Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

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Prepared for the Committees on Energy and Commerce and Appropriations of the U.S. House of Representatives and the Committees on Environment and Public Works and Appropriations of the U.S. Senate

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1. Introductory Information

1.1. Executive Summary

The *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (Public Law [P.L.114-182]) ("Lautenberg Act"),[1] signed by President Obama on June 22, 2016, substantially amended the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq*. Under the Lautenberg Act, the U.S. Environmental Protection Agency (EPA) was required to meet new statutory deadlines and mandates to evaluate chemical substances based on their health and environmental risks, to address unreasonable chemical risks identified in risk evaluations, to assess new chemical risks and document affirmative determinations of safety, to increase transparency of chemical data while protecting legitimate confidential business information (CBI), and to establish fees to carry out its responsibilities.

While the Lautenberg Act ("Act") was passed with bipartisan support, the EPA's TSCA program funding level has remained largely unchanged from levels prior to the law's amendment in 2016. As a result, the EPA has not met many of the statutory deadlines in the Act, including completing only one of the first 10 agency-initiated chemical risk evaluations on time. The agency also faces capacity issues to review new chemicals and document the results of those reviews in the way Congress intended.

In the fiscal year (FY) 2023 budget request, the President has asked for an increase of $59 million and 175 additional FTE above FY 2022 enacted levels to support the TSCA program. Those additional resources, together with establishing and collecting fees that reflect the estimated cost of the EPA's TSCA work, are critical to ensuring the TSCA program can deliver on the promise of TSCA reform.

This report acknowledges compounding failures on the EPA's part to adequately assess its resource needs in the years immediately following enactment of the Lautenberg Act. The FY 2023 President's budget request, along with an updated TSCA fees rule expected in calendar year 2022, reflects the EPA's current costs of implementing TSCA. The EPA recognizes its responsibility to identify and implement opportunities to reduce those costs as it incorporates lessons learned since the law was enacted and builds the scientific, regulatory and other infrastructure needed to effectively implement the program. For example:

- The resources included in the FY 2023 President's budget request would allow the EPA to modernize its information technology (IT) systems, which at times hinder and significantly slow chemical review work. These improvements will ultimately reduce TSCA implementation costs.

[1] See https://www.epa.gov/sites/default/files/2016-06/documents/bills-114hr2576eah.pdf.

- The resources included in the FY 2023 budget request would allow the EPA to increase and further diversify the expertise of the TSCA program's scientific workforce, which will reduce re-work and enable more timely and robust chemical reviews, and thus ultimately reduce TSCA implementation costs.

- As the EPA further develops its scientific and regulatory tools (including but not limited to systematic review, techniques to assess chemical risks to potentially exposed and susceptible subpopulations, and potential measures to address occupational safety), EPA expects costs of developing these tools to decrease.

- The EPA has made significant efforts to enhance its intra- and inter-agency coordination to improve the efficiency of the prioritization, risk evaluation, and regulatory processes by identifying and resolving concerns earlier, and thus increase EPA's capacity to implement the law in accordance with statutory deadlines.

- Many of the first 30 chemicals subject to the amended TSCA risk evaluation and regulatory process are high production volume substances used by many sectors for many purposes, and about which health and environmental concerns are known to exist. As the EPA continues to meet the TSCA mandate to continuously select and evaluate chemical substances from among the thousands of chemical substances in commerce, it is reasonable to expect that a reduction in the scope and complexity of each risk evaluation as well as the associated risk management actions would reduce implementation costs.

This report provides point-in-time estimates of the EPA's current estimated capacity and resources needed to implement the 2016 TSCA amendments. The combination of the resources included in the 2023 budget request, an amended fees rule, and EPA's ongoing efforts to build and improve the scientific, regulatory, and other infrastructure needed to more efficiently implement TSCA should, over time, reduce the levels of resources needed in the future.

1.2. Purpose of this Report

The *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (Public Law [P.L.114-182]) ("Lautenberg Act"),[2] signed by President Obama on June 22, 2016, substantially amended the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 *et seq*. Under section 26(m) of TSCA, as amended, the EPA was required to submit an initial report to Congress not later than six months after the date of enactment of the Lautenberg Act and is required to submit updated reports not less frequently than once every five years thereafter. The report must include estimations of:

[2] See https://www.epa.gov/sites/default/files/2016-06/documents/bills-114hr2576eah.pdf.

- The capacity of the EPA to conduct and publish risk evaluations under TSCA sections 6(b)(4)(C)(i) (EPA-initiated risk evaluations) and (ii) (manufacturer-requested risk evaluations):

- The resources necessary to conduct the minimum number of required EPA-initiated risk evaluations;

- The likely demand for manufacturer-requested risk evaluations and the anticipated schedule for accommodating that demand;

- The EPA's capacity to promulgate TSCA section 6(a) risk management rules as required to address unreasonable risks identified in risk evaluations conducted and published under TSCA section 6(b); and

- The EPA's actual and anticipated efforts to increase capacity to conduct and publish risk evaluations under TSCA section 6(b).

