chemical Reviews

EPA has engaged in some initial planning activities to help align its workforce with EPA's TSCA chemical review responsibilities. We have reported that strategic workforce planning is an essential tool to help agencies align their workforce with their current and emerging missions and develop long-term strategies for recruiting, developing, and retaining staff.[40] When agencies engage in strategic workforce planning, they are able to identify and focus investments on long-term human capital issues that most affect their ability to attain their mission. We have identified five key principles with which federal agencies' strategic workforce planning efforts should align (see fig. 5). EPA officials agreed that these principles are relevant and reasonable for its TSCA workforce planning efforts.

[40]GAO-04-39. See also GAO, *FDA Workforce: Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs*, GAO-22-104791 (Washington, D.C.: Jan. 14, 2022); *Automated Technologies: DOT Should Take Steps to Ensure Its Workforce Has Skills Needed to Oversee Safety*, GAO-21-197 (Washington, D.C.: Dec 18, 2020); and *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, GAO-15-183 (Washington, D.C.: Jan. 30, 2015).

Figure 5: GAO's Five Key Strategic Workforce Planning Principles

Source: GAO. | GAO-23-105728

EPA's initial planning activities include the following:

- **Completed workforce analysis.** For example, as recommended by EPA's Office of Inspector General (OIG), senior management directed OPPT to conduct a workforce analysis.[41] In December 2020, the office completed its analysis, which provided a "general overview" of the office's then-current workforce structure and identified mission-critical occupations for its risk assessment and risk management programs.[42] According to the document, the analysis was intended to help OPPT retool its workforce and help the office create action plans that focus on specific gaps.
- **Identified planning and monitoring improvements.** OPPT also identified some workforce planning and monitoring improvements in its Strategic Plan FY 2021 – FY 2023. For example, according to the plan, OPPT's New Chemicals Division aims to improve how it allocates resources and develops its human capital assets, among other improvements. The plan also identifies some performance indicators associated with these improvements, such as updating

[41]In August 2020, EPA's OIG recommended that OSCPP conduct a workforce analysis to assess OPPT's capability to implement TSCA and specify what skill gaps must be filled in fiscal year 2021 to meet TSCA requirements. See EPA OIG, *Lack of Planning Risks EPA's Ability to Meet Toxic Substances Control Act Deadlines*, Report No. 20-P-0247 (Aug. 17, 2020).

[42]See OPPT, *Workforce Analysis Fiscal Year 2015 - Fiscal Year 2020*.

human health training materials and developing standard operating procedures. According to OPPT, the division is engaged in a comprehensive effort to update these materials and procedures. For example, OPPT officials told us that the New Chemicals Division developed new procedures for assessing chemicals in certain sectors, such as biofuels, as described previously. Additionally, OPPT officials told us they plan to update the office's human health risk assessment template to provide more detailed instructions for assessors.

- **Conducted skills gap assessment.** Additionally, in March 2021, OPPT completed a skills gap assessment, which includes hiring targets and anticipated attrition counts for fiscal years 2021, 2022, and 2025. The assessment projected workforce needs by occupation, including mission-critical occupations, within OPPT as a whole, as well as within OPPT's underlying divisions based on a reorganization that occurred in October 2020. The assessment was intended to give OPPT a better understanding of its future workforce needs by occupation and, according to OCSPP officials, helped to inform EPA's budget request for fiscal year 2023.
- **Improved strategies to fill critical skills gaps.** OCSPP provided us with an April 2020 document that summarized the office's strategy to fill mission-critical occupations in OPPT's chemical risk assessment and risk management programs, among other objectives. For example, OCSPP officials stated they standardized vacancy announcements and augmented the office's hiring strategy by using existing human capital flexibilities, such as fellowships and student intern positions, to recruit scientists with specialized experience in the areas of toxicology, biological sciences, and chemistry. According to OPPT, the office's recruitment outreach also targeted academic institutions, scientific societies, and special interest groups representing underrepresented communities to ensure an inclusive and diverse workplace. OPPT plans to share the lessons learned from this expanded recruitment outreach with other divisions and use it for recruiting scientists in other disciplinary teams that support the new chemical review process. OCSPP officials told us that EPA's Office of Human Resources also provides tools to help OCSPP monitor hiring actions. For example, EPA provides a report that communicates the office's monthly performance in meeting EPA's 90-day time-to-hire goal.

