

REGULATORY BRIEF

To: International Chemical Manufacturer

From: Don Ewert, Toxicologist (IH)
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Date: July 9, 2024

Re: Chemical Import Regulations – USEPA TSCA Section 5

Introduction to the Regulatory Brief

Reddwall Solutions has a long history of engagement with the industrial and manufacturing community. As a result, we bring a unique approach to rendering the professional services needed for a diverse and complex consortium. A perspective which leverages our vast expertise to resolve regulatory issues and/or problems utilizing superior performance rather than a sizable resource outlay. Having spent our careers working within the regulated community, RWS' TSCA professionals understand the needs of our clientele and offer the quality services necessary to assure success while minimizing costs.

One example of the competitive stance offered by Reddwall Solutions is our ability to leverage a subsidiary organization, "RW Specialty Imports" (RWSI) to assist international clientele with gaining access to US EPA's TSCA system and American import market. By serving as the US Importer of Record, RWSI fulfills our client's need for an importation agency while facilitating immediate commercial distribution. Thereafter, and once US-based operations are in order, TSCA's Consent Decree approval can be transferred to the client, utilizing EPA's Successor in Interest process. All the while, our clients benefit from Reddwall Solution's TSCA expertise while simultaneously leveraging the advantages of having a commercial import relationship with RW Specialty Imports.

Herein are a Regulatory Brief, detailing the regulatory language associated with RWSI's role in the EPA-TSCA filing process for Premanufacturing, Significant New Use and Bona Fide Intent to Import Notices as well as the important, Successor in Interest Consent Order transfer. While the TSCA approval processes are extremely complex, they are nevertheless, activities which our professionals know well and conduct routinely. With this in mind, we welcome further inquiry or interest into how we might become your professional consultants and importer of choice.

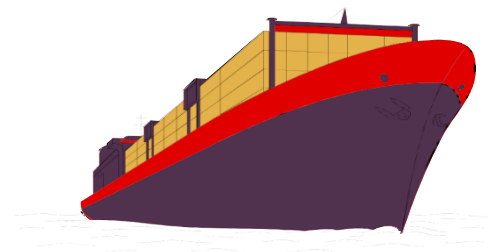
RW Specialty Imports; Business Profile and Import Conditions

Company – RW Specialty Imports, LLC
PA Registered LLC – wholly owned by Reddwall Solutions, LLC
Address TBD – Local Office/Warehouse
Import Commitment – Based on Client's Annual Expectation
Letter of Support – Optional TSCA Support Filing by Client
NOC – Filed upon receipt of TSCA Consent Order and initial product import
Distribution – Negotiable, with client-provided marketing and support
Contractual Agreement – Between RW Specialty Imports, LLC and Client



RW SPECIALTY IMPORTS, LLC

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If you import chemical substances, mixtures or articles, you are subject to TSCA and generally must meet the same requirements under TSCA as a chemical manufacturer in the United States.

It is important to ensure that you are in full compliance with all applicable TSCA regulations and other relevant statutes (e.g., Clean Air Act, Resource Conservation and Recovery Act) before you import TSCA-covered chemical substances, mixtures, or articles into the United States. Non-compliance with TSCA can result not only in detained shipments and/or denied entry but can lead to substantial civil and/or criminal penalties.

WHAT CHEMICAL SUBSTANCES, MIXTURES AND ARTICLES ARE COVERED BY TSCA?

EPA's authority under TSCA extends to all materials that are considered "chemical substances," "mixtures," or "articles" as defined under TSCA. The definitions of these terms are provided below.

TSCA Section 3 defines the term "chemical substance" as: ". . . any organic or inorganic substance of a particular molecular identity, including –

- 1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and
- 2) any element or uncombined radical."

It is important to note that the term "chemical substance" also includes microorganisms.

A "mixture" is defined under Section 3 of TSCA as: "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 chemical reaction; except that such term does not 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 mixture is a new chemical substance and if the combination could have been manufactured [(including imported)] for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined."

TSCA Section 13 Entry Into the Customs Territory of the United States (see 40 CFR Part 707.20 "General Import Requirements and Restrictions" and 19 CFR sections 12.118 through 127.128)

TSCA Section 13 requires that any chemical substance be refused entry into the customs territory of the United States if it fails to comply with any rule in effect under TSCA or is offered for entry in violation of section 5, 6, or 7 of TSCA.

EPA's Policy Statement, 40 CFR 707.20, requires that importers "certify" their imported chemical substances or mixtures are either: (1) in compliance with TSCA Sections 5, 6 and 7 at the time of import; or (2) not subject to TSCA.