The EPA's first TSCA section 26(m) report was delivered to Congress in January 2017.[3]

1.3. Overview

The Lautenberg Act provided the 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 the EPA's 1989 ban on asbestos. The Lautenberg Act changed that by requiring the EPA to systematically and comprehensively prioritize and evaluate at least 20 existing chemicals at once and to provide protections against the identified unreasonable risks through regulations. Under the amended law, the EPA is required to complete assessments and make and document its findings regarding the likelihood of risk for all new chemicals, before they enter commerce. Previously, written determinations were not required for all submissions, and the EPA made written determinations on approximately 20% of submissions. The new law also provided new responsibility for increasing transparency by limiting unwarranted claims of confidentiality associated with chemicals and new data-gathering authority to support our assessments.

The new authorities and obligations provided to the EPA by the Lautenberg Act included elements such as:

- **Expanded scope and challenging deadlines.** The EPA is required to systematically prioritize and evaluate existing chemicals on a specific schedule. Following the initial 10 risk evaluations, the EPA's chemicals program must ensure that risk evaluations are

[3] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/initial-report-congress-epas-capacity-implement-certain.

being conducted on at least 20 high-priority substance chemicals at a time, beginning another risk evaluation each time one is completed.

- **Requirement to evaluate chemical substances based on their human health and environmental risks.** The EPA must evaluate a chemical substance's risks to human health and the environment, including to people who may face greater susceptibility or exposure to chemicals. This may include infants, children, pregnant women, the elderly, or others who because of where they live or work may face greater health risks than the general population from exposure to chemicals. Through that evaluation, the EPA must determine if the chemical substance presents unreasonable risk of injury to human health or the environment, without consideration of costs or other non-risk factors, under the substance's conditions of use.

- **Requirement to address unreasonable risks.** Following completion of a risk evaluation in which the EPA determines that the existing chemical substance presents unreasonable risk under the conditions of use, the EPA must conduct timely rulemaking to address unreasonable risks, an activity known as "risk management." Risk management requirements may include, but are not limited to, labeling, restrictions, bans, and/or phase-outs, where warranted, so that the chemical substance in question will no longer present an unreasonable risk. When making certain risk management decisions, the EPA must consider to the extent practicable if technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute. Costs and benefits of regulatory actions and other factors will be considered when determining appropriate action to address unreasonable risks. The EPA may grant an exemption from a risk management rule for a specific condition of use if the EPA finds that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the requirement, as applied with respect to the condition of use would significantly disrupt the national economy, national security, or critical infrastructure; or the condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

- **Requirement that the EPA make a safety determination on new chemicals and make an affirmative determination of safety before allowing a new chemical to enter commerce**. Before a new chemical is allowed to enter commerce, the EPA must make an affirmative determination as to whether the new chemical presents an unreasonable risk to human health or the environment under known, intended, or reasonably foreseen conditions of use. The EPA must take any necessary risk management action before a new chemical can enter the marketplace and before a significant new use is allowed for an existing chemical, subject to certain exemptions.

- **Requirement to increase transparency of chemical data while protecting legitimate confidential business information (CBI)**. The EPA must review most chemical identity

CBI claims within 90 days and 25 percent of a subset of other types of CBI claims within 90 days.

- **Requirement to establish fees to carry out its responsibilities.** The EPA is authorized to set fees to defray 25 percent of the costs to the Administrator of carrying out TSCA sections 4, 5 and 6, and of collecting, processing, reviewing, providing access to, and protecting from disclosure, as appropriate, chemical information under TSCA section 14. This provision enables the collection of fees to cover part of the agency-wide costs of carrying out relevant sections of TSCA.

Despite this increase in responsibility, appropriations for the EPA's TSCA program have remained relatively level since the Lautenberg Act was passed. As a result, the EPA has not increased capacity, including employees (quantified as full-time equivalents (FTEs)), appropriated funds, and TSCA fees to achieve many of the Act's new statutory deadlines. For example, only one of the first 10 agency-initiated chemical risk evaluations was completed on time, and the agency's existing chemicals workload has now more than doubled with more than 20 risk evaluations underway along with risk management rules for the first 10. The EPA also continues to operate with less than half of the resources it needs to review new chemicals in the way Congress intended and will continue to struggle to quickly review the safety of new chemicals.

The EPA estimates that its capacity needs total approximately $125 million and 175 FTE above the FY 2022 enacted levels. President Biden asked for a down payment in the FY 2022 budget request with an additional $15 million and 88 FTE to help make the TSCA program more sustainable, but the EPA did not receive all it requested in H.R. 2471, the "Consolidated Appropriations Act, 2022." In the FY 2023 budget request the President has asked for an increase of $59 million and 175 additional FTE above FY 2022 enacted levels to support the TSCA program. In addition to articulating its needs through budget formulation and other means, the EPA is prioritizing hiring in critical occupations such as biologists, chemical engineers, chemists, economists, information technology specialists, physical scientists, and toxicologists. Those additional mission critical resources, together with establishing and collecting fees that capture the updated cost of EPA's TSCA work, are critical to ensuring the TSCA program can operate in a sustainable manner and in the way Congress intended.

