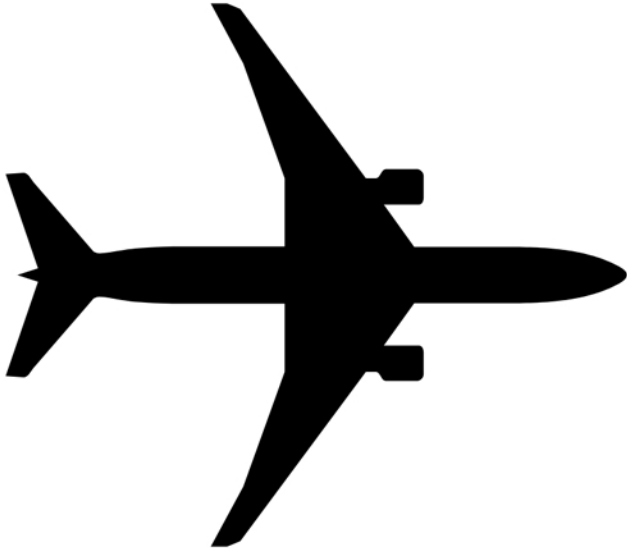




TSCA Section 13 Import Compliance Checklist



~ TSCA Section 13 Import Compliance Checklist ~

LEGAL DISCLAIMER

This checklist does not create any legal rights or defenses to enforcement actions for failure to comply with TSCA §13 or its regulations. This checklist is not a substitute for the TSCA statute and regulations and is not designed to provide importers with sufficient detail to ensure complete certainty of the compliance status of some chemicals. The information and analysis provided herein may not be complete. For greater certainty, importers should refer to the TSCA statute, regulations, interpretive guidance, and personnel at the U.S. Bureau of Customs and Border Protection and/or U.S. Environmental Protection Agency. Compliance with the TSCA import certification requirements will be based solely on TSCA and its regulations. Please also note that, while the current TSCA import rule requires certification of compliance with only sections 5, 6 and 7, other TSCA requirements may apply to imported chemicals, for example, under sections 4, 8 and 12(b) of TSCA.

~ TSCA Section 13 Import Compliance Checklist ~

~ PURPOSE ~

HOW TO COMPLY WITH TSCA IMPORT CERTIFICATION REQUIREMENTS

This checklist provides a simplified roadmap to help chemical importers walk through the logical analysis needed to determine how to certify their chemical imports in order to comply with the regulatory requirements under section 13 of the Toxic Substances Control Act (TSCA). This checklist is not the TSCA certification statement itself. There is no requirement that importers use this document or submit it to the government.

The import requirements under section 13 of TSCA ([15 USC 2612](#)) and related regulations ([19 CFR §§ 12.118-12.127](#) and [127.28\(i\)](#)) are jointly administered by the U.S. Department of Homeland Security, Bureau of Customs and Border Protection (CBP), in consultation with the U.S. Environmental Protection Agency (EPA) which administers all other provisions of TSCA Title I. EPA's policy statement on imports of chemicals under TSCA appears at [40 CFR 707.20](#).

Under the TSCA section 13 import requirements, *importers* (defined at [19 CFR 101.1](#)) *must certify* that *imported chemical substances* (including chemical substances in **mixtures** and certain *intergeneric microorganisms*) either:

- comply with TSCA (*positive certification*), or
- are not subject to TSCA (*negative certification*).

However, certain chemicals require *no certification*, and according to the Customs regulations and EPA's policy statement, the certification applies only to TSCA sections 5, 6 and 7, but not sections 4 and 8. (Currently there are no section 7 actions.)

~ INSTRUCTIONS ~

HOW TO USE THIS CHECKLIST

The following analysis should be applied to each chemical you intend to import, including chemicals in mixtures. Answer the questions below to help determine which certification option is appropriate for your chemical import. **For most chemicals, this entire analysis can be resolved by a single affirmative response in either Section I, Section II, or one subsection of Section III.** (However for some chemicals, multiple affirmative responses may be necessary in section III to certify TSCA compliance.) The three main sections below are:

I. No Certification Required -- A single "yes" indicates that no certification is required.

II. Non-TSCA/Negative Certification -- A single "yes" indicates that the imported material is not subject to TSCA jurisdiction.

