

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

Prepared for the Committees on Energy and Commerce, and Appropriations of
the U.S. House of Representatives, and the Committees on Environment and
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1 Introduction

1.1 Overview of New Law

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law [P.L.114-182]), signed by President Obama on June 22, 2016, substantially amended the Toxic Substances Control Act (TSCA) to enhance public health, chemical safety and interstate commerce by providing the Environmental Protection Agency (EPA) with significant new authorities and obligations such as:

- **Clear and enforceable deadlines.** The EPA is now required to systematically prioritize and evaluate existing chemicals on a specific schedule. Within a few years, the EPA’s chemicals program will have to ensure that risk evaluations are being conducted on at least 20 chemicals at a time, beginning another chemical risk evaluation as soon as one is completed.
- **Requirement to evaluate chemicals purely on the basis of the health and environmental risks they pose.** Now, the EPA will have to evaluate a chemical’s safety purely based on the health and environmental risks it poses—including to susceptible and highly exposed populations, like children and the elderly, and to workers who use chemicals daily as part of their jobs—without consideration of costs or other non-risk factors and then take steps to eliminate any unreasonable risks the EPA finds.
- **Requirement to address risks:** EPA must take timely action to address identified risks, an activity known as “risk management” which may include, but is not limited to, labeling, restrictions, bans, and/or phase-outs, where warranted, so that the chemical in question will no longer present an unreasonable risk. However, when taking steps to reduce risk, the Administrator must consider if technically and economically feasible alternatives are available and if restriction on a condition of use would disrupt the national economy, national security, or critical infrastructure.
- **Requirement that the EPA make an affirmative determination on every new chemical.** Previously, new chemicals were allowed to enter the marketplace unless the EPA made a specific determination that regulatory controls were needed. Now, an affirmative safety determination must be made before a new chemical can enter the marketplace and before a significant new use is allowed for an existing chemical.
- **Increased 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.
- **A source of sustainable funding for the EPA to carry out its new responsibilities.** The EPA will now be able to collect 25 percent of its costs for administering certain sections of TSCA as amended, or up to \$25 million a year for the first three years, whichever is less, in user fees from chemical manufacturers and processors, supplemented by congressional budgeting, to pay for implementation of the amended law.

1.2 Purpose of this Report

Under section 26(m)(1) of TSCA as amended, the EPA is required to submit this initial report to Congress not later than 6 months after the date of enactment. The agency is directed to include several elements in the report, including descriptions of the EPA's capacity to conduct and publish risk evaluations under TSCA sections 6(b)(4)(C)(i) and (ii) and 6(b)(2) and the resources necessary to conduct such risk evaluations, the likely demand for risk evaluations and the anticipated schedule for accommodating that demand under TSCA section 6(b)(4)(C)(ii), and EPA's capacity to promulgate rules to address risks identified in these risk evaluations under TSCA section 6(a) as required, based on risk evaluations conducted and published under TSCA section 6(b). The EPA is also directed to discuss efforts to increase capacity to conduct and publish the EPA-initiated risk evaluations under TSCA section 6(b).

1.3 Overview of Relevant Statutory Requirements

1.3.1 EPA-Initiated Risk Evaluations

Under TSCA section 6(b)(2)(A), the EPA is required to ensure that risk evaluations are being conducted on 10 chemical substances within 180 days of enactment. The law further requires that these first 10 chemicals be drawn from the 90 chemicals on the EPA's TSCA Work Plan. On November 29, 2016, the EPA named the first 10 chemicals that will undergo risk evaluation under the new law: <https://www.epa.gov/newsreleases/epa-names-first-chemicals-review-under-new-tsca-legislation>. From publication date, December 19, 2016, EPA has a three-year timeframe, by law, to complete risk evaluations for these chemicals.

For the EPA-initiated risk evaluations beyond these first 10 chemicals, the EPA must establish a risk-based prioritization process to determine which chemicals will be evaluated, identifying them as either "high" or "low" priority substances as set forth in TSCA section 6(b)(1)(A). A high priority designation is required when the EPA determines, without consideration of cost or other non-risk factors, that the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and a potential route of exposure, including to susceptible subpopulations [TSCA section 6(b)(1)(B)]. High priority designation triggers a requirement that the EPA conduct a risk evaluation to determine whether a 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 [TSCA section 6(b)(4)(A)]. The amended law requires that these risk evaluations include all known or reasonably foreseen uses of the chemical, while requiring that they be completed within 3 years (with a possibility of 6-month extension) [TSCA section 6(b)(4)(G)].

