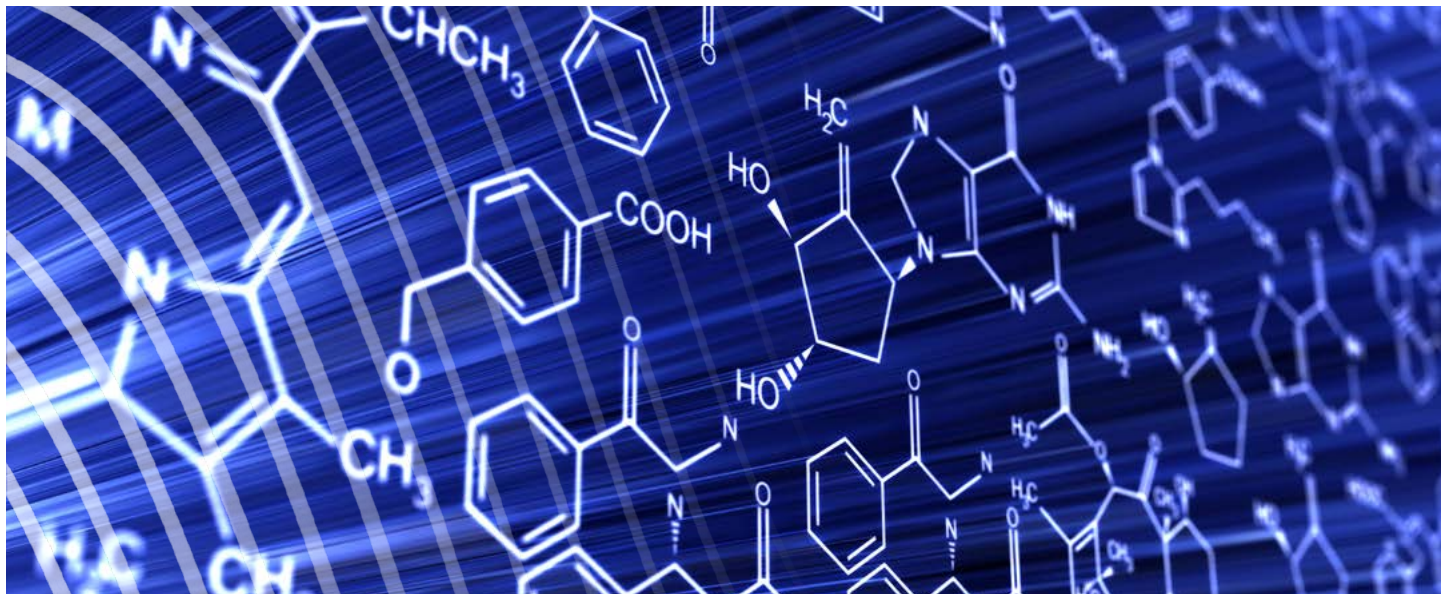


## CHEMICAL REGULATORY IMPLICATIONS FOR CONSUMER PRODUCTS UNDER TSCA



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### OVERVIEW

The U.S. Environmental Protection Agency (EPA) has begun to remove the traditional exemptions under the Toxic Substances Control Act (TSCA) for articles, including certain consumer products. This fact sheet provides an overview of how consumer products are currently regulated under TSCA and the resulting compliance and implementation challenges for retailers, particularly in their role as importers of finished products. Resources for more information are provided.

### BACKGROUND

Enacted in 1976, the [Toxic Substances Control Act](#) (TSCA) is a federal statute providing EPA with the authority to require reporting, recordkeeping, and testing and to impose restrictions relating to chemical substances and/or mixtures. EPA's regulations implementing TSCA are available at [40 C.F.R. Parts 700 to 799](#). Certain substances are generally excluded from TSCA, including food, drugs, cosmetics, and pesticides, which are regulated under other statutes.

For decades, TSCA has been considered of concern only to companies manufacturing, processing, or distributing industrial chemicals. TSCA was significantly amended in 2016 by the [Frank R. Lautenberg Chemical Safety for the 21st Century Act](#) (Lautenberg Act), and EPA's implementation of "new TSCA" has drawn many entities in the value chain -- including retailers -- squarely into TSCA's broad reach. EPA has begun to use its authority under TSCA to regulate consumer products such as textiles, carpet, furniture, electronics, and household appliances.

