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

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Summary

In 1976, the Toxic Substances Control Act (TSCA; P.L. 94-469) was enacted to direct the U.S. Environmental Protection Agency (EPA) to obtain information relevant to evaluating 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. Concerns that EPA lacked sufficient authority to take such actions, among other concerns, led to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182), which amended TSCA, in 2016. Still, Congress requires that implementation of the amended TSCA balance two objectives—the protection of public health and the environment from unreasonable risks and the regulation of chemicals in a manner that does not "impede unduly or create unnecessary economic barriers to technological innovation."

TSCA as amended requires EPA to gather existing information (e.g., production volumes, health and safety studies) regarding potential chemical risks from chemical manufacturers, processors, and distributors. Manufacturers of new chemicals must notify EPA prior to the chemical being commercialized. Similar notification requirements apply to chemicals proposed for uses determined by EPA to be significant new uses.

If EPA has inadequate information on a chemical to determine whether it presents unreasonable risks, TSCA authorizes the agency to require the development of new information necessary for the evaluation of risks. For information submitted under TSCA, the act establishes a framework to protect from disclosure information that warrants confidential treatment and to ensure that certain types of information are disclosed.

To identify which chemicals may warrant regulation, TSCA requires EPA to systematically prioritize chemicals for risk evaluation and to regulate those chemicals that present unreasonable risks to ensure they no longer do so. If EPA finds that a chemical presents unreasonable risk, TSCA requires the agency to undertake rulemaking to regulate the chemical.

EPA must take regulatory action on specific chemicals that exhibit characteristics known to present greater risks in an expedited manner. For instance, EPA may promulgate requirements to address risks presented by certain persistent, bioaccumulative, and toxic chemicals without conducting a risk evaluation. Additionally, TSCA authorizes EPA to commence a civil action against imminently hazardous chemicals and expedite review of chemicals that present significant risk of serious or widespread harm.

For new chemicals and chemicals proposed for a significant new use determined to warrant evaluation by EPA, the agency must make a determination regarding unreasonable risk within 90 days of the required notification unless extended for good cause.

Under TSCA, requirements that apply to chemical manufacture apply in the same way to chemical importation. TSCA establishes procedures for handling imports of chemicals that do not comply with requirements under the act. Chemicals marked for export only are subject to recordkeeping and reporting requirements unless EPA has previously taken regulatory action to require the development of new information or establish a requirement to protect against unreasonable risk.

TSCA includes provisions to allow citizens to challenge EPA implementation of the act. Additionally, TSCA includes provisions for enforcement, including inspection and administrative subpoena authority, establishment of civil and criminal penalties for violations, and citizen suits to allow any person to enforce the act.

TSCA provides a federal role for the evaluation and restriction of chemicals, but, unlike most other federal environmental statutes, does not provide for delegation to, or implementation by, states. However, states may evaluate and regulate chemicals under their own authorities. TSCA provides limited explicit preemption of state requirements, although long-standing state requirements are generally preserved. If a state requirement does not meet one of the exceptions from preemption, waivers from preemption may be available under certain circumstances.

Although authorization of appropriations to carry out TSCA expired in 1983, Congress has continued to fund TSCA activities through annual discretionary appropriations. TSCA authorizes EPA to collect fees from chemical manufacturers and processors to partially defray costs that the agency may incur from evaluating information submissions, conducting risk evaluations, and developing regulations.

The original 1976 act, which was amended by P.L. 114-182, is referred to as Title I. Since 1976, Congress has added five other titles to TSCA to address specific chemical concerns. The five additional titles of TSCA are not discussed in this report.

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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 1976, 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. None of the additional titles made amendments to 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 has required chemical manufacturers and processors to report information on chemicals being manufactured or processed in the United States to the agency. For certain chemicals that EPA determined not to have adequate information to evaluate risks, the agency has required 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.[4] For chemicals introduced into commerce after 1976, EPA established a program to identify which of those chemicals warranted regulation and has taken regulatory action on a subset of such chemicals. However, over time as EPA administered TSCA, environmental and public health organizations questioned whether the agency had sufficient information to evaluate risks from chemicals and whether the agency could demonstrate that the risks of a chemical met the threshold for regulating a chemical. To address these issues and others, multiple proposals to amend TSCA were introduced beginning in the 109th Congress through the 114th Congress.

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182), which amended TSCA.[5] P.L. 114-182 broadly amended the

[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] Under TSCA, EPA has promulgated regulations to prohibit or restrict (1) chlorofluorocarbons used in aerosol propellants, (2) nitrosamines in metalworking fluids (40 C.F.R. Part 747), (3) hexavalent chromium used in certain water cooling towers (40 C.F.R. Part 749), (4) new uses of asbestos (40 C.F.R. Part 763, Subpart I), (5) dioxin-contaminated wastes, and (6) polychlorinated biphenyls (40 C.F.R. Part 761). Regulations that pertain to chlorofluorocarbons and dioxin-contaminated wastes under TSCA were later superseded by regulations promulgated under other environmental statutes.

[5] For committee reports of bills reported to the House and Senate that resulted in P.L. 114-182, 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).

information gathering, chemical evaluation, and regulation authorities of TSCA and also provided additional procedures and standards for confidential treatment or disclosure of information submitted to EPA under TSCA. To supplement funding provided for TSCA implementation, P.L. 114-182 expanded EPA authority to collect fees from chemical manufacturers and processors to partially defray the costs of conducting risk evaluations. With these amendments to TSCA, EPA implementation of the statute is ongoing, and, to date, no additional chemicals reported to have been in commerce before 1976 have been regulated, though the agency continues to gather information on, and evaluate risks for, a wide variety of chemicals.

