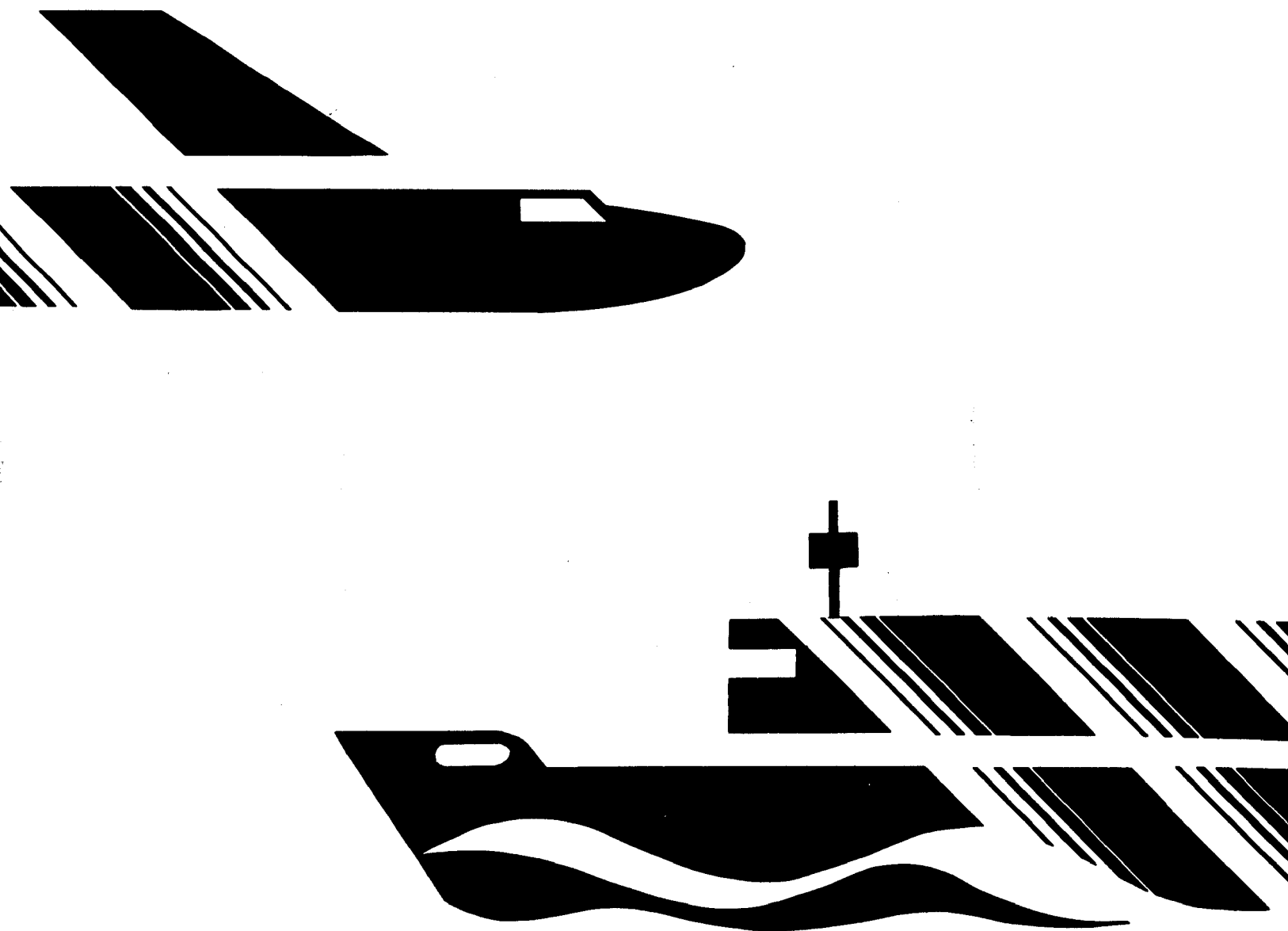




Toxic Substances Control Act

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) export requirements and chemicals which are relevant to section 13, Imports, of TSCA. 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 second edition was compiled as of August 1986. Future Agency actions will require periodic updating and republishing.

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

Edward Klein, Director
TSCA Assistance Office (TS-799)
Office of Toxic Substances
Environmental Protection Agency, Room E-543
401 M Street, SW.
Washington, D.C. 20460
Telephone: 202-554-1404

<p>This is an informational publication. Any rules or orders issued by EPA or U.S. Customs take precedence over the guidance included herein.</p>
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 EXPORT REQUIREMENTS

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:

- o It fails to comply with any rule in effect under TSCA;
or
- o 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 (except as discussed on page 6) at the port of entry for shipments entering commerce in the U.S. that either:

- o The shipment is subject to TSCA and complies with all applicable rules and orders thereunder; or
- o 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."

* 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:

- o 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
- o That have been ordered seized because of imminent hazards as specified under section 7 of TSCA (15 USC 2606).

Detention at Port of Entry

- o 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;
- o Whenever the district director has reasonable grounds to believe the shipment is not in compliance with TSCA; or
- o 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:

- o Notify the consignee and the EPA Administrator of the entry refusal, including the reasons for the detention;
- o Not release the shipment, except under bond (when appropriate); and
- o 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:

- o Determine whether detained shipments and their entries comply;
- o Notify Customs when EPA is aware of shipments that should be detained;
- o Identify steps necessary to bring detained shipments into compliance, or that must be taken when shipments are not brought into compliance; and
- o Take action to store or dispose of abandoned noncomplying shipments. (Importer is liable for any expenses involved in the storage or disposal).