Significant Workforce Planning Gaps Contribute to Missed Deadlines for Chemical Reviews

Although EPA has engaged in initial workforce planning, significant planning gaps remain that impede the agency's ability to effectively implement its TSCA chemical review responsibilities. These planning gaps include:

- **Limited employee involvement.** Office of Program Support officials told us that OCSPP's strategic workforce planning process only involved management officials. The office typically included non-management staff in general discussions, such as during staff retreats. According to these officials, involving top management in workforce planning activities is most important because they plan OCSPP's chemical review work and have the vision to fully understand what is needed to accomplish all the organization's work. However, workforce planning principles state that involving employees in strategic workforce planning can help agencies identify ways to streamline processes and improve human capital strategies.[43]
- **Outdated skills gap assessment.** According to OCSPP officials, OPPT's 2021 skills gap assessment reflected the best available information that the office had at the time, but no longer reflects current workforce needs. According to estimates in the assessment, OPPT would need 374 employees in fiscal years 2022 and 2025.[44] OCSPP officials told us they plan to hire a contractor to help the office update its assessment to reflect current workforce needs. Workforce planning principles state that agencies should determine the critical skills and competencies needed to achieve current and future programmatic results.
- **Incomplete workforce planning.** As we discussed earlier in this report, EPA's recruitment and training challenges are particularly acute in OPPT's New Chemicals Division. As we noted, OPPT's Strategic Plan FY 2021 – FY 2023 addressed some of these challenges by including some performance indicators related to workforce planning. However, the plan does not address other key planning challenges, such as recruitment targets specifically for filling

[43]GAO-04-39.

[44]EPA's budget request for its TSCA activities (i.e., the Toxic Substances: Chemical Risk Review and Reduction program project) increased from $75.5 million in fiscal year 2022 to $124.2 million in fiscal year 2023, a total that included 532 FTEs. EPA also provided estimates for the fiscal year 2022 and 2023 resources necessary to complete risk evaluations according to the schedule set in the statute in its 2021 annual plan for chemical risk evaluations under TSCA. Appendix III provides further information on the number of staff in mission-critical and other occupations for reviewing new and existing chemicals since the end of fiscal year 2021.

mission-critical occupations. Without developing strategies tailored to address gaps in needed critical skills, skill gaps will continue to hinder existing and new chemical reviews. Moreover, OCSPP has not developed a strategic workforce plan for implementing its TSCA responsibilities. Strategic workforce planning could help the office develop long-term strategies for recruiting, developing, and retaining staff.[45] OCSPP officials told us they have begun to develop a comprehensive plan to ensure employees have the training they need to complete new chemical reviews consistently. For example, OPPT has developed a training framework for new employees to the New Chemicals Division. The framework provides an overview of risk assessment and risk management under TSCA as well as discipline-specific training associated with the new chemicals review process.

- **Unused hiring authority.** Although Congress provided EPA with Title 42 hiring authority for OCSPP for fiscal years 2022 through 2025, OCSPP officials told us the office did not employ any staff under this authority during fiscal year 2022 because it was still in the process of completing required administrative steps.[46] Workforce planning principles state that it is important for agencies to consider the full range of flexibilities available under current authorities and to ensure stakeholder input in developing flexibilities-related policies and procedures by, for example, educating managers and employees on the availability and use of flexibilities.

OCSPP officials stated they have not developed a process to fully align the office's workforce planning efforts for implementing EPA's chemical review responsibilities with relevant workforce planning principles. Officials noted they currently lack the resources and expertise needed to

[45]We have reported that agency approaches to such planning can vary with each agency's particular needs and mission. The success of the workforce planning process can be judged by its results—how well it helps the agency attain its mission and strategic goals—not by the type of process used. See GAO-04-39.

[46]Under this special hiring authority, EPA can fill certain mission-critical positions, generally scientists, without regard to the civil service laws. *See* 42 U.S.C. § 209(f), (g). EPA asked Congress to consider extending this authority to OCSPP in its budget justification for FY 2022. The Consolidated Appropriations Act, 2022 authorized the EPA Administrator, after consultation with the Office of Personnel Management, to employ up to 25 persons at any one time in OCSPP under this authority during each of fiscal years 2022 through 2025. Pub. L. No. 117-103, div. G, tit. II, 136 Stat. 49, 389. According to OCSPP officials, the office developed a new handbook and amended EPA's Title 42 delegation—two steps they told us were necessary to complete before using the authority. Officials noted OCSPP is consulting with the Office of Personnel Management and expects to begin using its authority when the consultation process is complete.

conduct more sophisticated workforce planning activities, including those needed to close the gaps we identified.