As Congress debated whether to expand EPA authority to regulate chemicals under TSCA leading up to the enactment of P.L. 114-182, federal preemption of state requirements became a key issue. As enacted in 1976, TSCA preempted state and local requirements for specific chemicals for which EPA has required the development of new information or taken regulatory action under the act. In the years between the original enactment of TSCA in 1976 and the enactment of P.L. 114-182 in 2016, some states and localities enacted their own laws or promulgated regulations pertaining to chemicals. States and localities took regulatory action 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. P.L. 114-182 established additional conditions in which TSCA requirements would or would not preempt state chemical regulatory requirements.

The following sections of the report summarize the major authorities of TSCA and cover 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 in 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.

This report summarizes selected statutory provisions of TSCA but does not discuss agency regulations and guidance that may provide more detailed direction for conducting risk evaluation and selecting regulatory options to prevent unreasonable risks of specific chemicals.

Chemicals Covered by TSCA and Limitations on Authority

The scope of chemicals covered by TSCA is broad, but to prevent redundancy with other federal pollution control and public health laws, Congress excluded groups of chemicals already covered under such laws from the information gathering and regulatory authorities of TSCA. Congress excluded groups from the reach of TSCA through the statutory definition of "chemical

substance," which broadly includes substances that have a particular molecular identity but excludes

- pesticides;
- tobacco and tobacco products;
- certain radioactive materials;
- firearms (including pistols and revolvers), shells, cartridges, and their components;
- food (including poultry, meat, and eggs), food additives (including food contact substances), drugs, cosmetics, and medical devices; and
- mixtures.[6]

Although the definition of a chemical substance excludes mixtures, multiple TSCA provisions apply to mixtures, which the act generally defines as combinations of chemical substances not resulting from a chemical reaction.[7] References hereinafter to "chemicals" in the report collectively refer to chemical substances and mixtures. Provisions that apply specifically to chemical substances or mixtures are noted accordingly. Generally, mixtures are subject to requirements under TSCA if requirements that pertain to the constituent chemical substances of a mixture are not adequate in evaluating or controlling risks. 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 the chemical substance presents an unreasonable risk or meets 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 placed general limitations on the extent to which regulatory actions may be taken on a chemical under TSCA. In effect, the exclusions and limitations in TSCA may restrict the applicability or scope of the regulatory authorities under the act.

For example, in multiple provisions under TSCA, an "unreasonable risk" finding or determination is a prerequisite for EPA to take action to require information on, or regulate, a chemical. TSCA does not explicitly define what constitutes unreasonable risk, which, in effect, gives discretion to EPA on the interpretation of the statutory term. In 1991, however, 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.'"[8] This interpretation led the court to vacate parts of an EPA rule that regulated various asbestos uses.

Though P.L. 114-182 did not amend TSCA to explicitly define *unreasonable risk*, it prohibited EPA from considering cost or nonrisk factors when evaluating risks, although those factors must be considered in rulemaking to restrict a chemical identified for regulatory control. Additionally,

[6] 15 U.S.C. §2602(2).

[7] 15 U.S.C. §2602(10).

[8] Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1222 (5th Cir. 1991) (quoting prior version of 15 U.S.C. §2605(c)(1)).

P.L. 114-182 codified existing agency practice to consider risks for "potentially exposed or susceptible subpopulations" when evaluating the risks of a chemical.

Even if EPA were to determine unreasonable risk, TSCA provides that authorities under other federal law supersede TSCA authorities to address unreasonable risks. If EPA were to determine that a risk associated with a chemical may be eliminated or reduced to a sufficient extent by actions taken under the authorities of other federal law 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.[9] If EPA were to determine that a chemical presents an unreasonable risk that may be prevented or reduced sufficiently by action taken under a federal law administered by another federal agency, Section 9(a) directs EPA to submit to that other agency a report describing the risk and a request for response.[10] The federal agency receiving 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 that the chemical presents unreasonable risk identified by EPA or initiates action to protect against such risk, then EPA may not regulate the chemical under TSCA.[11]

Role of Scientific and Technical Information

Under TSCA, scientific and technical information about a chemical serves as the starting point to a risk evaluation that may lead to regulatory action. The chemical industry and environmental and public health organizations have contested on occasion the quality of scientific and technical information that EPA relies upon to make regulatory decisions under TSCA. P.L. 114-182 added various provisions to TSCA to specify how EPA is to use scientific and technical information to carry out the act. In determining whether to require development of new information or to regulate a chemical that presents unreasonable risks, EPA must consider, as applicable, the "best available science" and factors generally used to assess the quality of scientific information.[12] EPA must also consider "reasonably available information" that relates to the conditions of use of chemicals and make decisions based on the "weight of the scientific evidence."[13] By June 2018, EPA must develop policies, procedures, and "guidance" necessary to carry out the amendments to TSCA made by P.L. 114-182.[14] 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, TSCA directs EPA to establish a Science Advisory Committee on Chemicals for providing independent scientific and technical advice to the agency regarding implementation of the act.[15] The committee's advice is not binding on EPA.

[9] 15 U.S.C. §2608(b). 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.

[10] 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.

[11] 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 in 1985. OSHA, "Occupational Exposure to 1,3-Butadiene," 51 *Federal Register* 35003, October 1, 1986.

[12] 15 U.S.C. §2625(h).

[13] 15 U.S.C. §2625(i) and (k).

[14] 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.

[15] 15 U.S.C. §2625(o). As a federal advisory committee, the Science Advisory Committee on Chemicals is subject to (continued...)

