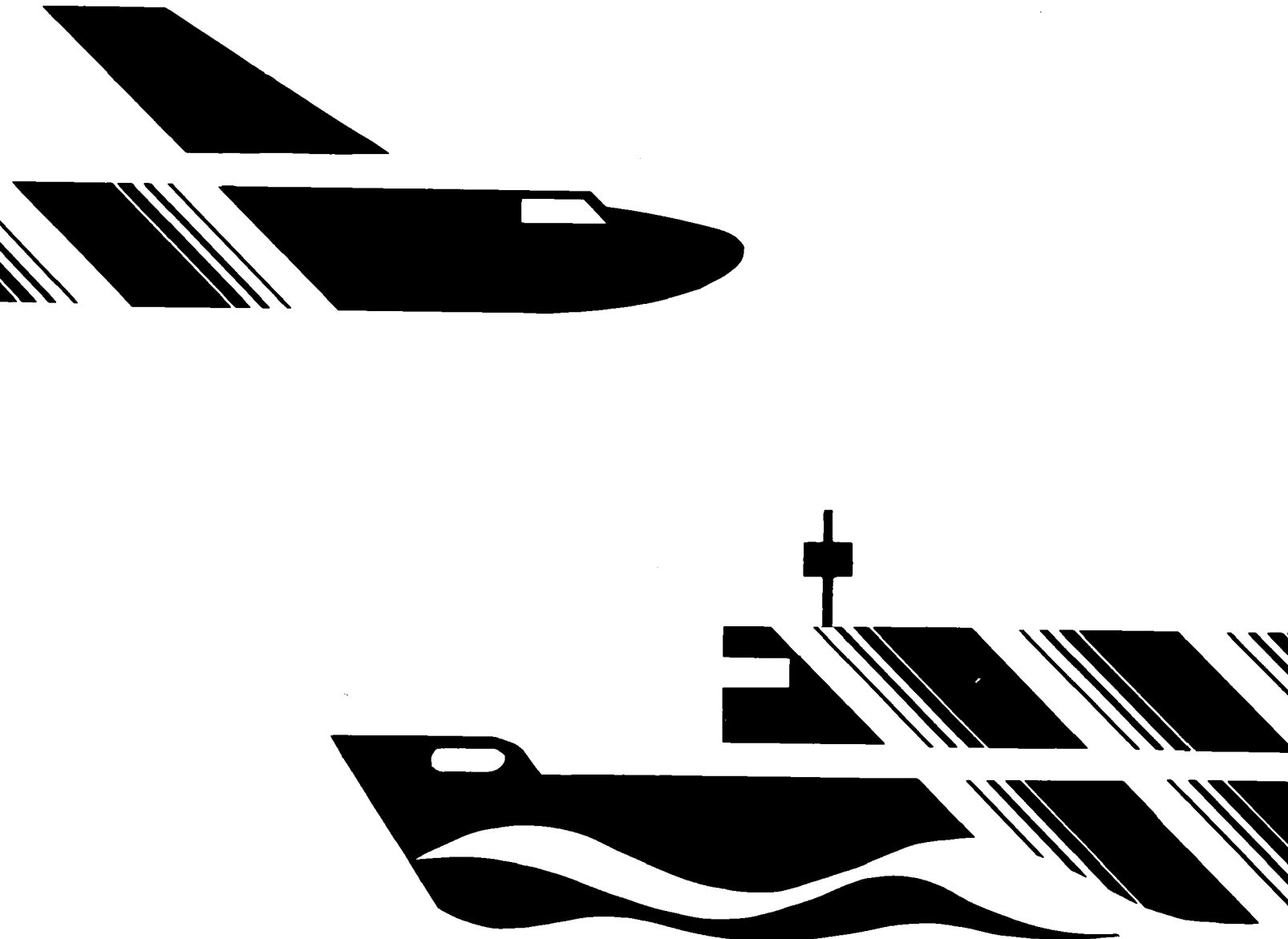




# Toxic Substances Control Act

## A Guide for Chemical Importers/Exporters

### Volume 1: Overview



Volume 1 of this publication has been compiled to summarize the requirements of sections 12(b), Exports, and 13, Imports, of the Toxic Substances Control Act (TSCA) and of the rules and policies issued under these sections. Volume 2 provides an alphabetical listing of chemical substances that are subject to section 12(b) and 13 requirements as of this date. It also provides excerpts and key points of each applicable rule, as well as Federal Register citations of specific rulemaking actions applicable to each of the chemicals listed. Each chemical substance subject to TSCA regulations that is imported into the United States (for other than solely research and development purposes) must be listed on the TSCA Inventory of Chemical Substances.

The Environmental Protection Agency (EPA) issued a policy statement on December 13, 1983 (48 FR 55462) which explains how the Agency will interpret the chemical substances import rule issued by the U.S. Customs Service on August 1, 1983 (48 FR 34734), effective January 1, 1984 under section 13 of TSCA. This publication supplements the guidance provided by that policy, and is designed as a quick reference guide for importers, exporters, and Regional EPA and Customs inspectors. Those involved or interested in chemical imports/exports may find the information useful for other purposes.

Material for this first edition was compiled as of January 1984. Future Agency actions will require periodic updating and republishing.

Send all questions, comments, or recommendations on the contents to:

Jack P. McCarthy, Director  
TSCA Assistance Office (TS-799)  
Office of Toxic Substances  
Environmental Protection Agency, Room E-543  
401 M Street, SW.  
Washington, D.C. 20460  
Toll-free: 800-424-9065  
In Washington, D.C.: 554-1404  
Outside U.S.A.: Operator-202-554-1404.

**This is an informational publication. Any rules or orders issued by EPA or U.S. Customs take precedence over the guidance included herein.**

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**IMPORTED CHEMICALS**

## IMPORTED CHEMICALS

The statutory mandate of section 13 of TSCA requires the Secretary of the Treasury to refuse entry into the U.S. Customs territory of any chemical substance, mixture, or article\* if:

- It fails to comply with any rule in effect under TSCA; or
