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Title I of the Toxic Substances Control Act (TSCA): A Summary of the Statute

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Title I of the Toxic Substances Control Act (TSCA): A Summary of the Statute

In 1976, Congress enacted the Toxic Substances Control Act (TSCA; P.L. 94-469) to direct the U.S. Environmental Protection Agency (EPA) to evaluate the lifecycle (i.e., manufacture, importation, processing, distribution, use, and disposal) of industrial and commercial chemicals for “unreasonable risks” and, if warranted, to regulate such chemicals. In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA; P.L. 114-182) to amend Title I of TSCA due, in part, to long-standing concerns that EPA lacked sufficient authority to obtain information and regulate chemicals that present unreasonable risks.

TSCA, as amended, requires EPA to gather existing information from chemical manufacturers, processors, and distributors about risks that industrial and commercial chemicals may present to human health or the environment. Prior to introducing a new chemical into commerce, its manufacturer must notify EPA to allow the agency to evaluate the chemical for unreasonable risks. Similar notification requirements apply to existing chemicals proposed for uses determined by EPA to be “significant new uses.”

If EPA has inadequate information about a chemical to determine whether it presents unreasonable risks, the agency may require the manufacturer to develop new information necessary to evaluate risks. TSCA establishes a framework to protect from disclosure submitted information that warrants confidential treatment.

To identify which chemicals may warrant regulation, TSCA requires EPA to systematically prioritize chemicals for risk evaluation. Based on the evaluation, EPA must regulate those chemicals that present unreasonable risks to ensure they no longer do so. Regulatory options available to EPA range from labeling requirements to an outright ban on manufacturing. TSCA directs EPA to take expedited action on chemicals that exhibit characteristics known to present greater risks. Additionally, TSCA authorizes EPA to expedite review of chemicals that present significant risk of serious or widespread harm and initiate enforcement actions against imminently hazardous chemicals.

Requirements for chemicals regulated under TSCA apply to chemicals manufactured in the United States and imported into the United States. TSCA establishes additional procedures for handling imports of chemicals for which EPA has promulgated requirements under the act. Chemicals marked for export only are subject to recordkeeping and reporting requirements unless EPA has required the development of new information or established a requirement to protect against unreasonable risk.

TSCA authorizes citizen petitions and citizen suits to challenge EPA’s implementation of the act and enforce certain requirements under the act through litigation. Additionally, TSCA includes enforcement provisions and establishes civil and criminal penalties for violations.

TSCA does not allow chemical evaluation and restriction to be delegated to states. While states may evaluate and regulate chemicals under their own authorities, TSCA provides an explicit, though limited, preemption of state requirements for chemicals that EPA has evaluated and either determined to present no unreasonable risks or regulated to protect against unreasonable risks. TSCA generally preserves long-standing state requirements and allows preemption waivers under certain circumstances.

Congress funds TSCA activities through annual discretionary appropriations. TSCA also authorizes EPA to collect fees from chemical manufacturers and processors to partially defray costs that the agency may incur from implementing the statute.

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Introduction

In 1976, President Ford signed into law the Toxic Substances Control Act (TSCA), which requires the U.S. Environmental Protection Agency (EPA) to identify and regulate chemicals in U.S. commerce that present an “unreasonable risk of injury to health or the environment” or an imminent hazard.¹ In proposing the legislative framework for TSCA, the Council on Environmental Quality (CEQ) of President Nixon’s Administration highlighted concerns with risks from metals (e.g., lead, cadmium, mercury, and vanadium), metal compounds, and synthetic organic chemicals (e.g., polychlorinated biphenyls, nitrilotriacetic acid, orthonitrochlorobenzene). CEQ noted that pollution control and consumer or occupational safety statutes in effect at the time limited the federal government to controlling pollution at the end of the chemical lifecycle or restricting chemicals that have specific uses (e.g., pesticides, food).²

Since TSCA was originally enacted, Congress has added five other titles to TSCA to address specific chemical concerns.³ The original 1976 act is referred to as Title I, which is the focus of this report. The additional titles did not amend the core chemical evaluation and regulatory program under Title I and therefore are not discussed in this report.

To determine which chemicals warrant regulation under TSCA, EPA requires chemical manufacturers, importers, and processors to provide certain information about the manufacture, importation, and processing of chemicals to the agency. When EPA determines that it does not have adequate information to evaluate risks of a particular chemical, the agency may require chemical manufacturers and processors to develop new information necessary to evaluate risks.

Based on the evaluation of information available to the agency, EPA has restricted few chemicals reported to have been in commerce prior to 1976. EPA has promulgated regulations to prohibit or restrict the following chemicals under TSCA:

- chlorofluorocarbons used in aerosol propellants;
- nitrosamines in metalworking fluids;⁴
- hexavalent chromium used in certain water cooling towers;⁵
- certain uses of asbestos in paper products and any proposed new use of asbestos after 1990;⁶
- dioxin-contaminated wastes;
- polychlorinated biphenyls not used in a totally enclosed manner;⁷
- methylene chloride for certain consumer uses;⁸ and
- certain persistent, bioaccumulative, and toxic chemicals.⁹

¹ P.L. 94-469. TSCA, as amended, is codified at 15 U.S.C. §2601 *et seq.*

² CEQ, *Toxic Substances*, 1971.

³ The other specific chemical concerns include asbestos (Title II), indoor radon (Title III), lead-based paint (Title IV), environmental exposures in schools (Title V), and formaldehyde in composite wood products (Title VI).

⁴ 40 C.F.R. Part 747.

⁵ 40 C.F.R. Part 749.

⁶ 40 C.F.R. Part 763, Subpart I.

⁷ 40 C.F.R. Part 761.

⁸ 40 C.F.R. Part 751, Subpart B.

⁹ 40 C.F.R. Part 751, Subpart E. Bioaccumulation generally refers to the retention of a chemical in an organism at ever-

Regulations that pertain to chlorofluorocarbons and dioxin-contaminated wastes under TSCA were later superseded by regulations promulgated under other environmental statutes.

For chemicals introduced into commerce after 1976, EPA established a program to identify which of those chemicals warranted regulation.¹⁰ Through that program, EPA has taken regulatory action to restrict a subset of such chemicals based on an evaluation of available risk information.¹¹ Over time, environmental and public health organizations began to question whether the agency had sufficient information to evaluate risks from chemicals and whether the threshold for regulating a chemical was attainable.¹² To address these issues and other concerns, several Members introduced proposals to amend TSCA beginning in the 109th Congress.¹³

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA; P.L. 114-182), which amended Title I of TSCA.¹⁴ The LCSA broadly amended EPA's information gathering, chemical evaluation, and regulatory authorities under TSCA and provided additional procedures and standards for confidential treatment or disclosure of information submitted to EPA under TSCA. To supplement funding provided for TSCA implementation, the LCSA expanded EPA's authority to collect fees from chemical manufacturers and processors to partially defray the costs of conducting risk evaluations.

In broad terms, TSCA, as amended, establishes a multistep prioritization and review process for existing chemicals. Under this revised process, EPA must

1. identify chemicals to prioritize for evaluation;
2. establish the scope of the risk evaluation for each selected chemical substance;
3. conduct risk evaluations for each selected chemical substance; and
4. implement regulations to restrict or prohibit the manufacture, processing, distribution, or use of the chemical substances as appropriate.¹⁵

TSCA also generally prohibits specific state and local actions, and it restricts the reach of those prohibitions through limitations, exceptions, and waivers.¹⁶ As originally enacted, TSCA

increasing levels.

¹⁰ To implement TSCA Section 5 (15 U.S.C. §2604), EPA established a program to evaluate chemicals introduced into commerce after 1976 (i.e., new chemicals). EPA, "Toxic Substances Control Act; Premanufacturing Notification Requirements and Review Procedure; Statement of Interim Policy," 44 *Federal Register* 28564, May 15, 1979.

¹¹ See "Statistics Prior to June 22, 2016" tab at EPA, "Statistics for the New Chemicals Review Program under TSCA," last updated June 11, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

¹² For at least a decade prior to the enactment of amendments to TSCA in 2016, several congressional committees held hearings that offered the opportunity for different stakeholders, including environmental and public health organizations, to present their perspectives on the implementation of TSCA. For example, see testimony from U.S. Congress, Senate Committee on Environment and Public Works, *Strengthening Public Health Protections by Addressing Toxic Chemical Threats*, 113th Cong., 1st sess., July 31, 2013, S. Hrg. 113-724 (Washington: GPO, 2015).

¹³ In the 109th Congress, the Kid Safe Chemicals Act (S. 1391, H.R. 4308) would have amended TSCA for various purposes. Between the 109th and 114th Congresses, at least one bill that would amend TSCA was introduced in each Congress.

¹⁴ For committee reports of bills reported to the House and Senate that resulted in the LCSA, see U.S. Congress, House Committee on Energy and Commerce, *TSCA Modernization Act of 2015*, report to accompany H.R. 2576, 114th Cong., 1st sess., June 23, 2015, H.Rept. 114-176 (Washington: GPO, 2015); and U.S. Congress, Senate Committee on Environment and Public Works, *Frank R. Lautenberg Chemical Safety for the 21st Century Act*, report together with minority views to accompany S. 697, 114th Cong., 1st sess., June 18, 2015, S.Rept. 114-67 (Washington: GPO, 2015).

¹⁵ 15 U.S.C. §2605.

¹⁶ 15 U.S.C. §2617.

contained a preemption provision; the 2016 amendments established additional conditions in which TSCA requirements would or would not preempt state chemical regulatory requirements.

This report summarizes the major authorities of TSCA through the following topics:

1. the overall scope and applicability of authorities under TSCA;
2. the information gathering authorities;
3. the confidentiality and disclosure of information submitted to EPA under the act;
4. the framework for prioritizing chemicals for evaluation, evaluating risks, and regulating those chemicals that present unreasonable or imminent risks;
5. the applicability of the act to chemical imports;
6. the requirements for chemical export notification;
7. the process of filing citizen petitions and bringing citizen suits;
8. the enforcement of the act;
9. the federal and state roles under the act; and
10. the resources to administer the act.

In some cases, the discussion of certain topics may align with a specific section of TSCA, but other topics involve multiple sections or subsections of TSCA.

Chemicals Covered by TSCA and Limitations on Authority

TSCA applies to “chemical substances,” which the statute defines broadly to include substances that have a “particular molecular identity.”¹⁷ To avoid redundancy with other federal pollution control and public health laws, Congress generally excluded from regulation under TSCA groups of chemicals where the risks were considered sufficiently addressed under such other laws.¹⁸ Congress also specifically excluded the following substances without regard to their regulation under other laws:

- pesticides;
- tobacco and tobacco products;
- certain radioactive materials;
- firearms (including pistols and revolvers), shells, cartridges, and their components;¹⁹
- food (including poultry, meat, and eggs), food additives (including food contact substances), drugs, cosmetics, and medical devices; and
- mixtures.²⁰

¹⁷ 15 U.S.C. §2602(2).

¹⁸ 15 U.S.C. §2608. See *infra* “Unreasonable Risk” Threshold and Relationship with Other Federal Laws.”

¹⁹ Relatedly, Section 108 of America’s Conservation Enhancement Act (P.L. 116-188) prohibits EPA from taking any action to regulate lead content of sport fishing equipment or sport fishing equipment components under TSCA for five years after enactment (i.e., until October 30, 2025). This provision is codified as a note to 15 U.S.C. §2601.

²⁰ 15 U.S.C. §2602(2). TSCA Section 3(10) (15 U.S.C. §2602(10)) defines “mixtures” as combinations of chemical substances not resulting from a chemical reaction.

Since these exclusions are generally framed based on the intended uses of a chemical substance (e.g., a pesticide), the same chemical substance may be subject to TSCA and other federal pollution control and public health laws depending on the intended use. For example, EPA has examined the risks of bisphenol A under TSCA with regard to its use in manufacturing polycarbonate plastics and epoxy resins.²¹ However, the use of bisphenol A as a food contact substance is not covered by TSCA based on the statutory exclusion.

Although the definition of a chemical substance excludes mixtures, multiple TSCA provisions apply to mixtures. References hereinafter to “chemicals” in the report collectively refer to chemical substances and mixtures. Provisions that apply only to chemical substances or mixtures are noted accordingly.

Generally, a mixture is subject to requirements under TSCA if the requirements that pertain to its constituent chemical substances will not result in adequate evaluation or control of the risks anticipated from the mixture.²² Additionally, as a practical matter, articles (i.e., manufactured items) that contain chemical substances subject to TSCA may be regulated by the act to the extent that those chemical substances present an unreasonable risk or meet other criteria.

“Unreasonable Risk” Threshold and Relationship with Other Federal Laws

In addition to excluding groups of chemicals from the scope of chemicals covered under TSCA, Congress generally limited the extent to which EPA may regulate a chemical. For example, EPA must make an *unreasonable risk* finding or determination before requiring information on, or regulating, a chemical.²³ TSCA does not explicitly define what constitutes an unreasonable risk. In 1991, the U.S. Court of Appeals for the Fifth Circuit held that the “unreasonable risk” standard as originally set forth in TSCA meant that “[i]n evaluating what is ‘unreasonable,’ the EPA is required to consider the costs of any proposed actions and to ‘carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.’”²⁴ This interpretation led the court to vacate parts of the 1989 EPA rule that regulated various asbestos uses.