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.

APPLICABILITY OF TSCA

TSCA covers chemical substances and mixtures which are broadly defined in section 3 of TSCA. EPA, together with other Federal agencies, has recently issued a policy statement on biotechnology (51 FR 23313, June 26, 1986) in which EPA clarified that microorganisms are "chemical substances" under TSCA. Importers of microorganisms must bear in mind that they are subject to TSCA import certification requirements as discussed in this volume. In the remainder of this volume, references to "chemical substances" and "chemicals" include microorganisms.

Section 3 of TSCA specifies that certain chemicals are excluded from the definition of "chemical substance" based on their use. These chemicals 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. Examples of exempted chemicals for which the importer could sign the negative certification statement shown under Importer Responsibilities (Page 4) include the following:

- o Any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when imported for use as a pesticide;
- o 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);
- o 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.

- o 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).
- o Tobacco or any tobacco product.

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 jurisdiction) 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.

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), clarified on September 13, 1983 (48 FR 41132), and amended on April 22, 1986 (51 FR 15096) (40 CFR 720). A principal importer must submit a 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.

An importer may qualify for one of the exemptions EPA has issued under TSCA section 5(h)(4): chemical substances manufactured or imported in quantities of 1,000 kilograms or less per year (40 CFR 723.50, 50 FR 16488, April 26 1985); chemical substances used in or for the manufacturing or processing of instant photographic or peel-apart film articles (40 CFR 723.175, 47 FR 24317, June 4, 1982); or certain polymers (40 CFR 723.250, 49 FR 46086, November 21, 1984).

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 to EPA before import for a significant new use.

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, Part I.

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.

Section 12(b) Rules - Export

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 (see Volume 2, Part III). 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 rules under 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).

<p>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.</p>

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 TSCA Chemical Substance Inventory: 1985 Edition lists over 63,000 chemical substances. Of these, some 4,500 have had their identity claimed as confidential and have been assigned generic names.

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 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, 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. The Agency will provide an 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 (40 CFR 720.25) (48 FR 21722, 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.

TSCA INVENTORY OF CHEMICAL SUBSTANCES

All bona fide 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 should be sent to:

OTS Document Control Officer (TS-790)
U.S. Environmental Protection Agency
Office of Toxic Substances
401 M Street, SW.
Washington, D.C. 20460
ATTN: Chemical Inventory Section

To order the printed public version of the TSCA Inventory, call the U.S. Government Printing Office (202) 783-3238, or write Superintendent of Documents, Washington, D.C. 20402-9325. Visa, MasterCard and Choice are accepted. Checks should be made out to the Superintendent of Documents.

The 5-volume TSCA Chemical Substance Inventory: 1985 Edition costs \$161.00 per set shipped to addresses in the United States and Canada, and \$201.25 when shipped to all other countries. The order number is: S/N 055-000-00254-1.

Nonconfidential subsections of the TSCA Inventory are also on computer tape and sold by the National Technical Information Service (NTIS) of the U.S. Department of Commerce.

Requestors should ask for the tapes by their PB numbers.

			*	**
Production Tape	(1977 data)	PB 86-220803	\$275	\$550
Plant Site Tape	(1977 data)	PB 86-220795	\$160	\$320
Synonym Tape	(1985 data)	PB 86-220860	\$370	\$740
Preferred Name Tape	(1985 data)	PB 86-220878	\$275	\$550

* Mailed to addresses in the United States, Canada or Mexico.
Add \$3.00 for handling charges.

** Mailed to all other addresses. Add \$4.00 for handling charges.

To order any of the tapes from NTIS, call (703) 497-4650. Visa, MasterCard and American Express are accepted.

The NTIS address is 5285 Port Royal Road, Springfield, VA 22161. Make checks out to NTIS.

Searches of the NTIS computer tape of the Inventory are available from a number of commercial sources. Note that importers and domestic manufacturers of substances on the TSCA Inventory must comply with the recent rule on the Partial Updating of TSCA Inventory Data Base; Production and Site Reports (40 CFR Part 710) (51

FR 21438, June 12, 1986) Final Rule--Section 8(a). Persons required to report under the rule must submit their reports by December 23, 1986. Recurring reporting is required every four years.

For information, instruction manual, and reporting forms, contact:

OTS Document Control Officer (TS-790)
U.S. Environmental Protection Agency
Office of Toxic Substances
401 M St., SW.
Washington, D.C. 20460
Attn: Inventory Update Rule
Telephone: (202) 382-3698 or (202) 755-4880.

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
617-223-0585

EPA REGION II

Pesticides and Toxic Substances Branch
Raritan Depot, Building 209
Woodbridge Avenue
Edison, NJ, 08837
201-321-6769

EPA REGION III

Toxics and Pesticides Branch
841 Chestnut Street
Philadelphia, PA 19107
215-597-8598

EPA REGION IV

Pesticides and Toxic Substances Branch
345 Courtland Street, NE.
Atlanta, GA 30365
404-347-3222

EPA REGION V

Pesticides and Toxic Substances Branch
230 South Dearborn Street
Chicago, IL 60604
312-353-2192

EPA REGION VI

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

EPA REGION VII

Toxics and Pesticides Branch
726 Minnesota Avenue
Kansas City, KS 66101
913-236-2835

EPA REGION VIII

Toxic Substances Branch
1860 Lincoln Street
Denver, CO 80295
303-293-1730

EPA REGION IX

Pesticides and Toxic Substances Branch
215 Fremont Street
San Francisco, CA 94105
415-974-8138

EPA REGION X

Pesticides and Toxic Substances Branch
1200 Sixth Avenue
Seattle, WA 98101
206-442-1198

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?
- o Check the materials exempted from TSCA. These are listed on Page 6 of this volume.
 - o If your chemical substance falls into any of these categories, follow Steps II and III--otherwise, go to Step IV.
- Step II Is my chemical substance in the category requiring negative certification?
- o 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).
 - o 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?
- o 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).
 - o 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 on the Inventory?
- o Verify whether your chemical substance is listed on the TSCA Chemical Substance Inventory: 1985 Edition.