- It is offered for entry in violation of sections 5 or 6, a rule or order under sections 5 or 6, or an order issued in a civil action brought under sections 5 or 7.

The Secretary of the Treasury, after consultation with the Administrator of the Environmental Protection Agency (EPA), promulgated a final Customs rule under section 13 on August 1, 1983 (48 FR 34734), (19 CFR sections 12.118 through 12.127 and 127.28 (amended)). In order to explain how it will interpret and carry out its responsibilities under this Customs rule, the EPA issued a policy statement on December 13, 1983 (48 FR 55462), (40 CFR Part 707). This policy statement is available from the TSCA Assistance Office (see inside front cover).

Following are highlights of the rule and policy for guidance to importers and EPA and Customs regional inspectors.

### IMPORTER RESPONSIBILITIES

Under the Customs rule, the importer of a chemical shipment must certify at the port of entry for shipments entering commerce in the U.S. that either:

- The shipment is subject to TSCA and complies with all applicable rules and orders thereunder; or
- The shipment is not subject to TSCA.

An importer can accomplish the certification and discharge his obligations related to the import by signing, at the time of Customs clearance, one of the following brief statements to be typed or preprinted on an entry document or invoice or other attachment:

For shipments subject to TSCA: "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 under TSCA."

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\* See Articles Containing Chemical Substances, Page 8.

For other shipments: "I certify that all chemicals in this shipment are not subject to TSCA."

#### CUSTOMS RESPONSIBILITIES

Customs officers must review the Customs papers for chemical shipments to determine if the certification is present. The Customs rule defines detention of shipments of chemical substances, mixtures, or articles at port of arrival and port of entry as follows:

Detention at Port of Arrival (Port of Entry if the Same) - The district director must detain shipments of chemical substances, mixtures, or articles:

- That have been banned from Customs territory of the U.S. by a rule or order issued under sections 5 or 6 of TSCA (15 USC 2604 or 2605); or
- That have been ordered seized because of imminent hazards as specified under section 7 of TSCA (15 USC 2606).

