

Glossary

Article: A manufactured item (1) that is formed to a specific shape or design during manufacture, (2) that has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) that has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.¹

Blanket certification: A certification that all chemical substances in all shipments of listed products imported from listed suppliers are either in compliance with the Toxic Substances Control Act (TSCA) or not subject to TSCA. Blanket certification can be used in lieu of separate import certifications for each individual shipment. The blanket certification is made on an annual basis, subject to renewal. The certification must be made on the letterhead of the certifying firm, signed by an authorized person, and submitted to the District Director of the U.S. Customs and Border Protection (CBP). The commercial invoice or entry document for each shipment covered by the blanket certification must include a statement incorporating the blanket certification by reference.²

Bona fide intent (BFI) to manufacture notice: A request by a manufacturer or importer that the U.S. Environmental Protection Agency (EPA) search its TSCA Confidential Inventory if the identity of a particular chemical substance has been claimed a trade secret, or if the chemical substance is not listed on the public version of the TSCA Chemical Substance Inventory and a manufacturer or importer has reason to believe that the chemical substance may be listed on the TSCA Confidential Inventory.

Byproduct: A substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).³

Chemical Abstracts Service Registry Number (CAS RN): A unique number assigned by the Chemical Abstracts Service to a specific chemical substance.

Chemical substance: Any organic or inorganic substance of a particular molecular identity, including (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (2) any element or uncombined radical.⁴

Code of Federal Regulations (C.F.R.): The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the federal government, available at <https://www.govinfo.gov/app/collection/cfr/>.

¹ 40 C.F.R. §§ 704.3, 710.3(d), 720.3(c) (2023). See also 19 C.F.R. § 12.120(a) (2024).

² See TSCA § 13, 15 U.S.C. § 2612; 19 C.F.R. §§ 12.118–127 (2024); 40 C.F.R. § 707.20 (2023).

³ 40 C.F.R. § 710.3(d) (2023).

⁴ TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A); 40 C.F.R. § 710.3(d) (2023).

Conditions of use (COUs): 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.⁵

Confidential business information (CBI): Pursuant to 5 U.S.C. § 552(b)(4), CBI is considered “trade secrets and commercial or financial information obtained from a person and privileged or confidential.”

Dose-response assessment: The determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question.⁶

Due diligence: The process of investigation carried on usually by a disinterested third party (as an accounting or law firm) on behalf of a party contemplating a business transaction (as a corporate acquisition or merger, loan of finances, or especially purchase of securities) for the purpose of providing information with which to evaluate the advantages and risks involved.⁷

Entered for warehouse: Defined as meaning that a warehouse entry summary, or documentation or electronic submission of data necessary for CBP to assess duties, collects statistics on imported merchandise and determines compliance with applicable laws or regulations. The summary has been filed with CBP in proper form through the Automated Commercial Environment (ACE) or any other CBP-authorized electronic data interchange system.⁸

Existing chemical substance: A chemical substance that is listed on the TSCA Inventory.

Export notification: Notice to EPA that the notifier has exported, or intends to export, a chemical substance or mixture subject to TSCA section 12(b) export notification requirements. Chemical substances subject to export notification requirements are those for which data have been required under TSCA section 4 or TSCA section 5(b), an order has been issued under TSCA section 5, a rule has been proposed or promulgated under TSCA section 5 or 6, or an action is pending or relief has been granted under TSCA section 5 or 7. EPA maintains a list of chemical substances for which export notification is required. No notice is required for articles unless EPA requires otherwise.⁹

Exporter: The principal party in interest in the export who has the power and responsibility for controlling the shipment of the chemical substance or mixture outside of the customs territory of the United States.¹⁰

⁵ TSCA § 3(4), 15 U.S.C. § 2602(4).

⁶ National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983), <https://doi.org/10.17226/366>.

⁷ *Due Diligence*, Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/due%20diligence> (last visited Sept. 27, 2024).

⁸ 19 C.F.R. § 141.0a (2024).

⁹ See TSCA § 12(b), 15 U.S.C. § 2611(b); 40 C.F.R. pt. 707, subpt. D (2023).