- o 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.

- o 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. Your chemical substance may be eligible for a 21-day review period if it qualifies for EPA's polymer exemption or low volume exemption. (See p.) You may call the TSCA Assistance Office (see inside front cover) for additional information.
- o If you are importing the substance solely in small quantities for purposes of research and development as defined in the PMN rule and in accordance with the restrictions on such activities, you may sign the positive certification without further checking. See 40 CFR 720.3(cc) and 720.36 to determine if you qualify.

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

- o 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 VI Do I have any further obligations under TSCA?

- o 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).
- o 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:

- o Any person who exports or intends to export a chemical substance or mixture for which submission of data is required under section 4 or 5(b), for which an order has been issued under section 5, for which a rule has been proposed or promulgated under section 5 or 6, or with respect to which an action is pending, or relief has been granted under section 5 or 7, must so notify the EPA Administrator.
- o The EPA then must notify the importing country's government
 - Of the availability of test data on the chemical submitted to EPA under section 4 or 5(b) of TSCA; and
 - Of any rule, order, action, or relief under section 5, 6, or 7 of TSCA.

In addition, 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 export reporting rule in the Federal Register on December 16, 1980 (45 FR 82844) (40 CFR 707). Under this rule, an exporter must submit a notice of the first export, within the calendar year, of the substance or mixture. Submit the notice by letter to EPA, and include the following information:

- o Name and address of the exporter;
- o Name of the chemical substance or mixture;
- o Date(s) of export or intended export;
- o Country (countries) of import;
- o 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:

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

APPLICABLE CHEMICALS AND REGULATIONS

A list of the substances (or classes 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, 6, or 7 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.

CHEMICAL IMPORTS

Questions and Answers

about

Requirements Under Section 13
of the
Toxic Substances Control Act (TSCA)

CHEMICAL IMPORTS

Questions and Answers

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I. ARTICLES AND MIXTURES UNDER TSCA SECTION 13

The TSCA Assistance Office has received a number of questions concerning classification of various imported materials as chemical substances (subject to certification) or articles (not subject to certification). (Refer to PART IV: CERTIFICATION REQUIREMENTS for details.) Those listed below were all determined by EPA to be chemical substances. As such, they require positive certification of compliance with TSCA.

Aluminum oxide	Oxalic acid
Bauxite	Peat Moss, except as peat
Bismuth	pots, which are articles
Coal	Pitch
Crude oil	Potassium sorbates, unless
Crushed stone	used as a food additive
Gasoline	Sorbic acid, unless used as
Leather hides	a food additive
Liquified petroleum gas	Tetraethyl lead
Lysine, unless used as a	
food additive	
Natural gas	

Q. 1. How is "chemical substance" defined under TSCA?

A. 1. "Chemical substance" is defined in section 3 of TSCA 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.

Chemical substance does not include -

(i) any mixture;

(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide;

(iii) tobacco or any tobacco product;

(iv) any source material, special nuclear material or by-product material (as such terms are defined in the Atomic Act of 1954 and regulations issued under such Act);

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- (v) any article [i.e., 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 section 4182 or 4221 or any other provision of such Code); and
- (vi) 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.

A chemical substance in bulk form is defined in the Customs rule at 12.120(b) as "a chemical substance (other than part of a mixture or article) in containers used for purposes of transportation or containment, provided the chemical substance is intended to be removed from the container and has an end use or commercial purpose separate from the container."

Q. 2. How is "article" defined?

- A. 2. (1) "Article," in the Customs rule at section 12.120(a)(1) is 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); below; 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.

Q. 3. For which articles is a certification required pursuant to section 12.121(b) of the Customs rule?

A. 3. Articles, as defined by TSCA, require no certification at this time; however, any future regulations on articles may specify import requirements.

Q. 4. Are metallurgical intermediates classified as chemical substances or articles?

A. 4. If an item is manufactured in a particular shape for the purpose of shipping convenience and the shape of the item has no function in the end use, it is not considered an article. Thus, items such as metal ingots, billets, and blooms are viewed as chemical substances, require TSCA certification, and are subject to PMN requirements. (The blanket certification procedures described in Part III of this document may provide the most convenient option.)

For purposes of compliance with section 5 and section 13, OTS will consider items being imported as articles if they are manufactured in a specific shape or design for a particular end use application, and this design is maintained as an essential feature in the finished product. Thus, materials such as metal or plastic sheets, wire, coated fabric, rolled carpet, sheets of plywood and other similar materials will be viewed as articles by OTS, even if, for example, subsequent to import they are rolled or drawn thinner, cut, printed, laminated, or thermoformed, as long as they meet the above criteria. None of these items would be subject to TSCA import certification unless they contained a chemical substance or mixture for which certification is required by a specific rule under TSCA. Also, they would not be subject to Premanufacture Notice (PMN) requirements.