1.4. Relevant Statutory Requirements and Actions to Date

1.4.1. EPA-Initiated Risk Evaluations

Under TSCA section 6(b)(2)(A), the EPA was required to ensure that risk evaluations were initiated for 10 chemical substances within 180 days of enactment of the Lautenberg Act. The law further required that the first 10 chemical substances be drawn from the 90 chemicals on the

EPA's 2014 Update to the *TSCA Work Plan for Chemical Assessments*.[4] On November 29, 2016, the EPA identified the first 10 chemical substances that would undergo risk evaluation under the law.[5] The EPA released scope documents for those chemical substances in June 2017 and problem formulation documents in June 2018. The EPA began releasing draft risk evaluations for the chemical substances in November 2018. From the date of initiation of the risk evaluations for the first 10 chemicals, the EPA had three years, with a possible six-month extension, to complete risk evaluations for those chemicals. These risk evaluations were completed between June 2020 and January 2021.[6] The statutory deadline for their completion was missed for all but one of these risk evaluations.

On June 30, 2021, the EPA announced its intent to take several actions affecting the first 10 chemical substance risk evaluations.[7] The EPA intends to formally supplement the 1,4-dioxane risk evaluation to consider additional exposure pathways, such as drinking water and ambient air, and conditions of use for which 1,4-dioxane is generated as a byproduct. For six of the first 10 chemical substances (methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, n-Methylpyrrolidone (NMP), and 1-bromopropane), the EPA plans to further examine whether the previous Administration's policy decision to exclude certain exposure pathways (i.e., air, water) from the risk evaluations may have led to a failure to identify potential unreasonable risks from these exposure pathways. The approach also resulted in a failure to appropriately address the statutory requirement to evaluate potential exposures to potentially exposed or susceptible subpopulations, including fenceline communities (i.e., communities near industrial facilities). Depending on the outcome of this screening-level analysis, EPA may move forward to proposed risk management rulemakings or may conduct a more comprehensive exposure assessment of fenceline communities and formally supplement the risk evaluation for that chemical with the new information.

The EPA also is revisiting the assumption that personal protective equipment (PPE) is always properly used in occupational settings when making risk determinations in a TSCA risk evaluation for a chemical substance. This assumption was not appropriate because, by its own admission, many OSHA standards "are outdated and inadequate for ensuring protection of worker health. Most of OSHA's [permissible exposure limits] were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that

[4] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-assessments-2014-update.

[5] See https://archive.epa.gov/epa/newsreleases/epa-names-first-chemicals-review-under-new-tsca-legislation.html and https://www.federalregister.gov/documents/2016/12/19/2016-30468/designation-of-ten-chemical-substances-for-initial-risk-evaluations-under-the-toxic-substances

[6] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca

[7] See https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

time."[8,9] OSHA standards do not cover risks to all potentially exposed or susceptible subpopulations of workers, such as self-employed individuals and public sector workers not covered by OSHA-approved workplace safety and health programs operated by individual states or U.S. territories.[10] In addition, TSCA requires the EPA to evaluate whether a chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, which must be read to include risks to workers. Moreover, TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints derived using more recent scientific information and working populations than those available to OSHA decades ago, and the EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented.

The EPA plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address any identified unreasonable risk during the risk management process. This shift could change some of the risk conclusions for some conditions of use for six of the first 10 chemical substances for which "no unreasonable risk" findings were made based on the use of PPE but does not create a need for new analyses of the chemicals. Specifically, this shift could impact conclusions about risk for some conditions of use for methylene chloride, 1-bromopropane, cyclic aliphatic bromide cluster (HBCD), NMP, perchloroethylene, and 1,4-dioxane. The EPA has finalized revised risk determinations for two of the first 10 chemical substance risk evaluations and has issued six additional draft revised risk determinations. The EPA has sought public comment on such an approach for each of these actions. In conjunction with the issuance of "whole chemical" risk determinations, the EPA intends to withdraw previously issued orders for conditions of use for which no unreasonable risk was found in the first 10 risk evaluations.

After the first 10 risk evaluations were completed, TSCA required the agency to double the number of risk evaluations being conducted and to select those chemicals pursuant to a rule that described a risk-based prioritization process to identify chemical substances as either "high" priority substances for risk evaluations or "low" priority substances for which risk evaluations are not warranted at the time.[11,12] A high-priority substance designation is required when the EPA determines, without consideration of cost or other non-risk factors, that the chemical substance may present an unreasonable risk of injury to health or the environment due to a potential hazard and a potential route of exposure, including to a potentially exposed or susceptible subpopulation.[13] A high-priority substance designation requires that the EPA conduct

[8] See https://www.osha.gov/top10citedstandards

[9] See https://www.osha.gov/annotated-pels

[10] See https://www.osha.gov/stateplans/

[11] See TSCA section 6(b)(2)(B).

[12] See TSCA section 6(b)(1)(A).

[13] See TSCA section 6(b)(1)(B).

a risk evaluation to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, under the conditions of use.[14] TSCA requires that these risk evaluations be completed within three years (with a possibility of a six-month extension).[15]

TSCA requires the agency to begin a risk evaluation for a new high-priority substance each time a risk evaluation (other than a manufacturer-requested risk evaluation) is completed such that the EPA always has at least 20 EPA-initiated risk evaluations underway.[16] TSCA requires the EPA to have completed the prioritization process for a substance prior to initiating the new risk evaluation for that substance.[17]

In August 2019, the EPA released proposed designations of 20 high-priority substances.[18] In December 2019, the EPA finalized the designations and commenced risk evaluations on those substances.[19] The EPA released draft scope documents for these chemical substances for public comment in March and April 2020 and finalized them in September 2020. Statutory timelines require the EPA to publish final risk evaluations within three years of initiation of the risk evaluations, with a possible six-month extension. Given current resources, without reprioritizing other work, the EPA does not anticipate completing any of these risk evaluations by the statutory deadline.