III. TSCA-Compliant/Positive Certification -- In general, a single "yes" in a subsection of Section III indicates that the imported chemical substance complies with TSCA.

(For rules on one-year port-specific "blanket certifications," see [19 CFR 12.121\(a\)\(2\)\(ii\)](#)).

~ WHERE TO FILE CERTIFICATIONS ~

According to [19 CFR 12.121\(a\)\(2\)](#), TSCA import certification statements must be filed with the director of the port of entry of the shipment. For chemical imports that do not enter through a customs port, such as import via regular mail or courier, certification statements may be submitted to the following EPA addresses. (See “Toxic Substances Control Act: A Guide for Chemical Importers/Exporters” (EPA 5601/1-91-001) US EPA, Office of Toxic Substances, April 1991, p.32, Q&A#55; "Chemicals in Progress Bulletin," US EPA, Office of Pollution Prevention and Toxics, April 1992, p.7.) Again, please note that this checklist is not the TSCA certification statement itself and should not be submitted to the government.

Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001 (Attention: TSCA Section 13 Coordinator).

Hand Delivery/Courier: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW, Washington, DC. (Attention: TSCA Section 13 Coordinator). Such deliveries are only accepted during the Docket’s normal hours of operation. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930.

~ FOR FURTHER INFORMATION ~

If you have questions about TSCA section 13 import certification, visit www.epa.gov/oppt/import-export or contact the TSCA Hotline at (202) 554-1404 or tsc hotline@epa.gov. If not attached, view “Introduction to the Chemical Import Requirements of the Toxic Substances Control Act” (EPA 305-B-99-001), US EPA, Office of Enforcement and Compliance Assurance, June 1999, available at www.epa.gov/oppt/import-export/pubs/importguide.pdf. Another relevant guidance document is “Toxic Substances Control Act: A Guide for Chemical Importers/Exporters” (EPA 5601/1-91-001), US EPA, Office of Toxic Substances, April 1991. For questions related specifically to section III.B. on New Chemical Substances, contact an EPA Pre-Notice Communications Coordinator at (202) 564-9262.

~ GETTING STARTED ~
CHEMICAL SUBSTANCE IDENTIFICATION

Identifying the chemical substance you are importing, including the individual chemical constituents within mixtures, is critical to determining compliance with the various TSCA requirements and the appropriate certification option.

What is the Chemical Abstracts Index Name and Chemical Abstracts Service (CAS) Registry

Number of the chemical substance being imported?

Specific Chemical Name: _____

CAS # (if available): _____

If an intergeneric microorganism, what is the genus/species name of the microorganism?

Microorganism Name: _____

Generic Identity and Accession Number: _____

(TSCA Accession Numbers are 5 or 6-digit identifying numbers assigned by EPA to protect the confidentiality of chemical substances listed in the confidential portion of the TSCA Inventory. To determine whether a chemical that you wish to import is listed in the confidential portion of the TSCA Inventory, importers may be able to obtain an Accession Number: (1) from the supplier of the chemical; (2) from EPA per the "bona fide" procedures in [40 CFR 720.25\(b\)](#); or (3) if the PMN number is known, by consulting the CD-ROM product "Toxic Substances Control Act (TSCA): Searchable Database" sold and distributed by the National Technical Information Service (NTIS) (www.ntis.gov) or from one of the private databases that carries this information.)

I. NO CERTIFICATION REQUIRED

No TSCA import certification is currently required if you respond affirmatively to the following:

1. The chemical substance is being imported as part of an "article" as defined at [19 CFR 12.120\(a\)](#) and thus, per [19 CFR 12.121\(b\)](#), certification is not required. (Note that §12.121(b) states that a specific rule or order can require TSCA import certification for components of articles; however, none currently exist as of the last revision of this document. Also, although certification is not required, the import of certain articles is still regulated by TSCA. For example, for articles containing polychlorinated biphenyls (PCBs) or asbestos, review the information in Sections III.E. and III.F. below.)