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Q. 5. We import small plastic sheets with chemical coatings for analysis in our quality control laboratories. Do these require certification?

A. 5. See A.4. above.

Q. 6. Is waste imported for disposal in drums and not removed from the drums considered an article?

A. 6. No, such waste is not an article, it is a bulk chemical and requires a positive certification. However, see questions 70 and 71.

Q. 7. If an importer imports a piece of machinery which contains PCBs, is a positive certification necessary?

A. 7. Because TSCA considers the term "import" to be synonymous with "manufacture", no PCB equipment can be imported after July 2, 1979, unless an exemption is obtained from EPA. If the exemption has been obtained, no TSCA certification is required for the import of the machinery, since the PCBs are part of an article (the machinery) and are not removed from that article. However, the PCBs are subject to the provisions of the TSCA section 6(e) PCB rules.

Q. 8. Can a "new" (not on the Inventory) dielectric fluid (not a PCB) be imported in a capacitor or transformer?

A. 8. As long as it is not removed from the capacitor or transformer, the fluid is considered to be part of an article and may be imported as such. Import separate from the article would require a premanufacture notice 90 days before import.

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Q. 9. A large number of exports, such as argon, hydrogen and oxygen, are shipped in pressure containers, such as cylinders, tank trucks, and tank cars. Upon return, the containers and any residuals are released as Instruments of International Traffic without entry papers. Is a certification required for these residuals?

A. 9. Containers are considered articles and, as such, do not require certification as long as residuals therein do not constitute bulk quantities.

Q. 10. How is mixture defined under TSCA?

A. 10. The term mixture is defined in section 3 of TSCA as follows: "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 which 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."

Q. 11. How are mixtures to be treated? If each item is identified in the TSCA Inventory, can certification be made?

A. 11. Each chemical substance in the mixture (other than impurities) must be identified. [However, there are certain complex chemicals (e.g., Castor oil, Barium iron oxide) which are designated "Class 2" substances on the TSCA Inventory to which this will not apply.] After identifying each chemical substance, you must determine whether all the individual substances are on the Inventory and are in compliance with specific rules under sections 5, 6, and 7 of TSCA before signing the positive certification.

Q. 12. Do mixtures such as paints, cleaners, and the like have to be certified?

I. ARTICLES AND MIXTURES UNDER TSCA SECTION 13

- A. 12. Yes, the procedure outlined in the answer to the preceding question must be followed and a positive certification signed.

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- Q. 13. Does the certification requirement apply to shipments of final products that are chemical mixtures? For example, would the rule apply to a shipment of cartons of carburetor cleaner?

- A. 13. Yes, certification is required for shipments of final products that are chemical mixtures.

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II. CERTIFICATION FORMAT

- Q. 14. What is the acceptable certification language and format and on what document should the certification be made?

- A. 14. The specific language for a positive certification is:

"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."

Or, for a negative certification:

"I certify that all chemicals in this shipment are not subject to TSCA."

No other language may be substituted. Both positive and negative statements may be preprinted, typed or stamped on an entry document, invoice or other attachment. The preferred document on which certification can be made is the U.S. Customs Form CF 3461 or the entry summary.

II. CERTIFICATION FORMAT

Certification on a packing slip or bill of lading is acceptable if either of these is included in the entry package. In many cases, however, the bill of lading is not part of the entry package. The certification statements may be signed by means of an authorized facsimile signature.

Q. 15. Can a single or "blanket" certificate be used to cover several shipments of the same chemical made over a one-year period?

A. 15. Yes, if a "blanket" certification (see Section III) has been authorized by the appropriate District Director of U.S. Customs and a statement to that effect is included on the commercial invoice or entry document.

Q. 16. Is it necessary for the importer to include the Chemical Abstracts Service (CAS) number for each chemical covered by the certification?

A. 16. No, CAS numbers are not required, but they could be useful in speeding verification of proper certification. Note that only a few of the existing CAS numbers are actually on the TSCA Inventory. Importers must not assume that the existence of a CAS number means that TSCA requirements are met.

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III. BLANKET CERTIFICATION

Q. 17. Can you discuss procedures for "blanket" certification?

A. 17. "Blanket" certification must be made on the letterhead of the certifying firm and signed by an authorized person. All blanket certifications shall initially be annual on a calendar year basis, subject to renewal. Once accepted, a blanket certification may be revoked for cause by the District Director of the U.S. Customs Service at any time.

Importers authorized to use blanket certifications must also include a statement on the commercial invoice or entry document referring to the blanket certification and incorporating it by reference. Such statement need not be signed. Separate blanket certifications will be required for chemicals subject to TSCA and those not subject to TSCA.

The format to be used for blanket certifications, and the format for the required statement referencing the blanket certification, is shown on pages 7, 8, and 9. A copy of every accepted blanket certification will be forwarded by the District Director, to the Cargo Control Program, Office of Inspection and Control, Customs Service Headquarters, Washington, D.C.

Q. 18. Is it necessary to list tariff item numbers on blanket certifications?

A. 18. Blanket certifications will be one of the sources U.S. Customs will use to develop its TSCA data base which will ultimately facilitate the clearance of goods subject to TSCA. Since this data base is Tariff Schedule of the U.S.A. (TSUSA)-oriented, tariff item numbers are necessary.