1.4.2. Manufacturer-requested Risk Evaluations

TSCA section 6(b)(4)(C)(ii) provides a mechanism for manufacturers to submit a request that the EPA evaluate chemical substances manufactured by those entities, in a form and manner and using criteria prescribed by the EPA in a risk evaluation process rule mandated by the law. For manufacturer-requested risk evaluations (MRREs), if the EPA receives a sufficient number of compliant requests, the law requires that those risk evaluations account for between 25 and 50 percent of the total number of the EPA-initiated risk evaluations. For example, if 20 EPA-initiated risk evaluations are underway, the EPA would be authorized to undertake between five and 10 MRREs assuming that sufficient requests are made that comply with the criteria as described in the Risk Evaluation Rule.[20] TSCA requires that manufacturers requesting risk

[14] See TSCA section 6(b)(4)(A).

[15] See TSCA section 6(b)(4)(G).

[16] See TSCA section 6(b)(2).

[17] See TSCA section 6(b)(3)(A).

[18] See https://www.federalregister.gov/documents/2019/08/23/2019-18134/proposed-high-priority-substance-designations-under-the-toxic-substances-control-act-tsca-notice-of.

[19] See https://www.federalregister.gov/documents/2019/12/30/2019-28225/high-priority-substance-designations-under-the-toxic-substances-control-act-tsca-and-initiation-of.

[20] See https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0654-0108.

evaluations pay costs as discussed below. To date, the EPA has received four manufacturer requests for risk evaluation.[21]

The law also provided manufacturers an opportunity to request, by September 19, 2016, that the EPA conduct risk evaluations for certain persistent, bioaccumulative, and toxic (PBT) chemicals in the *TSCA Work Plan for Chemical Assessments: 2014 Update*[22] as an alternative to expedited risk management action under TSCA section 6(h) as described in Section 1.4.3 below.

1.4.3. Risk Management

When unreasonable risks are identified through TSCA risk evaluations, the EPA generally must finalize risk management actions within two years, or a maximum of four years under some circumstances.[23] Costs and benefits of regulatory actions and other factors will be considered when determining appropriate action to address unreasonable risks.[24] Risk management rules must take effect as soon as practicable and generally must also require full compliance with risk management requirements as soon as practicable but no later than five years after rule promulgation (with some exceptions).[25] Bans and phase-outs must begin no later than five years after promulgation and be fully implemented as soon as practicable.[26]

TSCA section 6(h) includes a specific process to address certain PBT chemicals on the 2014 Update to the TSCA Work Plan. The EPA identified chemical substances subject to this process and issued five final rules on January 6, 2021.[27] On March 8, 2021, the EPA announced it was opening a 60-day comment period for the public to provide new input on whether the rules sufficiently reduce exposure to these chemicals, including exposures to potentially exposed or susceptible subpopulations, and the environment, compliance issues associated with the final rule on phenol, isopropylated phosphate (3:1) (PIP (3:1)), and whether to consider additional or alternative measures or approaches.[28] On September 3, 2021, the EPA announced that it is considering revising all five of the final rules for PBT chemicals to further reduce exposures, promote environmental justice, and better protect human health and the environment.[29] The EPA

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[21] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca.

[22] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#updates.

[23] See TSCA section 6(c)(1).

[24] See TSCA section 6(c)(2)(A).

[25] See TSCA section 6(d)(1).

[26] See TSCA section 6(d).

[27] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals.

[28] See https://www.epa.gov/newsreleases/epa-seeks-public-comment-protecting-human-health-and-environment-pbt-chemicals.

[29] See https://www.epa.gov/chemicals-under-tsca/epa-announces-plan-new-rulemaking-pbt-chemicals-extends-existing-compliance.

plans to issue a proposal for a new separate rulemaking for PBT chemicals in spring 2023. The provisions of the January 2021 rules remain in effect while EPA works on this new rulemaking effort, except that the EPA extended certain compliance dates for PIP (3:1) to March 8, 2022,[30] and then again to October 31, 2024,[31] to address the hardships inadvertently created by the original applicable compliance dates in the January 2021 final rule to ensure that supply chains are not disrupted for key consumer and commercial goods.

2. Capacity to Implement Specific Provisions of the Law Regarding Risk Evaluations and Regulatory Actions

The EPA is continuing to implement the provisions of the Lautenberg Act as expeditiously as possible. This report, as directed under section 26(m) of TSCA as amended, provides:

- The capacity of the EPA to conduct and publish risk evaluations under section 6(b)(4)(C)(i), and the resources necessary to conduct the minimum number of risk evaluations required under section 6(b)(2);

- The capacity of the EPA to conduct and publish risk evaluations under section 6(b)(4)(C)(ii), the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

- The capacity of the EPA to promulgate rules under section 6(a) as required H. R. 2576—57 based on risk evaluations conducted and published under section 6(b); and

- The actual and anticipated efforts of the EPA to increase the agency's capacity to conduct and publish risk evaluations under section 6(b).