Though the LCSA did not amend TSCA to explicitly define *unreasonable risk*, it prohibited EPA from considering cost or nonrisk factors when evaluating risks.²⁵ However, EPA must consider “reasonably ascertainable economic consequences” and other nonrisk factors when restricting uses of a chemical.²⁶ Additionally, the LCSA codified existing agency practice to consider risks for “potentially exposed or susceptible subpopulations” when evaluating the risks of a chemical.²⁷

²¹ EPA, “Risk Management for Bisphenol A (BPA),” last updated March 4, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-bisphenol-bpa>.

²² For example, see 15 U.S.C. §§2603(a)(1)(B), 2607(a)(1)(B).

²³ For example, see 15 U.S.C. §§2603(a)(1)(A)(i)(I), §2604(f), and §2605(a).

²⁴ *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1222 (5th Cir. 1991) (quoting prior version of 15 U.S.C. §2601(c)).

²⁵ For example, see P.L. 114-182 §§5(1)(B), 6(3) (amending TSCA to add Sections 5(a)(3) and 6(b)(4) and specifying that risk evaluations and unreasonable risk determinations are “without consideration of costs or other nonrisk factors”).

²⁶ For example, see P.L. 114-182 §6(4) (adding Section 6(c)(2) to TSCA to require the consideration of various factors in promulgating a rule to restrict a chemical).

²⁷ A list of risk assessment guidelines is available at EPA, “Risk Assessment Guidelines,” last updated February 2, 2021, <https://www.epa.gov/risk/risk-assessment-guidelines>. Several guidelines discuss evaluating risks for potentially

Even if EPA concludes under TSCA that a chemical presents an unreasonable risk, TSCA provides that other federal laws supersede EPA's authority under TSCA to address unreasonable risks. If EPA determines that a risk associated with a chemical may be sufficiently eliminated or reduced by actions taken under other federal laws that the agency administers, Section 9(b) requires the agency to use those authorities to protect against the risk unless the agency determines that it is in the public interest to take action under TSCA.²⁸

If EPA determines that a chemical presents an unreasonable risk that may be sufficiently prevented or reduced by action taken under a federal law a different federal agency administers, Section 9(a) directs EPA to submit to that other agency a report describing the risk and a request for a response.²⁹ A federal agency that receives such a report from EPA must respond within 90 days (or a shorter period if specified by EPA). If that federal agency issues an order disagreeing with EPA about the unreasonable risk or initiates action to protect against such risk, then EPA may not regulate the chemical under TSCA.³⁰

Use of Scientific and Technical Information

Under TSCA, EPA relies on scientific and technical information about a chemical to evaluate risks associated with the chemical and determine whether to regulate the chemical. The chemical industry and environmental and public health organizations have contested on occasion the quality of scientific and technical information that EPA has relied upon to make regulatory decisions under TSCA.³¹ To that end, the LCSA added various provisions specifying how EPA is to use scientific and technical information to carry out the act.

In determining whether to require development of new information about a chemical or whether to regulate a chemical that presents unreasonable risks, EPA must consider the “best available science” and any applicable factors generally used to assess the quality of scientific information.³²

exposed or susceptible subpopulations such as children. For example, see EPA, “Guidelines for Exposure Assessment,” EPA/600/Z-92/001, May 1992. Section 3(4) of the LCSA added Section 3(12) to TSCA to define “potentially exposed or susceptible subpopulation,” which is referenced in various provisions relevant to evaluating risks, added by the LCSA to TSCA.

²⁸ 15 U.S.C. §2608(b)(1). EPA administers various federal pollution control laws, such as the Clean Air Act, Clean Water Act, Safe Drinking Water Act, Solid Waste Disposal Act, and Federal Insecticide, Fungicide, and Rodenticide Act.

²⁹ 15 U.S.C. §2608(a). For example, in 1985, EPA referred 1,3-butadiene to the Occupational Safety and Health Administration (OSHA) of the Department of Labor. EPA, “1,3-Butadiene; Decision to Report to the Occupational Safety and Health Administration,” 50 *Federal Register* 41393, October 10, 1985. In February 1986, EPA and the Department of Labor entered into a memorandum of understanding that established a process for notification and consultation for TSCA Section 9(a) reports intended for submission to OSHA. EPA and the Department of Labor, *Memorandum of Understanding Between the Environmental Protection Agency and the Department of Labor*, EPA Agreement No. PW 16931704-01-1, February 6, 1986, <https://www.osha.gov/laws-regs/mou/1986-02-06>.

³⁰ For example, in 1986, OSHA announced initiation of a regulatory action on 1,3-butadiene to address unreasonable risks that EPA had identified and referred to OSHA. OSHA, “Occupational Exposure to 1,3-Butadiene,” 51 *Federal Register* 35003, October 1, 1986.

³¹ See, for example, *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1211 (5th Cir. 1991); Opening Briefs for Petitioners Neighbors for Environmental Justice et al. and for Petitioners State of New York et al., *Neighbors for Env't Justice v. EPA*, No. 20-72091, Doc. Nos. 39 at 52-55, 42 at 49-56 (9th Cir. Jan. 25, 2021).

³² 15 U.S.C. §2625(h).

EPA must also consider “reasonably available information” that relates to chemicals’ conditions of use³³ and make decisions based on the “weight of the scientific evidence.”³⁴

More generally, EPA must develop policies, procedures, and “guidance” necessary to carry out the amendments to TSCA made by the LCSA.³⁵ EPA must periodically review these policies, procedures, and guidance for their adequacy in carrying out the law and revise them if necessary to reflect new scientific developments or understandings.

Related to the requirements on the use of scientific and technical information, the LCSA directs EPA to establish a Science Advisory Committee on Chemicals (SACC) to provide nonbinding, independent scientific and technical advice to the agency regarding implementation of the act.³⁶ SACC held its first in-person meeting in June 2019 to discuss EPA’s draft risk evaluation for C.I. Pigment Violet 29.³⁷ Since then, SACC has convened multiple times to provide scientific review to other EPA draft risk evaluations.

Recordkeeping and Reporting Requirements and Confidentiality or Disclosure of Information

The information gathering framework under TSCA uses various recordkeeping and reporting requirements to provide EPA with sufficient information to evaluate chemical risks, while prohibiting EPA from disclosing information that, if disclosed, may harm commercial interests.

Through the reporting requirements, EPA receives from chemical manufacturers, processors, and distributors existing information on (1) chemicals already being manufactured or processed for commercial purposes, (2) new chemicals, and (3) chemicals proposed for uses determined by EPA to be significant new uses. If EPA determines that the information available to the agency is insufficient to evaluate a chemical’s risks and determines that additional information is necessary, EPA may require chemical manufacturers, processors, and distributors to develop new information.

Because information that EPA obtains may contain material that, if disclosed, would harm commercial interests, TSCA prohibits the disclosure of submitted information for which the submitter has claimed and justified the need for confidentiality. EPA regulations establish procedures to protect such confidential business information from public disclosure.

³³ Section 3(4) of TSCA defines “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. §2602(4).

³⁴ 15 U.S.C. §2625(i) and (k).

³⁵ 15 U.S.C. §2625(l). For purposes of TSCA, Section 3(6) (15 U.S.C. §2602(6)) defines the term *guidance* to mean any “significant” written guidance of general applicability prepared by EPA.

³⁶ 15 U.S.C. §2625(o). As a federal advisory committee, the Science Advisory Committee on Chemicals is subject to Federal Advisory Committee Act (FACA) requirements in addition to relevant TSCA requirements. For more information on FACA requirements, see CRS Report R44253, *Federal Advisory Committees: An Introduction and Overview*, by Meghan M. Stuessy.

³⁷ For more information on the SACC and its activities, see EPA, “TSCA Scientific Peer Review Committees,” last updated October 1, 2020, <https://www.epa.gov/tsc-peer-review>.

Existing Information Regarding Chemical Risks

Section 8 directs EPA to promulgate rules that require chemical manufacturers and processors (other than small manufacturers and processors) to maintain records pertaining to the chemicals they use.³⁸ EPA may require these records to include information such as chemical identity, uses, volumes produced, byproducts, health and environmental effects, exposure, and disposal methods.³⁹ EPA may also require chemical manufacturers and processors to report such records to the agency.⁴⁰ For small manufacturers and processors, EPA may promulgate recordkeeping and reporting requirements only for chemicals for which the agency has already required the development of new information or that are already regulated under the act.⁴¹

Based on information gathered by EPA, the agency must maintain a list of chemical substances manufactured or processed for commercial purposes in the United States.⁴² EPA refers to this list as the TSCA Inventory. The list includes approximately 60,000 chemical substances that were reported to the agency soon after the original enactment of TSCA.⁴³ EPA refers to these substances as “existing” substances.⁴⁴ New chemical substances are to be listed on the inventory upon their manufacture in the United States.⁴⁵ The list excludes substances that are manufactured or processed in small quantities for research and development, and chemicals that were not manufactured or processed in the United States within three years before the effective date of EPA’s recordkeeping rules.⁴⁶ Since the original enactment of TSCA, more than 26,000 chemical substances have been added to the TSCA Inventory as new chemical substances. The LCSA amended TSCA Section 8 to require EPA to divide the TSCA Inventory into “active substances” and “inactive substances,” depending on whether or not the substance was manufactured or processed between June 2006 and June 2016.⁴⁷ Based on reporting from chemical manufacturers and processors, EPA determined that over 41,000 chemical substances on the TSCA Inventory met the criteria for designation as “active substances.”⁴⁸

³⁸ 15 U.S.C. §2607(a)(1).

³⁹ 15 U.S.C. §2607(a)(2).

⁴⁰ 15 U.S.C. §2607(a). EPA regulations establishing recordkeeping and reporting requirements under TSCA are codified at 40 C.F.R. Parts 704, 711, and 712. Reporting may be required for exceeding certain manufacturing or processing volume thresholds at a single site or for specific chemicals, such as nanoscale materials.

⁴¹ 15 U.S.C. §2607(a)(3). For purposes of defining small manufacturers and processors subject to recordkeeping and reporting requirements, EPA, after consultation with the Small Business Administration, must promulgate standards for determining whether an entity qualifies as a small manufacturer or processor. EPA established general small manufacturer standards (40 C.F.R. §704.3), but the agency has also codified variations of the general standards for specific recordkeeping and reporting requirements (e.g., 40 C.F.R. §704.45).

⁴² 15 U.S.C. §2607(b).

⁴³ EPA, “About the TSCA Chemical Substance Inventory,” last updated July 20, 2021, <https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory>.

⁴⁴ *Ibid.*

⁴⁵ 15 U.S.C. §2607(b). See also EPA, “Toxic Substances Control Act; Premanufacturing Notification Requirements and Review Procedure; Statement of Interim Policy,” 44 *Federal Register* 28564, May 15, 1979; and EPA, “Premanufacture Notification Requirements and Review Procedures,” final rule and notice form, 48 *Federal Register* 21722, May 13, 1983.

⁴⁶ 15 U.S.C. §2607(b)(1).

⁴⁷ Pursuant to TSCA Section 8, EPA promulgated regulations that require chemical manufacturers and processors to submit commercial activity notifications identifying the chemicals that were manufactured or processed between June 2006 and June 2016. These regulations are codified at 40 C.F.R. Part 710, Subpart B.

⁴⁸ To access the TSCA Inventory, see EPA, “How to Access the TSCA Inventory,” last updated February 25, 2021, <https://www.epa.gov/tsca-inventory/how-access-tsca-inventory>.

Section 8 also authorizes EPA to require reporting of information documenting “significant adverse reactions” to human health or the environment alleged to have been caused by a chemical, as well as lists and copies of available health and safety studies.⁴⁹ Additionally, Section 8 requires chemical manufacturers or processors to report to EPA any evidence of “substantial risk” of injury to human health or the environment with regard to a chemical.⁵⁰

For a specific group of chemicals—per- and polyfluoroalkyl substances (PFAS)—that has received heightened attention for potential risks to human health and the environment, Congress has required EPA to gather more information about such chemicals.⁵¹ Section 7351 of the National Defense Authorization Act for FY2020 (P.L. 116-92) amended TSCA Section 8(a) to require EPA to issue a data call among manufacturers of PFAS by January 1, 2023, to collect additional information on the potential health and environmental risks of these chemicals in commerce. On June 28, 2021, EPA proposed reporting and recordkeeping requirements for PFAS under TSCA Section 8(a).⁵²

New Chemical Substance and Significant New Use Notifications

Under Section 5, chemical manufacturers must submit a notice to EPA at least 90 days prior to the initial commercial manufacture of a new chemical substance, unless the chemical substance meets certain criteria for an exemption from notification.⁵³ This notification is known as a premanufacture notice (PMN).⁵⁴ According to EPA, the agency has received more than 40,000 PMNs since the enactment of TSCA in 1976.⁵⁵

Chemical manufacturers and processors must also submit a notice to EPA before manufacturing or processing a chemical for a use that EPA has determined to be significant and new. EPA determines significant new uses through rulemakings on a chemical-by-chemical basis after

⁴⁹ Regulations that govern reporting of “significant adverse reactions” alleged to have been caused by a chemical are codified at 40 C.F.R. Part 717. Regulations that govern reporting of health and safety studies are codified at 40 C.F.R. Part 716.

⁵⁰ In 1978, EPA issued its statement of interpretation and enforcement policy for the notification of substantial risks. EPA, “Notification of Substantial Risk under Section 8(e),” statement of interpretation and enforcement policy, 43 *Federal Register* 11110, March 16, 1978. For additional EPA guidance on reporting substantial risk notification, see EPA, “Reporting a TSCA Chemical Substantial Risk Notice,” last updated January 21, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/reporting-tsca-chemical-substantial-risk-notice>.