Yes No

2. The material being imported is tobacco or a tobacco product per TSCA §3(2)(B)(iii). (See the 1991 and 1999 guidance documents referenced in the "Further Information" section.)

Yes No

If you answered "yes" to either of the above questions in Section I, no certification is required. If you answered "no" to both of the above questions, proceed to Section II below.

II. NON-TSCA / NEGATIVE CERTIFICATION

Certain materials and/or uses are not subject to TSCA. If you respond affirmatively to any **one** of the following specific exclusions under TSCA §3(2), then you may certify as follows: **“I certify that all chemical substances in this shipment are not subject to TSCA.”**

1. The material being imported will be used only as a pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act). Note: Pesticide intermediates are subject to TSCA.

Yes No

2. The material being imported is source material, special nuclear material or byproduct material (as defined by the Atomic Energy Act and related regulations). (Note however that radioactive materials not defined as above by the Atomic Energy Act are subject to TSCA, e.g Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM).)

Yes No

3. The material being imported will be used only as a firearm, shell or cartridge (taxable under §4181 of the Internal Revenue Code of 1954).

Yes No

4. The material being imported will be used only as a food, food additive, drug, cosmetic, or device (as defined by the Federal Food Drug and Cosmetic Act), including components thereof.

Yes No

If you answered "yes" to any of the above questions in Section II, you should certify that the material being imported is not subject to TSCA. If you answered "no" to all the above questions, proceed to Section III below.

Note – If, in addition to the types of non-TSCA uses listed above, the material to be imported will also be used for a use that is subject to TSCA or the use is unknown, then it is ineligible for the negative certification and must qualify for the positive certification, which is discussed in Section III below.

III. TSCA-COMPLIANT / POSITIVE CERTIFICATION

This section probes whether the chemical to be imported is subject to various TSCA requirements and, if so, whether the chemical complies with, and may be legally imported under, TSCA. If so, the importer may certify as follows: **“I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or**

order thereunder.” For many imported chemicals, a single affirmative response in any one of the following subsections of Section III indicates compliance with TSCA. However, for some imported chemicals, multiple affirmative responses may be necessary. For example, a new chemical substance may require an affirmative response in both subsections III.B. and III.D.

A. Import for Export Only

Section 12(a) of TSCA states that all TSCA requirements (except those under section 8 of TSCA) do not apply to any chemical substance that is manufactured, imported, processed or distributed in commerce solely for export from the United States and labeled as such.

1. Is the chemical substance imported solely for export from the United States, i.e., not for use in the United States, and is it and any container in which it is enclosed stamped or labeled as intended for export only?

Yes No

B. New Chemical Substance Requirements (under [40 CFR Part 720](#) or [723](#); For intergeneric microorganisms see §III.C.)

Under TSCA §5(a)(1)(A), no person shall import a new chemical substance (defined as a chemical not on the TSCA Inventory) unless such person submits to EPA 90-days advance written notice in the form of a pre-manufacture notice (PMN), or qualifies for one of several exemptions. In order to certify that the chemical substance complies with the “new chemical” notice requirements under TSCA, you should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). For those PMNs and exemptions that require submission of an exemption application to EPA, identifying the case number assigned by EPA should help those submitters verify the correct response. If you cannot respond affirmatively to **any** of the following specific alternatives, your chemical substance may not comply with the “new chemical” notice requirements under TSCA, in which case it may not be legally imported.

1. Is the chemical substance on the TSCA Inventory of existing chemical substances? (If importers do not find the chemical substance on the public portion of the TSCA Inventory, they should follow the “*bona fide*” procedure at [40 CFR 720.25](#) to request EPA to search the Confidential Inventory. For additional guidance, see www.epa.gov/opptintr/newchems/pubs/invntory.htm.)

