ABA SEER Overview of the Toxic Substances Control Act (TSCA)

American Bar Association
Section of Environment, Energy, and Resources (SEER or Section)¹

EXECUTIVE SUMMARY²

The ABA SEER Pesticide, Chemical Regulation and Right-to-Know Committee,³ with the support of the Section’s Special Committee on Congressional Relations, developed this paper outlining core provisions and the scope of the Toxic Substances Control Act (TSCA or the Act, 15 U.S.C.§ 2601 et seq.) to provide a frame of reference for policy development. Enacted in 1976, TSCA most directly regulates the chemical industry. The law gives the Environmental Protection Agency (EPA or the Agency) authority to govern the manufacture, import, processing, distribution, use and disposal of chemical substances. The following sections of the law are highlighted:

- **Section 3** – Contains definitions which underpin how EPA administers TSCA, including the term “chemical substance,” which is defined in such a way so as to establish the reach of EPA’s authority under the Act.

- **Section 4** – Gives EPA authority to require companies (manufacturers, importers, and processors) to test existing chemical substances or mixtures for their effects on human health and the environment.

- **Section 5** – Gives EPA the authority to regulate new chemical substances prior to their manufacture, import, processing, or distribution for commercial purposes and to regulate existing chemical substances for their significant new uses.

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² The ABA is a diverse, non-partisan nongovernmental organization that includes legal practitioners from private sector, public sector, non-profit world, and academia, reflecting a wide diversity of political and policy views. As such, the Section has not taken a formal position endorsing or opposing specific policy proposals or draft bills.

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• **Sections 6 and 7** – Gives EPA additional authority with these sections to regulate existing chemicals (including bans on their continued commercial use) based upon EPA finding that manufacture, processing, distribution, use, or disposal poses an unreasonable risk to human health or the environment. Before a final TSCA section 6 rule is published, EPA has the authority under section 7 to seize an “imminently hazardous” chemical substance or mixture.

• **Section 8** – Gives EPA authority to require manufacturers and processors to collect, maintain, and submit data on chemical substances.

• **Sections 11, 15, 16 and 17** – Provides the compliance and enforcement sections of the Act that authorize EPA to inspect facilities, issue subpoenas, assess penalties and related authorities.

• **Sections 12 and 13** – Requires companies to notify the Agency in advance of exporting regulated chemical substances. Companies must certify when they import chemical substances whether or not the chemical substance is in compliance with TSCA.

• **Section 14** – Extends confidential business information protection to certain information submitted to EPA, excluding health and safety data.

• **Section 18** – Contains a limited express preemption provision under which States are generally free to impose testing or restrictions on a chemical substance if EPA has not enacted the same requirement. States may impose requirements that are more stringent than EPA.

• **Sections 20 and 21** – A “savings clause” that preserves the right of citizens to “seek any other relief” under state statutory and common law and to petition EPA to take action concerning a chemical substance.

This paper addresses how these sections currently operate to address the risks that may be associated with the chemical substances that are regulated by EPA through TSCA. As pointed out in an earlier evaluation, unlike most other environmental statutes that focus on controlling the end products of economic activity (e.g., emissions, discharges, and wastes), TSCA is largely a “front-loaded” statute that provides EPA with the authority to regulate chemicals before and during their use. In that sense, TSCA is essential to the concept of “cradle-to-grave” regulation of commercial activity. TSCA complements several other statutes available to EPA to regulate human health and environmental effects associated with chemical substances (e.g., Clean Air Act, Clean Water Act, Resource Conservation and Recovery Act, Federal Insecticide, Fungicide, and Rodenticide Act).

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4 Regulation of Nanoscale Materials under the Toxic Substances Control Act, ABA SEER, June 2006.
OVERVIEW

TSCA’s roots date back to 1971, when the President’s Council on Environmental Quality (CEQ) identified a need for federal legislation. Given the passage of 43 years, it is hard to imagine the world as it was then. Environmental contamination was very much in the news with the contamination of the Hudson River with polychlorinated biphenyls (PCBs), concerns with ozone depletion caused by chlorofluorocarbon emissions, and related instances of environmental and human health degradation believed to be caused by “toxic” substances. The CEQ prepared a report outlining what it believed was a need for a federal system to manage the manufacture, distribution, processing, use, and sale of chemicals thought to be dangerous and not otherwise regulated by other federal laws. In the 1970s, environmental legislation was evolving addressing clean air, clean water, and waste management. In 1972 and 1973, the House and Senate, respectively, passed bills addressing toxic substances but failed to achieve consensus on core provisions. It was not until October 11, 1976, that President Gerald Ford signed TSCA into law.