Under TSCA as amended, the EPA is required to begin a risk evaluation for a new chemical each time a risk evaluation (other than an industry-requested evaluation) is completed such that the EPA maintains the pace of at least 20 EPA-initiated risk evaluations underway from the end of calendar year (CY) 2019 forward [TSCA section 6(b)(2)]. The EPA plans to initiate additional risk evaluations in 2018 and 2019, ramping up to having twenty EPA-initiated risk evaluations underway by the end of CY 2019.

1.3.2 Manufacturer-requested Evaluations

TSCA section 6(b)(4)(C)(ii) provides a mechanism for manufacturers to submit a request that the EPA evaluate specific chemicals as prescribed by a risk evaluation process rule mandated by the new law. The new law also gave 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 EPA's 2014 Work Plan, as an alternative to expedited risk management action as described in "Section 6 Risk Management Rules" below. Requests for risk evaluations were made for two such chemicals that can be used in fragrance mixtures. As a result, the EPA will be evaluating these two PBT chemicals.

For these manufacturer-requested risk evaluations, if the EPA receives a sufficient number of compliant requests, the law requires that they account for between 25-50 percent of the number of the EPA-initiated risk evaluations. Under full implementation (meaning, that the full number of risk evaluations actions are underway), the EPA will be undertaking 5-10 manufacturer-requested evaluations assuming that not more than 20 EPA-initiated evaluations are underway and that sufficient requests are made that comply with the criteria EPA is required to promulgate as mandated by the new law. In resourcing the costs for these manufacturer-requested risk evaluations, the law requires that manufacturers requesting evaluations pay costs as follows:

- For chemicals on the TSCA Work Plan, manufacturers pay 50 percent of costs of the risk evaluations.
- For all other chemicals, manufacturers pay 100 percent of the costs of risk evaluation.

1.3.3 Section 6 Risk Management Rules

When unreasonable risks are identified, the EPA generally must finalize risk management actions within two years, or four years if an extension is needed. [TSCA section 6(c)(1)] Costs, benefits of the substance, and other factors will be considered when determining appropriate action to address risks. Risk management rules must require full compliance as quickly as practicable. For requirements other than ban and phase-out requirements, rules must require full compliance by no later than five years after promulgation; bans or phase-outs must begin no later than five years after promulgation and be completed as soon as practicable. [TSCA section 6(d)].

Under TSCA section 6(h), there is a specific process to address certain PBT chemicals on the 2014 TSCA Work Plan. For these chemicals, unless a manufacturer requests that they undergo a risk evaluation, a risk evaluation is not required if EPA determines that exposure is likely, and action to reduce exposure to the extent practicable must be proposed no later than three years after enactment and finalized 18 months later. The EPA determined that seven chemicals met the PBT criteria set forth in the new law and subsequently received a request that two be evaluated under TSCA section 6(b). The remaining five PBT chemicals are being addressed as noted above.

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

The EPA is continuing to expeditiously implement the provisions of the new law, which became effective upon enactment. An overview of the immediate actions and other early steps that the EPA is undertaking in our First-Year TSCA Implementation Plan are found here: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-5>.

For purposes of this report, as directed under section 26(m)(1) of TSCA as amended, estimated resources necessary to conduct the anticipated minimum number of risk evaluations is provided as well as information on capacity specifically related to risk evaluations and associated promulgation of rules.

2.1 Estimated Resources Necessary for Risk Evaluations

The estimates for resources necessary for risk evaluations take into account the requirement to identify 10 chemicals for risk evaluation by 180 days after enactment and to complete these risk evaluations within a three-year timeframe from publication of the list of chemicals. In addition, EPA must have at least 20 EPA-initiated risk evaluations underway from the end of CY2019 forward. To accomplish an ongoing pace of at least 20 EPA-initiated risk evaluations underway by the end of CY2019, EPA anticipates ramping up from 10 risk evaluations in FY2017 to 15 in FY2018, reaching 20 by the end of FY2019.