Yes No

2. If the chemical substance is not on the TSCA Inventory, have you submitted to EPA any of the following TSCA §5 notices for it and are you in full compliance with all the pertinent requirements? (Note that these notices and exemptions are person-specific. Until a substance is added to the TSCA Inventory, submission of a notice by one company does not relieve any other person from the pre-manufacture notice requirement.)

a. Pre-Manufacture Notice (PMN, [40 CFR Part 720](#)). PMN# _____

Yes No

b. Low Volume Exemption (LVE, [40 CFR 723.50](#)). LVE # _____

Yes No

c. Low Release and Exposure Exemption (LOREX, [40 CFR 723.50](#)). LOREX # _____

Yes No

d. Test Market Exemption (TME, [40 CFR 720.38](#)). TME # _____

Yes No

3. If the chemical substance is not on the TSCA Inventory and you have not submitted one of the above notices, does the chemical substance comply with all the requirements for any of the following **exemptions** for new chemicals?

a. the R&D Exemption ([40 CFR 720.36](#)).

Yes No

b. the Polymer Exemption ([40 CFR 723.250](#)).

Yes No

c. any exemption listed in [40 CFR 720.30\(a\)](#) through [\(i\)](#), for example, chemicals manufactured solely for export, byproducts, impurities, non-commercial R&D. Indicate specifically which paragraph in [§720.30](#) applies: _____

(Note that while "mixtures" as a whole, as defined in [40 CFR 720.3\(u\)](#), are exempt from the TSCA §5 PMN requirement, new chemical substances that are imported as part of a mixture are subject to the PMN requirement. See [40 CFR 720.30\(b\) fn.1.](#))

Yes No

d. exempt as part of an article ([40 CFR 720.3\(c\)](#) and [720.22\(b\)\(1\)](#)). (Note: Under [19 CFR 12.121\(b\)](#), no TSCA section 13 import certification is generally required for chemicals imported as part of an article. See Section I above.)

Yes No

e. exempt as a Naturally Occurring Chemical Substance ([40 CFR 710.4\(b\)](#); considered automatically included on the Inventory).

Yes No

C. New Intergeneric Microorganism Requirements (under [40 CFR Part 725](#))

Intergeneric microorganisms are subject to the TSCA section 5 notice requirements per [40 CFR Part 725](#). In order to certify that an intergeneric microorganism complies with these requirements under TSCA, you should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). For those exemptions requiring submission of an exemption application to EPA, identifying the case number assigned by EPA should help those submitters verify the correct response. If you cannot respond affirmatively to **any** of the following specific alternatives, your intergeneric microorganism may not currently comply with the “new chemical” notice requirements under TSCA, in which case it may not be legally imported.

1. The shipment does not contain an “intergeneric microorganism” per [40 CFR 725.3](#) (formed by the deliberate combination of genetic material originally isolated from organisms of different genera)? (Microorganisms that are not intergeneric are considered implicitly included on the Inventory per [40 CFR 725.8\(b\)](#).)

Yes No

2. Does the shipment contain an intergeneric microorganism that is included on the TSCA Inventory of existing chemical substances? (If importers do not find the microorganism on the Public Inventory, they should follow the “*bona fide*” procedure at [40 CFR 725.15](#) to request EPA to search the Confidential Inventory. For additional guidance, see www.epa.gov/opptintr/newchems/pubs/invntory.htm.)

Yes No

3. If the microorganism is intergeneric and not expressly included on the Inventory, have you submitted any of the following **TSCA §5 notices** for it and are you in full compliance with all the pertinent requirements?

a. Microbial Commercial Activity Notice (MCAN, [40 CFR Part 725.100](#)).