However, without developing a process and timeline to ensure its workforce planning efforts fully align with strategic workforce planning principles, EPA will likely continue to struggle to recruit, develop, and retain the workforce it needs to meet TSCA-required deadlines for completing existing and new chemical reviews. Moreover, it may prolong any unmanaged risks to human health and the environment of high-priority existing chemicals currently under review and delay the introduction of new chemicals that could replace existing chemicals that currently may pose more risk of injury to human health and the environment.[47]

Conclusions

The Lautenberg Act, enacted in 2016, expanded EPA's authority and responsibility to regulate toxic chemicals. As a result, EPA's responsibilities and workload expanded and the agency struggled to implement TSCA's chemical review requirements and meet deadlines. However, we found that EPA missed most TSCA deadlines for reviewing existing chemicals and rarely completed new chemical reviews by TSCA deadlines. According to EPA officials, the agency missed these deadlines primarily due to resource constraints, particularly insufficient staff capacity, including in mission-critical occupations.

Although EPA has engaged in some initial workforce planning activities for its amended chemical review responsibilities, significant workforce planning gaps have contributed to missed deadlines for chemical reviews. For example, OCSPP has not developed a strategic workforce plan for implementing its TSCA responsibilities, which could help the office develop long-term strategies for recruiting, developing, and retaining staff. In its 2021 annual plan for chemical risk evaluations under TSCA, EPA provided estimates for the resources necessary to complete risk evaluations according to the schedule set in the statute.

Moreover, OCSPP officials told us they have not developed a process to ensure its workforce planning efforts fully align with relevant workforce planning principles. Key workforce planning principles can help agencies ensure that their workforce supports their current and emerging missions.

[47]During a June 2022 congressional committee hearing, OCSPP's Assistant Administrator agreed that delays in the TSCA new chemicals review process have delayed the introduction of new chemicals into commerce and noted that new chemicals are sometimes designed to replace older and riskier existing chemicals. *See* "Toxic Substances Control Act Amendments Implementation", https://www.epw.senate.gov/public/index.cfm/2022/6/toxic-substances-control-act-amendments-implementation

They can also help agencies develop long-term strategies for recruiting, developing, and retaining staff. Without ensuring its efforts fully align with these principles, EPA will likely continue to struggle to recruit, develop, and retain the workforce it needs to meet TSCA deadlines for completing existing and new chemical reviews. Moreover, continuing to miss deadlines for chemical reviews may slow the introduction of new chemicals, which could replace existing chemicals that currently may pose more risk of injury to human health and the environment.

Recommendation for Executive Action

The Administrator of EPA should direct the Assistant Administrator of OCSPP to develop a process and timeline to fully align its workforce planning efforts for implementing EPA's TSCA chemical review responsibilities with workforce planning principles and incorporate the results, as appropriate, into EPA's annual plan for chemical risk evaluations under TSCA. (Recommendation 1)

Agency Comments and Our Evaluation

We provided a draft of this report to EPA for review and comment. In written comments provided by OCSPP (reproduced in appendix IV), EPA agreed with our recommendation. EPA also provided technical comments, which we incorporated as appropriate. In its comments, EPA indicated that we overstated the extent to which workforce planning affected EPA's progress in implementing TSCA. However, as we noted in the report, strategic workforce planning is an essential tool to help agencies align their workforce with their current and emerging missions and develop long-term strategies for recruiting, developing, and retaining staff. As the report states, workforce planning gaps were one among several factors that contributed to missed TSCA deadlines. We therefore do not believe our findings overstate the importance of workforce planning in EPA's ability to implement TSCA more effectively.

In addition, EPA stated that the draft report lacked context and did not fairly convey the circumstances in the first years following the TSCA amendments in 2016. The agency stated that other factors played a more significant role in missing TSCA deadlines—notably that EPA did not receive appropriations that were commensurate with the significant increase in its responsibilities as a result of the TSCA amendments. Recognizing this concern, our report repeatedly communicates EPA's position about such resource shortages. Moreover, the contributing factors discussed in our report reflect those identified by EPA officials during interviews and through our information requests. We therefore believe the report provides sufficient context for our reporting objectives.

We further acknowledge that EPA is now taking steps to implement process and policy improvements intended to improve its performance in meeting TSCA chemical review deadlines. Similarly, as EPA stated in its

comments, the agency has planned and ongoing efforts to improve its workforce planning, such as augmenting its workforce analysis and developing a hiring plan for fiscal year 2023.