#### Detention at Port of Entry

- Whenever the EPA Administrator has reasonable grounds to believe that the shipment is not in compliance with TSCA and notifies the district director to detain the shipment;
- Whenever the district director has reasonable grounds to believe the shipment is not in compliance with TSCA; or
- Whenever the importer does not certify compliance with TSCA as required.

Refused Entry - If a shipment is refused entry, the Secretary of the Treasury must:

- Notify the consignee and the EPA Administrator of the entry refusal, including the reasons for the detention;
- Not release the shipment, except under bond (when appropriate); and
- Cause its disposal or storage, if the shipment has not been exported by the consignee within 90 days from date of receipt of the notice of entry refusal.

## EPA RESPONSIBILITIES

Under the Customs Rule, the EPA Administrator must:

- Determine whether detained shipments and their entries comply;
- Notify Customs when EPA is aware of shipments that should be detained;
- Identify steps necessary to bring detained shipments into compliance, or that must be taken when shipments are not brought into compliance; and
- Take action to store or dispose of abandoned noncomplying shipments.

## BASIS FOR CERTIFICATION

Whenever the documents accompanying the imported shipment identify the chemical exactly, the person who is certifying compliance can check the identity against requirements under TSCA. When the chemical substance or mixture is imported under a name that does not identify it exactly, and the person certifying does not otherwise know the identity, he should attempt to discover the chemical constituents of the shipment by contacting another party to the transaction (e.g., his principal or the foreign manufacturer). This person may be able to identify the components of the substance or mixture, or at least state that the substance or mixture complies with TSCA. The greater the effort an importer makes to learn the identities of the imported substances, the smaller his chances of committing a violation by importing a noncomplying shipment. If a shipment were ultimately determined to have violated TSCA, the good faith efforts of the importer to verify compliance, as evidenced by documents contained in his files, might obviate or mitigate the assessment of a civil penalty under section 16 of TSCA.

## APPLICABLE REGULATIONS AND CHEMICALS

The TSCA regulations that apply to importers (who are defined as "manufacturers" under TSCA) include the following:

Section 5 Premanufacture Notification and Significant New Use Rules

These rules impose notification requirements for chemical manufacturers and processors. Each chemical substance (subject to TSCA regulations) that is imported into the United States must be listed on the TSCA Inventory of Chemical Substances unless it is imported in small quantities solely for research and development. (See subsequent section entitled TSCA Inventory of Chemical Substances, Page 11.) An importer must verify that all such chemical substances in each of his shipments are listed on



this Inventory. Chemicals exempt from this requirement include, but are not limited to, foods, drugs, cosmetics, and active ingredients in pesticides. Such exempt chemicals, however, still require a certification that they are not subject to TSCA, except when exempt from negative certification as specified below. All others must appear on the Inventory, or importation is prohibited. Examples of exempted chemicals for which the importer could sign the negative certification statement shown under Importer Responsibilities (Page 4) include the following:

- Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when imported for use as a pesticide;
- Source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act);
- Firearms and ammunition, the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by sections 4182 or 4221 or any other provision of such Code).

Customs has decided that the following items do not require any certification because there are other controls on the importation of those items involving other Federal agencies.

- Any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device if accompanied by an FDA import form, FD701. The term "food" includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act).
- Tobacco or any tobacco product.

Persons who wish to import chemical substances which do not appear on the Inventory, except for those small quantities imported solely for research and development purposes, must comply with Premanufacture Notification (PMN) Requirements and Review Procedures in section 5(a)(1) of TSCA. These are specified in an EPA Final Rule issued in the Federal Register on May 13, 1983 (48 FR 21722) (40 CFR 720). A principal importer must submit a standard PMN using EPA Form 7710-25(4-26-83). Importers are required to provide information only on exposure which occurs within the United States. The principal importer is the first importer who selects the new chemical substance and determines the

total amount to be imported. The principal importer must know that the substance will be imported. Only a person incorporated, licensed, or doing business in the United States may submit the notice. You may prepare and submit the premanufacture notice with another person. A joint submission may be useful where different persons have information required in the notice. It also may be useful when another person has information fundamental to the notice, but wishes to keep it confidential.