TSCA was intended to given expression to three federal policies set forth in TSCA section 2(b) (Policy) with regard to chemical substances. First, Congress intended that adequate data should be developed to identify the effect of chemical substances on human health and the environment. Second, adequate authority should exist to regulate chemical substances and mixtures that present an “unreasonable risk of injury to human health or the environment.” Third, Congress intended that the federal government’s exercise of authority over chemical substances “should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation.”

Over four decades later, Congress and many stakeholders continue to embrace these policies. These same stakeholders, however, have not agreed on how EPA has interpreted its delegation of authority under TSCA and deployed that authority in rulemakings and other TSCA directives and guidance documents. The one point of consensus seems to be the need for TSCA modernization, and legislative reform of certain core aspects of how TSCA should operate. This paper discusses the “core” TSCA statutory provisions to outline what entities are subject to TSCA, what substances are regulated under TSCA, and what substances are exempt because they are regulated under other federal authorities.

I. TSCA’S CORE PROVISIONS

A. Section 3. Definitions

Key terms which underpin how EPA administers TSCA are found in section 3 of the Act. Principal among them is the term “chemical substance,” which is defined in such a way so as to establish the reach of EPA’s authority under the Act. The term “chemical substance” is inclusive of nearly every chemical intended for commercial purposes in the U.S. unless specifically excluded. Examples of substances excluded by statute include foods, drugs, cosmetics and pesticides (when used solely for those purposes). EPA interprets the term “chemical substance” broadly to include naturally occurring substances, microorganisms, and nanoscale materials. However, the term “chemical substance” does not include mixtures made using such substances. Individual substances generally have been the focus of EPA regulatory activities under TSCA,
more so than mixtures and articles manufactured using specific chemical substances (although the Agency retains the authority under TSCA to regulate both).

A key related term is “new chemical substance.” Section 3(9) defines the term to mean any chemical substance not on the list developed under section 8(b), known as the TSCA Inventory of Existing Chemical Substances (Inventory). The authority provided to EPA to regulate chemical substances under the rest of TSCA varies depending on whether a chemical substance is considered new or existing. New chemicals are reviewed under section 5(a)(1) and potentially regulated under other parts of section 5. Existing chemical substances are regulated under either section 6 or section 5(a)(2) and other parts of section 5. In general, it is much easier for EPA to regulate new chemical substances than existing ones. This distinction is based on Congressional recognition that when TSCA was enacted, there were thousands of chemicals in commerce for which economic expectations had already built up. In contrast, there were no such expectations for new chemical substances. Those chemical substances reported for the original Inventory were added to the Inventory without review for their effects on health and the environment. In contrast, new chemical substances are only added to the Inventory after EPA conducts such a review. Some stakeholders have referred to chemical substances originally reported for the Inventory as having been “grandfathered.”

Also of note, TSCA makes clear that the term “manufacture,” as used under the Act, includes importation. For simplicity this paper discusses TSCA’s provisions as they relate to manufacturers, but note that this term also includes importers. In its subsequent provisions, TSCA places most of the responsibility for TSCA compliance upon manufacturers and processors of chemical substances. In implementing those authorities, EPA has by regulation placed most of the burdens on manufacturers, rather than on processors.

B. Section 4. Testing

Section 4 of TSCA gives EPA authority to issue rules requiring manufacturers and processors to undertake and submit the results of new testing on chemical substances or mixtures for their effects on human health and the environment. EPA may require such testing by rule if it makes certain findings. One of the findings is that a chemical substance “may present” an unreasonable risk to human health or the environment. This is less than a finding of “presents or will present” such a risk, which is the finding required for regulation of existing chemicals under section 6. In litigation over the meaning of this provision, the courts have set a relatively low threshold. Nevertheless, some stakeholders have labeled it a “Catch-22” that requires EPA to have risk information before requiring risk information to be developed. EPA also may promulgate a test rule without a risk-based finding if it determines that chemical is or will be produced in substantial quantities and there is or may be significant or substantial human or environmental exposure to the chemical substance. In either case, EPA must find that there are