MCAN # _____

Yes No

b. TSCA Experimental Release Application (TERA, [40 CFR 725.250](#)). TERA# _____

Yes No

c. Tier I Exemption (Tier I, [40 CFR 725.424](#)). TIER I# _____

Yes No

d. Tier II Exemption (Tier II, [40 CFR 725.428](#)). TIER II# _____

Yes No

e. Test Market Exemption (TME, [40 CFR 725.300](#)). TME # _____

Yes No

4. Is the microorganism exempt under any of the R&D Exemptions for microorganisms ([40 CFR 725.200](#) to [725.239](#))?

Yes No

D. Other Section 5 Requirements

When appropriate, EPA issues §5 regulatory requirements on new chemicals or significant new uses of chemicals via a TSCA §5(e) Order or §5(a)(2) Significant New Use Rule (SNUR, [40 CFR Part 721](#) or [725](#) Subparts L and M). TSCA §5(e) Orders may include use prohibitions, labeling and Material Safety Data Sheet (MSDS) requirements, restrictions on the amount of the chemical allowed to be manufactured or imported, as well as other restrictions. (The import/production limits often serve as triggers for toxicity or related testing requirements.) The SNUR requires notifying EPA at least 90 days before manufacture, import, or processing for uses/activities designated by EPA as a significant new use. You should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). If you cannot respond affirmatively to **one** of the following specific alternatives, your chemical substance may not currently comply with the requirements under TSCA §5, in which case it may not be legally imported.

1. This chemical substance is subject to neither a TSCA §5(e) Order to which you are a party nor to a Significant New Use Rule.

Yes No

2. This chemical substance is subject to a TSCA §5(e) Order to which you are a party or a Significant New Use Rule and you do not qualify for an exemption therefrom, but this particular shipment complies with all requirements of the Order or SNUR. The chemical substance is not being imported for a prohibited use, it satisfies all applicable labeling and MSDS requirements, it does not exceed any restrictions on permissible import volume, is not being imported for a designated significant new use, and it complies with any other applicable requirements.

Yes No

a. If this chemical substance is subject to a TSCA §5(e) Order to which you are a party, what is the EPA-designated PMN, MCAN or SNUN case number? _____

b. If this chemical substance is subject to a Significant New Use Rule (SNUR, [40 CFR Part 721](#) or [725](#)), what is the CFR citation in [40 CFR Part 721](#) or [725](#)? _____

3. This chemical substance is subject to a TSCA §5(e) Order to which you are a party or a Significant New Use Rule, and this particular importation might otherwise exceed a restriction or constitute a significant new use requiring the submission of a SNUN, but you qualify for the exemption you have identified below.

Yes No

a. If this chemical substance is subject to a TSCA §5(e) Order to which you are a party, what is the EPA-designated PMN, MCAN or SNUN case number? _____
What is the applicable exemption (e.g., R&D, byproduct)? _____

b. If this chemical substance is subject to a Significant New Use Rule (SNUR, [40 CFR Part 721](#) or [725](#)), what is the CFR citation in [40 CFR Part 721](#) or [725](#)? _____
What is the applicable exemption in [40 CFR 721.45](#) or [725.912](#): _____

4. This chemical substance is subject to a Significant New Use Rule, but the importer has submitted a Significant New Use Notice (SNUN) and completed the 90-day review period, and the import complies with any requirement (e.g., per a §5(e) Order to which the importer is a party) imposed by EPA pursuant to the review. The SNUN number assigned by EPA is _____

Yes No

E. Polychlorinated Biphenyls (PCBs) Requirements

The import of polychlorinated biphenyls (PCBs) and articles containing PCBs is generally prohibited under TSCA §6(e) and [40 CFR Part 761](#). **If your shipment contains PCBs**, in order to certify that the chemical substance complies with the PCB requirements of TSCA, you should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). If you cannot respond affirmatively to **any** of the following specific alternatives, your chemical substance may not currently comply with the PCB requirements of TSCA, in which case it may not be legally imported.

1. The shipment being imported does not contain PCBs.

Yes No

2. Is this shipment eligible for one of the exemptions identified in [40 CFR 761.80](#)?

Identify specific exemption by CFR citation: _____

Yes No

3. Does this shipment contain PCB waste that qualifies as an “other transboundary shipment” under [40 CFR 761.99](#)?

Yes No

4. Does this shipment include products that contain PCBs generated inadvertently through an excluded manufacturing process as defined in [40 CFR 761.3](#)? (Note that there are subsequent associated recordkeeping and reporting requirements in [40 CFR 761.185](#) and [40 CFR 761.187](#).)