⁵¹ For more information on PFAS, including actions taken by EPA under TSCA, see CRS Report R45986, *Federal Role in Responding to Potential Risks of Per- and Polyfluoroalkyl Substances (PFAS)*, coordinated by David M. Bearden.

⁵² EPA, “TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances,” 86 *Federal Register* 33926-33966, June 28, 2021.

⁵³ 15 U.S.C. §2604(a). EPA regulations governing the notification requirements for new chemical substances are codified at 40 C.F.R. Part 720. EPA has also promulgated regulations to require notice for new intergeneric microorganisms (i.e., microorganisms formed by the deliberate combination of genetic material from species that do not belong to the same genus classification) produced for commercial purposes. These EPA regulations are codified at 40 C.F.R. Part 725.

⁵⁴ A sample PMN form is available at EPA, “Sample Premanufacture Notification (PMN) Form,” OMB No. 2070-0012, approval expires December 31, 2022, https://www.epa.gov/sites/production/files/2020-02/documents/section_5_main_form_updated_omb_and_expiration_01142020.pdf.

⁵⁵ EPA, “Reviewing New Chemicals under the Toxic Substances Control Act (TSCA), Statistics for the New Chemicals Review Program Under TSCA,” last updated June 11, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>. For discussion of EPA’s regulation of new chemical substances and significant new uses, see “Regulation of New Chemical Substances and Significant New Uses” section.

considering all relevant factors, including projected volumes of manufacture and processing and changes in the manufacture, processing, distribution, use, or disposal that may increase exposure to the chemical. These rules are known as significant new use rules (SNURs), and notifications submitted under a SNUR are known as significant new use notices (SNUNs).⁵⁶ Although EPA promulgates multiple SNURs per year, the agency does not receive, and generally does not expect, many SNUN submissions per year, based on prior experience.⁵⁷

Although most significant new use determinations are associated with new chemicals,⁵⁸ EPA has determined that certain non-ongoing uses (i.e., discontinued uses) are new uses for specific existing chemicals.⁵⁹ EPA generally determines that a discontinued use of an existing chemical is a significant new use for which notification is required when a manufacturer or processor seeks to reintroduce such discontinued use of the existing chemical into commerce. This notification is intended to give the agency an opportunity to prevent the reintroduction of a discontinued use of an existing chemical if such a reintroduction would pose unreasonable risks. As an example, in April 2019, EPA determined that “any discontinued uses of asbestos cannot re-enter the marketplace without EPA review.”⁶⁰

Promulgation of a SNUR does not imply EPA would approve the significant new uses of a chemical reported in a SNUN if the agency were to receive one. Receipt of a SNUN triggers EPA review of the risks associated with the SNUN and a determination of whether such risks warrant control. SNURs are intended to allow EPA the opportunity to review specific significant new uses proposed in a SNUN on a case-by-case basis before such uses of the chemical enter commerce. EPA does not predetermine the outcome of a SNUN review when promulgating a SNUR. EPA review of a SNUN puts the agency in the position of reviewing the risks of specific significant new uses only when introduction into commerce is imminent.

The LCSA amended TSCA Section 5 to direct EPA to review a PMN or a SNUN within 90 days of receipt to determine if regulatory action is warranted.⁶¹ EPA may extend the review period up to 90 days with appropriate justification.⁶² Regulatory authorities for new chemical substances and significant new uses of chemical substances are discussed in “Regulation of New Chemical Substances and Significant New Uses.”

Under Section 5(h), EPA may exempt a chemical manufacturer or processor from submitting a PMN or a SNUN when the agency determines that the use of a chemical substance would not

⁵⁶ SNURs are codified at 40 C.F.R. Part 721. The sample PMN form referenced in footnote 54 is also the sample form for submitting a SNUN.

⁵⁷ EPA, *Supporting Statement for a Request for OMB Review Under the Paperwork Reduction Act: Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances*, October 16, 2019, <https://www.reginfo.gov/public/do/DownloadDocument?objectID=87850802>.

⁵⁸ See “Statistics Prior to June 22, 2016” tab at EPA, “Statistics for the New Chemicals Review Program under TSCA,” last updated June 11, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

⁵⁹ For example, EPA, “PBBs and Tris; Significant New Uses of Chemical Substances,” final rule, 52 *Federal Register*, 2699, January 26, 1987; and EPA, “Perfluoroalkyl Sulfonates; Significant New Use Rule,” final rule, 67 *Federal Register* 11008, March 11, 2002.

⁶⁰ EPA, “Restrictions on the Discontinued Uses of Asbestos; Significant New Use Rule,” final rule, 84 *Federal Register* 17345, April 25, 2019.

⁶¹ Prior to the enactment of the LCSA, EPA had discretion on whether to review PMNs and SNUNs submitted to the agency.

⁶² 15 U.S.C. §2604(c).

pose an unreasonable risk, or when the agency already has information about the chemical substance.⁶³ In some circumstances, EPA may not grant an exemption unless an entity applies for one.⁶⁴ For exemptions that require an application, EPA must grant or deny the exemption within 45 days of receiving the application.⁶⁵ According to EPA, the agency has received over 14,000 exemption applications since the enactment of TSCA in 1976.⁶⁶

Development of New Information Regarding Chemicals

Section 4(a) authorizes EPA to require any person (e.g., chemical manufacturers or processors) to develop new information necessary to evaluate the risks of a chemical if

1. available information on the chemical is insufficient for the agency to evaluate risks associated with the chemical;
2. testing is necessary to develop such information; and
3. *either* there may be unreasonable risk associated with the chemical, *or* the chemical is or will be produced in substantial quantities and may enter the environment in substantial quantities or result in substantial human exposure.⁶⁷

EPA may require the development of new information through a rulemaking, administrative order, or consent agreement. If EPA issues an administrative order, the agency must justify that the order is needed over a rule or a consent agreement.⁶⁸

Generally, EPA must justify the need for the new information (e.g., to assess a new chemical substance or significant new use, prioritize chemicals for risk evaluation, or conduct a risk evaluation) to require its development.⁶⁹ A requirement to develop new information for prioritizing chemicals for risk evaluation is limited to information necessary to meet that objective.⁷⁰ EPA may not establish a broadly applicable “minimum information requirement” for purposes of prioritizing chemicals for risk evaluation.⁷¹

⁶³ 15 U.S.C. §2604(h). EPA regulations implementing the process for granting or denying exemption applications from PMN and SNUN requirements are codified at 40 C.F.R. Parts 720 and 723. EPA has established several exemptions, including for specified low volumes and certain types of polymers. The sample PMN form referenced in footnote 54 is also the sample form for submitting a request for an exemption from PMN or SNUN requirements.

⁶⁴ 15 U.S.C. §2604(h)(1), (2), (4), and (5).

⁶⁵ 15 U.S.C. §2605(h)(6).

⁶⁶ EPA, “Statistics for the New Chemicals Review Program under TSCA,” last updated June 11, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

⁶⁷ 15 U.S.C. §2603(a). Regulations that govern procedures for entering into consent agreements or promulgating a rule to require the development of new information for chemicals are codified at 40 C.F.R. Part 790. Additionally, regulations that establish “good laboratory practice” standards and testing guidelines are codified at 40 C.F.R. Parts 792, 795, 796, 797, and 798. Rules requiring the development of new information for specific chemicals (also known as test rules) are codified at 40 C.F.R. Part 799.

⁶⁸ Prior to the LCSA, TSCA Section 4 authorized EPA to require the development of new information on a chemical through rulemaking. Under Section 4, EPA promulgated regulations that permitted the agency to enter into enforceable consent agreements with a chemical manufacturer or processor to develop new information on a chemical. The LCSA codified this authority and also authorized EPA to issue orders for the same purpose.

⁶⁹ 15 U.S.C. §2603(a)(3).

⁷⁰ 15 U.S.C. §2603(a)(2)(B).

⁷¹ A minimum information requirement generally refers to a predetermined set of information about a chemical that is required to be submitted without the review of available information to determine whether subsets of the predetermined information may not be necessary for the evaluation of risks. In contrast, EPA must use a tiered approach that requires

Upon application, EPA may provide exemptions from requirements to develop new information for a chemical when the requested information has already been developed or is being developed by another entity.⁷² TSCA establishes a process for exempt entities to reimburse testing costs to the entity that developed or is developing the required information.⁷³

Section 4(d) requires EPA to publish a notice in the *Federal Register* of the receipt of any new information required to be developed within 15 days of its receipt.⁷⁴ Unless the submitted new information warrants confidential treatment in accordance with Section 14 (as discussed in “Confidentiality and Disclosures of Information”), EPA must make this information available for examination by any person upon request.

Interagency Testing Committee

TSCA establishes an interagency committee to make nonbinding recommendations to EPA regarding which chemicals the agency should prioritize when requiring the development of new information.⁷⁵ Section 4(e) further directs the committee to designate chemicals that warrant the development of new information within 12 months of designation; up to 50 chemicals may be designated for priority testing at any one time.⁷⁶ The committee must review its recommendations and designations at least once every six months to determine if revisions are necessary. In April 2021, the TSCA interagency testing committee added 39 chemicals to the list of recommended chemicals for the development of new information.⁷⁷ None of these designated chemicals were recommended for expedited priority testing.

Strategy to Minimize Animal Testing

Generally, the development of new information on chemicals relies on animal testing, unless an alternative approach is shown to reliably produce information suitable for evaluating risks. Stakeholders have disagreed about whether animal testing is necessary to develop new information on chemicals, particularly with respect to the usefulness of any new information and whether alternative testing methods can reliably produce information that traditionally has been produced through animal testing. The LCSA added Section 4(h) to TSCA to require EPA to develop a strategic plan to minimize, to the extent practicable, the use of vertebrate animals when requiring the development of new information pertaining to a chemical.⁷⁸ EPA published the strategic plan in June 2018.⁷⁹

the agency to first review available information about a chemical then determine what additional information is needed for the evaluation of risks.

⁷² 15 U.S.C. §2603(c).

⁷³ 15 U.S.C. §2603(c)(3). Regulations that govern the process for reimbursement of costs associated with required testing of chemical substances are codified at 40 C.F.R. Part 791.

⁷⁴ 15 U.S.C. §2603(d).

⁷⁵ 15 U.S.C. §2603(e).

⁷⁶ 15 U.S.C. §2603(e)(1)(A).

⁷⁷ EPA, “Seventy-Fourth Report of the TSCA Interagency Testing Committee to the Administrator of the Environmental Protection Agency; Receipt of Report and Request for Comments,” 86 *Federal Register* 22414, April 28, 2021. For more information on prior meetings of the TSCA interagency testing committee, see EPA, “Interagency Testing Committee (ITC) Reports,” last updated April 28, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/interagency-testing-committee-itc-reports>.

⁷⁸ 15 U.S.C. §2603(h).

⁷⁹ EPA, “Final Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Supporting the Toxic Substances Control Act (TSCA); Notice of Availability,” 83 *Federal Register* 30167, June 27, 2018. For

Research, Development, and Monitoring Activities

Section 10 directs EPA, in consultation and cooperation with other federal agencies, to conduct basic and applied research, development, and monitoring activities, such as toxicological screening and environmental monitoring, for purposes of carrying out the act.⁸⁰ Generally, these research, development, and monitoring activities are not focused on a specific chemical but on scientific methods or technologies to better understand risks from chemicals more generally. EPA may also enter into contracts and award grants for these purposes. Additionally, EPA must develop information systems for the collection, dissemination, and use of information submitted to the agency under TSCA and for federal, state, and local entities to exchange relevant research and development information.

Confidentiality and Disclosures of Information

Some of the information chemical manufacturers and processors submit to EPA under TSCA is proprietary. To balance the objectives of protecting sensitive or proprietary information from public disclosure and maintaining the public's right of access to information about the agency's activities, Section 14 of TSCA protects information from disclosure under certain conditions. TSCA builds upon protections from disclosure set forth in the Freedom of Information Act (FOIA).⁸¹ FOIA generally requires federal agencies to disclose information requested by any person unless the information falls under one of nine exemptions. Section 14 of TSCA requires EPA to withhold from disclosure information that meets the criteria under FOIA Exemption 4 for which a confidentiality claim has been properly asserted.⁸² FOIA Exemption 4 protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential."⁸³ Knowing and willful disclosure of such information is subject to a criminal penalty under TSCA.⁸⁴

Section 14(b) also provides that certain categories of information are not protected from disclosure. In particular, information from "health and safety studies" is not protected, unless disclosure would reveal specific manufacturing and processing information or a mixture's chemical proportions.⁸⁵ The LCSA also established a presumption that information can be released when it pertains to chemicals that EPA has banned or phased out.⁸⁶ For specific chemical identities determined to warrant confidential treatment, the LCSA amended TSCA Section 14 to

more information, see EPA, "Alternative Test Methods and Strategies to Reduce Vertebrate Animal Testing," February 5, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

⁸⁰ 15 U.S.C. §2609.

⁸¹ 5 U.S.C. §552. EPA's FOIA regulations are codified at 40 C.F.R. Part 2. Special rules governing confidentiality or disclosure of information obtained under TSCA are codified at 40 C.F.R. §2.306. For further discussion of FOIA, see CRS Report R46238, *The Freedom of Information Act (FOIA): A Legal Overview*, by Daniel J. Sheffner.