In addition, chemical substances imported into the United States may be subject to significant new use rules (SNURs) under section 5(a)(2). Such rules would require a notice before import. While no SNURs are in effect now, several are being developed and may become effective in the near future.

See Importer's Checklist (Page 21) for further clarification of PMN and other requirements in the subsequent section of this publication entitled TSCA Inventory of Chemical Substances (Page 11).

#### Section 6 Rules

These rules cover regulation of selected chemical substances and mixtures. EPA may take certain regulatory actions (as specified under section 6) to protect against an unreasonable risk of injury to health or the environment for the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture. Certain chemicals imported into the United States may be subject to restrictions under this section. These chemicals are listed in Volume 2, Parts I and II.

#### Section 7 Judicial Actions

This section authorizes EPA to commence a civil action for seizure of an imminently hazardous chemical; for relief against any person who manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical; or for both seizure and relief. Chemicals that have been ordered seized by a court because of imminent hazards may not be imported into the United States. EPA has not taken action under section 7 to date.

#### Section 12(b) Rules

If entry is denied for an intended import, and the importer chooses to export the non-complying shipments to a foreign country, rules under this section apply. Such rules may require the exporter to notify EPA of the intended shipment. EPA, in turn, must notify the foreign government of the intended export to that country. (See Volume 2, Part IV.)

### Section 4 and 8 Rules

Importers may be subject to these rules because TSCA defines importers as manufacturers. However, because these rules do not apply to individual chemical shipments, and because compliance with such rules may be a lengthy procedure, importation does not depend on importers satisfying section 4 or 8 requirements at the time of certification. However, if a section 8 rule requires notification of EPA prior to the import of a specified chemical, any importer of that chemical should ensure that the required notification has been completed before certifying that a shipment containing the chemical is in compliance with TSCA.

In addition, importers are responsible for submitting to EPA any lists and copies of unpublished health and safety studies, or references to them, in their possession for the chemicals subject to section 8(d) of TSCA. Importers need only search files located in the United States; they are not required to secure studies in the possession of a foreign subsidiary or parent. However, if an importer knows of a study in the possession of a foreign entity, then that study must be listed and the list submitted to EPA.

### Articles Containing Chemical Substances

The Customs rule does not require certification for chemical substances imported as part of articles unless EPA has required reporting under a specific TSCA rule. At this time, there are no TSCA rules that require certification for articles. However, future TSCA rules may require certification of articles containing certain chemical substances. In such cases, the individual rules will specify whether certification is required.

### Chemicals Subject to Specific Rules

The specific rules issued under these TSCA sections and the chemical substances to which they apply are indicated on the tabular lists in Volume 2, Parts I through IV. Each chemical substance is followed by its appropriate Chemical Abstract Services (CAS) registry number. This is a unique number assigned to each chemical substance. Another listing of these chemicals, by CAS number, appears in Volume 2, Part V.

To be sure that your import shipment complies with all of the above rules and regulations, refer to Importer's Checklist (Page 21).

**Importers may contact the TSCA Assistance Office to obtain additional information on requirements and to get on the mailing list for the Chemicals-In-Progress Bulletin for information on current rulemaking actions.**

**TSCA INVENTORY OF CHEMICAL SUBSTANCES**

## TSCA INVENTORY OF CHEMICAL SUBSTANCES

Section 8(b) of the Toxic Substances Control Act (TSCA) requires the Administrator of the U.S. Environmental Protection Agency to identify, compile, keep current, and publish a list of chemical substances manufactured, imported, or processed for commercial purposes in the United States.

The Initial Inventory and the Cumulative Supplement II constitute the Revised Inventory representing a total of about 60,000 chemical substances. An appendix to the Inventory includes 1,800 generic names generated for chemical substances whose identities have been claimed as confidential.