### ENTITIES SUBJECT TO TSCA REQUIREMENTS

Depending on the particular provision, TSCA may apply to any company that manufactures (including imports), processes, distributes in commerce, uses commercially, or disposes of a chemical substance, including as part of mixtures and articles. It is the broad definition of "manufacturers" that includes importers where many retailers are captured, regardless of their involvement in the production or ownership of the brand (e.g., private label).

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Of note, while companies that import or process a chemical substance as part of an article may be exempt from certain TSCA requirements (e.g., TSCA Section 5 premanufacture notice (PMN) requirements and, generally, significant new use notification (SNUN) requirements discussed below), EPA increasingly has been using its authority covering these companies in actions under TSCA and regulating the manufacture (including import), processing, and distribution in commerce of chemical substances as part of articles in TSCA regulations.

## HOW EPA USES TSCA TO REGULATE CONSUMER PRODUCTS

EPA uses its TSCA authority to regulate chemicals in articles. [40 C.F.R. Section 704.3](#) of the TSCA regulations defines an article as a manufactured item formed to a specific shape that has an end use function dependent upon its shape and that has no change in chemical composition during use. Some examples of articles include consumer products such as televisions, phones, cigarette lighters, automobiles, clothing, carpet, sheets of plywood, and batteries.

## ACTIONS EPA CAN TAKE UNDER TSCA

### TSCA SECTION 5 (PMNS AND SNURS)

Chemicals listed on the [TSCA Inventory](#) are existing chemical substances, and chemicals that are not listed are new chemical substances. Under [TSCA Section 5 \(15 U.S.C. § 2604\)](#), companies that intend to manufacture (including import) a new chemical substance for a non-exempt commercial use must first [submit a PMN](#) to EPA. After EPA reviews a PMN and makes an affirmative finding on the safety of the new chemical, it may issue a [significant new use rule](#) (SNUR) for the new chemical substance. EPA may also issue SNURs to require notice before existing chemical substances are used in ways that might create concerns.

While retailers are unlikely to manufacture or import new chemicals, they should be aware of any SNURs applicable to retail products. The Lautenberg Act amended TSCA Section 5 to allow EPA to require notification for the import or processing of a chemical substance as part of an article or category of articles if EPA finds that the reasonable potential for exposure to the chemical substance through the article or category of articles justifies notification.

EPA used this expanded authority in a July 2020 [final SNUR](#) for certain long-chain per- and polyfluoroalkyl substances (PFAS) as surface coatings and carpet containing perfluoroalkyl sulfonate chemical substances. Under the SNUR, companies cannot import products such as textiles, carpet, furniture, electronics, and household appliances that could contain these chemicals unless EPA first reviews and approves the use or puts in place the necessary restrictions to address any unreasonable risks. This SNUR is the first example of EPA lifting the article exemption, and retailers should be aware that future SNURs could apply to specific consumer products.

### TSCA SECTION 6 (RISK EVALUATIONS)

[TSCA Section 6 \(15 U.S.C. § 2605\)](#) requires EPA to address unreasonable risks of injury to health or the environment that the EPA Administrator has determined are presented by a chemical substance under the conditions of use. The Lautenberg Act amended TSCA to include specific deadlines and procedures for prioritizing chemicals for risk evaluations, conducting the risk evaluations, and promulgating regulations to address any unreasonable risks identified.

After the Lautenberg Act was enacted in June 2016, in December 2016, EPA designated the first [ten chemical substances](#) for risk evaluation under TSCA. The purpose of a risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use. [TSCA Section 3 \(15 U.S.C. § 2602\)](#) defines conditions of use as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

TSCA requires EPA to address any unreasonable risks of injury that it identifies by issuing a risk management rule. Under TSCA, EPA can take [a number of actions](#) to address unreasonable risks. These actions include:

- Prohibiting or limiting the manufacture (including import), processing, or distribution in commerce of the substance or mixture; and

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- Prohibiting or limiting the manufacture (including import), processing, or distribution in commerce of the substance or mixture for a particular use or above a set concentration for a particular use.

For example, EPA's final risk evaluation for chrysotile asbestos identified unreasonable risk from conditions of use of chrysotile asbestos. In April 2022, EPA issued a [proposed risk management rule](#) that would ban ongoing uses of chrysotile asbestos. EPA proposed, among other actions, to prohibit manufacture (including import), processing, and distribution in commerce of aftermarket automotive chrysotile asbestos-containing brakes/linings for consumer use and other chrysotile asbestos-containing gaskets for consumer use.