Q. 19. Must suppliers' names and addresses be listed?

A. 19. Yes, names and addresses must be listed to simplify resolution of compliance problems which may arise.

III. BLANKET CERTIFICATION

Q. 20. Is it necessary to file blanket certifications at each port of entry?

A. 20. No, blanket certifications need to be filed with each district where importations are anticipated, since their acceptance is at the option of each Customs' District Director for his or her district.

Q. 21. Who is responsible for forwarding a copy of the accepted blanket certification to Cargo Control?

A. 21. This is the responsibility of the District Director.

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IV. CERTIFICATION REQUIREMENTS

Q. 22. What does an importer need to know to determine the certification requirements for his imported chemical?

A. 22. a) Is my substance exempt from TSCA section 13 certification requirements?

- ° Check the categories of materials that do not require any certification (see questions 23 and 24).
- ° If your substance falls into any of these categories, you are not required to sign any certification statement if the shipment is accompanied by the appropriate forms.

b) Is my substance in the category requiring negative certification?

- o Check the categories of materials that require negative certification (see questions 23 and 24).

IV. CERTIFICATION REQUIREMENTS

- o If your substance falls into any of these categories, you must sign the negative certification statement that the substance you intend to import is not subject to TSCA.
- c) Is my substance in the category requiring positive certification?
 - o If your substance does not fall into any of the categories, either requiring negative certification, or exempt from certification altogether, it is subject to positive certification.
- d) Is my substance being imported solely for research and development purposes?
 - o If yes, you are exempt from PMN requirements.
- e) Is my substance a new chemical substance, potentially subject to PMN requirements?
 - o Prior to import, you must determine whether or not your chemical substance is actually on the printed TSCA Inventory or Master File. You may ask EPA to search the Inventory, including the confidential portion, by establishing a "bona fide intend to import" as discussed in 48 FR 21722, 40 CFR 720.25, the PMN rule.
 - o If your chemical substance is not listed on the Master Inventory, and you wish to import it, other than for research and development, you must file a premanufacture notification with EPA at least 90 days prior to import. Your chemical substance may qualify for a polymer exemption or a low volume exemption, which require notification at least 21 days prior to import; the notification requirements are reduced as well. You may call the TSCA Assistance Office for additional information.

IV. CERTIFICATION REQUIREMENTS

- f) My chemical substance is on the Inventory or imported solely for research and development. Do I have any further requirements under TSCA section 13?
- o You must determine whether there are any specific regulations or actions regarding this chemical substance under TSCA section 5, 6 or 7.
 - o Check the lists of chemicals subject to proposed or final regulations under those sections in A Guide for Chemical Importers/Exporters, Volume 2: List of Import/Export Chemicals. You must meet all the requirements outlined for the specified chemicals in order to sign the positive certification statement.
 - o If the chemical is not listed as subject to any proposed or final rule under TSCA section 5, 6 or 7, you are responsible for verifying 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.
- g) Do I have any further obligations under TSCA?
- o Since importers are defined under TSCA as manufacturers, they must comply with all testing, reporting, and recordkeeping requirements imposed on manufacturers under TSCA section 4, 8(a), 8(c), 8(d), and 8(e).
 - o Some section 8 rules require notification to EPA prior to the import of a specified chemical. Importers should 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 Volume 2.

IV. CERTIFICATION REQUIREMENTS

NOTE: It is your responsibility to verify that the information has not changed since the date of publication of A Guide for Chemical Importers/Exporters.

Q. 23. Which imported chemicals require TSCA positive certification, negative certification, and which are exempt and require no certification?

A. 23. A positive certification of compliance with TSCA is required for all chemical substances under TSCA jurisdiction as discussed in PART I: ARTICLES AND MIXTURES UNDER SECTION 13 in this document.

A negative certification is required for chemicals not subject to TSCA jurisdiction (except food, drugs, etc., as listed directly below under "no certification"). Chemicals which require negative certification are pesticides, nuclear source materials, special nuclear materials or nuclear by-product materials, firearms and ammunition.

No certification is required for articles, as defined in section 12.120(a) of the rule, and for chemicals not subject to TSCA because Customs has other controls and certification requirements involving other federal statutes. These chemicals are any food, food additive, drug, drug intermediate, cosmetic, cosmetic intermediate, or device subject to the Federal Food, Drug and Cosmetic Act (FFDCA), and any tobacco or tobacco products, when accompanied by the appropriate forms.

Q. 24. Can Customs schedules be used to determine the need for certification?

A. 24. Customs schedules alone are insufficient to determine the need for certification. All chemicals are subject to the TSCA section 13 rule and must have a negative or positive certification except for tobacco or tobacco products, articles, and 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

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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). Customs schedules contain insufficient detailed chemical identity information to be used for TSCA Inventory purposes.

Q. 25. Is listing of the chemical substance on the TSCA Inventory of Chemical Substances sufficient basis for certification of compliance with TSCA?

A. 25. No, you must also check for any rules applicable to the chemical substance under section 5, 6, or 7 of TSCA and meet their requirements.
[See Volume II of the Chemical Importers Guide.]

Q. 26. Does positive certification require compliance with sections 4 and 8 of TSCA at the time of certification?

A. 26. No, although testing, reporting, and recordkeeping requirements under sections 4 and 8(a), 8(c), 8(d), and 8(e) apply to specific chemical substances, positive certification of compliance with TSCA under section 13 does not generally require compliance with section 4 or 8 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.