**Chemical substances which are not included on the Inventory are considered "new" and are therefore subject to premanufacture notification requirements under section 5 of TSCA.**

The Inventory does not purport to identify all chemical substances currently in U.S. commerce, because some such substances are specifically excluded by statute or regulation (40 CFR Part 710). Additionally, no printed version of the Inventory can be completely up-to-date because it is continually subject to change. New substances for which premanufacture review (PMN) under section 5 has been completed and that are being manufactured or imported will continue to be added to the Inventory. A few substances that have been included on the Inventory may be deleted if the Agency, after a careful review of the Inventory, decides that they should not have been reported. Furthermore, information regarding chemical identities claimed as confidential is not included in the published version of the Inventory. Recognizing these limitations, the Agency maintains a Master Inventory File, which includes all eligible substances that have been reported. The file is continually updated as new information becomes available.

The Agency provides a service to assist those who, for various reasons, wish to query the Inventory. A person who intends to manufacture or import a chemical substance that does not appear on the published Inventory may ask EPA to determine whether the substance in question is included in the Agency's Master Inventory File. If the substance is confidential, the Agency will provide a conclusive answer only if the person who submits the inquiry is able to demonstrate a "bona fide intent" to manufacture or import the substance for a commercial purpose. The exact procedures for establishing and submitting a bona fide intent are discussed in detail in the Premanufacture Notification Requirements and Review Procedures (48 FR 21722) (40 CFR 720.25, May 13, 1983). When a bona fide intent has been established with a formal submission, the Agency will perform a comprehensive search of the entire Master Inventory File -- i.e., both confidential and non-confidential portions -- to determine conclusively whether the substance in question is already included.

If a person does not wish to comply with the bona fide intent submission requirements and still wishes the Agency to determine whether a particular chemical is included on the Inventory, the Agency will, upon receipt of such a request, perform a search of the non-confidential portion of the Master Inventory File. In this case, because the confidential portion of the file is not searched, the results may not be conclusive.

All Inventory inquiries must be submitted in writing and accompanied by appropriate documentation. Incomplete inquiries or submissions will not be processed until all materials have been received. Special care should be taken with the submissions that contain TSCA Confidential Business Information. Bona fide intent submissions as well as requests for non-confidential searches should be sent to:

U.S. Environmental Protection Agency  
Document Control Officer (TS-793)  
Office of Pesticides and Toxic Substances  
401 M Street, SW.  
Washington, D.C. 20460

Address all other Inventory inquiries, submissions, and corrections to:

U.S. Environmental Protection Agency  
Office of Toxic Substances  
Inventory Control Team (TS-793)  
401 M Street, SW.  
Washington, D.C. 20460

**EPA ENFORCEMENT**

## EPA ENFORCEMENT

EPA and the Customs Service will monitor chemical imports to determine if shipments and their import comply with the certification requirements and the substantive mandates of TSCA. Customs will refuse entry to any shipment until such time as the certification is properly submitted. Customs will also detain a shipment if there are reasonable grounds to believe that such shipment or its import violates TSCA or regulations or orders thereunder. A violative shipment must either be brought into compliance, exported, destroyed, or voluntarily abandoned within the time periods prescribed in §12.124 of the section 13 rule.

When EPA determines that a shipment should be detained, EPA will identify the reasons for the detention and the necessary actions for an importer to bring the shipment into compliance with TSCA. If EPA has given this information to Customs before the district director issues the detention notice, the information will become part of the detention notice. The importer should contact one of the following EPA regional offices for guidance as to the proper procedures to correct any deficiencies in the shipment.