The TSCA program undertook multiple actions to address well-known capacity issues such as leveraging existing resources within the agency to carry out the TSCA mandates by conducting a reorganization of the Office of Chemical Safety and Pollution Prevention in 2020 to allocate additional resources for existing and new chemical reviews, announcing details for specific mission critical occupations, training staff on risk management, and drawing on expertise across the agency from the Office of Research and Development, and Office of Air, and the Office of Land Emergency Management to aid in evaluating chemicals for risk management action. The EPA has also identified needs in a Workforce Analysis as a result of audits initiated by the U.S. Government Accountability Office (GAO) and the Office of Inspector General (OIG) as further addressed below in Section 2.2. The EPA's TSCA program funding level has remained flat for six years and is essentially the same as it was before the law was amended in 2016. These

[30] See https://www.federalregister.gov/documents/2021/09/17/2021-19516/regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca-section-6h-phenol.

[31] See https://www.federalregister.gov/documents/2022/03/08/2022-04945/regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca-section-6h-phenol.

funding levels will not allow the program the ability to develop the capacity to meet its statutory obligations, and to deliver on the promise of TSCA reform.

2.1. Estimated Resources Necessary for Risk Evaluations

The EPA's current estimates for resources necessary to complete risk evaluations in accordance with statutory deadlines factor in all efforts conducted on the first 10 TSCA risk evaluations published between June 2020 and January 2021 (all but one of which was not completed by the statutory deadline), plus the additional time and effort to substantially rework as many as seven of those initial evaluations as described above and to conduct the second part of the asbestos risk evaluation. For the purposes of this cost estimation, based on its experience during the last several years, the EPA estimates it will typically have five MRREs underway for TSCA work plan chemicals.

On average, between FY 2018 and FY 2021, EPA collected approximately $10 million per year through TSCA fees. Although the Lautenberg Act was enacted in 2016, the 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 ten risk evaluations were exempted from the fees, and the last Administration did not conduct a budget analysis to calculate the actual costs of implementing the new law to use as its baseline. The 2018 fees rule resulted in the collection of only about 13% of the artificially low baseline cost estimate for the program. Additional information about the EPA's actions to correct this situation is provided below.

EPA currently estimates that the resources needed to complete a single risk evaluation, in accordance with statutory deadlines (which, as noted above, would be expected to decline over time as EPA builds the scientific, regulatory, and other infrastructure of the program and implements additional efficiencies drawn from further experience), is $2.99 million per year. Completing a risk evaluation in the maximum time allowed by TSCA (3.5 years) may cost approximately $10.48 million. To comply with TSCA, EPA anticipates having 20 EPA-initiated risk evaluations underway at all times, as well as five manufacturer-requested risk evaluations (MRREs). While MRREs are estimated to cost as much as EPA-initiated risk evaluations, the Lautenberg Act provided the EPA with expanded authority to collect fees from chemical manufacturers and importers to help defray up to 25% of the costs associated with overall TSCA implementation efforts.

In addition to the EPA's regular process for prioritizing and evaluating the risk of existing chemicals, TSCA section 21 allows any person to petition the EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, 8, 5(e), or 6(b)(2).[32] The EPA is required to grant or deny the petition within 90 days from the day the petition is filed. If

[32] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21

the petition is granted, the EPA must promptly commence an appropriate proceeding. If EPA denies the petition, the reasons for denial must be published in the *Federal Register*.

Since September 2007, the EPA has received 29 TSCA section 21 petitions. Of those, the EPA granted five of the petitions and partially granted one of the petitions. The 90-day review of the TSCA section 21 petitions creates a resource demand, but such demand is short-lived and unpredictable in terms of when and how many petitions the agency will receive. Similarly, the resources associated with activities related to TSCA section 21 petitions are challenging to predict, as the appropriate actions, the agency's final determination, and the complexity of the chemical substance that is the subject of each petition are unknown. When a TSCA section 21 petition is received, the EPA shifts resources to respond within the 90-day period required by TSCA. If a TSCA section 21 petition is granted, the EPA shifts resources to implement an appropriate process for addressing the concerns in the petition. Due to the uncertainties related to TSCA section 21 petitions, this report does not account for the petitions.

In its 2019 report evaluating EPA's implementation of the Lautenberg Act, GAO cited concerns about appropriate resources and staff capacity within two OPPT divisions implementing key portions of TSCA's requirements. Additionally, in response to the EPA OIG draft report titled "Lack of Planning for Staff and Resources Puts EPA's Ability to Meet TSCA Deadlines at Risk," OCSPP agreed to the following recommendations: 1) develop a workforce analysis focused on the Office of Pollution Prevention and Toxics and its ability to implement the requirements of TSCA, and 2) specify what skill gaps must be filled to achieve TSCA implementation capacity and how and when those gaps will be filled in the fiscal year 2021 workforce plan that the EPA agreed to develop in their Corrective Action Plan to the U.S. Office of Personnel Management.

The workforce skills gap analysis, developed in mid-FY 2021 after the submittal of the FY 2022 President's Budget Request, found that the EPA would likely have at least 165 fewer employees on board than necessary to effectively implement TSCA, and that that staffing gap would grow to at least 199 employees by the end of FY 2025. Of the occupational categories included in the EPA's TSCA workforce analysis, the categories with the highest identified need are epidemiologists, chemists, toxicologists, and physical scientists. In FY 2022, the enacted budget provided appropriated funds for an additional 25 FTEs. The hiring of these employees is underway and includes chemists, toxicologists, risk experts, economists, data analysts, and rule writers distributed across four of OPPT's five divisions. These additional FTEs will support improved implementation of TSCA, especially in the new chemicals science, existing chemicals systematic review, and existing chemicals risk management areas. Additional actions the EPA has taken in response to these recommendations are provided in section 2.4 of this report.