Q. 27. Does a chemical subject to TSCA under the statutory definition of "chemical substance" (section 3(2)(a)), but exempt from section 5 regulations (e.g., R & D substances), require a negative certification?

IV. CERTIFICATION REQUIREMENTS

A. 27. No, the chemical substance is subject to TSCA under section 3(2)(a), and this requires that a positive certification be signed.

Q. 28. Does the importer need to know the identity of an imported chemical.

A. 28. The importer may opt to rely on the warranty or certification from the foreign supplier in making his TSCA certification. However, the importer is liable if the certification is not correct. The liability can be reduced if the importer has verifiable evidence that he made good faith efforts to comply.

Q. 29. Can my foreign supplier request an Inventory search?

A. 29. No. All bona fide requests must contain a statement of bona fide intent to import, signed by a U.S. importer. However, your foreign supplier may submit technical data in support of your bona fide submission. Any information submitted by your foreign supplier and claimed confidential by him will be treated accordingly by EPA.

Q. 30. Is Volume 2 of A Guide of Chemical Importers/Exporters--List of Import/Export Chemicals a complete list of chemicals covered by the new certification requirement?

A. 30. It is a complete list only of chemicals subject to specific rules and regulations under sections 4, 5, 6, 8 and 12(b) of TSCA as of its publication date. It is not a list of the TSCA Inventory of Chemical Substances.

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V. WHO CERTIFIES

Q. 31. Who must make the TSCA certification to U.S. Customs?

A. 31. The importer of record (with Customs) or his broker if acting as his agent with power of attorney is responsible for TSCA certification.

Q. 32. May the importer of record be a foreign company?

A. 32. Yes, provided that in the state or territory where the port of entry is located, there is a resident who is authorized to accept service of process. Such resident must file a bond having a resident corporation surety to secure payment of any increased or additional duties that may be found due.

Q. 33. Who may sign the certification for the company?

A. 33. The certification may be signed by an employee or officer authorized by the company to do so, or by any agent with power of attorney for the company.

Q. 34. Are purchasers of items from importers (or customers of importers) required to make any certification?

A. 34. No.

Q. 35. Border Custom house brokers receive documents from U.S. Customs for follow-up entry only after shipments have passed through Customs. How, then, can an importer comply with certification requirements?

A. 35. There are several ways this can be resolved. The broker may:

1. Use the bonding provision to secure release of the shipment, with subsequent certification.

V. WHO CERTIFIES

2. Give power of attorney to the foreign supplier to put the certification on the invoice, especially in the case of repeat shipments.
 3. Use the "blanket" certification.
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Q. 36. Who is responsible for TSCA certification if a chemical substance is purchased from Canada or Mexico (freight on board--F.O.B.--shipping point freight allowed--with freight charges "prepaid"--at the rate from a domestic point to destination) so title theoretically passes at point of shipment?

A. 36. Whoever is the importer of record with U.S. Customs is responsible for certification. If your customer is the importer and you are acting as agent of the importer with power of attorney, you may certify.

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VI. FOODS, DRUGS, AND COSMETICS

Q. 37. Are imported foods, food additives, drugs, drug intermediates, cosmetics, cosmetic intermediates, and devices exempt from TSCA certification?

A. 37. Yes, if these substances are imported solely for use as a food, drug, cosmetic, device or for use in manufacturing a food, drug, cosmetic, or device. They do require separate certification, as specified by U.S. Customs under the Federal Food, Drug and Cosmetic Act (FFDCA).

Q. 38. What if part of the shipment is for other than FFDCA uses?

A. 38. Identify each chemical for non-FFDCA use and certify accordingly.

VI. FOODS, DRUGS, AND COSMETICS

Q. 39. What if subsequent to importation these materials are used by the importer for other purposes?

A. 39. This could constitute a violation of TSCA, and the importer could be subject to penalties.

Q. 40. What if the chemical is on the TSCA Inventory of Chemical Substances?

A. 40. If the substance is intended solely for FFDCA use, no TSCA certification is required and a TSCA Inventory listing is irrelevant.

Q. 41. What if bulk chemicals are imported for manufacture into drug products, such as tablets or capsules?

A. 41. TSCA certification is not required; however, appropriate FFDCA certification is required.

Q. 42. What if Form FDA 701 is not present with the entry documents though the substance is regulated under FFDCA?

A. 42. You could sign the negative TSCA certification to expedite Customs release and subsequently submit the FDA 701 form.

Q. 43. Are biochemical substances intended for laboratory testing covered by TSCA--for example, enzymes, coenzymes, etc. which may be used in FDS products but, nonetheless, have other uses not related to FDA?

A. 43. Yes, if the biochemical substances are for a use governed by TSCA, they require positive certification.

VI. FOODS, DRUGS, AND COSMETICS

- Q. 44. What if a cosmetic ingredient is imported without TSCA certification, since only cosmetic uses are contemplated, but the sale for cosmetic uses fails to materialize? What should the importer do to sell it for non-cosmetic use?
- A. 44. If only cosmetic uses were contemplated at the time of import and an FDA 701 form was used, the importer may later sell the substance for a non-cosmetic use (a use governed by TSCA) provided it complies with TSCA (i.e., is on the TSCA Inventory, or a PMN has been filed and cleared), and the substance is not further regulated under section 5, 6 or 7 of TSCA.