### EPA REGION I

Pesticides and Toxic Substances Branch  
John F. Kennedy Federal Building  
Boston, MA 02203  
617-223-0586

### EPA REGION II

Pesticides and Toxic Substances Branch  
Raritan Depot, Building 209  
Woodbridge Avenue  
Edison, NJ, 08837  
201-321-6681

### EPA REGION III

Environmental Programs Branch  
Curtis Building  
6th & Walnut Streets  
Philadelphia, PA 19106  
215-597-7668

### EPA REGION IV

Pesticides and Toxic Substances Branch  
345 Courtland Street, NE.  
Atlanta, GA 30365  
404-881-3864



## EPA REGION V

Toxic Materials Branch  
230 South Dearborn Street  
Chicago, IL 60604  
312-353-2291

## EPA REGION VI

Pesticides and Toxic Substances Branch  
1201 Elm Street  
Dallas, TX 75270  
214-767-2734

## EPA REGION VII

Air and Waste Compliance Branch  
324 East 11th Street  
Kansas City, MO 64106  
816-374-3036

## EPA REGION VIII

Toxic Substances Branch  
1860 Lincoln Street  
Denver, CO 80295  
303-837-3926

## EPA REGION IX

Toxics and Waste Programs Branch  
215 Fremont Street  
San Francisco, CA 94105  
415-974-8124

## EPA REGION X

Toxic Substances Control Branch  
1200 Sixth Avenue  
Seattle, WA 98101  
206-442-2871

If Customs detains or refuses entry of a shipment (other than for failure to make the general certification) and the importer takes measures necessary to bring the shipment into conformity with the requirements of TSCA, EPA officials will reassess the shipment to determine its current compliance status. Assuming a shipment is no longer in violation, EPA will notify the district director and the importer. The district director will then release the shipment. This notice will also serve as a determination to permit entry under §12.123(c) if a shipment is brought into

compliance before the §12.123(c) decision-making process has been completed. If compliance is achieved after a §12.123(c) determination (adverse to the importer) has been made, the EPA notice to the district director will serve as a reversal of the decision to refuse entry.

You can obtain assistance in determining whether a chemical shipment is in compliance with TSCA from: the Director, Compliance Monitoring Staff, Office of Pesticides and Toxic Substances (EN-342), U.S. Environmental Protection Agency, 401 M Street, S W., Washington, D.C. 20460.

Any questions concerning Customs matters should be directed to the District Director of Customs at the port of entry. Addresses of local Customs Offices can be found in the local telephone directory under United States Government, Department of the Treasury, United States Customs Service.

**IMPORTER'S CHECKLIST**

## IMPORTER'S CHECKLIST

- Step I Is my chemical substance exempt from positive certification?
- Check the list of materials exempted from TSCA. These are listed on Page 6, this volume.
  - If your chemical substance falls into any of these categories, follow Steps II and III.
- Step II Is my chemical substance in the category requiring negative certification?
- Check the list of chemicals on page 6 that do not require positive certification (pesticides, source material, special nuclear material, byproduct material, firearms and ammunition).
  - If your chemical substance falls into any of these categories, you must sign the negative certification statement that the chemical you intend to import is not subject to TSCA.
- Step III Is my chemical substance exempt from both positive and negative certification?
- Check the list of chemicals on Page 6 that do not require any certification (food, food additive, drug, cosmetic or device, tobacco or any tobacco product).
  - If your chemical falls into any of these categories, and if it is accompanied by FDA Import Form FD701, you are not required to sign any certification statement.
- Step IV
- Is my chemical substance being imported solely for research and development purposes, and is it a TSCA regulated chemical substance?
- If yes, you must sign the positive certification statement without further checking.
- Step V Is my chemical substance on the Inventory?
- Verify that your chemical substance is listed on the TSCA Inventory and the Cumulative Supplement II.

- If your chemical substance is not listed, it may have been included previously but does not appear in the printed version because it was added to the list since the last revision, or because it was submitted confidentially.

Prior to import, you must determine whether or not this chemical substance appears on the Master Inventory File. You must submit a "bona fide intent to import" so that EPA can review the Master Inventory File.

- If your chemical substance is not listed on the Master Inventory, and you wish to import it, you must file a premanufacture notification with EPA at least 90 days prior to import. You may call the TSCA Assistance Office (see inside front cover) for additional information.

Step VI My chemical substance is on the Inventory. Do I have any further requirements under this rule?