Recordkeeping and Reporting Requirements and Confidentiality or Disclosure of Information

Under TSCA, EPA relies on scientific and technical information regarding chemicals to evaluate risks and determine if regulation is warranted. This information may be obtained through various recordkeeping and reporting requirements under the act. TSCA directs EPA to require chemical manufacturers, processors, and distributors to report information that relates to existing chemicals, new chemical substances, and significant new uses of chemical substances. If information available to EPA is insufficient to evaluate risks of a chemical and the agency has a need for additional information, TSCA authorizes EPA to require the development of new information regarding that chemical. Information that EPA obtains from chemical manufacturers and processors may contain material that, if disclosed, would harm commercial interests, so TSCA provides protection from disclosure of submitted information if the submitter can justify that the information meets certain criteria.

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 that pertain to chemicals (e.g., chemical identity, uses, volumes produced, byproducts, health and environmental effects, exposure, and disposal methods). EPA may also require that chemical manufacturers and processors report those records to the agency.[16] 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 has previously regulated under the act.[17]

From information gathered, EPA must maintain a list of chemical substances manufactured or processed for commercial purposes in the United States, excluding from the list those substances manufactured or processed in small quantities for research and development. 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. EPA refers to these substances as "existing" substances. New chemical substances are to be included on the inventory upon their manufacture in the United States. Since the original enactment of TSCA, more than 24,000 chemical substances have been added to the TSCA Inventory as new chemical substances. P.L. 114-182 amended TSCA Section 8 to require the division of the TSCA Inventory into "active

(...continued)

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.

[16] 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.

[17] 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).

substances" and "inactive substances," depending on whether or not the substance was manufactured or processed between June 2006 and June 2016.[18]

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.[19] Section 8 also 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.

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 exempted.[20] This notification is known as a premanufacture notice (PMN).[21] According to EPA, the agency has received more than 40,000 PMNs since the enactment of TSCA in 1976.[22]

Chemical manufacturers and processors must also submit a notice to EPA prior to the manufacture or processing of a chemical for a use determined by EPA to be significant and new. EPA determines significant new uses through rulemaking on a chemical-by-chemical basis after considering all relevant factors, including projected volumes of manufacture and processing and changes in the manufacture, process, distribution, use, or disposal that may increase exposure to the chemical. A rule determining significant new use is known as a significant new use rule (SNUR), and notifications submitted under a SNUR are known as significant new use notices (SNUNs).[23]

The types of information required in a PMN or SNUN are relevant to assessing risk (e.g., chemical identity, uses, volumes produced, byproducts, health and environmental effects, exposure, and disposal methods). P.L. 114-182 amended TSCA Section 5 to direct EPA to review a PMN or SNUN within 90 days of receipt to determine if regulatory action is warranted.[24] EPA may extend the review period by 90 days with appropriate justification. 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."

[18] 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.

[19] 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.

[20] 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 produced for commercial purposes. These EPA regulations are codified at 40 C.F.R. Part 725.

[21] A sample PMN form is available at EPA, *Premanufacture Notice for New Chemical Substances*, O.M.B. No. 2080-0173, https://www.epa.gov/sites/production/files/2015-10/documents/final_pmn_print_form070709.pdf.

[22] EPA, "Reviewing New Chemicals Under the Toxic Substances Control Act (TSCA), Statistics for the New Chemicals Review Program Under TSCA," last updated March 22, 2018, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[23] SNURS are codified at 40 C.F.R. Part 721. The sample PMN form referenced in footnote 21 is also the sample form for submitting a SNUN.

[24] Prior to P.L. 114-182, EPA had the discretion to review PMNs and SNUNs submitted to the agency.

Under Section 5(h), EPA may exempt from PMN and SNUN requirements circumstances in which the use of a chemical substance would likely present a lesser degree of risk or in which EPA already has information on the chemical substance.[25] In some circumstances, entities must apply to receive the exemption. For exemptions that require an application, EPA must grant or deny the exemption within 45 days upon receiving the application. According to EPA, the agency has received over 14,000 exemption applications since the enactment of TSCA in 1976.[26]

Development of New Information Regarding Chemicals

Section 4(a) authorizes EPA to request chemical manufacturers or processors to develop new information necessary to evaluate the risks of a chemical if available information on the chemical is insufficient for the agency to evaluate risks associated with the chemical and the agency suspects unreasonable risks associated with the chemical that may warrant regulation.[27] 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.[28] 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. A requirement to develop new information for prioritizing chemicals for risk evaluation is limited only to information necessary to meet that objective. EPA may not establish a broadly applicable "minimum information requirement" for purposes of prioritization of chemicals for risk evaluation.[29]

Section 4(e) establishes an interagency committee for purposes of recommending chemicals to the agency to consider requiring the development of new information.[30] No more than 50 chemicals may be designated at any one time as those that warrant the development of new information within 12 months of the designation. The committee must review its recommendations and designations at least once every six months to determine if revisions are necessary. However, the committee's recommendations and designations are not binding on EPA.

[25] EPA regulations implementing the process for granting or denying exemption applications from PMN and SNUN requirements are codified at 40 C.F.R. Part 723. EPA has established several exemptions, including for specified low volumes and certain types of polymers. The sample PMN form referenced in footnote 21 is also the sample form for submitting an exemption from PMN or SNUN requirements.

[26] EPA, "Reviewing New Chemicals Under the Toxic Substances Control Act."

[27] Regulations that govern procedures for entering into consent agreements or promulgating a rule to require the development of new information for chemicals is 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.