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

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

J. Alfredo Gómez
Director, Natural Resources and Environment

Appendix I: EPA's Performance in Meeting TSCA Deadlines for Reviewing the Initial 10 Existing Chemicals

Table 1: Environmental Protection Agency's (EPA) Performance in Meeting Toxic Substances Control Act (TSCA) Deadlines for Reviewing the Initial 10 Existing Chemicals

Chemical substance	After initiation, TSCA 6-month deadline for publishing scope of the risk evaluation[a]		After initiation, TSCA 3-year deadline for completing the risk evaluation (plus possible 6-month extension)[b]		After publication of risk evaluation, TSCA 1-year deadline for proposed rule to no longer present unreasonable risk, if determined[c]		After publication of risk evaluation, TSCA 2-year deadline for finalizing rule to no longer present unreasonable risk, if determined[c]	
	Deadline	Month completed	Deadline, if extended	Month completed	Deadline	Month completed	Deadline	Month completed
Asbestos (part 1: chrysotile asbestos)[d]	June 2017	June 2017	June 2020	Dec. 2020	Dec. 2021	Apr. 2022	Dec. 2022	[e]
1-Bromopropane (1-BP)	June 2017	June 2017	June 2020	Aug. 2020	Aug. 2021	[e]	Aug. 2022	[e]
Carbon tetrachloride	June 2017	June 2017	June 2020	Nov. 2020	Nov. 2021	[e]	Nov. 2022	[e]
C.I. pigment violet 29 (PV29)	June 2017	June 2017	June 2020	Jan. 2021	Jan. 2022	[e]	Jan. 2023	[e]
Cyclic aliphatic bromide cluster (HBCD)	June 2017	June 2017	June 2020	Sept. 2020	Sept. 2021	[e]	Sept. 2022	[e]
1,4-Dioxane	June 2017	June 2017	June 2020	Jan. 2021[f]	Jan. 2022	[e]	Jan. 2023	[e]
Methylene chloride	June 2017	June 2017	June 2020	June 2020[g]	June 2021	[e]	June 2022	[e]
N-Methylpyrrolidone (NMP)	June 2017	June 2017	June 2020	Dec. 2020	Dec. 2021	[e]	Dec. 2022	[e]
Perchloroethylene	June 2017	June 2017	June 2020	Dec. 2020	Dec. 2021	[e]	Dec. 2022	[e]
Trichlorethylene (TCE)	June 2017	June 2017	June 2020	Nov. 2020	Nov. 2021	[e]	Nov. 2022	[e]

Source: GAO analysis of EPA notices and rules. | GAO-23-105728

Note: As required by TSCA, in December 2019, EPA initiated risk evaluations on a subsequent set of 20 high-priority chemical substances. Those substances included: p-dichlorobenzene; 1,2-dichloroethane; trans-1,2- dichloroethylene; o-dichlorobenzene; 1,1,2-trichloroethane; 1,2-dichloropropane; 1,1-dichloroethane; dibutyl phthalate (DBP) (1,2-benzene-dicarboxylic acid, 1,2-dibutyl ester); butyl benzyl phthalate (BBP) - 1,2-benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester; di-ethylhexyl phthalate (DEHP) - (1,2-benzene-dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester); diisobutyl phthalate (DIBP) - (1,2-benzene-dicarboxylic acid, 1,2- bis-(2methylpropyl) ester); dicyclohexyl phthalate; 4,4'-(1-methylethylidene)bis[2, 6-dibromophenol] (TBBPA); tris(2-chloroethyl) phosphate (TCEP); phosphoric acid, triphenyl ester (TPP); ethylene dibromide; 1,3-butadiene; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB); formaldehyde; and phthalic anhydride.

[a]The statutory deadline for EPA to publish the scope of the risk evaluations was June 19, 2017. EPA filed the scoping documents in the *Federal Register* on June 20, 2017.

[b]In June 2021, EPA announced policy changes that affected completed risk evaluations on the initial 10 existing chemicals. For example, EPA will make risk determinations just once for the whole chemical, when warranted, rather than for each condition of use.

[c]EPA's completed evaluation determined that each of the initial 10 existing chemicals presented an unreasonable risk to human health or the environment. By statute, EPA may extend the deadlines for the publication of a proposed or final rule for not more than two years, as long as the aggregate length of such extensions, as well as any extension to the 3-year risk evaluation deadline, does not exceed two years, subject to certain additional conditions. Specifically, such extensions are also subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance. 15 U.S.C. § 2605(c)(1)(C).