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5 See Chemical Manufacturers Ass'n v. EPA, 859 F.2d 977, 988 (D.C. Cir. 1988) (“A test rule is warranted when there is a more-than-theoretical basis for suspecting that some amount of exposure occurs and that the substance is sufficiently toxic at that exposure level to present an ‘unreasonable risk of injury to health.’”); Ausimont U.S.A., Inc. v. EPA, 838 F.2d 93, 97 (“the statute prevents a testing rule based on little more than mere curiosity, yet allows the Agency to act when an existing probability of harm raises reasonable and legitimate cause for concern.”).

6 A court directed EPA to elaborate on this standard, recognizing that “EPA has considerable latitude in defining and
insufficient data available to determine the environmental or health effects of the chemical substance, and that testing is necessary to provide such data. The threshold findings to require testing constitute an administrative hurdle and so the number of test rules is not high.7

EPA also obtains test data without going through the rulemaking process. The agency may issue a consent decree requiring testing where a consensus exists among EPA and interested parties and the public about the adequacy of a proposed testing program.8 This process is not reflected in TSCA itself.9 TSCA section 4(e) contemplates that EPA will use its section 4 authority to address not only EPA’s own need for health and safety data, but also the health and safety data needs of sister agencies, such as the National Institute of Occupational Safety and Health, the Occupational Safety and Health Administration, and the National Cancer Institute. EPA has done so to a limited degree.10

C. Section 5. Premanufacture notification and significant new use rules

Section 5(a)(1) requires that manufacturers of new chemical substances submit a notification (known as a premanufacture notice or PMN) to EPA prior to manufacturing the substance for non-exempt commercial purposes. Neither the statute nor EPA’s implementing regulations call for the up-front submission of a defined, “base set” of data.11 Some stakeholders have criticized the situation that EPA must review PMNs without such a base set of data. Where such data is not provided, EPA relies on conservative modeling and a robust, structure-activity relationship database on thousands of chemicals in order to identify whether the new chemical substance is in need of testing and/or regulation.

Under section 5(a)(2), EPA can by rule require similar notification prior to the manufacture or processing of listed existing chemical substances for what EPA finds are “significant new uses.” The rules are known as significant new use rules (SNURs), and the notices are known as significant new use notices (SNUNs). Upon review of a PMN or SNUN, EPA can impose restrictions intended to minimize risks, such as production and use restrictions, the use of personal protective equipment in the workplace, and limiting discharges to water.


7 See 40 C.F.R. Part 799, Subparts B and D.

8 See 40 C.F.R. Part 799, Subpart C.

9 EPA’s original process for negotiating voluntary testing agreements was found to be inconsistent with section 4, Natural Resources Defense Council v. EPA, 595 F. Supp. 1255 (S.D.N.Y. 1984). EPA subsequently adopted requirements for enforceable testing consent orders. See 40 C.F.R. §§ 790.22 and Part 790, Subpart D.

10 See 40 C.F.R. §§ 799.5055 (hazardous waste constituents subject to testing); 799.5075 (drinking water contaminants subject to testing); 799.5115 (chemical testing requirements for certain chemicals of interest to the Occupational Safety and Health Administration).

11 EPA requires the submission of all test data relating to the health and environment effects of the chemical substance in the submitter’s possession or control. 40 C.F.R. § 720.50.
These restrictions can be imposed by a consent order with the Submitter, although sections 5(e) and 5(f) give EPA the authority to issue an order unilaterally if it makes certain findings.

Under section 5(h), EPA is authorized to adopt exemptions from PMN and SNUR requirements. Substances used in research and development generally are not subject to either set of requirements under section 5(a)(1), nor are impurities, some byproducts, and chemicals used as intermediates in the manufacture of other substances when the intermediate is used in a contained system and is not isolated or stored. Certain other low-risk substances, such as polymers, are subject to limited PMN exemptions established by EPA through regulations. Chemical substances imported as parts of articles are exempt from PMN requirements. At EPA’s discretion, chemical substances in an imported article also may be exempt from SNURs.