¹⁰ 40 C.F.R. § 707.63 (2023).

Exposure assessment: The determination of the extent of human exposure before or after application of regulatory controls.¹¹

Federal Register (Fed. Reg.): Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents, available at <https://www.govinfo.gov/app/collection/FR/>.

Hazard identification: The determination of whether a particular chemical is or is not causally linked to particular health effects.¹²

High-priority substance (HPS): A chemical substance that EPA “concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.”¹³

Import certification: Certification to CBP either that all chemical substances and mixtures in an import shipment comply with all applicable rules and orders under TSCA and are not offered for entry in violation of TSCA (positive certification) or that all chemicals in the shipment are not subject to TSCA (negative certification). Under TSCA section 13, the Secretary of the Treasury shall refuse entry into the customs territory of the United States any chemical substance or mixture or any article containing a chemical substance or mixture if it fails to comply with TSCA. Under CBP regulations, chemical substances or mixtures that are imported as part of an article are subject to the certification requirements only if required by a TSCA rule or order.¹⁴

Importer: Any person who imports any chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. “Importer” includes the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his or her behalf. The importer may be (1) the consignee; (2) the importer of record; (3) the actual owner of the merchandise, if an actual owner’s declaration and superseding bond has been filed in accordance with 19 C.F.R. § 141.20; or (4) the transferee of the merchandise, if the right to withdraw merchandise in a bonded warehouse has been transferred in accordance with 19 C.F.R. Part 144, Subpart C.¹⁵

Impurity: A substance unintentionally present with another chemical substance.¹⁶

¹¹ National Research Council, *supra* note 6.

¹² *Id.*

¹³ TSCA § 6(b)(1)(B)(i), 15 U.S.C. § 2605(b)(1)(B)(i).

¹⁴ See TSCA § 13, 15 U.S.C. § 2612; 19 C.F.R. §§ 12.118–.127 (2024); 40 C.F.R. § 707.20 (2023).

¹⁵ 40 C.F.R. § 710.3(d) (2023); 19 C.F.R. § 101.1 (2024).

¹⁶ 40 C.F.R. § 710.3(d) (2023).

Low-priority substance (LPS): A chemical substance that EPA “concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, that such substance does not meet the standard identified in [section 6(b)(1)(B)(i)] for designating a chemical substance a high-priority substance.”¹⁷

Low releases and low exposures exemption (LoREX): An exemption from premanufacture notice (PMN) requirements for a chemical substance that satisfies certain criteria for low environmental releases and low human exposure. The presumptive criteria are as follows: for consumers and the general population, there will be no dermal and inhalation exposure and no exposure in drinking water greater than one milligram per year; for workers, adequate controls will ensure there will be no dermal or inhalation exposure; there will be no releases to ambient surface water resulting in concentrations exceeding one part per billion; there will be no releases to ambient air from incineration in excess of one microgram per cubic meter (annual average); and there will be no releases to groundwater, land, or a landfill. Higher quantities of releases may be allowed if EPA is satisfied such quantities will not pose a hazard to human health or the environment. Persons wishing to manufacture or import a new chemical substance under the LoREX exemption must submit a notice to EPA at least 30 days prior to such manufacture or import, demonstrating the criteria will be met. If EPA takes no action within 30 days, the submitter may begin manufacture or import of the chemical substance.¹⁸

Low volume exemption (LVE): An exemption from PMN requirements for a chemical substance to be manufactured or imported in quantities of 10,000 kilograms per year or less. A person who wishes to manufacture or import a new chemical substance under the LVE must submit a notification to EPA at least 30 days before such manufacture or import. If EPA takes no action within 30 days, the submitter may begin manufacture or import of the chemical substance. EPA will permit more than one person to use the LVE for a given substance, as long as EPA determines the total quantity manufactured or imported will not pose a hazard to health or the environment.¹⁹

Manufacture: To import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.²⁰ Under TSCA, “manufacture” is also defined to mean “manufacture . . . for commercial purposes.”²¹

Manufacture for commercial purposes: To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer.²²

¹⁷ TSCA § 6(b)(1)(B)(ii), 15 U.S.C. § 2605(b)(1)(B)(ii).

