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**TSCA SECTION 13 IMPORTER CERTIFICATION PROCEDURE**

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**INTRODUCTION**

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**PURPOSE**

To outline the steps required for the importation of chemical substances (including microorganisms) and provide either positive or negative certification of compliance with the Toxic Substances Control Act (TSCA).

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**APPROVED BY:** \_\_\_\_\_  
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**REASON FOR ISSUE:**

To define an internal process for complying with the TSCA import requirements for chemical substances (including microorganisms). This procedure documents the elements of the program.

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**DESCRIPTION OF CHANGE:**

New

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**DISTRIBUTION:**

Department Head(s)  
TSCA Coordinator  
EH & S

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**1.0 GENERAL**

TSCA is intended to assure protection of health and the environment from unreasonable risks associated with chemical substances, whether they are produced domestically or imported into the United States. Under Section 13 of TSCA, a chemical importer must either certify that the chemical substances being imported comply with all applicable rules or orders under TSCA (positive certification) or certify that the chemical substances are not subject to TSCA (negative certification). Although the certification process specifically requires the importer to certify compliance with TSCA Sections 5, 6 and 7, importers are required to comply with all applicable rules or orders.

Any and all imported chemical substances including microorganisms received by the University must be certified under TSCA via either a negative or positive certification. Failure to meet these requirements could result in significant fines and penalties for the University. Articles as defined below are not subject to TSCA import certification requirements.

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## **2.0 DEFINITIONS**

### **Article**

Customs Service regulations under 19 CFR section 12.120 (a) define an “article” as:

(1) A manufactured item which: (i) is formed to a specific shape or design during manufacture, (ii) has end use functions dependent in whole or in part upon its shape or design during the end use, and (iii) has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in section 12.120 (a)(2); except that fluids and particles are not considered articles regardless of shape or design.

(2) The allowable changes of composition, referred to in section 12.120(a)(1), are those which result from a chemical reaction that occurs upon the end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleaners or other household products, fuels and fuel additives, water softening and treatment agents, photographic films, batteries, matches, and safety flares in which the chemical substance manufactured upon end use of the article is not itself manufactured for distribution in commerce or for use as an intermediate.

Importation of an article does not require TSCA certification.

### **Chemical Substance**

Section 3 of TSCA defines a “chemical substance” as:

“...any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical.”

51 FR 23313, (June 26, 1986) expanded the definition of a chemical substance to include microorganisms.

Certain chemicals are excluded from the definition of chemical substance subjected to TSCA rules and orders based on their use. These include, but are not limited to:

- Tobacco or any tobacco product
- Pesticides
- Source material, special nuclear material or byproduct material
- Firearms or ammunition
- A food, food additive, drug, cosmetic or device

Importation of the above mentioned chemical substances will require completion of a negative certification. Section 3 of TSCA provides a complete definition of substances regulated under TSCA.

### **Importer**

An importer is any person who imports a 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.

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## **3.0 SUPPLEMENTARY INFORMATION**

Positive certification can only be provided under TSCA if the imported chemical substance does not violate any rules or orders issued under Sections 5, 6 or 7 of TSCA. These sections are summarized below; importers should consult the regulations for a comprehensive guidance.

### **Section 5 – New Chemical Substances**

Under Section 5, persons who intend to import a new chemical substance (one that is not already in commerce or being imported into the United States, based on EPA's TSCA Inventory of Chemical Substances) must get EPA approval by submitting a pre-manufacture notice to the EPA at least 90 days prior to importation. This allows EPA to determine whether the new chemical may present an unreasonable risk to human health or the environment. In addition, the importer must determine whether EPA has designated the use of an imported chemical substance as a "significant new use" which requires submission of information prior to importing.

Exemptions to the 90-day review period include:

- Research and Development Exemption (40 CFR Section 720.36)
- Test Marketing Exemption (40 CFR Section 720.38)

- Low volume/low release/low exposure Exemption (40 CFR 723.50)
- Polymer Exemption (40 CFR 723.250)

Importers are still required to certify TSCA compliance to import these substances.

The research and development exemption applies to the use of “small quantities” on a “laboratory scale” under “prudent laboratory practices”. “Small quantities” are generally referred to as what one person can lift or carry. Records must be maintained of quantities and distribution outside the organization. R&D operations are still potentially subject to applicable TSCA regulations under Sections 4, 8 & 13.

### **Section 6 – Regulation of Hazardous Chemical Substances**

Under Section 6 the EPA may take regulatory action to protect against unreasonable risk of injury to human health or the environment due to the importation of a chemical substance or mixture. For example, EPA has promulgated regulations under Section 6 of TSCA applicable to polychlorinated biphenyls (PCBs). The importation of PCBs or articles containing PCBs is banned under TSCA with a few minor exemptions. Similarly, some asbestos containing articles are also banned under TSCA.

Importers should verify that the chemical substance that they are importing complies with Section 6 by contacting the University’s EH&S Department.

### **Section 7 – Imminent Hazards**

Section 7 authorizes EPA to begin judicial action against importers and to seize chemical substances that it has determined are imminently hazardous. Importers should verify that the chemical substance that they are importing is not considered imminently hazardous by contacting the University’s EH& S Department.

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## **4.0 TSCA IMPORTATION PROCEDURE**

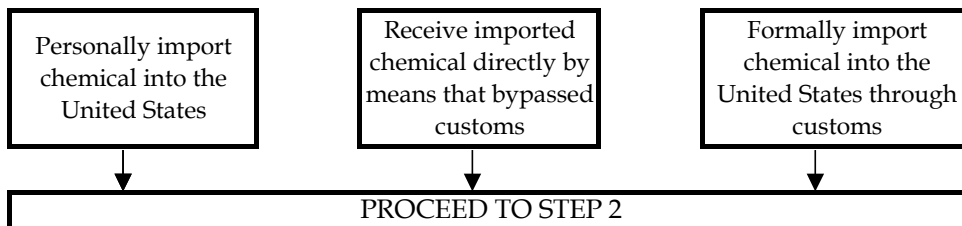
The following steps are depicted in the attached flowchart that is included at the end of this section. Please utilize the flowchart when determining TSCA importation requirements for each specific case.