D. Section 6. Chemical regulation

Section 6 authorizes EPA to adopt rules regulating the manufacture, processing, commercial distribution, use, and/or disposal of an existing chemical when there is a reasonable basis to conclude that the substance “presents or will present an unreasonable risk of injury to health or the environment.” EPA has the authority under section 6 to promulgate regulations:

- prohibiting or limiting the manufacture, processing, or distribution in commerce of the chemical substance generally or for a particular use, as well as prohibiting or regulating the commercial use of a chemical substance;
- requiring that the chemical substance, or any article containing the chemical substance, be labeled or accompanied by warnings and instructions for use, distribution, or disposal;
- requiring creation and maintenance of records of manufacturing/processing methods and reasonable monitoring or testing necessary to assure regulatory compliance;
- regulating disposal of the chemical substance, or any article containing the chemical substance; or
- requiring notification to distributors, other persons in possession of the chemical substance, and the general public of the unreasonable risk of injury.

Section 6 provides EPA with the capacity to prohibit or limit outright certain activities, but the exercise of that authority must be established through on-the-record rulemaking based upon a finding of unreasonable risk and a requirement that EPA impose the least economically burdensome controls to manage that risk.

Under section 6(a), EPA must select the least burdensome requirements from those potential requirements that would protect adequately against the unreasonable risk. Under

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13 See 40 C.F.R. Part 725.

14 See 40 C.F.R. § 720.22(b)(1).

15 See 40 C.F.R. § 721.45(f).
section 6(c)(1), in adopting its regulations, EPA must consider and publish a statement concerning, among other factors, the benefits of the chemical substance for various uses, the availability of substitutes for such uses, and the reasonably ascertainable economic consequences of the requirements. In reviewing EPA’s rule banning most uses of asbestos, a federal appeals court found that EPA had failed to meet its obligations under these provisions. Additional discussion of section 6 appears in the ABA SEER TSCA Standard for Taking Regulatory Action Briefing Paper.

E. Section 7. Imminent hazards

Section 7 gives EPA authority to respond rapidly when it determines that chemical substances or mixtures represent an imminent hazard. Section 7 authorizes EPA to initiate a civil action to seize an imminently hazardous chemical substance, mixture, or article containing them, and seek other relief against any person who manufactures, processes, distributes, uses, or disposes of an imminently hazardous substance, mixture, or article containing them. It authorizes EPA to seek a court order requiring recalls, replacements/repurchases, public notices of risk, or a combination of any of these requirements; this authority is rarely or never used.

F. Section 8. Reporting and retention of information

Section 8 gives EPA broad authority to require manufacturers and processors to collect, maintain, and submit data on chemical substances.

Under section 8(a), EPA has issued regulations (the Chemical Data Reporting rule) requiring manufacturers and importers to provide reports to EPA every four years for many chemical substances on the Inventory, providing production volume and use information on chemical substances produced above certain threshold levels, including low volumes of regulated chemicals. EPA has promulgated a number of other information-gathering rules under this provision, including rules to gather detailed information on specific chemicals.

Section 8(b) relates to reporting for the Inventory. This provision is discussed above in connection with the definition of “new chemical substance.”

Section 8(c) requires manufacturers and processors of chemicals to create and maintain records of “allegations”—whether written or oral—that the chemical “caused a significant adverse reaction to health or the environment.” These records must be made available to EPA upon request. This is a very broad information-gathering tool because it encompasses allegations that can come from any source and that can be made without formal proof or regard for evidence. Thus EPA could, for example, request section 8(c) records from certain sectors to determine if

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17 40 C.F.R. Part 711.

18 40 C.F.R. Parts 704, 712.
there are significant numbers of allegations regarding adverse reactions associated with particular chemical substances or products containing them.19

Under section 8(d), EPA can, by rule, requires reporting of unpublished health and safety studies on specific chemicals.20 This authority permits EPA to require manufacturers, importers, processors and distributors of specific substances and mixtures to submit to EPA within certain timeframes copies of any unpublished health and safety studies within their possession and a list of unpublished health and safety studies not in their possession but known to them. There is a requirement to report if the designated chemical has been manufactured, imported, or processed within ten years prior to issuance of the rule. Section 8(d) contains a ten-year “sunset date,” which requires that reporting continue on new studies for ten years from the initial rule date. The final 8(d) rule was issued in 1982 for numerous chemicals and categories, and more have been periodically added. Several hundred substances and mixtures listed at 40 C.F.R. § 716.120 have been subject to 8(d) reporting; however, the last sunset date expired in 2006 and EPA has not finalized any new rules to utilize this reporting tool recently. Section 8(e) requires manufacturers, processors, or distributors of chemicals to “immediately inform EPA if they obtain information that reasonably supports the conclusion that the chemical substance . . . presents a substantial risk of injury to health or the environment.” This is an important information-gathering tool for EPA, and it is actively enforced by the Agency. Companies must submit to EPA any new information that a chemical substance or mixture presents a substantial risk of injury to health or the environment within 30 days of receiving the information.21