Yes No

F. Asbestos Requirements

Imports of some asbestos-containing products are prohibited by the TSCA section 6(a) regulations at [40 CFR 763 Subpart I](#). In order to certify that the chemical import complies with TSCA, you should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). If you cannot respond affirmatively to **one** of the following specific alternatives, your chemical substance may not currently comply with the asbestos requirements of TSCA, in which case it may not be legally imported.

1. The shipment being imported does not contain asbestos.

Yes No

2. The shipment being imported contains asbestos, but the asbestos-containing product is not being imported for use in flooring felt, commercial paper, corrugated paper, rollboard, specialty paper, or new uses of asbestos, as defined in [40 CFR 763.163](#).

Yes No

3. The asbestos-containing product is being imported solely for export from the United States and will not be further repackaged or processed in the United States, per [40 CFR 763.165\(c\)\(1\)](#).

Yes No

4. The asbestos-containing product is being imported in small quantities solely for personal use in the United States, per [40 CFR 763.165\(c\)\(2\)](#).

Yes No

5. The asbestos-containing product is the subject of a current exemption approved by EPA per [40 CFR 763.173](#). Describe the exemption: _____

Yes No

G. Metalworking Chemicals Requirements

Certain chemical substances that may be used in metalworking fluids are regulated under the TSCA section 5(f)/6(a) regulations at [40 CFR Part 747](#). In order to certify that the chemical shipment complies with the metalworking fluid rules in [40 CFR Part 747](#), you should be able to

respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). If you cannot respond affirmatively to **one** of the following specific alternatives, your chemical substance may not currently comply with the metalworking fluid requirements of TSCA, in which case it may not be legally imported.

1. The shipment being imported does not contain any of the chemical substances regulated by [40 CFR Part 747](#).

Yes No

2. This shipment contains a chemical substance regulated by [40 CFR Part 747](#), but not as part of a metalworking fluid or in any form in which it could be used as a component of a metalworking fluid.

Yes No

3. This shipment contains a chemical substance regulated by [40 CFR Part 747](#) as part of a metalworking fluid, but the metalworking fluid contains no nitrosating agents and the warnings and instructions required by the rule have been provided.

Yes No

4. This shipment contains a chemical substance regulated by [40 CFR Part 747](#), but the material is exempt from the regulations because it is being imported only in small quantities solely for research and development in accordance with section 5(h)(3) of TSCA, as an impurity, as part of an article, or solely for export and is labeled accordingly.

Yes No

H. Hexavalent Chromium Requirements

Hexavalent chromium-based water treatment chemicals are regulated under TSCA section 6(a) regulations at [40 CFR §749.68](#). In order to certify that the chemical shipment complies with the water treatment chemicals rules in [40 CFR §749.68](#), you should be able to respond affirmatively to **one** of the following specific alternatives (although more detailed analysis is necessary to be certain of full compliance with all requirements). If you cannot respond affirmatively to **any** of the following specific alternatives, your shipment may not currently comply with the hexavalent chromium requirements of TSCA, in which case it may not be legally imported.

1. The shipment being imported does not contain any hexavalent chromium-based water treatment chemicals.

Yes No

2. This shipment contains hexavalent chromium-based water treatment chemicals, but not for use in comfort cooling towers and the required warning label is affixed.

Yes No

If you answered "yes" to one or more of the above questions in Section III, you can probably certify that the material being imported complies with TSCA. However, if you answered "no" to all the above questions, the material may be ineligible for entry into the customs territory of the United States and may be subject to detention, refusal of entry/delivery, or a demand for redelivery per TSCA section 13 and [19 CFR 12.122 to 12.127](#). In that case, you may wish to consult the information sources in the "Further Information" section above.