⁸² 15 U.S.C. §2613(a). TSCA Section 14 cross-references 5 U.S.C. §552(b)(4), commonly known as FOIA Exemption 4. For more information on FOIA Exemption 4, see U.S. Department of Justice, "Exemption 4," *The United States Department of Justice Guide to the Freedom of Information Act*, last updated August 10, 2009, https://www.justice.gov/oip/foia_guide09/exemption4.pdf. See also CRS Report R46238, *The Freedom of Information Act (FOIA): A Legal Overview*, by Daniel J. Sheffner, p. 27.

⁸³ 5 U.S.C. §552(b)(4).

⁸⁴ 15 U.S.C. §2613(h).

⁸⁵ 15 U.S.C. §2613(b)(2).

⁸⁶ 15 U.S.C. §2613(b)(4).

require the use of unique generic identifiers when disclosing the chemical names may provide information about the structure and identity of a chemical substance.⁸⁷

In several ways, TSCA generally favors disclosure over confidentiality, placing the burden of demonstrating that confidentiality is warranted on the person seeking to protect information from disclosure. A person seeking to protect information from disclosure must file a confidentiality claim when submitting the information to EPA.⁸⁸ The submitter must substantiate the confidentiality claim unless the information falls into one of the categories of information explicitly exempt from disclosure.⁸⁹ The LCSA amended TSCA Section 14 to require further substantiation for claims regarding a specific chemical identity.⁹⁰ The LCSA also limited the duration of any substantiation to 10 years (though the submitter may renew the substantiation before its expiration).⁹¹ There are circumstances in which EPA may require a submitter to reassert and resubstantiate a confidentiality claim for information that has previously been protected: when chemicals are designated as an active substance (i.e., those reported as having been manufactured in the United States between 2006 and 2016),⁹² when chemicals are newly designated as a high-priority substance for risk evaluation under Section 6(b),⁹³ or if the agency determines that disclosure of protected information would be important in conducting risk evaluations or promulgating rules.⁹⁴ There are also circumstances in which EPA *must* require a submitter to reassert and resubstantiate a confidentiality claim: as necessary to determine whether the protected information is exempt from disclosure in connection with a pending FOIA request that seeks the protected information, if the agency has a reasonable basis to believe the information does not qualify for protection from disclosure, or when EPA makes an unreasonable risk determination about a chemical.⁹⁵ EPA must also review all claims or renewals for specific chemical identities, as well as a representative subset of confidentiality claims or renewals subject to substantiation requirements.⁹⁶

Even when information warrants confidential treatment, Section 14 establishes circumstances in which such information may or must be disclosed.⁹⁷ For instance, such information must be

⁸⁷ 15 U.S.C. §2613(g)(4). In June 2018, EPA issued its policy on assigning unique generic identifiers and applying such identifiers to nonconfidential information related to the chemical. EPA, “TSCA Chemical Structure; Unique Identified Assignment and Application Policy; Notice of Availability,” 83 *Federal Register* 30168, June 27, 2018. EPA also issued a guidance document on creating generic names. EPA, “Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under the Toxic Substances Control Act; Notice of Availability,” 83 *Federal Register* 30173, June 27, 2018.

⁸⁸ 15 U.S.C. §2613(c).

⁸⁹ 15 U.S.C. §2613(c)(3). Section 14(c)(2) generally exempts from disclosure (1) information describing the steps to manufacture or process a chemical; (2) marketing and sales information; (3) information identifying a supplier or customer; (4) mixture composition details; (5) specific information regarding a chemical’s use, function, or application in a process, mixture, or article; (6) production or import volumes; and (7) a chemical’s specific chemical identity before it is first offered for commercial distribution, if the identity was claimed as confidential when it was submitted in a PMN or a SNUN. 15 U.S.C. §2613(c)(2).

⁹⁰ 15 U.S.C. §2613(c).

⁹¹ 15 U.S.C. §2613(e).

⁹² See “Existing Information Regarding Chemical Risks” section for provision on dividing the TSCA inventory into “active substances” and “inactive substances.”

⁹³ See “Prioritization of Chemicals for Evaluation of Risks” section.

⁹⁴ 15 U.S.C. §2613(f)(1).

⁹⁵ 15 U.S.C. §2613(f)(2).

⁹⁶ 15 U.S.C. §2613(f)-(g).

⁹⁷ 15 U.S.C. §2613(d).

disclosed for certain law enforcement purposes, or to states, localities, tribes, and health or environmental professionals if EPA determines that disclosure is necessary to protect health or the environment against an unreasonable risk.⁹⁸ In June 2018, EPA published guidance on expanded access to confidential business information under certain conditions.⁹⁹

Federal Chemical Evaluation and Regulatory Authorities

EPA evaluates chemicals under TSCA to determine whether they meet the unreasonable risk threshold for regulation, and to determine how to regulate chemicals that meet that threshold. Section 6 of TSCA establishes a framework for EPA to prioritize which existing chemicals to evaluate for risks. It directs EPA to take expedited actions for the following chemicals and chemical categories:

- polychlorinated biphenyls;
- certain persistent, bioaccumulative, and toxic (PBT) chemical substances;
- imminently hazardous chemicals;
- chemicals that present significant risks; and
- new chemical substances and significant new uses of chemical substances.

The process by which EPA determines which chemicals to evaluate has been a long-standing issue for Congress and stakeholders, particularly in light of the finite resources the agency can dedicate to evaluating both chemicals already in commerce and new chemical substances.¹⁰⁰ Related to concerns about the risk evaluation prioritization process is how long EPA takes to complete a risk evaluation.

⁹⁸ Ibid.

⁹⁹ EPA, “Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability,” 83 *Federal Register* 30171, June 27, 2018.

¹⁰⁰ U.S. Congress, Senate Committee on Environment and Public Works, *Frank L. Lautenberg Chemical Safety for the 21st Century Act*, report to accompany S. 697, 114th Cong., 1st sess., S.Rept. 114-67 (Washington, DC: GPO, 2015), pp. 4, 13; see U.S. Congress, House Committee on Energy and Commerce, *TSCA Modernization Act of 2015*, report to accompany H.R. 2576, 114th Cong., 1st sess., June 23, 2015, H.Rept. 114-176 (Washington: GPO, 2015), p. 13; also see statement of Rep. Henry A. Waxman, Testimony of Beth D. Bosley, Responses to Additional Questions for the Record from Jeanne Rizzo, in U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact*, hearing, 113rd Cong., 1st sess., June 13, 2013 (Washington: GPO, 2013).

Prioritization of Chemicals for Evaluation of Risks

Prior to the enactment of the LCSA, EPA had discretion in selecting which chemicals to evaluate under TSCA.¹⁰¹ The LCSA amended TSCA Section 6 to establish a framework and a timetable for prioritizing chemicals for risk evaluation.¹⁰² Section 6 directed EPA to select 10 chemicals for risk evaluation from a list of chemicals that the agency identified in 2014 as warranting risk assessment, and to begin conducting risk evaluations for those chemicals by December 2016.¹⁰³ In December 2016, EPA published its selection of the initial 10 chemicals for risk evaluation.¹⁰⁴ **Table 1** presents a list of chemicals that EPA subsequently designated as high- or low-priority for risk evaluation.

The 2016 act also directed EPA to promulgate a rule establishing a risk-based screening process for designating chemicals as either high-priority or low-priority for risk evaluations.¹⁰⁵ The screening process must give preference to chemicals previously judged to present a greater level of risk (e.g., acute toxicity, carcinogenic, persistent and bioaccumulative) and consider the chemical substance's hazard and exposure potential, conditions of use, and volume manufactured or processed.¹⁰⁶

Based on this screening process, if EPA concludes that a chemical may present unreasonable risks, then the agency must designate the chemical as high-priority for risk evaluation and initiate a risk evaluation on the chemical.¹⁰⁷ If EPA concludes, based on sufficient information, that a chemical does not present an unreasonable risk, the agency must designate the chemical as low-priority for risk evaluation, though the agency has discretion to revise the designation based on subsequent available information.¹⁰⁸ If EPA has insufficient information to prioritize the chemical, the agency must require the development of new information from the chemical's manufacturer or processor and prioritize the chemical within 90 days of receiving the required information.¹⁰⁹

Initial 10 Chemicals for Risk Evaluation

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos
- Carbon tetrachloride
- Cyclic aliphatic bromide cluster (i.e., hexabromocyclododecane or HBCD)
- Methylene chloride
- N-methylpyrrolidone
- C.I. Pigment Violet 29
- Tetrachloroethylene (also known as perchloroethylene)
- Trichloroethylene

Source: EPA, "Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act," 81 *Federal Register* 91927, December 19, 2016.

¹⁰¹ Prior to the enactment of the LCSA, TSCA did not include provisions prescribing criteria or a process for EPA to select chemicals to evaluate.

¹⁰² 15 U.S.C. §2605(b)(1).

¹⁰³ 15 U.S.C. §2605(b)(2)(A).

¹⁰⁴ EPA, "Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act," 81 *Federal Register* 91927, December 19, 2016.

¹⁰⁵ 15 U.S.C. §2605(b)(1). EPA regulations establishing procedures for prioritization of chemicals for risk evaluation are codified at 40 C.F.R. Part 702, Subpart A.

¹⁰⁶ 15 U.S.C. §2605(b)(1)(i)(B)(i), (b)(2)(D).

¹⁰⁷ 15 U.S.C. §2605(b)(1)(B)(i), (b)(3)(A).

¹⁰⁸ 15 U.S.C. §2605(b)(1)(B)(ii).

¹⁰⁹ 15 U.S.C. §2603(a)(2)(B).

In October 2018, EPA published its approach for selecting potential chemicals to prioritize for risk evaluation.¹¹⁰

Table 1. EPA High-Priority and Low-Priority Chemicals for Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)

High-Priority Chemicals	Low-Priority Chemicals
1,3-Butadiene	1-Butanol, 3-methoxy-, 1-acetate
Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester)	D-gluco-Heptonic acid, sodium salt (1:1), (2.xi)-
Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester)	D-Gluconic acid
1,1-Dichloroethane	D-Gluconic acid, calcium salt (2:1)
1,2-Dichloroethane	D-Gluconic acid, .delta.-lactone
1,2-Dichloropropane	D-Gluconic acid, potassium salt (1:1)
Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester)	D-Gluconic acid, sodium salt (1:1)
Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	Decanedioic acid, 1,10-dibutyl ester
Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester)	1-Docosanol
Ethylene dibromide	1-Eicosanol
Formaldehyde	1,2-Hexanediol
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1-Octadecanol
4,4'-(1-Methylethylidene)bis[2, 6-dibromopheno] (TBBPA)	Propanol, [2-(2-butoxymethylethoxy)methylethoxy]-
o-Dichlorobenzene (Benzene, 1,2-dichloro-)	Propanedioic acid, 1,3-diethyl ester
p-Dichlorobenzene (Benzene, 1,4-dichloro-)	Propanedioic acid, 1,3-dimethyl ester
Phosphoric acid, triphenyl ester (TPP)	Propanol, 1 (or 2)-(2-methoxymethylethoxy)-, acetate
Phthalic anhydride (1,3-Isobenzofurandione)	Propanol, [(1-methyl-1,2-ethanediy)bis(oxy)]bis-
trans-1,2- Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-)	2-Propanol, 1,1'-oxybis-
1,1,2-Trichloroethane	Propanol, oxybis-
Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1"-phosphate)	Tetracosane, 2,6,10,15,19,23-hexamethyl-

Source: EPA, “High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability,” 84 *Federal Register* 71924, December 30, 2019; EPA, “Final Designation of Low-Priority Substances Under the Toxic Substances Control Act (TSCA); Notice of Availability,” notice, 85 *Federal Register* 11069, February 26, 2020; and EPA, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, at https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

¹¹⁰ EPA, “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization; Notice of Availability,” 83 *Federal Register* 50366, October 5, 2018.

Note: All 20 high-priority chemicals are among the 90 chemicals identified by EPA in the 2014 update of the TSCA Work Plan for Chemical Assessments.

Section 6 establishes a process for chemical manufacturers to request that EPA conduct a risk evaluation on a specific chemical, provided the manufacturer pays the requisite fee, discussed later in the “Resources and Fees to Administer TSCA” section of the report.¹¹¹ However, manufacturer requests for risk evaluation of a chemical identified in 2014 by EPA to warrant risk assessment are not subject to fees.¹¹² EPA has discretion to grant or deny requests for risk evaluation.¹¹³ In December 2019, EPA granted manufacturer-submitted requests to conduct risk evaluations for two phthalate chemicals—di-isononyl phthalate and di-isodecyl phthalate.¹¹⁴

Risk Evaluation Process

When Congress enacted TSCA in 1976, it directed EPA to regulate the lifecycle of chemicals that present unreasonable risks but did not specify how the agency should evaluate risks. Over time, EPA has developed guidelines to assess risks from chemicals.¹¹⁵ Generally, risk evaluation involves identifying the adverse health or environmental effects that exposure to a chemical may cause and the extent to which exposure may occur based on how the chemical is used. Ultimately, a risk assessor makes a risk determination by integrating and evaluating the scientific and technical information relevant to the chemical. The risk assessor may also rely on precedence established from the evaluation of similar chemicals, when appropriate.

The LCSA amended TSCA Section 6 to require EPA to promulgate a rule establishing a process for conducting risk evaluations to determine whether a chemical presents unreasonable risks.¹¹⁶ It also provided that EPA must conduct the risk evaluation without consideration of cost and other nonrisk factors.¹¹⁷

Timing of Risk Evaluations

Prior to the 2016 amendments, stakeholders expressed concerns about the low volume and slow pace of EPA’s risk evaluations under TSCA.¹¹⁸ To address these concerns, the LCSA imposed

¹¹¹ 15 U.S.C. §2605(b)(4)(C)(ii), (b)(4)(E)(ii). See also 15 U.S.C. §2625(b).