G. Sections 12 and 13. Exports and imports

Sections 12 and 13 of TSCA describe additional requirements related to export and import of chemical substances. Section 12(a) excludes chemical substances that are manufactured solely for export from all provisions of TSCA except for the testing provisions of section 4 and reporting provisions of section 8. This exclusion does not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article will present an unreasonable risk of injury to health or to the environment in the United States. Section 12(b) requires companies to notify EPA prior exporting chemical substances that are subject to certain TSCA regulations. By rule, EPA requires a company to make one submission per country of export, and the Agency recognizes a de minimis quantity exemption.22 Under section 13, companies must certify when they import chemical substances whether the substance is subject to the Act and whether the shipment is in compliance with TSCA.23

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21 EPA has no rulemaking authority under this provision, but it has issued guidance.

22 40 C.F.R. Part 707, Subpart D.

23 Implementing regulations appear in 40 C.F.R. § 707.20 and in 19 C.F.R. § 12.118 et seq.
H. Section 14. Disclosure of data

Section 14 addresses the confidentiality of information submitted to EPA. Section 14(a) is a reverse-FOIA provision, meaning that information protected from mandatory disclosure under exemption (b)(5) of the Freedom of Information Act, relating to trade secrets and confidential business information, cannot be disclosed under TSCA, with certain exceptions.

A key exception is that, under section 14(b), health and safety data submitted under TSCA is not subject to the reverse-FOIA provision, except to the extent that confidential process or percentage of mixture information would be revealed. EPA has provided guidance on the extent of this provision with respect to chemical identities that appear in health and safety data. This provision is addressed in greater detail in the ABA SEER TSCA Confidential Business Information Briefing Paper.

I. Sections 11, 15 and 16. Inspections, subpoenas, prohibited acts, penalties, seizure

These sections of TSCA are the compliance and enforcement sections of the Act. EPA is authorized to inspect facilities, issue subpoenas, and assess civil penalties for violations. The imposition of criminal penalties including imprisonment is available to the agency in cooperation with the U.S. Department of Justice.

J. Section 18. Preemption

Section 18 of TSCA contains a limited express preemption provision. States are generally free to enact restrictions on or call for the testing of a chemical substance if EPA has not enacted the same requirement. However, risk management actions by EPA preempt state and local restrictions addressing the same risks, except that state bans of a chemical substance are not preempted by a restriction for that substance. This provision is addressed in greater detail in the ABA SEER TSCA Preemption of State Law and Regulations Briefing Paper.

Sections 20 and 21. Citizen’s civil actions and petitions

TSCA provides citizens with mechanisms to ask EPA to take action concerning a chemical substance through a petition process and to bring actions in court seeking to enforce rules that have been issued under the Act. In particular, section 21 allows citizens to petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2) regarding chemical substances. A section 21 petition must set forth facts that the petitioner believes establish the need for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, it must promptly commence an appropriate proceeding. If EPA denies the petition, it must publish its reasons for the denial in the Federal Register. Within 60 days of denial, or the expiration of the 90-day period, if no action is taken, the petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding.
II. CONCLUSION

If a new chemical substance is manufactured (or imported), it is subject to PMN review under section 5(a)(1), and EPA draws upon extensive modeling and knowledge of harmful chemical structures to regulate as needed prior to the introduction of new chemical substances into commerce. EPA may regulate existing chemical substances under its section 5(a)(2) authority to promulgate SNURs. In addition, EPA may require health and environmental testing or reporting of information on production, exposure and effects of a chemical substance. EPA also has authority to promulgate rules regulating or prohibiting the manufacture, processing, distribution, and use of existing chemicals, but EPA has found this authority very difficult to exercise and has used it rarely.