In addition to the EPA-initiated risk evaluations, TSCA section 6(b)(4)(C)(ii) provides a mechanism for manufacturers to submit a request that the EPA evaluate specific chemicals. The new law also gave manufacturers an opportunity to request, by September 19, 2016, that the EPA conduct risk evaluations for certain persistent, bioaccumulative, and toxic (PBT) chemicals. Requests for risk evaluations were made for two such chemicals. In addition to the PBT chemicals, in a given year EPA currently estimates two manufacturer-requested evaluations underway for work plan chemicals and five to eight underway for non-work plan chemicals. This preliminary estimate is based on the possibility manufacturers may request a greater number of non-work plan chemicals be evaluated sooner than may otherwise occur under the prioritization process.

The estimates presented in the following table are for the EPA's annual costs, which are calculated by dividing the average lifecycle costs of the actions (estimated \$3.7 million per evaluation) by the number of years the statute provides for the agency to complete those actions (without the extension options provided in the statute), and then multiplying the result by the numbers of actions required/anticipated to be underway each year. See footnote explaining how risk evaluations for PBTs affect the numbers in the tables.

These are our best current estimates and in some areas costs may vary from averages. Separate estimates are provided for the EPA-initiated evaluations required under the statute and for manufacturer-requested risk evaluations (broken out between evaluations of chemicals on the

TSCA Work Plan¹ and for evaluation of chemicals not on the TSCA Work Plan²). Under full implementation (meaning, that the full number of risk evaluations actions are underway), the EPA will be undertaking 5-10 manufacturer-requested evaluations assuming that not more than 20 EPA-initiated evaluations are underway and that sufficient requests are made that comply with the required criteria. Our best current estimates for risk evaluations include both direct and indirect factors.

Note also that actions prompted by TSCA Section 21 Petitions are not addressed in this report as the number, nature and complexity of these petitions are unknown. However, it should be noted, the agency does expect to receive petitions under the new law which may result in additional risk evaluations.

Table 1: TSCA Risk Evaluations, Numbers Underway and Resources Estimates

	Total Dollars (Pay + Non-Pay) in Millions					
	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	Full³
Risk Evaluations						
<i>EPA-Initiated</i>						
Number Underway	10	15	20	20	20	20
Direct Annual Cost	\$10.0	\$15.1	\$20.1	\$20.1	\$20.1	\$20.1
Total Annual Cost	\$12.3	\$18.5	\$24.7	\$24.7	\$24.7	\$24.7
<i>Manufacturer-Requested: 50 percent Fee⁴</i>						
Number Underway	0	4	4	4	2	2
Direct Annual Cost	\$0.0	\$3.0	\$3.0	\$3.0	\$1.0	\$1.0
Total Annual Cost	\$0.0	\$3.7	\$3.7	\$3.7	\$1.2	\$1.2
<i>Manufacturer-Requested: 100 percent Fee</i>						
Number Underway	0	5	8	8	8	8
Direct Annual Cost	\$0.0	\$5.1	\$8.1	\$8.1	\$8.1	\$8.1
Total Annual Cost	\$0.0	\$6.2	\$9.9	\$9.9	\$9.9	\$9.9
<i>Total</i>						
Number Underway	10	24	32	32	30	30
Direct Annual Cost	\$10.0	\$23.2	\$31.2	\$31.2	\$29.2	\$29.2
Total Annual Cost	\$12.3	\$28.4	\$38.3	\$38.3	\$35.8	\$35.8

¹ For manufacturer-requested risk evaluations of TSCA Work Plan chemicals, user fees are set by the statute at 50 percent of the costs and EPA anticipates that the incidence of such evaluations identifying unreasonable risks will be the same as for the EPA-initiated evaluations (90 percent) because TSCA Work Plan chemicals had been identified as risk assessment priorities.

² For manufacturer-requested risk evaluations of chemicals not on the TSCA Work Plan, user fees are set by the statute at 100 percent of the costs. The EPA anticipates that the incidence of such evaluations identifying unreasonable risks will be less than that for the EPA-initiated evaluations, as manufacturers may request evaluations for chemicals they believe will not present significant risks. Pending future experience, the EPA developed an initial assumption that 50 percent of these evaluations will result in findings of unreasonable risks.