¹¹² 15 U.S.C. §2605(b)(4)(E)(iv)(II).

¹¹³ 15 U.S.C. §2605(b)(4)(E)(iii).

¹¹⁴ EPA, “List of Manufacturer-Requested Risk Evaluations under TSCA Section 6,” last updated April 1, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/list-manufacturer-requested-risk-evaluations-under-tsca>.

¹¹⁵ For example, EPA, “Guidelines for Exposure Assessment,” 57 *Federal Register* 22888, May 29, 1992. A list of risk assessment guidelines is available at EPA, “Risk Assessment Guidelines,” last updated February 2, 2021, <https://www.epa.gov/risk/risk-assessment-guidelines>. Several of these guidelines are also used to implement other environmental statutes administered by the agency.

¹¹⁶ 15 U.S.C. §2605(b)(1)(A). EPA’s regulations establishing procedures for chemical risk evaluations are codified at 40 C.F.R. Part 702, Subpart B. In November 2019, the U.S. Court of Appeals for the Ninth Circuit struck down a portion of EPA’s risk evaluation rule. *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). The court held that TSCA required EPA, when considering a chemical’s conditions of use in conducting a risk evaluation, to evaluate “legacy uses,” or the use of chemicals not currently or prospectively manufactured or distributed in commerce for that use, and disposals from such uses. *Id.* at 425.

¹¹⁷ 15 U.S.C. §2605(b)(4)(A).

¹¹⁸ See, for example, testimony in U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact*, hearing, 113rd Cong., 1st sess., June 13, 2013 (Washington: GPO, 2013).

deadlines for EPA to initiate and complete risk evaluations. As described above, EPA must initiate a risk evaluation when it designates a chemical as high-priority. In addition to requiring EPA to begin risk evaluations for the initial list of 10 chemicals by December 2016, Section 6 required EPA to begin conducting risk evaluations for at least 20 high-priority chemicals by the end of 2019.¹¹⁹

No later than six months after initiating a risk evaluation, EPA must publish the scope of the risk evaluation to be conducted.¹²⁰ EPA must complete a risk evaluation “as soon as practicable” but not later than three years after initiating the risk evaluation, though the agency may extend this time frame up to six months.¹²¹ Additionally, the LCSA added Section 26(n) to TSCA to require EPA to identify annually which chemical risk evaluations the agency intends to initiate or complete in the upcoming year.¹²²

EPA must continue to designate chemicals as high-priority for risk evaluation and conduct such evaluations at a pace consistent with the agency’s ability to complete the evaluations, though TSCA also establishes the minimum number of risk evaluations that EPA must ensure are ongoing at given time frames.¹²³ When EPA completes a risk evaluation, the agency must designate at least one other chemical as high-priority for risk evaluation and begin the risk evaluation process for that chemical.¹²⁴

On January 14, 2021, EPA finalized its evaluation of C.I. Pigment Violet 29, marking the completion of EPA’s first 10 risk evaluations.¹²⁵ All of the first 10 risk evaluations identified unreasonable risks associated with particular conditions of use that warrant proceeding to a rulemaking to address such risks (as discussed below).¹²⁶ On February 5, 2021, EPA announced that it would review the 10 risk evaluations in light of statutory obligations and policy objectives related to use of the best available science and protection of human health and the environment, in accordance with the executive orders and other direction provided by the Biden Administration.¹²⁷ Additionally, on February 16, 2021, EPA announced that the agency would change its approach to selecting and reviewing scientific studies used to inform its risk evaluations as a response to recommendations from a National Academies of Sciences, Engineering, and Medicine study requested by the agency.¹²⁸ On June 30, 2021, EPA announced policy changes that the agency would apply to future risk evaluations and to the reconsideration

¹¹⁹ 15 U.S.C. §2605(b)(2)(A)-(B).

¹²⁰ 15 U.S.C. §2605(b)(4)(D).

¹²¹ 15 U.S.C. §2605(b)(4)(G).

¹²² 15 U.S.C. §2625. EPA issued its most recent annual report on risk evaluation in May 2020. EPA, *2020 Annual Plan for Chemical Risk Evaluations under TSCA*, May 13, 2020, https://www.epa.gov/sites/production/files/2020-05/documents/annual_plan_for_chemical_risk_evaluations_under_tsca_2020.pdf.

¹²³ 15 U.S.C. §2605(b)(2)(B)-(C).

¹²⁴ 15 U.S.C. §2605(b)(3)(C).

¹²⁵ EPA, “C.I. Pigment Violet 29; Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability,” 86 *Federal Register* 6322, January 21, 2021.

¹²⁶ For more information on unreasonable risk determinations in EPA’s final risk evaluations, see entries for individual chemicals on EPA, “Chemicals Undergoing Risk Evaluation under TSCA,” last updated July 19, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>.

¹²⁷ EPA, “Updates on Chemical Safety Actions,” last updated February 5, 2021, <https://www.epa.gov/chemicals-under-tsca/updates-chemical-safety-actions>.

¹²⁸ EPA, “EPA Commits to Strengthening Science Used in Chemical Risk Evaluations,” last updated February 16, 2021, <https://www.epa.gov/newsreleases/epa-commits-strengthening-science-used-chemical-risk-evaluations>. For more general discussion of the process by which agencies may alter or rescind legislative rules, see CRS Report R46673, *Agency Rescissions of Legislative Rules*, by Kate R. Bowers and Daniel J. Sheffner.

of some of the 10 risk evaluations, including changes relating to consideration of exposure pathways, assumptions regarding the use of personal protective equipment, and the use of a whole-chemical approach instead of making separate unreasonable risk determinations for every condition of use of a chemical.¹²⁹

Rulemaking Procedures to Regulate Chemicals That Present Unreasonable Risks

If EPA determines that a chemical presents unreasonable risk based on a risk evaluation, Section 6 requires the agency to promulgate a rule to eliminate the unreasonable risk.¹³⁰ EPA may select among seven different regulatory options to regulate a chemical found to present unreasonable risk, which may be applied in combination or only to specific geographic areas. The seven regulatory options are as follows:

1. prohibition or restriction on manufacturing, processing, or distribution of the chemical;
2. prohibition or restriction on manufacturing, processing, or distribution of the chemical for particular uses;
3. requirement that the chemical (including as part of a mixture or an article) be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution, or disposal;
4. requirement to keep records on, or monitor, processes used to manufacture or process the chemical to assure compliance with the rule;
5. prohibition or regulation of the manner or method of commercial use of the chemical;
6. prohibition or regulation of the manner or method of disposal of the chemical (including as part of a mixture or an article); or
7. requirement that manufacturers or processors of the chemical notify distributors—and, to the extent reasonably ascertainable, downstream entities—and the public of the agency’s determination of unreasonable risks and replace or repurchase the chemical upon request.¹³¹

As amended by the LCSA, TSCA Section 6(g) authorizes EPA to grant exemptions from rules promulgated under Section 6(a).¹³² EPA may grant an exemption if it finds that doing so would be necessary to (1) maintain critical or essential uses of a chemical or (2) avoid significant disruption to the national economy, security, or critical infrastructure; or if (3) a specific condition of use provides substantial benefits to health, environment, or public safety despite risks associated with the chemical.¹³³ Additionally, EPA must exempt replacement parts for “complex durable goods” and “complex consumer goods” designed prior to a rule’s publication in the *Federal Register* unless the agency finds that such replacement parts contribute significantly to unreasonable risks

¹²⁹ EPA, “EPA Announces Path Forward for TSCA Chemical Risk Evaluations,” press release, June 30, 2021, <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

¹³⁰ 15 U.S.C. §2605(a), (c). EPA’s regulation establishing procedures for rulemaking to address a chemical found to present unreasonable risk is codified at 40 C.F.R. Part 750.

¹³¹ 15 U.S.C. §2605(a)(1)-(7).

¹³² 15 U.S.C. §2605(g).

¹³³ 15 U.S.C. §2605(g)(1).

identified in a risk evaluation.¹³⁴ When EPA grants an exemption, it must publish its analysis of the need for the exemption,¹³⁵ and also must establish a time limit on the exemption.¹³⁶

Section 6 directs EPA to promulgate one or more of the seven regulatory requirements in accordance with the Administrative Procedure Act's (APA's) provisions governing agency rulemaking.¹³⁷ Section 6 also imposes additional procedural requirements, such as considering the chemical's risks and benefits, "reasonably ascertainable economic consequences" of the requirements on the chemical, and alternative regulatory actions.¹³⁸

Under Section 6, as amended by the LCSA, EPA must propose a rule not later than one year after publishing the final risk evaluation and finalize the rule not later than two years after publishing the final risk evaluation.¹³⁹ However, EPA may extend these time frames up to two years for chemicals the agency has not already identified as persistent and bioaccumulative.¹⁴⁰

Section 6 also includes requirements regarding the effective date and compliance dates for rules issued under that section.¹⁴¹ EPA must establish mandatory compliance dates that are as soon as practicable but not later than five years after promulgation of the rule, except for uses being exempted.¹⁴² EPA may vary the mandatory compliance dates for different affected persons (e.g., chemical manufacturers, processors, and distributors).¹⁴³ Section 6 rules must provide for a reasonable transition period before the mandatory compliance dates become effective.¹⁴⁴ If, however, EPA determines that the manufacture, processing, distribution, use, or disposal of a chemical is likely to present an unreasonable risk before the effective date, EPA may declare a *proposed* rule to be effective to protect the public interest, in which case compliance with the proposed requirements is mandatory upon the proposed rule's publication in the *Federal Register* until the proposed rule is finalized or revoked.¹⁴⁵

Since the enactment of the LCSA in 2016, EPA has issued one final rule under TSCA Section 6 to prohibit the manufacture, processing, and distribution of a chemical. In March 2019, EPA issued a final rule to prohibit the manufacture, processing, and distribution of methylene chloride in all paint and coating removers for consumer use.¹⁴⁶ Although EPA had proposed to regulate

¹³⁴ 15 U.S.C. §2605(c)(2)(D). For purposes of exempting replacement parts, the terms *complex consumer goods* and *complex durable goods* are generally defined by the number of components making up the product, the intended useful lifetime of the product, and whether the product is typically reused. For example, automotive products may contain chemical substances subject to TSCA and be replaceable throughout the lifetime of the automobile.

¹³⁵ 15 U.S.C. §2605(g)(2).

¹³⁶ 15 U.S.C. §2605(g)(3).

¹³⁷ 15 U.S.C. §2605(c)(3). See also 5 U.S.C. §553. For more information on the APA, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, coordinated by Maeve P. Carey; and CRS Report R41546, *A Brief Overview of Rulemaking and Judicial Review*, by Todd Garvey.

¹³⁸ 15 U.S.C. §2605(c)(3).

¹³⁹ 15 U.S.C. §2605(c)(1)(A)-(B).

¹⁴⁰ 15 U.S.C. §2605(c)(1)(C).

¹⁴¹ 15 U.S.C. §2605(d).

¹⁴² 15 U.S.C. §2605(d)(1)(B).

¹⁴³ 15 U.S.C. §2605(d)(2).

¹⁴⁴ 15 U.S.C. §2605(d)(1)(E).

¹⁴⁵ 15 U.S.C. §2605(d)(3).

¹⁴⁶ EPA, "Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)," 84 *Federal Register* 11420, March 27, 2019. EPA based its rule on a 2014 risk assessment. TSCA Section 26(l)(4) (15 U.S.C. §2624(l)(4)) authorizes EPA to propose and finalize rules under Section 6(a) for chemicals listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA has published a completed risk

methylene chloride for other commercial paint and coating removal uses, the agency decided to further evaluate the risks from such uses to inform the development of an appropriate regulatory risk management approach.¹⁴⁷ Separate from the 2019 rule, EPA selected methylene chloride as one of the first 10 chemicals to undergo risk evaluation to examine risks posed by conditions of use not addressed by the rule. In June 2020, EPA concluded that certain conditions of use of methylene chloride presented unreasonable risks that warranted proceeding to rulemaking to address such risks.¹⁴⁸

Special Regulatory Authority for Certain Chemicals

In addition to the general provisions for evaluating chemicals for unreasonable risks and regulating those chemicals that present such risks, TSCA also authorizes EPA to take regulatory action with respect to the risks posed by specific categories of chemicals.

Polychlorinated Biphenyls (PCBs)

PCBs are a group of synthetic chemicals that were widely used as coolants and lubricants in electrical equipment until the late 1970s. Due primarily to certain characteristics and experience with PCBs (e.g., they bioaccumulate, do not readily break down in the environment, and have been associated with a variety of adverse health effects), Congress in 1976 included a provision in TSCA that directed EPA to prescribe methods for the disposal of PCBs and to require clear and adequate warnings and instructions with respect to their processing, distribution, use, and disposal.¹⁴⁹ Furthermore, TSCA made it unlawful to manufacture, process, and distribute PCBs after 1979 unless EPA grants, by rule, a petition for an exemption.¹⁵⁰ Exemptions are limited to one year and subject to terms and conditions that EPA may prescribe.

assessment prior to the enactment of the LCSA if the rule is consistent with the scope of the completed risk assessment and other applicable requirements under Section 6.

¹⁴⁷ EPA, “Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a),” 84 *Federal Register* 11420, March 27, 2019.