In addition, Section 13 provides that the Treasury Department (U.S. Customs), in conjunction with EPA, implement these requirements. For that reason, Customs can refuse entry of any shipment that does not have a TSCA certification. An importer of record provides the certification by signing one of the following statements to be typed, preprinted on the invoice, or otherwise included in the entry documentation:

Positive Certification Statement: "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."

Negative Certification Statement: "I certify that all chemicals in this shipment are not subject to TSCA."

Other Certification Considerations

Certification is also required for substances that are imported and are received by mail or commercial carrier, including those intended for research and development. In addition, a “blanket” certification may be requested from the Customs District Director on an annual basis to cover several shipments of the same chemical over a one-year period.

WHAT ARE THE MAJOR SECTIONS OF TSCA FOR WHICH TSCA IMPORT CERTIFICATION IS REQUIRED, AND WHAT REQUIREMENTS APPLY?

Current TSCA import certification requirements apply specifically to compliance with sections 5, 6, and 7 of TSCA. The following briefly and generally describes certain major requirements under those sections.

TSCA Section 5 Premanufacture Notification (see 40 CFR Parts 700, 720, 723, 725 and 747)

If you are importing chemicals into the U.S., you must determine whether or not any chemical imported in bulk is a TSCA chemical substance and/or a “new chemical substance” prior to its importation for a nonexempt commercial purpose. Under Section 5 of TSCA, persons who intend to import a “new chemical substance” into the United States must seek EPA approval by submitting a premanufacture notice (PMN) to EPA at least 90 days prior to importation to enable EPA to determine whether the new chemical may present an unreasonable risk to human health or the environment. A new chemical substance is one that is not already in commerce in the United States, as determined by inclusion in the TSCA Inventory of Chemical Substances maintained by EPA. New chemical substances include certain genetically modified microorganisms (also known as intergeneric microorganisms). When the PMN is approved and the substance is imported, a “Notice of Commencement” (NOC) is required to be submitted to EPA within 30 days of first importation. Following receipt of this NOC, the subject chemical substance will be added to EPA’s TSCA Inventory of existing chemical substances for the purposes of future importation and/or domestic production.

TSCA Section 5 (e) Consent Orders

If you are an importer who has signed a consent order issued by EPA under section 5(e) of TSCA, you must also ascertain whether a chemical substance intended to be imported into the United States is subject to that order. If so, the chemical substance must be in compliance with the provisions of the consent order before it may be imported into the United States.

TSCA Section 5 Significant New Use Rules (SNURs) (see 40 CFR Part 721)

In addition, prior to importation of a chemical substance subject to TSCA into the United States, an importer of record must determine whether the substance is subject to a Significant New Use Rule issued under Section 5 of TSCA. Section 5 of TSCA authorizes EPA to designate use of a chemical substance as a “significant new use,” and require the submission of information to EPA prior to the chemical substance being manufactured (including imported) or processed for that use.

WHAT OTHER TSCA PROVISIONS APPLY TO ME AS AN IMPORTER?

Importers need to be aware that imports must also be in compliance with certain other sections of TSCA, although current regulations require certification at the time of import only for compliance with TSCA sections 5, 6, and 7.

VI.A. TSCA Section 4 Testing of Chemical Substances (see 40 CFR Parts 790, 791, 792, 799, and 766)

Under Section 4 of TSCA, EPA has the authority to require importers and processors of chemical substances and mixtures to conduct testing on the health and environmental effects of chemical substances and mixtures. A person who imports or intends to import a chemical substance or mixture subject to a test rule under Section 4 must comply with Section 4 requirements unless the importation qualifies for an exemption included in the regulations at 40 CFR Section 790.42, or under a specific test rule listed under Parts 766 or 799. Following promulgation of a test rule under Section 4 of TSCA, the responsibility to comply with the rule continues for a period of five years from the date the data from all required tests have been submitted or an amount of time equal to that which was required to develop the test data, whichever is longer. Importers therefore have a continuing responsibility to determine whether a chemical substance or mixture which they import or intend to import is subject to a test rule.

TSCA Section 8 Reporting and Retention of Information

Section 8 of TSCA authorizes EPA to require persons engaged in the import, processing, and distribution in commerce of TSCA-covered chemical substances and mixtures to keep certain records and report certain information to EPA. Specific TSCA Section 8 rules (and implementing policy documents in the case of TSCA Section 8(e)) that apply to importers are:

- TSCA Section 8(a) Inventory Update Rule – see 40 CFR Part 710
- TSCA Section 8(a) Preliminary Assessment Information Reporting (PAIR) Rule – see 40 CFR Part 712
- TSCA Section 8(a) Chemical Specific Recordkeeping and Reporting Rules – see 40 CFR Part 704 Subpart B
- TSCA Section 8(c) Allegations of Significant Adverse Reactions Recordkeeping/Reporting – see 40 CFR Part 717
- TSCA Section 8(d) Unpublished Health and Safety Data Reporting Rule – see 40 CFR Part 716
- TSCA Section 8(e) Substantial Risk Information Reporting Requirement (Statutory Provision) – see implementing Policy Statement (43 FR 11110, March 16, 1978) as well as the TSCA Section 8(e) Reporting Guide (June 1991--available in hard copy from TSCA Hotline).