2.2. Capacity to Implement Specific Provisions of the Law

On November 12, 2021, the EPA OIG identified OCSPP's lack of capacity to fulfill its statutory obligations under TSCA as one of the EPA's top management challenges in FY 2022.[33] The OIG's assessment confirmed its August 2020 finding that "the EPA's TSCA risk evaluation capacity needs to dramatically increase to meet the statutory risk evaluation requirements of the 2016 TSCA amendments."[34]

The OIG found that OPPT "did not have enough internal capacity to timely conduct the first set of ten TSCA risk evaluations." The OIG noted that OPPT received support from personnel outside the Risk Assessment Division (now named the Existing Chemical Risk Assessment Division), including staff members from OPPT's pollution prevention program and from the EPA's Office of Research and Development, but still missed the deadlines for all but one of the first 10 risk evaluations. OIG's estimate is that for the EPA to have conducted 20 risk evaluations and four MRREs at a pace that allows the potential for meeting TSCA's deadlines, the agency's TSCA risk evaluation capacity would have required an increase of at least 140 percent beginning in FY 2020.[35]

In late FY 2021, the Office of Chemical Safety and Pollution Prevention completed its first comprehensive estimate of the resources necessary to conduct and complete TSCA risk evaluations according to the deadlines set in the statute. On the basis of that analysis, OCSPP estimates that $74.75 million (Pay and Non-Pay Resources) annually would be required to meet this goal. The EPA estimates that $29.46 million (Pay and Non-Pay Resources) annually would be required to meet the risk management provisions of TSCA section 6. EPA is currently reviewing these estimates in the context of its user fee review and budget formulation processes. While discussed as part of the agency's internal deliberations, the full estimate was not incorporated into the President's Budget request for FY 2022 because the aforementioned analysis OCSPP conducted had not yet been undertaken when that request was submitted to Congress. Based on current estimates, EPA anticipates that fully funding the FY 2023 President's Budget request for the TSCA program, continuing that level of funding into the future, increasing TSCA fee collections as a result of the new fees rule, and gaining experience and expertise in developing existing chemical risk evaluations will move the EPA much closer to consistent, timely implementation of TSCA.

As discussed above, the EPA conducted a workforce analysis to estimate its workforce needs for implementing TSCA. Of the total staffing gap of 199 FTEs projected for FY 2025, 106 FTEs are in the existing chemical risk evaluation elements of the TSCA program, 35 are in the existing

[33] See https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf.

[34] See https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf.

[35] See https://www.epa.gov/system/files/documents/2021-11/certified_epaoig_20211112-22-n-0004.pdf, p. 30.

chemical risk management elements, 32 are related to new chemical risk assessment and management, and 37 are in cross-program elements.

The EPA continues to work to increase its capacity to conduct and publish TSCA risk evaluations. These efforts are described in section 2.4 of this report.

2.3. Statutory Requirements for Appropriations and Fees

Under TSCA section 26(b), the EPA is authorized to set fees that ensure a sustainable source of funding to defray 25 percent of the costs to the Administrator of carrying out TSCA sections 4, 5 and 6, and of collecting, processing, reviewing, providing access to, and protecting from disclosure, as appropriate, chemical information under TSCA section 14. The authority to assess fees is conditioned on annual appropriations for EPA's Chemical Risk Review and Reduction (CRRR) Program, excluding fees, being held at least equal to the amount provided for that program in FY 2014.[36]

In October 2018, EPA published *Fees for Administration of Toxic Substances Control Act* ("fees rule") to implement the fee provisions of TSCA.[37] Affected businesses began incurring fees under the final rule in October 2018. The rule requires payment from manufacturers required to conduct testing under TSCA section 4, manufacturers who submit a notice under TSCA section 5, and manufactures of a chemical substance that is the subject of a risk evaluation under TSCA section 6(b). Fees also apply to processors in certain circumstances under TSCA sections 4 and 5.

Although the Lautenberg Act was enacted in 2016, the 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 were exempted from the fees, and the last Administration did not conduct a budget analysis to calculate the actual costs of implementing the new law to use as its baseline. As a consequence of these delays and inaction, the 2018 fees rule resulted in the collection of only about 13% of the artificially low baseline cost estimate for the program.

For the EPA-initiated risk evaluations commenced for 20 high-priority chemicals in December 2019, a flat fee of $1.35 million per risk evaluation was shared among manufacturers of the chemical substance. Total TSCA fees collected from the start of FY 2019 through March 15, 2022, totaled $37 million, which is about 16.5% of the funding required for risk evaluation during that period. About 70% of the total collection occurred in FY 2021, when EPA collected $24 million from 19 of the 20 TSCA section 6 EPA-initiated risk evaluations. In addition, in accordance with TSCA section 26(b), the fees rule established fees for MRREs at either 50% or 100% of the actual costs associated with the evaluation, depending on whether the chemical is

[36] See TSCA section 26(b)(5).