[28] Prior to P.L. 114-182, 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. P.L. 114-182 codified this authority and also authorized EPA to issue orders for the same purpose.

[29] A minimum information requirement generally refers to a pre-determined set of information about a chemical that is required to be submitted without the review of available information to determine whether subsets of the pre-determined information may not be necessary for the evaluation of risks. In contrast, a tiered approach to requiring the submission of information would first rely on a review of available information about a chemical to determine what additional information is needed for the evaluation of risks.

[30] 15 U.S.C. §2603(e).

Exemptions from requirements to develop new information for a chemical are provided for instances when the requested information has already been developed or is being developed by another entity. TSCA establishes a process for the reimbursement of testing costs by those receiving an exemption to the entity that developed or is developing the required information.[31]

EPA must publish a notice in the *Federal Register* of the receipt of any new information required to be developed within 15 days of its receipt. 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.

Research, Development, and Monitoring Activities

Section 10 authorizes EPA, in consultation and cooperation with other federal agencies, to conduct basic and applied research, development, and monitoring activities (e.g., toxciological screening, environmental monitoring) for purposes of carrying out the act.[32] 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.

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. A long-standing issue is whether animals are unnecessarily being used to test chemicals. P.L. 114-182 added Section 4(h) to TSCA to require EPA to develop a strategic plan for purposes of minimizing, to the extent practicable, the use of vertebrate animals when requiring the development of new information pertaining to a chemical under TSCA.

Confidentiality and Disclosures of Information

TSCA balances two objectives: (1) protecting sensitive or proprietary information submitted to EPA under TSCA from public disclosure and (2) maintaining the public's right of access to information about the agency's activities under the act. TSCA builds upon Freedom of Information Act (FOIA) protections from disclosure.[33] FOIA requires federal agencies to disclose information requested by any person unless the information falls under one of nine exemptions. TSCA Section 14 requires EPA to withhold from disclosure information that meets the criteria under FOIA Exemption 4 and for which a confidentiality claim has been properly asserted.[34] FOIA Exemption 4 refers to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Knowing and willful disclosure is subject to a criminal penalty.[35]

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[31] Regulations that govern data reimbursement are codified at 40 C.F.R. Part 791.

[32] 15 U.S.C. §2609.

[33] 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.

[34] 15 U.S.C. §2613. TSCA Section 14 cross-references 5 U.S.C. Section 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.

[35] 15 U.S.C. §2613(a), (h).

Notwithstanding confidential treatment for trade secrets and other confidential information, Section 14 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.[36] For specific chemical identities determined to warrant confidential treatment, P.L. 114-182 amended TSCA Section 14 to require the use of unique generic identifiers instead and also to establish a presumption that information pertaining to chemicals for which EPA has required a ban or phaseout can be released.[37]

A person seeking to protect information from disclosure must file a confidentiality claim when submitting the information to EPA and substantiation for the claim unless the information falls into one of the categories of information explicitly exempt from disclosure. P.L. 114-182 amended TSCA Section 14 to require further substantiation for claims regarding a specific chemical identity.[38] P.L. 114-182 also limited the validity of any confidentiality claim substantiation to 10 years and provides an opportunity to renew the substantiation before its expiration.[39] EPA must review a subset of confidentiality claims or renewals subject to substantiation requirements and all claims or renewals for specific chemical identity.[40]

Even when information is determined to warrant confidential treatment, Section 14 establishes circumstances in which such information may or must be disclosed. For instance, such information may be disclosed to states, localities, tribes, and health or environmental professionals under certain conditions and if EPA were to determine that disclosure is necessary to protect health or the environment against an unreasonable risk.[41]

Federal Chemical Evaluation and Regulatory Authorities

Determining which chemicals EPA should select to evaluate risks has been a long-standing issue given finite resources to evaluate chemicals already in commerce and new chemical substances. EPA evaluation of a chemical is intended to synthesize information to inform the agency's decisionmaking on whether the regulatory threshold is met to restrict that chemical. TSCA establishes a framework for EPA to prioritize which chemicals to evaluate for risks and directs EPA to take expedited actions for specific chemicals:

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

[36] 15 U.S.C. §2613(b)(2).
[37] 15 U.S.C. §2613(b)(4).
[38] 15 U.S.C. §2613(c).
[39] 15 U.S.C. §2613(e).
[40] 15 U.S.C. §2613(f)-(g).
[41] 15 U.S.C. §2613(d).

Prioritization of Chemicals for Evaluation of Risks

P.L. 114-182 amended TSCA Section 6 to establish a framework for the prioritization of chemical substances for risk evaluation.[42] Section 6 directs EPA to select 10 chemical substances for risk evaluation from a list of chemical substances that the agency identified to warrant risk assessment in 2014. In December 2016, EPA published its selection of the first 10 chemical substances for risk evaluation.[43]

EPA must also promulgate a rule that establishes a risk-based screening process for designating chemical substances as high priority or low priority for risk evaluations.[44] The screening process must give preferences to chemical substances previously judged to present a greater level of risk (e.g., acute toxicity, carcinogenic, persistent and bioaccumulative) and include the consideration of hazard and exposure potential for chemical substances, their conditions of use, and the volume manufactured or processed.

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. Otherwise, if EPA concludes, based on information sufficient to establish, 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 available information. If EPA has insufficient information to prioritize the chemical, the agency must require the development of new information and prioritize the chemical within 90 days of receiving the required information. EPA must prioritize chemicals and conduct risk evaluations for high-priority chemicals at a pace consistent with the agency's ability to complete risk evaluations, though TSCA also establishes the minimum number of risk evaluations that EPA must ensure are ongoing at given time frames. Upon the completion of a risk evaluation, EPA must designate at least one other chemical as high priority for risk evaluation.