¹⁴⁸ EPA, “Methylene Chloride (MC); Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability,” 85 *Federal Register* 37942, June 24, 2020. Environmental groups and a coalition of 11 states and 2 city governments filed lawsuits challenging EPA’s risk evaluation. See *Neighbors for Env’t Justice v. EPA*, No. 20-72091 (9th Cir.). The groups argue that EPA unlawfully analyzed the chemical’s risks on a use-by-use basis rather than comprehensively and holistically, failed to consider certain aspects of the risks posed by the chemical, improperly considered regulatory protections provided by other statutes, and did not support its risk evaluation with substantial evidence or appropriate data. Opening Briefs for Petitioners *Neighbors for Environmental Justice et al. and for Petitioners State of New York et al., Neighbors for Env’t Justice v. EPA*, Doc. Nos. 39, 42. On May 13, 2021, EPA requested that the Ninth Circuit Court of Appeals remand the risk evaluation to allow the agency to reconsider it, consistent with an executive order directing agencies to review actions (including the methylene chloride risk evaluation) for consistency with the Biden Administration’s scientific policies. Respondents’ Motion for Voluntary Remand, *Neighbors for Env’t Justice v. EPA*, Doc. No. 51. See also Executive Order 13990, “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,” 86 *Federal Register* 7037 (2021); The White House Briefing Room, “Fact Sheet: List of Agency Actions for Review” (Jan. 20, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/>. On July 14, 2021, the court granted EPA’s motion and remanded the risk evaluation “for the limited purpose of permitting the agency to reconsider the challenged no-unreasonable-risk determinations.” Order, *Neighbors for Env’t Justice v. EPA*, Doc. No. 80.

¹⁴⁹ 15 U.S.C. §2605(e). EPA regulations concerning PCB manufacture, processing, distribution, use, and disposal are codified at 40 C.F.R. Part 761. For more information on PCBs, see Agency for Toxic Substances Disease Registry, *Toxicological Profile for Polychlorinated Biphenyls (PCBs)*, November 2000.

¹⁵⁰ Exemptions for the manufacture, processing, and distribution of PCBs are codified at 40 C.F.R. §761.80.

Certain Persistent, Bioaccumulative, and Toxic Chemical Substances

The LCSA added Section 6(h) to TSCA to provide a pathway for regulating chemicals that EPA identified as persistent, bioaccumulative, and toxic (PBT) in 2014 and that also meet certain other criteria.¹⁵¹ Congress directed EPA to propose rules pursuant to Section 6(a) by June 2019 to address unreasonable risks presented by those chemicals.¹⁵² EPA must issue a final rule, which must reduce exposure to the extent practicable, on an expedited basis no later than 18 months after issuing a proposed rule.¹⁵³ EPA is not required to conduct a risk evaluation when undertaking a rulemaking under Section 6(h).¹⁵⁴ In January 2021, EPA finalized rules to prohibit or restrict the manufacture, processing, and distribution of five PBT chemicals for many industrial and commercial uses.¹⁵⁵

Imminently Hazardous Chemicals and Chemicals That Present Significant Risk of Serious or Widespread Harm

TSCA establishes procedures for addressing imminently hazardous chemicals and chemicals that present significant risk of serious or widespread harm. Section 7(f) defines an “imminently hazardous chemical substance or mixture” as a chemical that “presents an imminent and unreasonable risk of serious or widespread injury to health or the environment.”¹⁵⁶ Under Section 7, EPA may commence a civil action in U.S. district court to protect against an imminently hazardous chemical through seizure or other relief before promulgating a rule to regulate the chemical.¹⁵⁷ When appropriate, EPA must initiate promulgation of a rule for an imminently hazardous chemical at the same time as commencing the civil action or as soon as practicable thereafter.¹⁵⁸

Additionally, if EPA receives information indicating a chemical may present significant risk of serious or widespread harm to humans, Section 4(f) requires the agency to either initiate an action to prevent or reduce to a sufficient extent such risk or publish a finding that the risk is not

¹⁵¹ 15 U.S.C. §2605(h).

¹⁵² 15 U.S.C. §2605(h)(1).

¹⁵³ 15 U.S.C. §2605(h)(3), (4).

¹⁵⁴ 15 U.S.C. §2605(h)(2).

¹⁵⁵ EPA, “2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),” final rule, 86 *Federal Register* 866, January 6, 2021; EPA, “EPA, “Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),” final rule, 86 *Federal Register* 880, January 6, 2021; EPA, “Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),” final rule, 86 *Federal Register* 894, January 6, 2021; EPA, “Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),” final rule, 86 *Federal Register* 911, January 6, 2021; and EPA, “Hexachlorobutadiene (HCBd); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h),” final rule, 86 *Federal Register* 922, January 6, 2021. For more information, see EPA, “Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h),” last updated June 17, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under>.

¹⁵⁶ 15 U.S.C. §2606(f).

¹⁵⁷ 15 U.S.C. §2606.

¹⁵⁸ In 1984, EPA alleged that dielectric fluid containing PCBs from transformers and capacitors were an “imminently hazardous chemical substance” under TSCA Section 7. *U.S. v. Com. Edison Co.*, 620 F. Supp. 1404, 1410 (N.D. Ill. 1985).

unreasonable in the *Federal Register* within 180 days of receiving the information.¹⁵⁹ EPA may extend the 180-day deadline by an additional 90 days for good cause.

Regulation of New Chemical Substances and Significant New Uses

If EPA finds that a new chemical substance subject to a PMN or a significant new use of a chemical substance subject to a SNUN presents an unreasonable risk,¹⁶⁰ Section 5(f) directs the agency to either (1) propose a rule imposing one or more of the requirements specified in Section 6(a) to the extent necessary to protect against such risk, or (2) issue an order to prohibit or limit the manufacture, processing, or distribution of the chemical.¹⁶¹ If EPA issues a proposed rule under Section 5(f), the requirements in the proposed rule become effective upon its publication in the *Federal Register*, and EPA must, as expeditiously as possible, either finalize the rule (with or without modification) or revoke it.¹⁶² An issued order becomes effective at the end of the review period, which is 90 days unless extended with good cause.¹⁶³ Though more than 40,000 PMNs have been submitted to EPA, the agency has promulgated regulations under Section 5(f) for three chemical substances (i.e., certain nitrosating agents in metalworking fluids).¹⁶⁴

If EPA finds that available information is insufficient to evaluate risks of a new chemical substance or significant new use, Section 5(e) requires EPA to issue an administrative order to prohibit or otherwise restrict manufacture, processing, distribution, use, or disposal to the extent necessary to protect against unreasonable risks pending the development of further information.¹⁶⁵ An issued order becomes effective at the end of the review period. The submitter of the PMN or SNUN must comply with the order while the required information is being developed.¹⁶⁶ For new chemical substances or significant new uses for which information is insufficient to evaluate risks while Section 5(e) orders apply to the PMN or SNUN submitter, EPA may in practice also promulgate a SNUR to apply the restrictions outlined in an order to other manufacturers and processors.¹⁶⁷ Prior to June 2016, EPA reported that the agency had

¹⁵⁹ 15 U.S.C. §2603(f). As an example, in 1983, EPA initiated a 180-day review of 4,4'-methylenedianiline under TSCA Section 4(f). EPA, "4,4'-Methylenedianiline; Initiation of Review," 48 *Federal Register* 19078, April 27, 1983.

¹⁶⁰ See "New Chemical Substance and Significant New Use Notifications" section.

¹⁶¹ 15 U.S.C. §2604(f).

¹⁶² 15 U.S.C. §§2604(f)(2), 2605(d)(3)(B).

¹⁶³ 15 U.S.C. §2604(f)(3), (i)(3).

¹⁶⁴ EPA, "Prohibition of Nitrites in Metalworking Fluids," 49 *Federal Register* 2762, January 23, 1984; EPA, "Triethanolamine Salt of a Substituted Organic Acid Restrictions on Use in Metalworking Fluids," 49 *Federal Register* 24658, June 14, 1984; and EPA, "Mixed Mono and Diamides of an Organic Acid Restrictions on Use in Metalworking Fluids," 49 *Federal Register* 36846, September 20, 1984. See also EPA, "Substance Registry Services (SRS): TSCA 5(f) Orders," updated January 23, 2021, https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do?search=&searchCriteria.substanceList=155&searchCriteria.substanceType=-1.

¹⁶⁵ 15 U.S.C. §2604(e).

¹⁶⁶ *Ibid.*

¹⁶⁷ See, for example, EPA, "Significant New Uses of Chemical Substances; Certain Chemicals," 49 *Federal Register* 35011, September 5, 1984. Also see EPA, "Reviewing New Chemicals under the Toxic Substances Control Act (TSCA); Actions under TSCA Section 5," last updated June 17, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5>. EPA states that "TSCA section 5(e) or 5(f) Orders are only binding on the original PMN submitter for that substance. Consequently, after issuing a section 5 Order, EPA generally promulgates a SNUR that requires notice to EPA by any manufacturer or processor who wishes to manufacture or process the chemical in a way other than described in the terms and conditions contained in the Order."

issued 1,729 Section 5(e) orders.¹⁶⁸ Among the Section 5(e) orders, more than 760 were associated with SNURs.

For substances subject to PMN and SNUN restrictions that EPA subsequently finds are not likely to present unreasonable risk, the submitter of the notice may commence manufacture of the substance for the uses described in the notice after the agency publishes a statement of its finding.¹⁶⁹

Chemical Imports and Exports

Import Certification

Under TSCA, requirements that apply to the manufacture of chemicals also apply to their importation, because the statutory definition of *manufacture* includes importation.¹⁷⁰ Section 13 establishes a process for handling chemicals (including mixtures and articles that contain chemicals) imported into the United States that are subject to TSCA requirements.¹⁷¹ Pursuant to Section 13, U.S. Customs and Border Protection (CBP), an agency of the Department of Homeland Security, has promulgated regulations requiring certification of chemical imports as to whether TSCA requirements apply.¹⁷²

Export Notification

Section 12 provides that most of TSCA's requirements do not apply to chemicals manufactured or processed solely for export unless EPA has required the development of new information or promulgated requirements to address unreasonable risks presented by the chemical.¹⁷³ Generally, only recordkeeping and reporting requirements apply to chemicals (including mixtures and articles that contain chemicals) manufactured or processed for export only and marked as such.¹⁷⁴ If EPA has required the development of new information or has established requirements to prevent unreasonable risk for a chemical solely for export, the exporter must notify the agency of the export activity. In turn, EPA must notify the country receiving the chemical export of the TSCA requirements applicable to the chemical being exported.¹⁷⁵

¹⁶⁸ EPA, "Reviewing New Chemicals Under the Toxic Substances Control Act, Statistics for the New Chemicals Review Program under TSCA," last updated June 11, 2021, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>.

¹⁶⁹ 15 U.S.C. §2604(g).

¹⁷⁰ 15 U.S.C. §2602(9).

¹⁷¹ 15 U.S.C. §2612. Regulations governing importation of chemicals are codified at 19 C.F.R. §§12.118 through 12.127 and 127.28, and 40 C.F.R. Part 707. For general information on regulation of imports, see CRS Report R43014, *U.S. Customs and Border Protection: Trade Facilitation, Enforcement, and Security*, by Vivian C. Jones and Audrey Singer.

¹⁷² U.S. Customs and Border Protection, Department of Homeland Security, and Department of the Treasury, "Toxic Substance Control Act Chemical Substance Import Certification Process Revisions," December 27, 2016, 81 *Federal Register* 94980. CBP estimates that it receives approximately 2.8 million TSCA import certifications each year.

¹⁷³ 15 U.S.C. §2611.

¹⁷⁴ 15 U.S.C. §2611(b). EPA regulations governing export notification requirements are codified at 40 C.F.R. Part 707, Subpart D. For more information, see EPA, "TSCA Requirements for Exporting Chemicals," last updated July 19, 2021, <https://www.epa.gov/tsca-import-export-requirements/tsca-requirements-exporting-chemicals>.

¹⁷⁵ 15 U.S.C. §2611(b).

Mercury Export Ban Act

Congress enacted the Mercury Export Ban Act (MEBA; P.L. 110-414) in 2008 to reduce the availability of mercury in domestic and international markets. Mercury and mercury compounds may be used to manufacture chemicals and electrical equipment, although their use has declined due in part to concerns about human health and environmental effects from exposure.¹⁷⁶ MEBA added Section 12(c) to TSCA, which prohibits the export of elemental mercury unless EPA issues an exemption for a specified use as an “essential use” through a petition and rulemaking process, or unless the export involves coal.¹⁷⁷ Essential use exemptions may not exceed three years in duration or 10 metric tons of elemental mercury and are subject to other terms and conditions specified by EPA. To date, EPA has not granted any essential use exemptions. The LCSA further amended TSCA Section 12(c) to make it unlawful to export specific mercury compounds after January 1, 2020, and to require EPA to report to Congress on the status of mercury compound exports and disposal.¹⁷⁸

Other TSCA provisions complement the mercury export provision. MEBA added Section 6(f) to TSCA to make it unlawful for a federal agency to convey, sell, and distribute elemental mercury under its jurisdiction unless the transfer of elemental mercury facilitates its storage or involves coal.¹⁷⁹ Prior to MEBA’s enactment, the policy of the U.S. Department of Energy (DOE) and Department of Defense was to store, not sell, mercury stocks.¹⁸⁰ MEBA codified this existing policy in TSCA and also directed DOE to establish a program for long-term management and storage of elemental mercury generated within the United States.¹⁸¹ The LCSA amended MEBA with regard to the long-term storage of mercury.