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VII. R & D USE AND SAMPLES

- Q. 45. Do all chemical substances imported solely for R & D use require TSCA certification?
- A. 45. Yes, if they are for a use governed by TSCA, they require a positive certification.
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- Q. 46. What if the chemicals are samples only?
- A. 46. If they are for a use governed by TSCA, a positive certification is required.
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- Q. 47. What if the substances are test marketing samples?
- A. 47. TSCA certification requirements apply. If they are for a use governed by TSCA, they must be on the Inventory, or the importer must obtain a test marketing exemption from EPA. For further details, call the TSCA Assistance Office at (202) 554-1404.
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VII. R & D USE AND SAMPLES

Q. 48. Must the chemical substance for R & D use be on the TSCA Inventory of Chemical Substances?

A. 48. No, if the R & D activities with the chemical substance comply with the definition of "small quantities solely for research and development" in Section 720.3(cc) of the premanufacture notification (PMN) rules and the requirements of section 720.36, the substance need not be on the TSCA Inventory, a PMN is not required, and a positive certification is correct in this situation.

Q. 49. What if the imported R & D substances are not covered by TSCA?

A. 49. Negative TSCA certification is required for such substances, except for certain exempt substances. For those exempt substances, U.S. Customs requires a separate certification under another statute. Exempt items requiring no certification include any food, food additive, drug, drug intermediate, cosmetic, cosmetic intermediate, or device under FFDCA, and any tobacco or tobacco product, when accompanied by the appropriate form.

Also, a pesticide R & D chemical, not covered by an experimental use permit under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), would need positive TSCA certification because it is not yet considered to be a pesticide for FIFRA purposes.

Q. 50. How large a quantity can be imported for R & D purposes?

A. 50. There is no specific size or weight limitation. However, quantities that can be imported for R & D purposes are defined as those "not greater than reasonably necessary for such purposes". If a company sends multiple samples to different potential customers, EPA may question whether the amount imported is legitimately "not greater than reasonably necessary" for R & D.

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Q. 51. What if the imported R & D substance is used to manufacture an article for a customer?

A. 51. EPA does not consider the use of a chemical substance in the manufacture of an article for a customer to be research and development unless the article is itself manufactured solely for R & D. Therefore, if the substance is not listed on the Inventory it would be a violation of TSCA to import the substance into the U.S. for such purposes, before a PMN has been submitted and the PMN review completed.

Q. 52. Does sale of an R & D substance remove it from R & D status?

A. 52. Not necessarily. Companies may purchase R & D substances from an importer without triggering PMN requirements as long as they use the chemical substance only for R & D.

Q. 53. What is the certification procedure for mailed or parcel post R & D chemicals.

A. 53. The first receiver of the chemical in the U.S. is considered the importer and is responsible for the TSCA certification to U.S. Customs. He should inform his overseas supplier to include the necessary information or supporting documentation with the shipment mailed to him. His certification can then be based on the documentation received from his supplier.

Q. 54. In the case of R & D chemicals coming into the country via parcel post: Could the TSCA certification be placed in an envelope and taped to the package (with proper postage, of course)? Is that acceptable to U.S. Customs?

A. 54. Yes, U.S. Customs will accept preprinted or stamped certifications bearing the signature of the importer and previously forwarded to the supplier to accompany the shipment. However, the importer should recognize that he is responsible for this certification.

VII. R & D USE AND SAMPLES

- Q. 55. What is the importer's responsibility for his own staff receiving and using mailed R & D substances?
- A. 55. Company officials are responsible for the actions of their staff in this case. You should inform your staff of these TSCA requirements and set up internal procedures for preparation and submission of TSCA certifications to U.S. Customs.
- _____
- Q. 56. If an unsolicited shipment of an R & D chemical is sent by a foreign supplier and the addressee does not want to sign the certification or accept the shipment, who is responsible for its return or disposal? Suppose the addressee wishes to accept part of the shipment?
- A. 56. The addressee is responsible for the costs of returning or disposing of the shipment. He may then request reimbursement from the foreign supplier. It would be to the advantage of all parties involved for the addressee to inform his foreign suppliers of the TSCA certification requirements and request that they not send unsolicited samples. If the addressee wishes to accept part of the shipment, he may separate that part, sign the certification, and then return or request disposal, at his cost, of the remainder.

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VIII. IN-TRANSIT THROUGH US/EXPORT SHIPMENTS

- Q. 57. Is it necessary to certify TSCA compliance for chemicals that are in-transit through the U.S.?
- A. 57. No, certification is not required for chemicals imported under entry for transportation and exportation (T & E entry), e.g., from Mexico to Canada.
- _____
- Q. 58. Do shipments moving via mail between Canada and Mexico require certification?
- A. 58. No.
- _____

VIII. IN-TRANSIT THROUGH US/EXPORT SHIPMENTS

Q. 59. What if the chemicals are travelling through the U.S. in bond for clearance at another port of entry?

A. 59. The importer need not certify at the first port of arrival but must certify at the subsequent port of entry.

Q. 60. What TSCA requirements apply to an imported chemical that is:

(1) used in the U.S. to manufacture a product that will then be exported in its entirety (for example, used as an intermediate)?

(2) processed in the U.S. and then exported in its entirety?

A. 60. A positive certification would be required in both situations.

Q. 61. A chemical is manufactured in the U.S., sent to Canada for further refining and then returned to the U.S. Is TSCA certification required for importation of the refined chemical substance from Canada?

A. 61. If the chemical substance comes under TSCA jurisdiction, a positive certification would be required for importation into the U.S.