[d]EPA initially focused the risk evaluation for asbestos on chrysotile asbestos (i.e., part 1), the only asbestos fiber type that is currently imported, processed, or distributed in the U.S. However, as a result of a November 2019 court decision, EPA is also evaluating legacy uses and associated disposals of asbestos—conditions of use that EPA excluded from the initial evaluation. EPA finalized the scope for this supplemental effort (i.e., part 2) in June 2022 and expects to publish the final risk evaluation by December 1, 2024, as required by court order.

[e]EPA has not yet completed this review step.

[f]EPA has re-opened and will update the 1,4-dioxane risk evaluation to consider whether to include additional exposure pathways, like drinking water and ambient air, and conditions of use where 1,4-dioxane is generated as a byproduct that were excluded from the supplemental and final risk evaluations. EPA plans to finalize the supplemental risk evaluation by December 2024.

[g]EPA was required to complete the risk evaluation for methylene chloride on June 19, 2020. The EPA Administrator filed the completed evaluation in the Federal Register on June 23, 2020.

Appendix II: EPA Review Times, Determinations, and Completion Rates for New Chemical Reviews

Table 2: Environmental Protection Agency (EPA) Review Times and Determinations for Completed New Chemical Reviews, June 2016 through May 2022

New chemical review type	2016[a]	2017	2018	2019	2020	2021	2022[a]
Pre-manufacture notices (PMN)							
EPA determination for completed reviews							
Allowed to commercialize without restrictions	29	39	56	239	130	36	4
Allowed to commercialize with restrictions pending information development, if applicable	9	277	149	53	103	48	16
Not allowed to commercialize pending development of information	0	6	2	0	4	1	0
Prohibited from commercializing	0	0	0	0	0	0	0
EPA review time[b]							
Percentage of reviews completed in 90 days or less	66%	7%	3%	14%	8%	6%	0%
Percentage of reviews completed between 91 days and 180 days	29%	40%	8%	17%	22%	24%	10%
Percentage of reviews completed in 181 days or more	5%	53%	89%	69%	70%	71%	90%
Significant new use notices (SNUN)							
EPA determination for completed reviews							
Allowed to commercialize without restrictions	0	0	1	3	3	0	0
Allowed to commercialize with restrictions pending information development, if applicable	1	6	3	8	3	0	1
Not allowed to commercialize pending development of information	0	0	0	0	0	0	0
Prohibited from commercializing	0	0	0	0	0	0	0
EPA review time[b]							
Percentage of reviews completed in 90 days or less	0%	0%	0%	9%	0%	0%	0%
Percentage of reviews completed between 91 days and 180 days	100%	50%	0%	18%	33%	0%	100%
Percentage of reviews completed in 181 days or more	0%	50%	100%	72%	67%	0%	0%
Microbial commercial activity notices (MCAN)							
EPA determination for completed reviews							
Allowed to commercialize without restrictions	26	14	40	16	13	32	17

Allowed to commercialize with restrictions pending information development, if applicable	0	1	0	0	0	0	0
Not allowed to commercialize pending development of information	0	0	0	0	0	0	0
Prohibited from commercializing	0	0	0	0	0	0	0
EPA review time[b]							
Percentage of reviews completed in 90 days or less	62%	93%	73%	75%	92%	97%	65%
Percentage of reviews completed between 91 days and 180 days	38%	7%	25%	25%	8%	3%	35%
Percentage of reviews completed in 181 days or more	0%	0%	2%	0%	0%	0%	0%
Low Volume Exemption (LVE)/Low Release and Low Exposure (LoREX) Exemption							
Exemptions Granted	232	302	272	257	202	152	57
Exemptions Denied	68	60	1	1	2	64	65

Source: EPA. | GAO-23-105728

Note: Counts exclude new chemical submissions that (a) EPA determined to be invalid or incomplete, which includes 153 submissions from June 22, 2016, through May 16, 2022; or (b) submitters withdrew during the review process, which includes 380 PMNs, SNUNs, or MCANs and 145 LVEs or LoREX during the same period. Review time percentages may not add to 100 due to rounding. According to EPA, some new chemical review data fields are entered manually, which could result in data errors. EPA officials told us they conduct a monthly quality control process to help ensure manually entered data fields are accurate.