[37] See https://www.epa.gov/tsca-fees/fees-administration-toxic-substances-control-act.

included in the *TSCA Work Plan for Chemical Assessments: 2014 Update*.[38] For each of the three MRREs commenced in FY 2020 and FY 2021, a down payment of $1.25 million was collected by EPA. The remainder of the fees is due upon completion of the MRREs.

In March 2020, the EPA announced a plan to initiate a new rulemaking process to update the fees rule to resolve implementation issues raised by stakeholders.[39] In January 2021, EPA proposed changes to certain provisions of the 2018 fees rule including new fee categories, definitions of obligated fee payers and exempted entities, timing for payment and consortia notification, and a production volume-based fee allocation for companies producing chemicals subject to EPA-initiated risk evaluation, as well as other changes.[40] The 2021 proposed rule significantly underestimated implementation costs because it excluded the costs of risk management activities for the first 10 chemicals and 20 high-priority substances and the additional resources needed to implement the law as Congress intended.

The EPA is currently developing a supplemental notice of proposed rulemaking to revise its estimate of implementation costs as well as other provisions from the 2021 proposal. This rulemaking effort will provide a more fulsome response to Congress's statement in the FY 2022 federal budget that it "encourage[s] the Agency to properly consider full costs in its deliberations" on the TSCA fees rule. The agency expects to release this supplemental proposal for public comments in fall 2022.

TSCA also requires the EPA to review fees and, after consulting with stakeholders, update the fees every three years as necessary to adjust for inflation).[41] In 2021, EPA published a rule to increase TSCA fees by 18.9%.[42]

2.4. Improved Effectiveness in Implementing the Law

The EPA has taken numerous major steps in recent years to improve its effectiveness in implementing TSCA.

In October 2020, the EPA implemented a major reorganization of the Office of Pollution Prevention and Toxics (OPPT). The reorganization established a structure with OPPT that explicitly aligns with TSCA, allowing the existing chemicals risk evaluation, existing chemicals risk management, and new chemicals programs to operate as specific lines of business. By following the structure of the Lautenberg Act, the reorganization clarified responsibilities,

[38] See https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#updates.

[39] See https://www.epa.gov/newsreleases/epa-announces-plan-reduce-tsca-fees-burden-stakeholders.

[40] See https://www.regulations.gov/search?filter=EPA-HQ-OPPT-2020-0493.

[41] See TSCA section 26(b)(4)(F).

[42] See https://www.epa.gov/tsca-fees/tsca-fees-table.

allowed divisions and branches to develop new expertise, and supported greater efficiency in implementing TSCA.

In October 2021, the EPA announced several actions to enhance the scientific integrity of the TSCA program, including:

- Forming a new internal advisory group, the OCSPP Science Policy Council, to provide advisory support and recommendations on science policy and scientific integrity issues that arise within OPPT and the Office of Pesticide Programs.

- Establishing a new science policy advisor position that reports to the Assistant Administrator, provides guidance on emerging science policy and scientific integrity matters, and chairs the OCSPP Science Policy Council.

- Engaging in a top-to-bottom effort to catalogue, prioritize, and improve standard operating procedures, decision-making, and record-keeping practices related to review and management of new chemicals.

- Forming the New Chemicals Advisory Committee to serve as an advisory body to review both scientific and science policy issues related to new chemical submissions subject to TSCA.

- Implementing changes to the process for reviewing and finalizing new chemical human health risk assessments that provide additional opportunities for resolution of differing scientific opinions and invite input to the decision-making process to be provided by EPA subject matter experts outside of NCD.

- Enhancing procedures to ensure improved documentation of decisions and conducting further review to identify additional improvements, if any, including for new chemicals human health risk assessments.

In February 2022, the EPA launched a new effort to improve the process of and ensure the use of innovative science in reviewing new chemicals before they enter the marketplace. Through this effort, OCSPP proposed to develop and implement a multi-year collaborative research program in partnership with the agency's Office of Research and Development (ORD) and other federal entities focused on approaches for performing risk assessments on new chemical substances under TSCA. This multi-year research program will refine existing approaches and develop and implement new approach methodologies (NAMs) to ensure the best available science is used in TSCA new chemical evaluations. Key areas proposed in the TSCA New Chemicals Collaborative Research Program include:

- Updating OCSPP's approach using data from structurally similar chemicals to determine potential risks from new chemicals. This will increase the efficiency of new chemical

reviews promoting the use of the best available data to protect human health and the environment.

- Digitizing and consolidating information on chemicals to include data and studies that currently only exist in hard copy or in disparate TSCA databases. The information will be combined with publicly available sources to expand the amount of information available, enhancing chemical reviews and enabling efficient sharing of chemical information across EPA.

- Updating and augmenting the models used for predicting a chemical's physical-chemical properties and environmental fate/transport, hazard, exposure, and toxicokinetics to provide a suite of models to be used for new chemicals assessments. The goal of this effort is to update the models to reflect the best available science, increase transparency, and establish a process for updating these models as science evolves.

- Exploring ways to integrate and apply NAMs in new chemicals assessments, reducing the use of animal testing. The goal of this is to develop a suite of accepted, fit-for-purpose NAMs that could be used by external stakeholders for data submissions under TSCA as well as informing and expanding new chemical categories.

- Developing a decision support tool that integrates the various information streams specifically used for new chemical risk assessments. The decision support tool will more efficiently integrate all the data streams (e.g., chemistry, fate, exposures, hazards) into a final risk assessment and transparently document the decisions and assumptions made. This will facilitate the new chemicals program tracking decisions over time and evaluating consistency within and across chemistries.