The LCSA also added Section 8(b)(10) to TSCA to direct EPA to gather information regarding the supply, use, and trade of elemental mercury and mercury compounds in the United States and periodically publish such information in the *Federal Register*.¹⁸² In 2017, EPA published its initial report on the inventory of mercury supply, use, and trade in the United States.¹⁸³

¹⁷⁶ U.S. Geological Survey, “Mercury,” *Mineral Commodity Summaries*, January 2021, <https://pubs.usgs.gov/periodicals/mcs2021/mcs2021-mercury.pdf>; and Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Mercury*, March 1999, <https://www.atsdr.cdc.gov/ToxProfiles/tp46.pdf>.

¹⁷⁷ 15 U.S.C. §2611(c)(4), (c)(6).

¹⁷⁸ 15 U.S.C. §2611(c)(7).

¹⁷⁹ 15 U.S.C. §2605(f).

¹⁸⁰ U.S. Department of Defense, Defense Logistics Agency, “Record of Decision for the Final Mercury Management Environmental Impact Statement; Notice,” 69 *Federal Register* 23733, April 30, 2004.

¹⁸¹ Section 3 of MEBA added Section 6(f) (15 U.S.C. §2605(f)) to TSCA, and Section 5 of MEBA is codified at 42 U.S.C. §6939f. For more information, see DOE, “Long-Term Management and Storage of Elemental Mercury,” <https://energy.gov/em/services/waste-management/waste-and-materials-disposition-information/long-term-management-and>.

¹⁸² 15 U.S.C. §2607(b)(10). Regulations governing the reporting of mercury supply, use, and trade are codified at 40 C.F.R. Part 713.

¹⁸³ EPA, “Mercury; Initial Inventory Report of Supply, Use, and Trade,” 82 *Federal Register* 15522, March 29, 2017.

Enforcement, Citizens' Petitions, Citizens' Suits, and Judicial Review

Several TSCA provisions (Sections 11, 15, 16, and 17) relate to enforcement of the statute.¹⁸⁴ To enforce TSCA rules, orders, and consent agreements, the act provides EPA with inspection and administrative subpoena authority,¹⁸⁵ and provides the agency with administrative and judicial mechanisms to restrain violations and apply civil or criminal penalties to violators.¹⁸⁶

Administrative civil penalties are capped and further limited if a state undertakes enforcement for the same violation under its own law.¹⁸⁷ Separately, Section 22 authorizes the President through EPA to waive compliance with any TSCA requirement for national defense purposes.¹⁸⁸

Additionally, like many other environmental statutes, TSCA establishes a process by which citizens can request that EPA reexamine certain agency actions under the act or challenge EPA's implementation of the act. Under Section 21, any person may petition EPA to issue, amend, or repeal certain TSCA rules or orders.¹⁸⁹ EPA must either grant or deny a citizen petition within 90 days after the petition is filed.¹⁹⁰ If EPA denies a petition, the petitioner may file a lawsuit in federal district court to compel the agency to undertake the requested action.¹⁹¹

Under Section 20, any person may file a lawsuit (commonly called a citizen suit) against EPA to compel it to perform a nondiscretionary duty or against any other person (including government entities) alleged to be in violation of certain types of TSCA rules or orders.¹⁹² Section 20 generally requires a citizen suit plaintiff to give 60 days' notice of the claims to the EPA

¹⁸⁴ 15 U.S.C. §§2610, 2614, 2615, 2616. For background on the enforcement of federal pollution control laws more generally, see CRS Report RL34384, *Federal Pollution Control Laws: How Are They Enforced?*, by Robert Esworthy. See also EPA, "Compliance Monitoring Strategy for the Toxic Substances Control Act (TSCA)," last updated March 15, 2017, <https://www.epa.gov/compliance/compliance-monitoring-strategy-toxic-substances-control-act-tsca>.

¹⁸⁵ 15 U.S.C. §2610.

¹⁸⁶ 15 U.S.C. §§2615, 2616.

¹⁸⁷ Statutory civil penalties, as adjusted for inflation, for various environmental statutes, including TSCA, are codified at 40 C.F.R. §19.4. See "Coenforcement" for discussion of the relationship between federal civil enforcement and state enforcement for the same violation under TSCA.

¹⁸⁸ 15 U.S.C. §2621.

¹⁸⁹ 15 U.S.C. §2620. EPA's website includes a list of the more than 20 TSCA Section 21 petitions filed with the agency since September 2007. EPA, "TSCA Section 21," last updated July 12, 2021, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21>.

¹⁹⁰ 15 U.S.C. §2620(b)(3).

¹⁹¹ 15 U.S.C. §2620(b)(4). Section 21 provides that courts shall review the denial of a petition seeking issuance of a *new* rule in a *de novo* proceeding, but does not specify the standard of review for petitions seeking the amendment or repeal of existing rules. Courts have applied a more deferential standard to the latter category of petitions. See *Asbestos Disease Awareness Org. v. Wheeler*, No. 19-cv-00871, 2019 WL 6050752, *7 (N.D. Cal. Nov. 15, 2019); *Env't Def. Fund v. Reilly*, 909 F.2d 1497, 1505 (D.C. Cir. 1990).

Since the enactment of the LCSA, groups have challenged EPA's denial of TSCA Section 21 petitions. See *Food & Water Watch, Inc. v. EPA*, No. 3:17-cv-02162 (N.D. Cal.) (challenging denial of petition to issue rule pursuant to Section 6 banning fluoridation of drinking water); Order Granting Plaintiffs' Motion for Summary Judgment and Denying Defendant's Cross-Motion for Summary Judgment, *Asbestos Disease Awareness Org. v. EPA*, No. 19-cv-00871, 2020 WL 7625445 (N.D. Cal. Dec. 22, 2020) (ordering EPA to amend its Chemical Data Reporting rule to require additional information-gathering on the production, importation, and processing of asbestos, in response to lawsuit challenging agency denial of petition to amend rule).

¹⁹² 15 U.S.C. §2619. Regulations governing citizen suits under TSCA Section 20 are codified at 40 C.F.R. Part 702, Subpart C.

Administrator and the alleged violator, if applicable, prior to filing the suit.¹⁹³ A citizen suit may not proceed if EPA or the Department of Justice is already “diligently prosecuting” an administrative or judicial proceeding against the alleged violator.¹⁹⁴ However, the citizen who has given notice of the claims may intervene as a matter of right in the enforcement proceeding if it is initiated after notice is given.¹⁹⁵ If a citizen suit is successful, the court may require the violator to take actions to correct a violation and may impose civil penalties on the violator.

TSCA Section 19 governs judicial review of various EPA actions under the act.¹⁹⁶ In general, Section 19 requires that petitions for judicial review of certain rules and orders under TSCA, and civil actions challenging low-priority designations,¹⁹⁷ be filed within 60 days after EPA finalizes the action.¹⁹⁸ The federal courts of appeals have exclusive jurisdiction over challenges to rules and orders issued under TSCA.¹⁹⁹ For civil actions challenging low-priority designations, jurisdiction is limited specifically to the U.S. Court of Appeals for the District of Columbia Circuit.²⁰⁰ Review is presumptively limited to the administrative record.²⁰¹ Courts review EPA rules and orders under TSCA pursuant to a specific standard of review set forth in Section 19, rather than the more common (and more deferential) “arbitrary and capricious” standard of review under the Administrative Procedure Act.²⁰² Specifically, Section 19 provides that courts must “hold unlawful and set aside” such actions “if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole.”²⁰³

TSCA includes provisions intended to protect employees of regulated entities from retaliation for participating in a proceeding under the act or from potential effects on employment because of economic costs in implementing the act. Section 23 authorizes the Department of Labor (DOL) to investigate alleged retaliations and provides DOL with administrative and judicial mechanisms to resolve such allegations.²⁰⁴ Section 24 directs EPA to investigate allegations of potential effects on employment resulting from a TSCA requirement and to prepare recommendations based on the investigation.²⁰⁵

¹⁹³ 15 U.S.C. §2619(b).

¹⁹⁴ 15 U.S.C. §2619(b)(1)(B).

¹⁹⁵ *Ibid.* Intervention allows an entity that was not originally a party to ongoing litigation to join the case and present legal arguments to the court.

¹⁹⁶ 15 U.S.C. §2618.

¹⁹⁷ For a discussion of low-priority designations, see “Prioritization of Chemicals for Evaluation of Risks.”

¹⁹⁸ 15 U.S.C. §2618(a)(1). The implications of the act’s use of the term *civil action* rather than *petition* for low-priority designation challenges are not entirely clear.

¹⁹⁹ 15 U.S.C. §2618(a)(1)(A).

²⁰⁰ 15 U.S.C. §2618(a)(1)(C)(ii).

²⁰¹ 15 U.S.C. §2618(b).

²⁰² 5 U.S.C. §706(2)(E). See also *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213-14 (5th Cir. 1991) (“The substantial evidence standard mandated by [TSCA] is generally considered to be more rigorous than the arbitrary and capricious standard normally applied to informal rulemaking,” and “afford[s] a considerably more generous judicial review” than the arbitrary and capricious test.”) (quoting *Env’t Def. Fund, Inc. v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980), and *Abbot Labs. v. Gardner*, 387 U.S. 136, 143 (1967)).

²⁰³ 15 U.S.C. §2618(c)(1)(B)(i).

²⁰⁴ 15 U.S.C. §2622. Regulations that govern the handling of retaliation complaints under TSCA Section 23 and other environmental statutes are codified at 29 C.F.R. Part 24.

²⁰⁵ 15 U.S.C. §2623. Recommendations may include amending or repealing a rule or order, but the Administrator’s recommendations under this section are not binding.

Federal and State Relationship

To avoid potential conflict between federal requirements under TSCA and state requirements or restrictions on chemicals, TSCA identifies circumstances in which a federal requirement for a specific chemical under the act would preempt state requirements that apply to the same chemical unless exempted or waived.²⁰⁶ On the other hand, TSCA does not preempt states from requiring the development of new information or regulating a chemical for which EPA has not taken action under TSCA.²⁰⁷ Additionally, TSCA authorizes EPA to award grants to states to take action to address unreasonable risk associated with a chemical that the agency is unable or not likely to address.²⁰⁸

Preemption of State Requirements

Under the Supremacy Clause of the U.S. Constitution, state law and policy must yield to the exercise of Congress's powers if Congress so intends.²⁰⁹ As Congress debated whether to expand EPA authority to regulate chemicals under TSCA leading up to the enactment of the LCSA, federal preemption of state requirements was a key issue. As enacted in 1976, TSCA preempted state and local requirements only for specific chemicals. Some states and localities enacted their own laws or promulgated regulations pertaining to other chemicals in response to concerns regarding the risks of commercial chemicals and the absence of federal regulatory action. The chemical industry and associated entities (e.g., retailers) expressed concern over regulatory requirements that differed from one state to another.²¹⁰

The LCSA revised TSCA's preemption provisions. In broad terms, Section 18 as it is currently in effect prohibits specific state and local actions, and then restricts the reach of those prohibitions through limitations, exceptions, and waivers.²¹¹ Any preemption is chemical-specific, and EPA must take specific actions under TSCA in order to trigger the preemption of state regulation of chemicals.²¹² Exceptions to preemption may apply under certain conditions, and EPA may grant preemption waivers by rule.²¹³

As amended, Section 18 contains two preemption sections that prohibit different kinds of state or local regulations corresponding to different stages in EPA's review process under TSCA. The prohibitions in Section 18(b) apply while EPA is conducting its risk evaluation of a particular chemical, beginning on the date EPA determines the scope of its risk evaluation and ending either on the deadline for completion of the risk evaluation or when EPA publishes the risk evaluation,

²⁰⁶ 15 U.S.C. §2617.

²⁰⁷ *Ibid.* As discussed below, preemption under TSCA is specific to individual chemicals for which EPA has taken regulatory action, so consideration of whether a requirement or restriction is preempted under TSCA requires a chemical-specific analysis. As a general matter, however, TSCA's grandfathering exceptions, which are also discussed below, allow for certain laws, such as California's Proposition 65 and Massachusetts Toxics Use Reduction Act and their associated regulations, to remain in place. See Cal. Health & Safety Code §25249.5 *et seq.*; Mass. Gen. Laws ch. 211.

²⁰⁸ 15 U.S.C. §2627.

²⁰⁹ U.S. Const. art. VI, cl. 2.

²¹⁰ U.S. Congress, Senate Committee on Environment and Public Works, *Frank L. Lautenberg Chemical Safety for the 21st Century Act*, report to accompany S. 697, 114th Cong., 1st sess., S.Rept. 114-67 (Washington, DC: GPO, 2015), p. 6.

²¹¹ 15 U.S.C. §2617.

²¹² 15 U.S.C. §2617(a)-(c).