"Allowed to commercialize without restrictions" determinations include reviews for which EPA made not likely to present unreasonable risk determinations including reviews with associated SNURs. "Allowed to commercialize with restrictions pending information development, if applicable" determinations include reviews with associated section 5 orders that allow commercialization with restrictions (and may require testing of the substance). "Not allowed to commercialize pending development of information" determinations include reviews with associated section 5 orders requiring testing prior to commercialization of the substance. "Prohibited from commercializing" determinations represent a "will present unreasonable risk" finding and ban on commercialization.

[a]Counts for 2016 and 2022 are incomplete. Specifically, counts for 2016 include reviews from June 22, 2016, through December 31, 2016. Counts for 2022 include reviews from January 1, 2022, through May 16, 2022, the most recent information available for our review.

[b]Counts are based on the calendar year in which EPA completed the review. "EPA review time" reflects the calendar days between the date of receipt and the date of completion.

Table 3: Environmental Protection Agency (EPA) Percentage of New Chemical Reviews Not Completed, June 2016–May 2022

New chemical review type	2016[a]	2017	2018	2019	2020	2021	2022[a]
Pre-manufacture notices (PMN)	3%	5%	10%	10%	27%	79%	100%
Significant new use notices (SNUN)	16%	0%	0%	0%	33%	91%	100%
Microbial commercial activity notices (MCAN)	0%	0%	0%	0%	0%	0%	67%

Source: EPA. | GAO-23-105728

Note: Counts are based on the calendar year in which EPA received the notice. Counts exclude notices that (a) EPA determined to be invalid or incomplete, which includes 153 notices from June 22, 2016, through May 16, 2022; or (b) submitters withdrew during the review process, which includes 380 PMNs, SNUNs, or MCANs. According to EPA, some new chemical review data fields are entered manually, which could result in data errors. EPA officials told us they conduct a monthly quality control process to help ensure manually entered data fields are accurate.

[a]Counts for 2016 and 2022 are incomplete. Specifically, counts for 2016 include reviews from June 22, 2016, through December 31, 2016. Counts for 2022 include reviews from January 1, 2022, through May 16, 2022, the most recent information available for our review.

Appendix III: EPA Staff for Conducting New and Existing Chemical Reviews

Table 4: Environmental Protection Agency (EPA) Staff for Conducting New and Existing Chemical Reviews, by Mission-Critical Occupations, Fiscal Years (FY) 2021 and 2022

	FY 2021			FY 2022
	Workforce on 9/30/21	10/1/21–9/30/22		Workforce on 9/30/22
Occupations	**Onboards[a]**	**Hires[a]**	**Departures[a]**	**Onboards**
Mission-critical occupations				
Economist	13	2	2	13
Biologist	62	8	8	62
Toxicologist	18	1	0	19
Chemical engineer	14	0	0	14
Physical scientist	18	2	2	18
Chemist	14	4	0	18
Information technology specialist	5	2	0	7
Subtotal	**144**	**19**	**12**	**151**
Other occupations[b]	115	7	11	111
Total	**259**	**26**	**23**	**262**

Source: EPA. | GAO-23-105728

[a]In addition to reporting full-time equivalent (FTE) employment information for budgetary purposes, EPA also reports other workforce information, including onboard, hire, and departure information. EPA defines “onboards” as employees with a “position of record” within the Office of Chemical Safety and Pollution Prevention (OCSPP). Some onboards may be on a temporary detail to a different position inside or outside of OCSPP. EPA defines “hires” as the employees selected to fill a position within OCSPP, whether external or internal hires. EPA defines “departures” as employees who leave OCSPP for any reason (voluntary or involuntary), including resignation, termination, death, or retirement.

[b]Other occupations” include job series not represented in the list of “mission-critical occupations.” The vast majority of these are environmental protection specialists.

Appendix IV: Comments and our evaluation from the United States Environmental Protection Agency

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Dear Mr. Gomez:

Thank you for the opportunity to review and comment on GAO's December 7, 2022, Draft Report titled "EPA Chemical Reviews Workforce Planning Gaps Contributed to Missed Deadlines," GAO Project Number 105728.

The purpose of this letter is to provide EPA's response to the Draft Report. For your convenience, EPA has also prepared detailed technical comments transmitted with this response, but which EPA expects will remain internal to GAO.