EPA has yet to propose risk management rules for the other chemicals within the first group undergoing risk evaluation. In September 2022, EPA [announced](#) the availability of the final risk determination for one of those chemicals, Colour Index Pigment Violet 29 (PV29), finding that PV29 presents an unreasonable risk when evaluated under its conditions of use. EPA noted that four of the 14 conditions of use do not drive the unreasonable risk, including distribution in commerce; industrial and commercial uses in finished plastic and rubber products for automobile plastics and industrial carpeting; and consumer use in professional-quality watercolor and acrylic artist paint. EPA's proposed risk management rule, however, could well limit or prohibit these four conditions of use as a result of managing the risk posed by the other ten conditions of use.

The Lautenberg Act amended TSCA Section 6 to require EPA to expedite evaluation of persistent, bioaccumulative, and toxic (PBT) chemicals. In January 2021, EPA issued final rules intended to reduce exposures to [five PBT chemicals](#), including phenol, isopropylated phosphate (3:1) (PIP (3:1)), a common component in wire coatings and wire harnesses used in electronics. The [final PIP \(3:1\) rule](#) imposed a hard stop on the processing and distribution of PIP (3:1) as of March 8, 2021. The final PBT rule prohibited sell-through opportunities for finished goods already in the channels of trade. Shortly after EPA published the final rule, many stakeholders, including the electronics and electrical manufacturing sector and their customers, raised significant concerns about their

ability to meet the March 8, 2021, compliance date for PIP (3:1)-containing articles. EPA ultimately issued a [final rule](#) extending the compliance date applicable to the prohibition on processing and distribution in commerce of certain PIP (3:1)-containing articles, and the PIP (3:1) used to make those articles, until October 31, 2024. In its [announcement](#), EPA acknowledged that the extended deadline "will ensure the continued availability of important industrial equipment and consumer electronics, including cellular telephones and laptop computers."

EPA states in its announcement that it intends to issue a proposal for a new rulemaking on PIP (3:1) and other PBT chemicals in spring 2023. EPA is considering revising the final PBT rules to reduce further worker exposures, promote environmental justice, and better protect human health and the environment. EPA will consider as part of that forthcoming rulemaking any additional information on whether it is feasible for industry to meet the October 2024 compliance date for PIP (3:1), including the number of years that would be needed to incorporate any substitutes and distribute them throughout the supply chain, as well as any changes that may need to be made to current exclusions or additional measures that may further reduce exposures.

## TSCA SECTION 8 (REPORTING & RECORDKEEPING)

[TSCA Section 8\(a\) \(15 U.S.C. § 2607\(a\)\)](#) allows EPA to require manufacturers (including importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require. As amended by Congress through the fiscal year 2020 National Defense Authorization Act, Section 8(a)(7) mandates that EPA promulgate a rule "requiring each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011" to report certain information.

EPA issued a [proposed reporting and recordkeeping rule](#) on June 28, 2021. Under the proposed rule, certain persons who manufacture (including import) or have manufactured PFAS in any year since January 1, 2011, would be required to report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. EPA proposed that manufacturers report information to the extent that the information is "known to or reasonably ascertainable" by the manufacturer. EPA would define this to include "all



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information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." If adopted in final, reporting entities would be required to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. On November 28, 2022, EPA released an Initial Regulatory Flexibility Analysis (IRFA) for [public comment](#) as part of its development of the rule. The IRFA examines the type and number of small entities that may be impacted by the proposed rule, the estimated burden and costs of the proposed rule on small entities, and potential regulatory flexibility alternatives. When EPA proposed the rule in June 2021, the agency certified that it would not have a significant economic impact on a substantial number of small entities ("No SISNOSE"), based on information available at the time. Since EPA issued the proposed rule, however, it has received additional information prompting it to update its small entity impact analysis, including estimating the number of PFAS article importers.

## HOW RETAILERS CAN MONITOR FOR FUTURE EPA RULEMAKINGS

As amended by the Lautenberg Act, TSCA requires EPA to designate at least [20 chemical substances](#) as high priority for risk evaluation and at least [20 chemical substances](#) as low priority. In December 2019, EPA designated 20 chemical substances as high priority for risk evaluation. EPA also designated 20 chemical substances as low priority for which risk evaluation is not warranted at this time. As EPA completes each risk evaluation for a high-priority chemical, it must designate a new high-priority chemical to take its place.