³ The Full column reflects a generic future year when the EPA's implementation of all provisions of the statute have reached specified minimum levels.

⁴ Two PBTs to be assessed under TSCA section 6(h) are included in the Manufacturer-Requested: 50 percent Fee category commencing in FY 2018. These are expected to be completed in FY 2020, after which the estimated number of evaluations underway in this category is comprised of two other evaluations per year.

2.2 Statutory Requirements for Appropriations and Fees

Under TSCA section 26(b), the EPA is authorized to set fees which will ensure a sustainable source of funding to annually defray 25 percent of the costs to the Administrator of carrying out sections 4, 5 and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure, as appropriate, chemical information under section 14. For the first three years, fees are subject to a \$25 million cap. Thereafter, the fees can be adjusted on a recurring three-year basis for inflation, and to ensure the fees continue to be set at a level that is designed to defray 25 percent of the EPA's annual costs. [TSCA section 26(b)(4)(F)].

A rule to implement the fee collection provisions of the new law is currently under development. The EPA actively engaged with industry in 2016 to gather input on the potential fee structure. A one-day public meeting was held in August, an industry-specific consultation meeting was held in September, and a docket was opened to collect written comments from the public.

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 FY 2014 [TSCA section 26(b)(5)].

2.3 Capacity to Implement Specific Provisions of the Law

The EPA developed experience in conducting chemical risk assessments under TSCA over the past several years under the TSCA Work Plan Chemicals approach. This resulted in issuance of the first five chemical risk assessments under TSCA in more than 20 years, three of which identified risks warranting exercise of TSCA section 6 regulatory authorities. Through that experience, the EPA developed a better understanding of capacity needs, including skill sets, level of effort, and infrastructure.

The new law calls for a more comprehensive review of each chemical and its uses, accelerates the EPA's pace in undertaking assessments, mandates completion timeframes and requires immediate commencement of work to develop section 6 rules where risks are identified. The substantially increased requirements and tight deadlines under the new law require increased staffing levels and contractor resources dedicated to conducting and publishing risk evaluations and promulgating rules based on the risk evaluations. The agency has developed much of the needed experience to address these requirements and has begun bringing on the additional staff and contractor support needed. The agency is considering and expanding options to reduce the long lead times to bring on the highly skilled staff and specialized contractors needed for these scientifically demanding, technically complex tasks. The agency is also conducting in-house training of new and existing staff to better equip them to meet the expanded requirements and accelerated time frames for the risk evaluations and management actions.

In addition, implementation of TSCA as amended will necessitate a faster pace for information technology (IT) infrastructure and process improvements. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) is making progress on these systems and processes improvements and is also establishing a central project management tool for achieving milestones as well as facilitating alignment of skill sets with project needs. Further, as risk management actions are taken, additional regional work and agency implementation activities, such as education, outreach

and partnerships with external stakeholders, will be needed to ensure the efficacy and efficiency of the TSCA program.

3 Summary

TSCA as amended, provides the EPA with significant new authorities and obligations such as: clear and enforceable deadlines; requirement to evaluate chemicals purely on the basis of the health and environmental risks they pose, to address risks, and make an affirmative determination on every new chemical; increased transparency of chemical data while protecting legitimate confidential information; and a source of sustainable funding for the EPA to carry out its new responsibilities. The EPA is continuing to expeditiously implement the provisions of the new law, which became effective upon enactment.

Under TSCA section 26(b), the EPA is authorized to set fees which will ensure a sustainable source of funding to annually defray 25 percent of the costs of carrying out TSCA sections 4, 5 and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure as appropriate chemical information under TSCA section 14. For the first three years, fees are subject to a \$25 million cap and can be adjusted on a recurring three-year basis for inflation or if fees no longer are adequate to defray 25 percent of the EPA's annual costs described above [TSCA section 26(b)(4)(F)].

The EPA looks forward to a continued partnership with Congress to successfully implement the provisions of this law which created a framework and roadmap for taking regulatory action to enhance public health, chemical safety and interstate commerce. The Executive Branch will keep Congress updated as resource estimates are refined and the understanding of the workload becomes clearer.