As explained below, although the Office of Chemical Safety and Pollution Prevention (OCSPP) agrees with GAO's recommendation to improve workforce planning for EPA's Toxic Substances Control Act (TSCA) program, we have significant concerns that the Draft Report lacks context for GAO's findings and therefore conveys an inaccurate picture of EPA's recent efforts to address these problems. The Draft Report does not fairly convey the circumstances in the first years following enactment of the reformed law that created challenges the TSCA program continues to face. Most notably, by focusing on workforce planning in its sole recommendation and in the Draft Report's title, GAO overstates the extent to which workforce planning affected the Agency's progress in implementing TSCA.

OCSPP believes a host of other factors, including several discussed in GAO's Draft Report, played a much more significant role in missed TSCA deadlines. Examples of such factors include the primary factor of insufficient resources largely caused by the previous Administration's failure to request additional funding from Congress and the failure to fully meet budget requests in recent years, insufficient focus in the early years of TSCA implementation on building the scientific, information technology and related infrastructure of the new law, and court challenges related to past policy decisions that necessitated re-work and policy shifts.

Fundamentally, while OCSPP agrees that additional workforce planning could benefit its TSCA implementation efforts, we also believe that even the most robust and strategic workforce planning effort will be all but useless if the program does not receive the sustained levels of resources needed to implement it.

Background:

GAO's objective was to evaluate EPA's implementation of its TSCA chemical review responsibilities. The Draft Report reviewed the extent to which: (1) EPA met selected TSCA deadlines for reviewing existing and new chemicals since June 2016; and (2) EPA engaged in workforce planning for implementing its chemical review responsibilities. The discussion below includes some notable examples of challenges and/or OCSPP efforts we believe GAO should more fully consider in its evaluation:

- Resource shortages: The Lautenberg Act provided EPA with a great deal of new authority and responsibility. For existing chemicals, the law was changed from a discretionary statute, the power of which had been rendered largely ineffective due to litigation on EPA's 1989 ban on asbestos, to a requirement that EPA systematically and comprehensively prioritize and evaluate at least 20 existing chemicals at once and provide protections against the identified unreasonable risks through regulations. Under the amended law, EPA is also required to complete formal risk determinations for 100% of all new chemical submissions, as compared to the pre-2016 practice of completing formal risk determinations on about 20% of such submissions. The new law also provided new responsibility for increasing transparency and new data-gathering authority. Despite this significant increase in responsibility, appropriations for EPA's TSCA program remained relatively level for the first 6 and a half years of the new law, in no small part because the previous Administration did not once request any additional funding from Congress. President Biden asked for an increase for TSCA in the FY 2022 budget request with an additional $15 million and 88 FTE to help sustain the TSCA program, but EPA did not receive all it requested. In the FY 2023 budget request, using TSCA workforce and resource needs analyses conducted in late 2020 and early 2021, the President asked for an increase of $59.2 million and 175 FTE to support the TSCA program, but EPA received only $19.7 million.

  EPA faced an additional challenge with collecting fees, which Congress expected would defray up to 25% of authorized TSCA implementation costs. Although the law was enacted in 2016, EPA's first fees rule was not finalized until 2018, and no fees were collected until FY 2019. Under the 2018 rule, the costs of the first 10 risk evaluations (the costliest TSCA implementation activity at the time) were exempted from being subject to fees, and no budget analysis to calculate the costs of implementing the new law to use as its baseline was conducted. As a result, the 2018 fees rule resulted in the collection of only about 13% of the artificially low baseline cost estimate for the program. In November 2022, EPA issued a Supplemental Notice of Proposed Rulemaking that would change the fees associated with TSCA to reflect an estimate of the full costs of implementing the program.

- IT challenges: A critical need for improving EPA's performance on TSCA implementation is modernizing the outdated IT systems necessary for chemical data collation, storage, and curation and to make the data received under TSCA readily available in structured and consistent formats. The current legacy infrastructure (hardware and systems software) and application software systems are prone to problems such as latency, screen freezes, Virtual Desktop Interface (VDI) connectivity outages, disruptions in workflow application and related tools, drive mapping volatility, and wholesale downtime. These problems have resulted in productivity losses across OPPT. For example, the IT system used to house the work done by OCSPP's New Chemicals Division frequently crashes. In one notable instance in late 2021, the system remained unusable for about two weeks, bringing the program's work to a halt. Making the major investments required to modernize IT systems supporting TSCA implementation is impossible without sustained increased appropriations in the annual budget.