¹⁸ See 40 C.F.R. pt. 723, subpt. B (2023).

¹⁹ See *id.*

²⁰ TSCA § 3(9), 15 U.S.C. § 2602(9). See, e.g., 40 C.F.R. § 710.3(d) (2023) (“Manufacture means to manufacture, produce, or import for commercial purposes.”).

²¹ TSCA §§ 5(i)(1), 8(f), 15 U.S.C. §§ 2604(i)(1), 2607(f).

²² 40 C.F.R. §§ 704.3, 710.3(d), 716.3, 717.3(e), 720.3(r) (2023).

Manufacturer: A person who imports, produces, or manufactures a chemical substance.²³

Mixture: Any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination that occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.²⁴

Naturally occurring substance: Any chemical substance that is naturally occurring and (1) that is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (2) that is extracted from air by any means.²⁵

Negative import certificate: A negative import certificate is a signed statement submitted to CBP, certifying that the chemical substances contained in a shipment offered for entry into the United States customs territory are not subject to TSCA. TSCA section 13 requires the Secretary of the Treasury to refuse entry of any chemical substance, mixture, or article containing a chemical substance, if the chemical substance fails to comply with any TSCA rule or is offered in violation of an order under TSCA section 5, 6, or 7. CBP has promulgated regulations that require any importer of a shipment containing a chemical substance to submit either a positive certification that all chemical substances in the shipment comply with TSCA or a negative certification that all chemicals in the shipment are not subject to TSCA.²⁶

New chemical substance: Any chemical substance that is not included in the TSCA Inventory compiled and published under TSCA section 8(b).²⁷

New chemicals bias: This refers to a “bias” against a new chemical that is subject to a protective measure when compared to an existing substance of equal or greater hazard that is not (or not yet) subject to such measures. The “new chemicals bias” is a critical consideration for a company as it plans innovation cycles and market entries. If a business is to develop new chemical substances, it must account for the new chemicals bias if the company intends to supply TSCA markets. Avoiding or diminishing the effect of the new chemicals bias occurs only if the chemical supplies uses not covered by TSCA (e.g., food, drugs, cosmetics) or supplies markets outside of the United States.

Nonisolated intermediate: A substance formed during a chemical reaction that is reacted further without being isolated from the reaction vessel or ancillary equipment, including continuous flow reactors.²⁸

²³ Id. §§ 704.3, 716.3, 720.3(t).

²⁴ TSCA § 3(10), 15 U.S.C. § 2602(10). See also 40 C.F.R. § 720.3(u) (2023).

²⁵ 40 C.F.R. § 710.4(b).

²⁶ TSCA § 13, 15 U.S.C. § 2612; 19 C.F.R. § 12.121 (2024); 40 C.F.R. § 707.20 (2023).

²⁷ TSCA § 3(11), 15 U.S.C. § 2602(11); 40 C.F.R. § 720.3(v) (2023).

²⁸ 40 C.F.R. § 704.3 (2023).

Notice of commencement (NOC) of manufacture or import: A notice submitted to EPA that manufacture or import of a new chemical substance has commenced. Persons who intend to manufacture or import a new chemical substance for a nonexempt commercial purpose must submit a PMN to EPA at least 90 days prior to such manufacture or import. Subsequently, within 30 days of the date of manufacture of the first nonexempt amount of the chemical substance or import of the first nonexempt shipment of the chemical substance into U.S. customs territory, the manufacturer or importer must submit a NOC to EPA, using a form provided by EPA. Upon receipt of the NOC, EPA adds the chemical substance to the TSCA Inventory. The NOC must identify the specific chemical identity of the substance; a generic chemical name, if the specific name is claimed confidential; the date of commencement of manufacture or import for a nonexempt purpose; name, address, and telephone information for the submitter and a technical contact; the address of the site where commencement of manufacture occurred; and indications of whether information is being claimed as CBI. Submitters who claimed the chemical identity as CBI on the PMN, and who wish to maintain that confidentiality, must reassert and provide substantiation for the claim.²⁹