In addition, the EPA has developed experience in conducting existing chemical risk assessments under TSCA for chemicals listed on the TSCA Work Plan, has increased its experience in the five years since the Lautenberg Act was enacted through work on existing chemical substance risk evaluations, and has used that experience to improve its management of the program. In 2020 and 2021, management and staff members participated in discussions to identify lessons learned from developing the first 10 risk evaluations. Desired outcomes from this process included (1) identification of best practices developed during the risk evaluation process; (2) identification of and solutions to problems common to multiple risk evaluations that, when addressed, produce increased efficiencies in risk evaluation production; and (3) identification of common areas in the risk evaluations for which improved technical methods may lead to more robust assessments.

Examples of best practices include:

- Creation of a library of external and peer review comments and responses that arise during risk evaluation. This will enable staff to efficiently address recurring questions with pre-approved responses.

- Documentation of a technical process for curating scientific citations, hundreds of which may occur in a single risk assessment.

- Documentation of a series of standard operating procedures and workflows for the different kinds of disciplinary analyses needed to develop a risk evaluation. This will provide clarity in conducting future analyses and training staff in assessment methods.

Examples of solutions to common problems include:

- Implementation of a risk assessment training series to provide consistent high-level training in risk assessment practices for staff.

- Development of a standard template for risk evaluation documents to ensure that content is comprehensive, consistently organized, easy for external readers to understand, and effective in supporting the EPA's development of risk management rules.

- Creation of a style guide and template to streamline development of consistently formatted risk assessment documents, which often reach 1,000 pages in length.

- Establishment of a central project management tool for achieving milestones as well as facilitating alignment of skill sets with project needs.

Examples of areas for which improved technical methods may be warranted include:

- Development of scientific approaches for evaluating aggregate (multi-pathway) and cumulative (multi-toxicant) risk.

- Development of broader scientific approaches for assessing risks to potentially exposed or susceptible subpopulations to broaden the relevance of risk assessments and better support the EPA's focus on environmental justice.

- Development of modernized approaches for assessing byproducts and transformational products associated with chemical substances undergoing risk assessment to better understand and manage the entire lifecycle of risk associated with chemicals of interest.

The EPA also has worked diligently to address the resource shortfalls discussed at length above. With regard to funding, the EPA has undertaken efforts to accurately identify the resources necessary to meet TSCA's expectations, including developing per-unit costs for a range of exiting chemical and new chemical actions. The EPA has used these estimates to develop accurate funding requests and to pursue all available funding.

Similarly, as discussed above, the EPA quantified and categorized its workforce needs in a workforce skills gap analysis that responded to recommendations from the EPA Office of Inspector General. The workforce analysis, developed in mid-FY 2021 after the submittal of the FY 2022 President's Budget Request, found that the EPA would likely have at least 165 fewer

employees on board than necessary to effectively implement TSCA, and that that staffing gap would grow to at least 199 employees by the end of FY 2025. The EPA has attempted to further close this overall FTE gap by using additional TSCA fees to support payroll costs for FTEs above appropriated levels. While helpful, TSCA fees are insufficient to close the entire workforce gap and using fees for payroll renders those funds unavailable for other critical needs.

The workforce skills gap analysis has proven helpful to the EPA in identifying the positions it needs to improve its implementation of TSCA. As discussed above, as a result of an increase in the FY 2022 enacted budget, the EPA is in the process of hiring new employees into positions identified as needing additional staffing to meet TSCA's requirements, including chemists, toxicologists, risk experts, economists, data analysts, and rule writers. Some of the TSCA program's most acute staffing needs, such as the scientific review of new chemicals, the systematic review of existing chemical data, and the development of rules for test orders and existing chemical risk management, are being partially addressed in this staffing effort. If the FTE resources requested in the FY 2023 President's Budget Request are provided, the EPA will be able to further fill the skills gaps identified in the agency's analysis.

In addition, OPPT has focused its efforts on hiring qualified employees for mission-critical positions in the risk assessment and risk management programs. Specifically, OPPT has standardized vacancy announcements and posts and augmented its hiring strategy through Schedule A Authority, student interns, Public Health Service Officers, and ORISE Fellows. OPPT also provided support to its front-line managers by developing team lead positions in each of the branches within its divisions. This allows for closer coordination of the functions within each branch and allows the branch supervisor to engage in more strategic leadership of the branch. OPPT has carefully analyzed employee departures from the office, including formalizing an exit interview process to understand key drivers for departures. With this information, strategies can be developed to retain employees, prepare to transfer knowledge, and replace those who retire. OPPT is actively recruiting and hiring new employees into critical science and regulatory positions to strengthen the agency's TSCA implementation efforts. The office will expend its entire FY 2022 FTE appropriation.

3. Conclusion

The EPA appreciates the consideration of Congress as the agency continues to deliver on TSCA within available resources. Through identification and communication of resources and EPA's capacity, improved collection of TSCA fees, and strategic workforce management, the EPA will continue to strive for progress on its implementation of TSCA.

This report fulfills the obligations of the EPA under TSCA section 26(m), after reporting to Congress within six months after the date of enactment of the Lautenberg Act, to resubmit an updated report five years thereafter.