- You must determine whether there are any regulations or actions regarding this chemical substance under TSCA sections 5, 6, or 7.
  - Look in the list of chemicals requiring certification in Volume 2: List of Import/Export Chemicals. You must meet all the requirements outlined for the specified chemicals.
  - If the chemical is not listed in the list of chemicals requiring certification, it is your responsibility to verify that the information has not changed since the date of this publication. If necessary, call the TSCA Assistance Office to verify that information is up to date.

Step VII Do I have any further obligations under TSCA?

- Since importers are defined under TSCA as manufacturers, importers must comply with all testing, reporting, and recordkeeping requirements under TSCA sections 4, 8(a), 8(c), and 8(d).

- Some section 8 rules require notification to EPA prior to the import of a specified chemical. Importers must ensure that the required notification has been completed before certifying that a shipment containing the chemical is in compliance with TSCA. Consult the list of affected chemicals in this publication.

NOTE: It is your responsibility to verify that the information has not changed since the date of this publication.

**EXPORTED CHEMICALS**

## EXPORTED CHEMICALS

The statutory requirements of section 12(b) of TSCA require that:

- Any person who intends to export a chemical substance or mixture that is subject to certain testing or regulatory control requirements under TSCA must notify EPA of such export or intent to export.
- The EPA then must notify the importing country's government
  - Of the availability of test data on the chemical submitted to EPA under sections 4 or 5(b) of TSCA; and
  - Of any proposed or final rule, order, action, or relief under sections 5, 6, or 7 of TSCA.

Chemicals produced solely for export generally have not been subject to TSCA. EPA is, however, currently preparing a proposed section 8(a) reporting rule which would require manufacturers to notify the Agency when they manufacture new chemicals solely for export. Also, EPA may regulate a chemical produced for export if it presents an unreasonable risk of injury to health or the environment of the United States. The Agency may require testing of any such chemical if necessary to determine whether there is a risk to the United States.

### EXPORTER RESPONSIBILITIES

EPA issued a final section 12(b) export notification rule in the Federal Register on December 16, 1980 (45 FR 82844) (40 CFR 707). Under this rule, an exporter of regulated substances or mixtures must submit a notice of the first export within the calendar year of the substance or mixture. Such reporting is required for any substance or mixture that is the subject of a final TSCA section 4 test rule, and a proposed or final rule, action, or order under sections 5, 6, and 7. The notice must be submitted by letter to EPA, and must include the following information:

- Name and address of the exporter;
- Name of the chemical substance or mixture;
- Date(s) of export or intended export;
- Country (countries) of import;
- Section of TSCA (5 or 6) under which EPA has proposed action and the section of TSCA (4,5,6, or 7) under which EPA has taken action.



Submit the notice for your first export or intended export to a particular country in a calendar year. The notice must be postmarked within seven days after accepting a definite contractual obligation to export or an equivalent intracompany agreement to export. Where the actual export occurs less than seven days after the export obligation or agreement has been executed, submit the notice to EPA no later than the same day as the export.

The country of import to be entered on the section 12(b) notice is defined as:

". . . the country where the goods are to be consumed, further processed, or manufactured, as known to the shipper at the time of exportation. If the exporter does not know the country of ultimate destination, the shipment is credited to the last country to which the exporter knows that the merchandise will be shipped."

#### EPA RESPONSIBILITIES

Under the EPA final export rule, EPA must send a notice to the government of the importing country no later than five working days after receipt of the first annual notification from the exporter for each regulated chemical. The EPA notice includes the following information:

- Identification of the regulated chemical;
- Summarization of the EPA regulatory action taken, or an indication of the availability of data under TSCA sections 4 or 5(b);
- EPA official to contact for further information;
- Copy of the pertinent Federal Register notice.

#### APPLICABLE CHEMICALS AND REGULATIONS

A list of the substances (or class of substances) subject to the TSCA section 12(b) rule is provided in Volume 2, Part IV. A second listing of these chemicals, by CAS number, is included in Volume 2, Part V. Also listed in Part IV is a reference to the "triggering" action under sections 4, 5, or 6 of TSCA.

NOTE: If the EPA action that prompts the notice is a proposed rule, the section 12(b) notice must be submitted for exports beginning thirty days after publication of the action in the Federal Register.