- 1). Determine which import scenario applies.
  - Personally import chemical substance into US
  - Receive import chemical substance directly by means that bypassed customs
  - Formally import chemical substance in US through customs

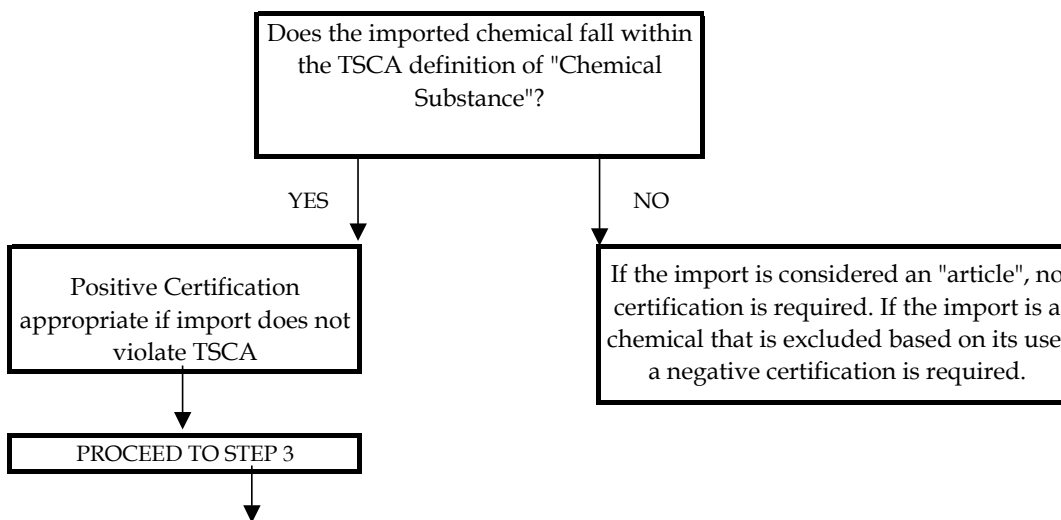
- 2). Determine whether the imported chemical comes under the authority of TSCA. Materials that are included under the definition of an “article” (see definition above) do not require certification. Chemical substances not excluded require a determination of TSCA compliance and a positive certification, if appropriate. Chemical substances that are excluded from TSCA (ie. pesticides, food, cosmetics) require a negative certification.
- 3). Positive certification states that the chemical complies with Sections 5, 6 and 7 of TSCA. If the chemical being imported is not on the TSCA Inventory of Chemical Substances, then it may be a new chemical substance that is potentially subject to Section 5 pre-manufacture notification requirements. In a University setting, many chemical substances that are imported may be exempt from Section 5 reporting under the Research and Development exemption. Determine whether the R&D exemption applies (consult with the University’s EH& S Department). If it does not, the substance may be subject to notification or reporting requirements under Section 5.
- 4). Certain chemical substances may be subject to regulations under Sections 6 or 7 of TSCA. Determine whether Section 6 or 7 regulations apply by checking the CORR (Chemicals on Reporting Rules) database. . If the substance is not subject to regulations under these sections, a positive certification may be made. If the substance is subject to regulations under sections 6 or 7, contact the University’s EH& S Department.
- 5). Complete certification based on import scenario.
- 6). Keep one copy of the import certification with the department responsible for the importation and forward one copy to the University’s EH& S Department.

# TSCA SECTION 13 IMPORTER CERTIFICATION PROCEDURE FLOWCHART

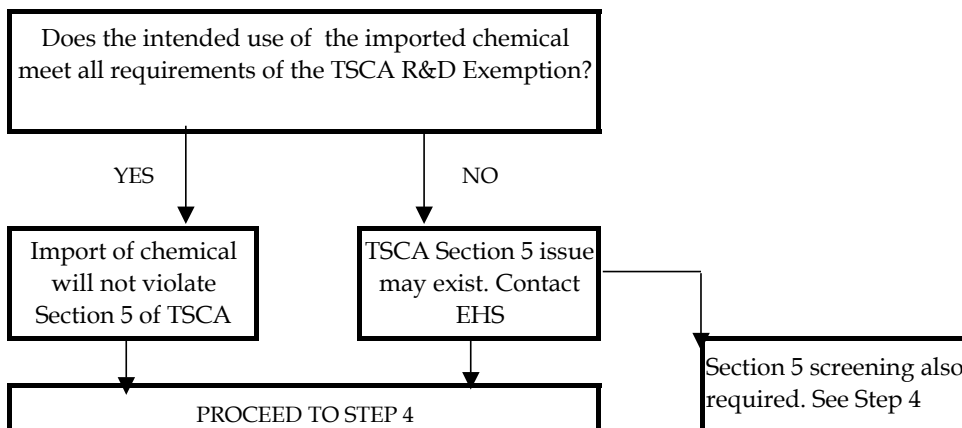
STEP 1 Determine which import scenario applies:



STEP 2 Determine whether imported chemical comes under the authority of TSCA



STEP 3 Determine if imported chemical is under TSCA Research and Development exemption



# TSCA SECTION 13 IMPORTER CERTIFICATION PROCEDURE FLOWCHART

**STEP 4** Determine if imported chemical is regulated under either TSCA Section 6 or 7