Section 6 establishes a process for chemical manufacturers to request EPA to conduct a risk evaluation on a specific chemical if the manufacturer were to pay the requisite fee, discussed later in the "Resources to Administer TSCA" section of the report. However, manufacturer requests for risk evaluation of a chemical identified in 2014 by EPA to warrant risk assessment are not subject to fees. EPA has discretion to grant or deny requests for risk evaluation.

Risk Evaluation Process

The original enactment of TSCA in 1976 directed EPA to regulate the lifecycle of chemicals that present unreasonable risks but did not specify how the agency would evaluate risks of chemicals. Over time, EPA has developed multiple guidance for the risk assessment of chemicals.[45]

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[42] 15 U.S.C. §2605.

[43] EPA selected the following 10 chemicals to be evaluated: (1) 1,4-dioxane; (2) 1-bromopropane; (3) asbestos; (4) carbon tetrachloride; (5) cyclic aliphatic bromide cluster (i.e., hexabromocyclododecane or HBCD); (6) methylene chloride; (7) N-methylpyrrolidone; (8) Pigment Violet 29; (9) tetrachloroethylene, also known as perchloroethylene; and (10) trichloroethylene. EPA, "Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act," 81 *Federal Register* 91927, December 19, 2016.

[44] EPA regulation establishing procedures for prioritization of chemicals for risk evaluation are codified at 40 C.F.R. Part 702, Subpart A.

[45] 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 March 1, 2018, https://www.epa.gov/risk/risk-assessment-guidelines. Several of these guidelines are also used to implement other environmental statutes administered by the agency.

Generally, risk assessment involves identifying the adverse health or environmental effects that may be caused by exposure to a chemical 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 assessing 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.

P.L. 114-182 amended TSCA Section 6 to require EPA to promulgate a rule that establishes the manner in which the agency is to conduct risk evaluations for purposes of determining whether a chemical presents unreasonable risks.[46] The risk evaluation must be done without consideration of cost and other nonrisk factors. EPA must complete a risk evaluation within three years after initiating the risk evaluation, though the agency may extend this time frame up to six months. Additionally, P.L. 114-182 amended TSCA Section 26 to require EPA to annually identify which chemical risk evaluations the agency intends to initiate or complete in the upcoming year.[47]

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 that would eliminate the unreasonable risk.[48] In proposing or promulgating a rule to regulate a chemical found to present unreasonable risk, EPA may select among seven different regulatory options, 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 on the manner or method of commercial use of the chemical;
6. Prohibition or regulation on the manner or method of disposal of the chemical (including as part of a mixture or an article); and
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.

[46] 15 U.S.C. §2605(b). EPA regulation establishing procedures for chemical risk evaluations are codified at 40 C.F.R. Part 702, Subpart B.

[47] 15 U.S.C. §2625.

[48] 15 U.S.C. §2605. EPA regulation establishing procedures for rulemaking to address a chemical found to present unreasonable risks is codified at 40 C.F.R. Part 750.

Section 6 directs EPA to promulgate these requirements in accordance with Section 553 of the Administrative Procedure Act (APA) and additional procedural requirements, such as the consideration of the chemical's risks and benefits, reasonably ascertainable economic consequences of the requirements on the chemical, and alternative regulatory actions.[49] Under Section 6, as amended by P.L. 114-182, 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. However, EPA may extend these time frames up to two years for chemicals the agency has not already identified as persistent and bioaccumulative.

Additionally, the effective date of a Section 6 rule must provide for a reasonable transition period before the mandatory compliance dates become effective. EPA must establish mandatory compliance dates not later than five years after promulgation of the rule except for uses being exempted and may vary the mandatory compliance dates for different affected persons (e.g., chemical manufacturers, processors, and distributors). EPA may declare a proposed rule to be effective, and compliance with the proposed requirements to be mandatory, upon its publication in the *Federal Register* until the proposed rule is finalized or revoked.

P.L. 114-182 amended TSCA Section 6 to require EPA to exempt replacement parts from the scope of regulation on a chemical 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 identified from a risk evaluation.[50] EPA may grant an exemption from a rule if doing so (1) maintains critical or essential uses of a chemical; (2) avoids potential disruption of the national economy, security, or critical infrastructure by a requirement; or (3) allows benefits to health, environment, or public safety from the chemical despite its risks.[51]

Special Regulatory Authority for Certain 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. Because PCBs bioaccumulate, do not readily break down in the environment, and are of concern for human health, in 1976, Congress included a provision in TSCA that directed EPA to promulgate rules to prescribe methods for the disposal of PCBs and require clear and adequate warnings and instructions with respect to their processing, distribution, use, and disposal.[52] Furthermore, after a transition period, TSCA made it unlawful to manufacture, process, and distribute PCBs unless exempted through a petition and rulemaking process. Exemptions are limited to one year and subject to terms and conditions that EPA may prescribe.

[49] For more information on 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.

[50] 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.

[51] 15 U.S.C. §2605(g).

[52] 15 U.S.C. §2605(e). EPA regulation concerning PCB manufacture, processing, distribution, use, and disposal are codified at 40 C.F.R. Part 761. Bioaccumulation generally refers to the retention of a chemical in an organism at ever increasing levels.