Under the Lautenberg Act, half of the candidates for prioritization include chemical substances from the [2014 Update to the TSCA Work Plan for Chemical Assessments](#). EPA has [opened individual dockets](#) for each of the remaining Work Plan chemicals, as well as a general docket to suggest additional chemicals for risk evaluation. Retailers can review the chemicals in the 2014 Update to the TSCA Work Plan and subscribe to receive e-mail notifications when new

materials are added to online dockets of interest. TSCA also allows manufacturers to request a risk evaluation for a chemical substance. [Manufacturer-requested risk evaluations](#) do not count toward the 20 high-priority chemical substances that EPA is required to have in its risk evaluation queue.

Each administration publishes a [Unified Agenda of Regulatory and Deregulatory Actions](#) that reports on the actions administrative agencies plan to issue in the near and long term. The Unified Agenda is published in the spring and fall each year. Items in the Unified Agenda typically include dates for future rulemakings, although these dates are often optimistic.

Retailers can obtain information regarding [risk management activities](#) for existing chemicals under TSCA on EPA's website. The web page includes [meetings, webinars, and other engagement opportunities](#). Retailers [can subscribe](#) to receive EPA's Office of Chemical Safety and Pollution Prevention news via e-mail.

Retailers that are members of RILA should consider joining the mailing distribution and/or monthly calls for RILA's Consumer Products Committee, which serves as a forum for regulatory matters impacting consumer products, to stay apprised of RILA's advocacy and information sharing on TSCA developments, including opportunities to provide feedback on public comments. Please contact [Susan Kirsch](#), Vice President, Regulatory Affairs with your interest.

## HOW ELSE RETAILERS CAN PREPARE

In its July 2020 SNUR regarding certain long-chain PFAS as surface coatings, EPA provided example steps that an importer can take to identify an article that could be subject to the SNUR. Those steps include:

- Gathering information through agreements with suppliers or declarations through databases or surveys; and
- Using a third-party certification system; or
- Requiring suppliers to provide certificates of testing analysis of the products or perform their own laboratory testing of certain articles.

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In addition to the steps identified by EPA above, retailers may wish to consider the following actions and/or approaches:

## **Inclusion of a product steward on the due diligence team.**

Product stewards are professionals with broad knowledge of global chemical issues. A product steward should be part of the team from the beginning. The Product Stewardship Society offers a credentialed certification program, the only one of its kind. Entering into a three-way non-disclosure agreement should be considered, along with retaining the services of a neutral third party, to ensure the confidentiality of chemical supplier information.

## **Periodic review/updates to due diligence protocols.**

Retailers should ensure that due diligence protocols are current, detailed, and tailored to priority products. Relevant federal, state, and international chemical programs pertinent to industrial, intermediate, agricultural, biocidal, and specialty chemicals should all be included in due diligence protocols. A regulatory chemist may also enhance the team by providing informed counsel on chemical components, their relative toxicity, global regulatory status, and commercial longevity. Prioritizing key products will assist with meeting the usually tight timeframes that apply.

## **Engaging chemical product legal counsel/expertise.**

Chemical product law is its own domain, not to be confused with environmental law, and retailers may wish to engage outside chemical product legal counsel/consultants. Those who have specialized in this separate area of the law offer additional value in many contexts, including in due diligence transactions.

## RESOURCES TO LEARN MORE ABOUT TSCA

The TSCA Hotline is an information service sponsored by EPA to answer questions about TSCA regulations and initiatives and requests for TSCA-related Federal Register notices, guidance documents, and other materials pertaining to the TSCA program. The hotline telephone number is (202) 554-1404. It is staffed Monday through Friday from 8:30 a.m. to 5:00 p.m., Eastern time. A large array of information regarding TSCA can also be found on the Internet at [EPA's website](#).

B&C's [TSCA Tutor](#)<sup>®</sup> online training platform offers expert, essential TSCA training in a modular format that allows companies and individuals to tailor regulatory training to meeting their unique business needs. B&C also publishes the [TSCAblog](#)<sup>®</sup>, which provides timely news and analysis regarding TSCA legal and administrative developments.

**Disclaimer:** This document is for informational purposes. The contents are not intended and cannot be considered as legal advice. Links to legislation are accurate as of the date of this publication. Retailers should reference official agency resources and/or the appropriate legislative documents for comprehensive guidance.

### ABOUT THE RETAIL COMPLIANCE CENTER

The Retail Compliance Center (RCC) provides resources on environmental compliance and sustainability for all types and sizes of retailers. The RCC's goal is to develop retail-specific resources, tools and innovative solutions to help companies cost-effectively improve their compliance and environmental performance.