Persistent, bioaccumulative, and toxic (PBT) chemicals: Chemicals identified in the 2014 update of the TSCA Work Plan for Chemical Assessments “(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under [section 4], prior to June 22, 2016 [the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act]; and (B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.”³⁰

Person: Any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any state or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the federal government.³¹

Positive import certificate: A signed statement submitted to CBP, certifying that the chemical substances contained in a shipment offered for entry into the U.S. customs territory comply with TSCA. TSCA section 13 requires the Secretary of the Treasury to refuse entry of any chemical substance, mixture, or article containing a chemical substance, if the chemical substance fails to comply with any TSCA rule or is offered in violation of an order under TSCA section 5, 6, or 7. CBP has promulgated regulations that require any importer of a shipment containing a chemical substance to submit either a positive certification that all chemical substances in the shipment

²⁹ Id. § 720.102.

³⁰ TSCA § 6(h)(1), 15 U.S.C. § 2605(h)(1).

³¹ 40 C.F.R. §§ 704.3, 710.3(d), 716.3, 717.3(f), 720.3(x) (2023).

comply with TSCA or a negative certification that all chemicals in the shipment are not subject to TSCA.³²

Potentially exposed or susceptible subpopulation (PESS): A group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.³³

Premanufacture notice (PMN): A notice submitted to EPA that the submitter intends to manufacture or import a new chemical substance.³⁴

Process: The preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce “(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (B) as part of an article containing the chemical substance or mixture.”³⁵

Process for commercial purposes: Processing “with the purpose of obtaining an immediate or eventual commercial advantage” and “[p]rocessing of any amount of a chemical substance or mixture”³⁶

Processor: Any person who processes a chemical substance or mixture.³⁷

Risk characterization: The description of the nature and often the magnitude of human risk, including attendant uncertainty.³⁸

Risk evaluation: An evaluation “to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], under the conditions of use.” Under section 6 of TSCA, EPA is directed to establish, by rule, a process to conduct risk evaluations in accordance with the above-listed definition.³⁹

Science Advisory Committee on Chemicals (SACC): Per TSCA section 26(o), not later than one year after the date of enactment, EPA shall establish the SACC with the purpose to “provide

³² TSCA § 13, 15 U.S.C. § 2612; 19 C.F.R. § 12.121 (2024); 40 C.F.R. § 707.20 (2023).

³³ TSCA § 3(12), 15 U.S.C. § 2602(12).

³⁴ TSCA § 5, 15 U.S.C. § 2604; 40 C.F.R. pt. 720 (2023).

³⁵ TSCA § 3(13), 15 U.S.C. § 2602(13); 40 C.F.R. § 720.3(aa) (2023). See also EPA, Question and Answer Summary: EPA Seminar on Industry Obligations under TSCA 1–2 (1986).

³⁶ 40 C.F.R. § 704.3 (2023).

³⁷ TSCA § 3(14), 15 U.S.C. § 2602(14); 40 C.F.R. § 720.3(bb) (2023).

³⁸ National Research Council, *supra* note 6.

³⁹ TSCA § 6(b)(4)(A)–(B), 15 U.S.C. § 2605(b)(4)(A)–(B).

independent advice and expert consultation, at the request of [EPA], with respect to the scientific and technical aspects of issues relating to the implementation of this title.” The SACC shall be composed of “representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.”⁴⁰

Self-executing exemptions: Exemptions from PMN requirements that do not require EPA approval.

Significant new use (SNU): A use of a chemical substance that EPA has designated under TSCA section 5(a)(2) as requiring notice prior to manufacture or processing for that use. In determining that a use is a SNU, EPA is to consider “all relevant factors,” including “(A) the projected volume of manufacturing and processing of the substance, (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.”⁴¹

Significant new use notice (SNUN): A notice that a manufacturer or processor wishing to engage in a designated SNU must submit at least 90 days before engaging in the new use, if EPA promulgates a SNUR. EPA states that this notification provides it with the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity.