Certain Persistent, Bioaccumulative, and Toxic Chemical Substances

P.L. 114-182 added TSCA Section 6(h) to direct EPA to propose rules by June 2019 to address unreasonable risks of chemical substances that the agency had identified as persistent, bioaccumulative, and toxic (PBT) in 2014 and that also meet certain other criteria.[53] Rulemaking under Section 6(h) would occur under an expedited basis that does not require conducting a risk evaluation. Section 6(h) directs EPA to finalize a rule to reduce exposures, to the extent practicable, to the identified PBT chemicals not later than 18 months after proposing the rule.

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. Under Section 7, EPA may commence a civil action in U.S. district court to protect against an "imminently hazardous chemical," which is defined as a chemical that likely presents unreasonable risk of serious or widespread injury prior to the promulgation of a rule to regulate the chemical.[54] Where 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.[55]

If EPA were to conclude that a chemical presents significant risk of serious or widespread harm to humans, Section 4(f) requires the agency, within 180 days of receiving information supporting the conclusion, to initiate an action to prevent or reduce to a sufficient extent such risk or publish a finding in the *Federal Register* that the risk is not unreasonable.[56] 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, Section 5(f) directs the agency to either propose a rule to apply one or more of the specified regulatory options to the extent necessary to protect against such risk or issue an order to prohibit or limit manufacture, processing, or distribution. A proposed rule becomes 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. An issued order becomes effective at the end of the review period. Though more than 40,000 PMNs have been submitted to EPA, the agency has promulgated

[53] 15 U.S.C. §2605(h). In December 2016, EPA identified five chemical substances that meet the criteria, which include (1) decabromodiphenyl ethers (DecaBDE), used generally as a flame retardant; (2) hexachlorobutadiene (HCBD), used generally as a solvent; (3) pentachlorothiophenol (PCTP), used to make rubber more pliable; (4) phenol, isopropylated, phosphate (3:1), used generally as a flame retardant; and (5) 2,4,6-Tris(tert-butyl) phenol, used as a fuel or lubricant additive. For more information, see EPA, "Persistent, Bioaccumulative, and Toxic (PBT) Chemicals Under TSCA Section 6(h)," last updated December 5, 2017, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under.

[54] 15 U.S.C. §2606.

[55] In one instance, 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).

[56] 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.

regulations under Section 5(f) for few chemical substances (e.g., nitrosating agents in metalworking fluids).[57]

If 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. An issued order becomes effective at the end of the review period. While the required information is being developed, the submitter of the PMN or SNUN must comply with the order. For new chemical substances in which information is insufficient to evaluate risks, EPA may promulgate a SNUR to apply the restrictions outlined in a Section 5(e) order to other manufacturers and processors. Prior to June 2016, EPA reported that the agency had issued 1,729 Section 5(e) consent orders.[58] Among the Section 5(e) consent orders, more than 750 were associated with SNURs.

For substances subject to PMN and SNUN requirements that EPA finds 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 EPA publishes a statement of the agency's finding.

Chemical Imports and Exports

Import Certification

Under TSCA, requirements that apply to the manufacture of chemicals also apply to their importation based on the inclusion of importation in the statutory definition of *manufacture*.[59] The same substantive requirements that apply to chemicals manufactured within the United States also apply to those manufactured outside the United States. Section 13 establishes a process for handling chemicals (including mixtures and articles that contain chemicals) imported to the United States that violate TSCA requirements.[60]

Export Notification

Section 12 limits the applicability of TSCA requirements on chemicals manufactured or processed solely for export unless EPA has already required the development of new information or promulgated requirements to address unreasonable risks presented by the chemical. Generally, only recordkeeping and reporting requirements apply for chemicals (including mixtures and articles that contain chemicals) manufactured or processed, and marked, for export only.[61] 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

[57] 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.

[58] EPA, "Reviewing New Chemicals Under the Toxic Substances Control Act."

[59] 15 U.S.C. §2602(9).

[60] 15 U.S.C. §2612. Regulations governing importation of chemicals is codified at 19 C.F.R. §§12.118-12.127 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 Lisa N. Sacco.

[61] 15 U.S.C. §2611. EPA regulations governing export notification requirements are codified at 40 C.F.R. Part 707, Subpart D.

export activity. In turn, EPA must notify the country receiving the chemical export of the TSCA requirements applicable to the chemical being exported.

Mercury Export Ban Act

In 2008, the Mercury Export Ban Act (MEBA; P.L. 110-414) was enacted 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 to concerns of human health and environmental effects from exposure.[62] MEBA added Section 12(c) to TSCA, which makes it unlawful to export elemental mercury unless exempted as an "essential use" through a petition and rulemaking process or the export involves coal.[63] Essential use exemptions are limited to three years in duration and 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. P.L. 114-182 amended TSCA to make it unlawful to export specific mercury compounds after January 1, 2020, and required EPA to report to Congress on the status of mercury compound exports and disposal.

Other TSCA provisions complement the mercury export provision. MEBA added Section 6(f) to TSCA to make it unlawful for federal agencies to convey, sell, and distribute elemental mercury under its jurisdiction unless the transfer of elemental mercury facilitates its storage or involves coal.[64] Prior to MEBA, the policy of the U.S. Department of Energy (DOE) and Department of Defense was to store, not sell, mercury stocks.[65] MEBA codified this existing policy and also directed DOE to establish a program for long-term management and storage of elemental mercury generated within the United States.[66] P.L. 114-182 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*.[67]

Citizens' Petitions, Citizens' Suits, and Enforcement

Like many other environmental statutes, TSCA establishes a process to resolve citizen petitions and citizen suits that challenge EPA implementation of the act. Under Section 21, any person may petition EPA to issue, amend, or repeal certain TSCA rules or orders.[68] EPA must either grant or deny a citizen petition within 90 days after the filing of the petition. Petition denials are judicially reviewable.