- Legal Challenges: OCSPP's efforts to implement TSCA have also been hampered by legal challenges, including challenges to policies adopted by the previous administration. EPA was sued on three of four TSCA procedural framework rules, various specific chemical actions, TSCA section 21 petition responses, transparency in the new chemicals program, and other issues. As an example, in late 2019, the court in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019) held that EPA's Risk Evaluation Rule, 82 FR 33726 (July 20, 2017) should not have excluded "legacy uses" (*i.e.,* uses without ongoing or prospective manufacturing, processing, or distribution for use) or "associated disposals" (*i.e.,* future disposal of legacy uses) from the definition of conditions of use. Following this ruling, EPA determined that the complete Risk Evaluation for Asbestos would have to be issued in two parts. Further, the Agency also determined that the risk evaluation framework rule had to be revised to reflect the court's findings and that it had to consider other policy changes that may anticipate future analogous challenges. EPA has considered these policy changes and reflected some of them in Agency actions (e.g., revised unreasonable risk determinations, fenceline screening methodology).

- Unused hiring authority and other personnel actions: GAO found that although Congress provided Title 42 hiring authority to OCSPP for fiscal years 2022 through 2025, OCSPP did not employ any staff under this authority during fiscal year 2022. GAO failed to note, however, that OCSPP is actively building the infrastructure and taking steps to use its new Title 42 hiring authority, which was provided in the FY 2022 federal budget enacted in mid-March 2022. Before OCSPP could use this authority, it was required to develop a new Title 42 handbook, which was completed on December 15, 2022. OCSPP also had to seek an amendment to EPA's Title 42 delegation, which was approved by the EPA Administrator on October 17, 2022. OCSPP must also consult with the U.S. Office of Personnel Management (OPM) on its prospective use of Title 42 authority, which it is currently doing. OCSPP expects to begin to use its Title 42 hiring authority when the consultation process is complete. Rather than acknowledge the expeditious manner in which OCSPP has taken the steps required before utilizing Title 42 hiring authority, GAO merely observes that it had yet to be used.

  Similarly, GAO uses a point-in-time August 2022 estimate of OPPT vacancies to exemplify personnel recruitment and retention challenges experienced by OPPT. Some of these vacancies, however, were new positions made possible by the spring 2022 enactment of the budget. Through the development of an innovative and aggressive recruitment strategy, OPPT hired 26 new employees since May 1, 2022, to work in priority TSCA implementation areas that have been most challenged by insufficient resources. OCSPP's efforts to support its staff have also resulted in year-over-year increases in positive responses to key questions in the Federal Employee Viewpoint Survey. Broadly, for the second year in a row, the OCSPP scores are among our highest ever. EPA looks forward to taking further steps that improve OCSPP's culture and satisfaction levels.

GAO Recommendation:

Recommendation 1: The Administrator of EPA should direct the Assistant Administrator of OCSPP to develop a process and timeline to fully align its workforce planning efforts for implementing EPA's TSCA chemical review responsibilities with workforce planning principles and incorporate the results, as appropriate, into EPA's annual plan for chemical risk evaluations under TSCA.

EPA Response:

EPA agrees with Recommendation 1. EPA has taken action to improve its workforce planning efforts for TSCA chemical review responsibilities.

- EPA has developed a task order to engage contractor support for additional workforce planning and technical support across OCSPP to augment the analysis OCSPP conducted in 2020. This effort is expected to get underway in January 2023.
- Since May 1, 2022, OPPT has hired 26 new employees across the office using the resources provided in the FY 2022 budget.
- EPA has developed a detailed plan for hiring actions under the enacted FY 2023 budget. This plan identifies at least 52 new hiring actions within OCSPP's Office of Pollution Prevention and Toxics, most of which are intended to strengthen the office's capacity in a range of key disciplines for TSCA implementation.

Thank you for the opportunity to review the Draft Report. If you have questions or need further information, please reach out to Janet L. Weiner, OCSPP's Senior Audit Liaison at weiner.janet@epa.gov.

Sincerely,

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2023.01.20 08:41:39 -05'00'

Michal I. Freedhoff, Ph.D.
Assistant Administrator

cc: EPA GAO Liaison Team
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Appendix V: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, the following staff members made key contributions to this report: Diane Raynes (Assistant Director), William Colwell (Analyst-in-Charge), Adrian Apodaca, Alisa Carrigan, Virginia Chanley, Jennifer Gould, Nacole King, Summer Lingard-Smith, Steven Lozano, Patricia Moye, Corinna Nicolaou, and Monica Scott.

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