Significant new use rule (SNUR): A rule limiting the manufacture and processing of a chemical substance for a use that EPA has determined to be a SNU.⁴²

Test marketing exemption (TME): An exemption from PMN requirements for a manufacturer or importer to distribute a predetermined amount of a chemical substance or mixture, or an article containing that chemical substance or mixture, “to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period.”⁴³

Tiered testing: “[A] tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to [EPA] justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting

⁴⁰ TSCA § 26(o), 15 U.S.C. § 2625(o).

⁴¹ TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2).

⁴² TSCA § 5(a)(2), 15 U.S.C. § 2604(a)(2); 40 C.F.R. pt. 721 (2023).

⁴³ TSCA § 5(a), (h)(1), 15 U.S.C. § 2604(a), (h)(1); 40 C.F.R. § 720.3(gg) (2023); id. § 720.38.

screening-level testing.” Tiered testing will be employed by EPA when the development of new information under TSCA section 4(a)(4) is required.⁴⁴

TSCA chemical substance imported as part of a mixture: A chemical substance as set forth in TSCA section 3(2) (15 U.S.C. § 2602(2)) that is part of a combination of two or more chemical substances as set forth in TSCA section 3(10).⁴⁵

TSCA chemical substance imported in bulk form: A chemical substance as set forth in TSCA section 3(2) (15 U.S.C. § 2602(2)) (other than as part of an article) in containers used for purposes of transportation or containment, provided that the chemical substance is intended to be removed from the container and has an end use or commercial purpose separate from the container.⁴⁶

TSCA Confidential Inventory: A portion of the TSCA Chemical Substance Inventory of chemical substances manufactured or processed in the United States that consists of chemical substances whose identities are confidential and only accessible to EPA.⁴⁷

TSCA Inventory: A list of each chemical substance that is manufactured or processed in the United States. The Inventory consists of two subsets—the Public Inventory and the Confidential Inventory.⁴⁸

TSCA Public Inventory: A portion of the TSCA Inventory of chemical substances manufactured or processed in the United States that consists of chemical substances whose identities are not confidential. The Public Inventory is accessible to everyone.⁴⁹

United States Code (U.S.C.): The codification by subject matter of the general and permanent laws of the United States. It is divided by broad subjects into 53 titles and published by the Office of the Law Revision Counsel of the U.S. House of Representatives.⁵⁰

Unreasonable risk of injury to health or the environment: A standard to be applied by EPA in determining whether to promulgate a rule or issue an order concerning a chemical substance or mixture. The unreasonable risk standard appears throughout TSCA. For example, EPA is to promulgate section 4 test rules to develop data necessary to determine whether a chemical substance or mixture presents an unreasonable risk of injury to health or the environment. Similarly, EPA is to promulgate a section 6 limitation or ban upon a finding that activities

⁴⁴ TSCA § 4(a)(4), 15 U.S.C. § 2603(a)(4).

⁴⁵ 19 C.F.R. § 12.120(c) (2024).

⁴⁶ Id. § 12.120(b).

⁴⁷ See TSCA § 8(b), 15 U.S.C. § 2607(b).

⁴⁸ TSCA § 8(b)(1), 15 U.S.C. § 2607(b)(1).

⁴⁹ See TSCA § 8(b), 15 U.S.C. § 2607(b).

⁵⁰ References to TSCA in this book are based on the U.S.C. version of TSCA, <http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim> (last visited Sept. 27, 2024).

involving a chemical substance or mixture present or will present an unreasonable risk of injury to health or the environment.⁵¹

⁵¹ See TSCA §§ 2(a), 2(b), 4(a), 4(e), 4(f), 5(b), 5(e), 5(f), 5(h), 6, 9(a), 12(a)(2), 21(b)(4)(B), 15 U.S.C. §§ 2601(a), 2601(b), 2603(a), 2603(e), 2603(f), 2604(b), 2604(e), 2604(f), 2604(h), 2605, 2608(a), 2611(a)(2), 2620(b)(4)(B).