Q. 62. What about pipeline shipments of crude oil or natural gas?

A. 62. Pipeline shipments of crude oil or finished products into the U.S. would require a positive certification. These shipments are candidates for "blanket" certification (see section II).

VIII. IN-TRANSIT THROUGH US/EXPORT SHIPMENTS

Q. 63. What about entry into Foreign Trade Zones for reexport?

A. 63. Import certification is not necessary for entry into Foreign Trade Zones. However, a certification is required for withdrawal if the chemical is intended for U.S. consumption. Withdrawals for exportation or transportation need not be certified.

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IX. SPECIAL CASES

Q. 64. We have been importing chemicals for the photographic industry for the past few years. How does the new rule impact on future imports of these chemicals?

A. 64. If the chemicals are under TSCA jurisdiction, a positive certification of compliance is required.

Q. 65. As an importer of hydraulic machinery, I understand that hydraulic fluids contained inside the machinery are not covered by these rules. However, sometimes my foreign supplier includes a can of additional fluid with the machinery shipment. What are my TSCA responsibilities for this can of fluid?

A. 65. Your responsibility is the same as for any other imported chemical substance governed by TSCA. A positive certification of compliance with TSCA is required.

Q. 66. Must an importer determine the possible contaminants and unknown chemicals in crude oil or gasoline before certification?

A. 66. No, this is not required as long as the petroleum crude oil or gasoline is on the Inventory, and the importer is not aware of any unusual contaminant and has no reason to suspect any. Only intentional additives must be identified, be on the TSCA Inventory, and be in compliance with any further rules or regulations under section 5, 6, or 7 of TSCA.

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Q. 67. I import an alkylation waste acid which is composed of 98% sulfuric acid with 2% trace contaminants. Must I determine what the trace contaminants are?

A. 67. No, as long as you are certain there are no PCBs in the trace contaminants, they are considered impurities, and you can sign the positive certification.

Q. 68. Powdered rubber tires are being imported. The main ingredients are isoprene and carbon black. The other ingredients are incidental contaminants with no commercial value. Do the contaminants need to be determined for positive certification?

A. 68. No, the answer to the preceding question also applies in this case.

Q. 69. Do wastes imported into the United States require TSCA certification?

A. 69. Yes, wastes imported into the United States are within TSCA jurisdiction, and each import requires a positive certification.

Q. 70. If wastes are imported solely for disposal or for recycling, what information do I need to make a TSCA import certification?

A. 70. In general, importers can make a positive certification for wastes imported to be burned as a fuel, disposed of, or for extraction of component chemical substances (see 40 CFR section 720.30(g) of the premanufacture notification regulations. If the wastes consist of "by-products" as defined in section 720.3(d) of the premanufacture notification regulations, i.e., chemical substances produced without a separate commercial intent during the manufacture, processing, or use of another chemical substance, they are not subject to premanufacture notification under section 5 of TSCA. It should be noted that "by-products" include by-products of use as well as manufacture and processing. Therefore, spent solvents,

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spent cleaning agents, and used motor oil are classified as by-products, in addition to manufacturing waste.

Q. 71. What if the wastes are accompanied by a manifest as required by the Resource Conservation and Recovery Act (RCRA)?

A. 71. A positive certification is still required.

Q. 72. What if the wastes are to be used as a feedstock for a manufacturing process?

A. 72. A positive certification is required, and the importer must check the TSCA Inventory to determine if the waste is a "new" chemical substance. However, if the use is solely for extraction of a commercial chemical substance, the waste is not subject to a PMN. The importer must also check rules or orders under sections 5, 6, and 7 of TSCA.

Q. 73. Are living plants and animals subject to certification?

A. 73. Living plants and animals, other than microorganisms, are not subject to certification. However, natural products such as lumber, peat, or rubber are subject to certification unless they are imported in the form of an article.

Q. 74. Do seeds sprayed with a pesticide require TSCA certification?

A. 74. No, as living plant matter, seeds are not subject to certification. The fact that they have been sprayed with a pesticide does not change their status.

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X. DETAINED SHIPMENTS

Q. 75. Assume there is a multiple shipment in which only 2 of 30 chemicals in the shipment lack a certification. Will the entire shipment be detained, or will Customs separate out only the noncomplying items for detention?

A. 75. Decisions of this kind will be made on a case-by-case basis, at the discretion of the Customs Officer, depending upon individual circumstances.

Q. 76. We believe that detention most frequently will occur because of a ministerial error by the broker or importer or an unforeseen problem in transit. For example, the certification might be left off the invoice or become separated from it. A simple procedure to resolve these minor problems before the shipment leaves the District Director's custody would be in the best interests of the importer, U.S. Customs and EPA. Can there be informal resolution of a problem shipment immediately upon notification by the District Director?

A. 76. To a degree, since there is a provision for a bond.

Q. 77. Concerning shipments which have arrived, but for which additional time is necessary to determine proper certification, please detail how and when a bond can be given for production of the certification.

A. 77. If a shipment is detained for lack of TSCA certification, its release may be secured by the importer or his authorized agent upon furnishing a bond on Customs Form 7551, 7553, or 7596 for the return of the shipment to Customs custody. The shipment must be held intact by the importer and not used or disposed of until brought into compliance.

X. DETAINED SHIPMENTS

Q. 78. Will the notification referred to in the first sentence of section 12.123(c) of the importers' rule be made in writing, and will it give the reasons for the Administrator's decision?

A. 78. EPA will provide notification in writing which will include the rationale to U.S. Customs and the importer.

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