²¹³ 15 U.S.C. §2617(d)-(g).

whichever is earlier.²¹⁴ Section 18(b) imposes a temporary prohibition on states from establishing any *new* prohibition or restriction on a chemical designated by EPA as a high-priority substance for risk evaluation. States are preempted from regulating only the hazards, exposures, risks, and uses included in the scope of EPA’s risk evaluation.²¹⁵

The prohibitions in Section 18(a) apply once EPA implements information requirements, notification of significant new use requirements, or restrictions or prohibitions based on its risk evaluation for the particular chemical.²¹⁶ Under Section 18(a), once EPA has acted to regulate a chemical, no state may establish or continue to enforce any of the following, subject to exemptions and potential waivers:²¹⁷

- A statute or administrative action that requires the development of information on a chemical that would be “reasonably likely” to be the same as information required under an existing EPA rule, order, or consent agreement under the act.
- A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical for which EPA has either (1) issued an order finding the chemical not to present an unreasonable risk or (2) found the chemical to present an unreasonable risk and promulgated a final rule to address the unreasonable risk after the effective date of the rule.
- A statute or administrative action requiring the notification of a use of a chemical for which EPA has already determined that notification as a significant new use is required.²¹⁸

Section 18 provides exceptions that, in effect, preserve state chemical requirements that otherwise would be preempted. States and localities may continue to enforce any chemical substance prohibitions or restrictions that were in effect before April 22, 2016.²¹⁹ States and localities also may adopt new regulations and other actions pursuant to any laws in effect on August 31, 2003.²²⁰ TSCA also leaves in place the “cooperative federalism” structure of several other federal environmental laws, under which states administer programs that either meet or exceed minimum federal requirements. Thus, it does not preempt a state from adopting or enforcing any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that (1) is adopted under the authority of or to satisfy any other federal law; (2) implements a reporting, monitoring, disclosure, or other information obligation not otherwise required by EPA under TSCA or required under other federal law; or (3) is generally adopted under a state law related to water quality, air quality, or waste treatment or disposal, with certain exceptions.²²¹

²¹⁴ 15 U.S.C. §2617(b).

²¹⁵ 15 U.S.C. §2617(b).

²¹⁶ 15 U.S.C. §2617(a).

²¹⁷ 15 U.S.C. §2617(f).

²¹⁸ 15 U.S.C. §2617(a)(1).

²¹⁹ 15 U.S.C. §2617(e)(1)(A).

²²⁰ 15 U.S.C. §2617(e)(1)(B). For example, California’s Safe Drinking Water and Toxic Enforcement Act of 1986 (California Health and Safety Code §§25249.5-25249.13), commonly known as Proposition 65, makes it unlawful within the state of California for a business to “knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual.”

²²¹ 15 U.S.C. §2617(d).

In addition to these exemptions from preemption, TSCA sets forth “savings clauses,” providing that the act’s requirements do not preempt penalties for criminal conduct or common law rights or statutes creating remedies for civil relief—such as damages—under any legal theory of liability.²²² TSCA also provides that determinations, such as risk assessments, made pursuant to the statute are not definitive proof in court for private actions.²²³

In addition to the specific statutory exemptions, Section 18 allows the EPA Administrator the discretion to exempt from preemption a state requirement under certain circumstances.²²⁴ If the state submits an application for the exemption, the Administrator may grant the exemption if he or she determines that compelling conditions warrant granting the waiver to protect health or the environment, that compliance with the requirement would not unduly burden interstate commerce and would not cause a violation of federal requirements, and that the risk identified by the state is based on sufficiently strong science.²²⁵

The Administrator *must* exempt from preemption *new* state requirements established during EPA’s risk evaluation period for a chemical if either (1) the state requirement is enacted within 18 months of EPA’s prioritization of the chemical for review; or (2) the Administrator determines that compliance with the requirement would not unduly burden interstate commerce or cause a violation of federal requirements, and that the state’s concern about the chemical is based on peer-reviewed science.²²⁶ The Administrator must act on a required exemption application within 110 days after an application is submitted.²²⁷ All waiver applications are subject to public notice and comment requirements, and decisions regarding such applications are final agency actions subject to judicial review.²²⁸

Coenforcement

Section 18 also establishes parameters for states that adopt and enforce requirements under their own laws that are identical to TSCA’s requirements.²²⁹ Penalties and other sanctions that are applicable to violations under state law must not be more stringent than those available under TSCA.²³⁰ Additionally, a state may not assess a penalty for a violation under its own law if EPA has already assessed an adequate penalty for the same violation under TSCA.²³¹ If a state has already assessed a penalty for a specific violation under state law, TSCA limits the penalty EPA may assess for the same violation so that the combined total penalty amount would not exceed the maximum penalty amount allowed under the act.²³² Under this scheme, regulated entities may face enforcement by either state or federal regulators.

²²² 15 U.S.C. §2617(g). TSCA’s savings clauses also specify that TSCA does not preempt the availability of specific tort causes of action for personal injury. 15 U.S.C. §2617(g)(1)(B). Lawsuits alleging one of those causes of action—for example, products liability—thus may be available even if a manufacturer has complied with TSCA.

²²³ 15 U.S.C. §2617(g)(2).

²²⁴ 15 U.S.C. §2617(f).

²²⁵ 15 U.S.C. §2617(f)(1).

²²⁶ 15 U.S.C. §2617(f)(2).

²²⁷ 15 U.S.C. §2617(f)(3).

²²⁸ 15 U.S.C. §2617(f)(5)-(6).

²²⁹ 15 U.S.C. §2617(d)(1)(B).

²³⁰ 15 U.S.C. §2617(d)(1)(B).

²³¹ 15 U.S.C. §2617(d)(1)(B)(ii)(I).

²³² 15 U.S.C. §2617(d)(1)(B)(ii)(II).

State Grants

TSCA Section 28 authorizes EPA to award grants to states to establish and operate programs intended to prevent or eliminate unreasonable risks associated with chemicals for which the agency “is unable or is not likely to take action” under the act.²³³ Section 28 limits grant awards to 75% of the establishment and operation costs of the program. The LCSA repealed the authorization of appropriations for state grants but not the program authority, and Congress has continued to provide TSCA grant funding to states through annual discretionary appropriations.²³⁴

Resources and Fees to Administer TSCA

Resource and staffing levels available to EPA to evaluate chemicals may affect the pace and thoroughness of evaluations and, in turn, whether chemicals are regulated under TSCA or the timing of when new chemicals may be introduced into commerce. Although the authorization of appropriations to carry out TSCA expired after FY1983, Congress has continued to fund the statute’s activities through annual discretionary appropriations.²³⁵

As originally enacted, TSCA Section 26(b) authorized EPA to collect fees from chemical manufacturers and processors for submissions of new information required by the agency or PMNs or SNUNs.²³⁶ Because there was no dedicated account in which to deposit fee receipts, however, the Miscellaneous Receipts Act required those receipts to be deposited in the U.S. Treasury as miscellaneous receipts, instead of being directly used to implement TSCA.²³⁷

The LCSA amended TSCA Section 26(b) to authorize the collection of fees from chemical manufacturers and processors to defray certain costs of administering TSCA programs.²³⁸ EPA may collect fees in a given fiscal year if appropriations for a related EPA “program project” match or exceed the level appropriated in FY2014.²³⁹ Fee collections are limited to 25% of EPA’s annual costs of administering TSCA activities and are not to exceed \$25 million per year.²⁴⁰ Section 26 requires the deposit of collected fees into the “TSCA Service Fee Fund” in the U.S. Treasury, and the fees are available to EPA, subject to the annual discretionary appropriations process, to partially defray the costs of activities to implement Title I of TSCA, including conducting chemical risk evaluations. This authority to collect fees expires in June 2026.

In 2018, EPA finalized a rule to collect fees from those required to submit information, such as test data or notices for new chemicals or significant new uses of chemicals, and those who

²³³ 15 U.S.C. §2627. Regulations that govern the Toxic Substances Compliance Monitoring grant program are codified at 40 C.F.R. §§35.310-35.318 for states and 40 C.F.R. §§35.710-35.718 for tribes.

²³⁴ Although authorization of appropriations for these grants expired after FY1983, Congress has continued to provide TSCA state grant funding through annual discretionary appropriations. Congress appropriates funding for TSCA state grants through the “Categorical Grants: Toxic Substances Compliance” subaccount within EPA’s State and Tribal Assistance Grant account in the Department of the Interior, Environment, and Related Agencies appropriations acts. For EPA guidance on this grant, see EPA, *Toxic Substances Compliance Monitoring Grant Guidance for Fiscal Year 2021*, April 2021, <https://www.epa.gov/sites/production/files/2021-04/documents/2021tscagrnt.pdf>.

²³⁵ 15 U.S.C. §2628.

²³⁶ 15 U.S.C. §2625(b).

²³⁷ 31 U.S.C. §3302(b).

²³⁸ 15 U.S.C. §2625(b).

²³⁹ 15 U.S.C. §2625(b)(5).

²⁴⁰ 15 U.S.C. §2625(b)(4)(B).

manufacture chemicals subject to an agency risk evaluation under the amended TSCA.²⁴¹ The rule establishes different fee amounts depending on the type of information being submitted to EPA or whether the risk evaluation was initiated by EPA or requested by a manufacturer.²⁴² The rule establishes fee amounts only for FY2019, FY2020, and FY2021. EPA states that the agency intends to adjust the fees for inflation and other factors once every three years. For FY2020, EPA reported total TSCA fee revenues of \$5.5 million.²⁴³ These fee revenues were primarily associated with PMN submissions. For FY2021, EPA expects total TSCA fee revenues of \$30.0 million, as the agency identifies chemical manufacturers and processors to assess fees to cover some of the costs of ongoing risk evaluations.²⁴⁴

Section 26(m) requires EPA to provide a report to Congress at least once every five years with estimates on the agency's capacity to complete the required number of chemical risk evaluations, including those requested by chemical manufacturers, and to promulgate rules to regulate chemicals that present unreasonable risks.²⁴⁵

Concluding Discussion

TSCA establishes a framework for EPA to obtain information about a vast and growing body of industrial and commercial chemicals to assess risks to human health and the environment. TSCA authorizes EPA to regulate any stage of the lifecycle of a chemical through rulemaking if the agency finds an unreasonable risk associated with that chemical. The statute's framework applies to a wide variety of chemicals and directs EPA to consider, when evaluating the risk of chemicals, different chemical characteristics, intended uses, exposure scenarios, and potential health effects associated with exposure. Due to limited staffing and resources to implement TSCA, EPA generally focuses on chemicals that are more likely to present greater risks than others.

EPA risk evaluations are intended to provide the agency with sufficient evidence to regulate a chemical. A risk evaluation involves characterizing potential health effects from exposure to a chemical and the likely exposure scenarios based on the use of a chemical. Whether EPA has sufficient information to evaluate the risks of a chemical depends in part on whether that information is already available to the agency or whether the agency has authority under TSCA to require the development of new information by manufacturers or processors. Various environmental and public health organizations and the chemical industry have differing

²⁴¹ EPA, "Fees for the Administration of the Toxic Substances Control Act," 83 *Federal Register* 52694, October 17, 2018. Regulations governing the collection of TSCA fees are codified in various sections of 40 C.F.R. Parts 700, 720, 723, 725, 790, and 791.

²⁴² For more information on TSCA administration fees, see EPA, "Toxic Substances Control Act (TSCA) Administration Fees," last updated June 3, 2021, <https://www.epa.gov/tsca-fees>.

²⁴³ EPA, *Fiscal Year 2022 Justification of Appropriation Estimates for the Committee on Appropriations*, EPA-190-R-21-002, May 2021, pp. 792-793 (pp. 824-825 of the PDF), <https://www.epa.gov/sites/production/files/2021-05/documents/fy-2022-congressional-justification-all-tabs.pdf>.

²⁴⁴ EPA, *Fiscal Year 2022 Justification of Appropriation Estimates for the Committee on Appropriations*, EPA-190-R-21-002, May 2021, pp. 389 and 793 (pp. 410 and 825 of the PDF), <https://www.epa.gov/sites/production/files/2021-05/documents/fy-2022-congressional-justification-all-tabs.pdf>.

²⁴⁵ 15 U.S.C. §2625(m). In January 2017, EPA submitted its initial report to Congress on its capacity to conduct risk evaluations under TSCA. EPA, *Initial Report to Congress on EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act*, January 2017, https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf.

perspectives on what types of information are necessary for EPA to evaluate the risks of a chemical.²⁴⁶

The scientific understanding of a chemical's risks is generally not static but evolves over time. Additional studies may generate a better understanding of the risks of a chemical. Some studies may suggest or demonstrate that a chemical presents more risk than previously thought, while other studies may suggest or demonstrate the opposite view. Ultimately, EPA exercises professional judgment in characterizing the body of scientific information with regard to the risks a chemical may present.

Even if EPA finds that a chemical presents unreasonable risks that warrant regulatory control, the agency must consider costs and other factors when selecting the appropriate regulatory requirement, potentially leading to disagreements about EPA's analysis and findings (e.g., the availability of alternatives to a chemical for a particular use). Furthermore, even if stakeholders concur with EPA's assessment of risks, they may hold different perspectives on whether the regulatory requirement selected by EPA adequately addresses the identified unreasonable risk and meets the statutory requirements. Such disagreements may result in litigation.²⁴⁷

Ultimately, the pace at which EPA can evaluate chemicals and promulgate regulations for chemicals that present unreasonable risks under TSCA could largely depend on resources, staffing, and the availability of relevant scientific and technical information that supports a finding of unreasonable risks. EPA authority to regulate a chemical under TSCA also depends on whether another law may be used to regulate that chemical for the identified unreasonable risk. Since the enactment of the LCSA in 2016, EPA has continued to evaluate chemicals for unreasonable risk, subject to applicable statutory time frames. With regard to EPA's findings of unreasonable risk, it generally remains to be seen whether the agency's findings are defensible from a scientific standpoint, what requirements might EPA propose to address such risks, and whether such proposals, if promulgated, are also found to be defensible.

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²⁴⁶ See, for example, testimony in U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *Testing of Chemicals and Reporting and Retention of Information under TSCA Sections 4 and 8*, hearing, 113rd Cong., 2nd sess., February 4, 2014 (Washington: GPO, 2013).

²⁴⁷ See footnote 148.

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