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[62] U.S. Geological Survey, "Mercury," *Mineral Commodity Summaries*, January 2018; and Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Mercury*, March 1999.

[63] 15 U.S.C. §2611(c).

[64] 15 U.S.C. §2605(f).

[65] 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.

[66] 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.

[67] 15 U.S.C. §2607(b)(10). Additionally, P.L. 114-182 amended Section 5 of MEBA (42 U.S.C. §6939f) with regard to the long-term storage of mercury.

[68] 15 U.S.C. §2620. EPA's website includes a list of TSCA Section 21 petitions filed with the agency since September 2007. EPA, "TSCA Section 21," last updated April 19, 2017, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21.

Under Section 20, any person may sue EPA to compel it to perform a nondiscretionary duty or may sue any other person (including government entities) alleged to be in violation of certain types of TSCA rules or orders.[69] Section 20 generally requires the plaintiff of the suit to have given 60 days' notice of the claims to the Administrator and the alleged violator prior to filing the suit. However, citizen suits are not available if EPA or the Department of Justice is already "diligently prosecuting" the alleged violator to require compliance with the act's requirements, though a citizen who has given notice may intervene in the ongoing enforcement proceeding as a matter of right. 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 many aspects of judicial review of various EPA actions. In general, Section 19 requires that petitions for judicial review of most rules and orders under TSCA, and civil actions challenging low-priority designations,[70] be filed within 60 days after EPA takes final action.[71] Section 19 gives exclusive jurisdiction to the federal courts of appeals. For civil actions challenging low-priority designations, jurisdiction is limited specifically to the U.S. Court of Appeals for the District of Columbia Circuit.[72] Review is presumptively limited to the administrative record.[73] The standard of review for most EPA rules and orders under TSCA is that "the court shall hold unlawful and set aside such rule [or order] if the court finds that the rule [or order] is not supported by substantial evidence" in the record[74] rather than the usual and more deferential "arbitrary or capricious" standard under APA.[75] Several other TSCA provisions (Sections 11, 15, 16, and 17) also relate to enforcement of the act.[76] To enforce TSCA rules, orders, and consent agreements, the act provides inspection and administrative subpoena authority to EPA and provides EPA with administrative and judicial mechanisms to restrain violations and apply civil or criminal penalties to violators. Administrative civil penalties are capped and further limited if a state enforces for the same violation under its own law.[77] Section 22 authorizes the President through EPA to waive compliance with any TSCA requirement for national defense purposes.[78]

TSCA includes provisions intended to protect employees of regulated entities from retaliation for taking part in a proceeding under the act or from potential effects on employment because of economic costs of the act. Section 23 authorizes the Department of Labor to investigate alleged retaliations and provides the department with administrative and judicial mechanisms to resolve such allegations.[79] Section 24 directs EPA to investigate allegations of potential effects on

[69] 15 U.S.C. §2619. Regulations governing citizen suits under Section 20 are codified at 40 C.F.R. Part 702, Subpart C.

[70] See "Prioritization of Chemicals for Evaluation of Risks."

[71] 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.

[72] 15 U.S.C. §2618(a)(1).

[73] 15 U.S.C. §2618(b).

[74] 15 U.S.C. §2618(c)(1)(B)(i).

[75] 5 U.S.C. §706(2)(E).

[76] For a brief background on the enforcement of federal pollution control laws, see CRS Report RL34384, *Federal Pollution Control Laws: How Are They Enforced?*, by Robert Esworthy. Also, in 2016, EPA published its compliance monitoring strategy for TSCA. EPA, "Compliance Monitoring Strategy for the Toxic Substances Control Act (TSCA)," https://www.epa.gov/compliance/compliance-monitoring-strategy-toxic-substances-control-act-tsca.

[77] Statutory civil penalties, as adjusted for inflation, for various environmental statutes, including TSCA, are codified at 40 C.F.R. §19.4.

[78] 15 U.S.C. §2621.

[79] 15 U.S.C. §2622. Regulations that govern the handling of retaliation complaints under Section 23 and other environmental statutes are codified at 29 C.F.R. Part 24.

employment resulting from a TSCA requirement and to prepare recommendations based on the investigation.[80]

Federal and State Relationship

To avoid potential conflict between federal requirements under TSCA and state requirements or restrictions on chemicals, TSCA provides 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.[81] 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.[82] Additionally, TSCA authorizes grants to states that take action against unreasonable risk associated with a chemical that EPA is unable or not likely to address.[83] For example, EPA may award a grant to a state to conduct inspections on behalf of the agency.

Preemption of State Requirements

Under the Supremacy Clause of the U.S. Constitution,[84] state law and policy must yield to the exercise of Congress's powers if Congress so intends. Congress set forth provisions for chemical-specific preemption of state requirements in TSCA as originally enacted and refined those preemption provisions in P.L. 114-182 while retaining essentially the same framework. Under TSCA Section 18 as amended, there is no preemption of state regulation of chemicals unless EPA takes certain actions under the act, in which case any preemption is chemical-specific.[85] Exceptions to preemption may apply, or EPA may grant waivers by rule.[86]

Under Section 18, subject to exemptions and potential waivers, no state may establish or continue to enforce any of the following:

- A statute or administrative action that requires the development of new information on a chemical in which an existing EPA rule, order, or consent agreement under the act would "reasonably likely" produce the same information.
- 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 (i) issued an order finding the chemical not to present an unreasonable risk or (ii) 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.

[80] 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.

[81] 15 U.S.C. §2617.

[82] 15 U.S.C. §2617.

[83] 15 U.S.C. §2627.

[84] U.S. Const. art. VI, cl. 2.

[85] 15 U.S.C. §2617(a)-(c).

[86] 15 U.S.C. §2617(d)-(g).

Section 18 also prohibits states from establishing any *new* prohibition or restriction on a chemical designated by EPA as a high-priority substance for risk evaluation. This restriction begins when EPA defines the scope of the risk evaluation for the chemical and ends either on the deadline for completion of the risk evaluation or when EPA publishes the risk evaluation, whichever is earlier.[87] Such preemption applies only to the extent of the hazards, exposures, risks, and uses included in the scope of the risk evaluation.[88]

Section 18 provides exceptions to preemption, which, in effect, would preserve state chemical requirements that would be preempted otherwise. Notably, all state requirements relating to specific chemical substances that were in effect before April 22, 2016, are generally preserved.[89] States may also continue to take actions on specific chemicals under state laws in effect on August 31, 2003.[90] TSCA also 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 other federal law; (2) implements a federal 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.[91] 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, courts' evidentiary determinations, or common law rights or statutes creating remedies for civil relief—such as damages—under any legal theory of liability.[92]

Section 18 allows the EPA Administrator to exempt from preemption a state requirement under certain circumstances.[93] If the state submits an application for the exemption, the Administrator may, in his or her discretion, grant the exemption if he or she determines that compliance with the requirement would not unduly burden interstate commerce and would not cause a violation of federal requirements, that compelling conditions warrant granting the waiver to protect health or the environment, and that the risk identified by the state is based on sufficiently strong science.[94] 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" and would not cause a violation of federal requirements and that the state's concern about the chemical is based on peer-reviewed science.[95] These required exemptions essentially take effect automatically if the

[87] 15 U.S.C. §2617(b).

[88] 15 U.S.C. §2617(b).

[89] 15 U.S.C. §2617(e)(1)(A).

[90] 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."

[91] 15 U.S.C. §2617(d).

[92] 15 U.S.C. §2617(g).

[93] 15 U.S.C. §2617(f).

[94] 15 U.S.C. §2617(f)(2).

[95] 15 U.S.C. §2617(f)(2).

Administrator misses the 110-day deadline for action on the state's application.[96] All waiver applications are subject to public notice and comment requirements and to judicial review.[97]

Coenforcement

For states that adopt and enforce requirements under their own law identical to those under TSCA, the penalties and other sanctions applied under state law must not be more stringent than those under TSCA.[98] 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.[99] If a state has already assessed a penalty for a violation under state law, TSCA limits EPA to assessing a penalty for the same violation so that the combined total penalty amount would not exceed the maximum penalty amount allowed under the act.

State Grants

TSCA Section 28 authorizes EPA to award grants to states for the establishment and operation of 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.[100] Section 28 limits grant awards to 75% of the establishment and operation costs of the program. P.L. 114-182 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.[101]

Resources 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. 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.[102]

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. The fee receipts were treated as miscellaneous receipts subject to the Miscellaneous Receipts Act and not directly used to implement TSCA.[103]

P.L. 114-182 amended TSCA Section 26(b) to authorize the collection of fees from certain types of information submissions if appropriations for a related EPA "program project" are at least as much as that appropriated in FY2014. Fee collections are limited to 25% of EPA's annual costs of

[96] 15 U.S.C. §2617(f)(3).

[97] 15 U.S.C. §2617(f)(5)-(6).

[98] 15 U.S.C. §2617(d)(1)(B).

[99] 15 U.S.C. §2617(d)(1)(B).

[100] 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.

[101] Although authorization of appropriations for these grants expired after FY1983, Congress 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 bill.

[102] 15 U.S.C. §2628.

[103] 31 U.S.C. §3302(b).

administering TSCA activities but are not to exceed $25 million per year. Collected fees are to be deposited into the "TSCA Service Fee Fund" in the U.S. Treasury and are made available to EPA subject to the annual discretionary appropriations process to partially defray the costs of conducting chemical risk evaluations. This authority to collect fees expires June 2026. Section 26(m) also requires EPA to periodically report to Congress estimates on its capacity to complete the required number of chemical risk evaluations, including those requested by chemical manufacturers, and promulgate rules to regulate chemicals that present unreasonable risks.[104]

Concluding Discussion

TSCA establishes a framework for EPA to obtain information on a vast and growing body of 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 were to find unreasonable risk. The 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. However, until EPA completes a systematic risk evaluation, the agency generally cannot 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 perspectives on what types of information are necessary for EPA to evaluate the risks of a chemical.

The scientific understanding of the risks of a chemical is generally not static. More studies may be conducted to better understand the risks of a chemical. Some studies may suggest that a chemical presents more risk than previously thought, while other studies may suggest the opposite view. Ultimately, risk assessors must exercise professional judgment in characterizing the body of scientific information with regard to the risks a chemical may present.

Even if EPA were to find that a chemical presents unreasonable risks that warrant regulatory control, the agency would be required to consider costs and other factors when selecting the appropriate regulatory requirement, potentially leading to disagreements regarding cost analyses and priorities. Furthermore, even if stakeholders concurred with EPA's assessment of risks, there may be different perspectives on whether the regulatory requirement selected by EPA adequately addresses the identified unreasonable risk and meets the statutory requirements. Disagreements may be resolved in litigation.

Ultimately, the pace at which EPA can evaluate chemicals and promulgate regulations for chemicals that present unreasonable risks under TSCA depends on resources, staffing, and the availability of relevant scientific and technical information about chemicals. Even then, EPA authority to regulate a chemical depends on existing regulations promulgated under other statutes.

[104] 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.

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