Bona Fide Intent to Manufacture (Import Only)

1. A person who intends to import a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to import the chemical substance for commercial purposes.
2. To file a bona fide intent to import, the person who proposes importation must first submit their request to EPA through the e-PMN system and CDX in accordance with §720.40(a)(2)(ii). Bona fide intent to import filings must contain:
 - a. Except as provided, the specific chemical identity of the substance that the person intends to import, using the correct CA Index name for the substance and other chemical identifying information in accordance with §720.45(a) (1), (2), and (3).
 - b. A signed statement that the person intends to import the chemical substance for commercial purposes. Additionally, the filing must contain:
 - i. A brief description of the research and development activities conducted to date related to the substance, including the year in which the person first started to conduct research or development activity on the substance, and the general types of research and development activities conducted thus far (e.g., synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of the substance.
 - ii. If an importer is unable to provide the information requested in this section from the foreign manufacturer or supplier, the following information shall be submitted:
 1. A brief statement indicating how long the substance has been in commercial use outside of the United States.
 2. The name of a country in which it has been commercially used.
 3. Whether the importer believes that the substance has already been used commercially, in any country, for the same purpose or application that the importer is intending.
 - iii. A specific description of the major intended application or use of the substance.

- iv. An infrared spectrum of the substance, or alternative spectra or other data which identify the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, the person must submit a spectrum or instrumental readout for the substance.
 - v. The estimated date (month/year) in which the person intends to submit a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.
 - vi. The address of the facility under the control of the submitter at which import, and processing of the substance would most likely occur, if any.
 - 1. For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the substance is not expected to be processed or used at any facility under the importer's control, a statement to this effect must be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.
- c. If an importer cannot provide the chemical identity information required by this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier must supply the required information directly to EPA in accordance with § 720.45(a) (1), (2), and (3) and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the importer's notice, the notice will be considered incomplete.
- d. If a manufacturer cannot provide all of the required information in accordance with § 720.45(a) (1), (2), and (3) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as known by the manufacturer. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of the proprietary reactant. The letter of support must reference the manufacturer's notice. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the manufacturer's notice, the notice will be considered incomplete.
3. EPA will review the information submitted by the proposed importer under this paragraph to determine whether it has a bona fide intent to import the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii).
4. If the proposed importer has shown a bona fide intent to import the substance and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed importer whether the chemical substance is on the confidential Inventory.
5. If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a bona fide intent to import the substance and therefore was told that the chemical substance is on the Inventory.

6. A disclosure of a confidential chemical identity to a person with a bona fide intent to import the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.
7. EPA will answer an inquiry on whether a particular chemical substance is on the confidential Inventory within 30 days after receipt of a complete submission.
8. If the required chemical identity information has not been reported correctly or completely in the notice (except as provided) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice directly to the submitter. The submitter must then resubmit the whole, completed bona fide notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

TSCA Section 5 - Successor in Interest Transfer

1. This section sets forth the procedures by which the Company's rights and obligations under a TSCA Section 5 Consent Order are transferred as the Company transfers its interests in a PMN substance, including the right to import the PMN substance, to another person outside the Company (the "Successor in Interest").
 - a. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of import ("NOC") for the PMN or SNUN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN or SNUN to EPA and comply fully with Section 5(a)(1)(B) of TSCA and 40 CFR part 720 before commencing with import of the PMN or SNUN substance.
 - b. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of the existing Consent Order and shall not be required to submit a new PMN or SNUN to EPA.
2. The following definitions apply to the Successor Liability section of the Consent Order:
 - a. "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to import the PMN or SNUN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN or SNUN substance, such as a licensee who has acquired a limited license to the patent rights associated with the PMN or SNUN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).
 - b. "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN or SNUN substance, including the right to import the PMN or SNUN substance, from the Company to the Successor in Interest.

3. Notices applicable to Successor in Interest transfers.
 - a. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the “Notice of Transfer” document which is incorporated by reference as Attachment B to this Order.
 - b. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to EPA.
 - c. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN or SNUN substance is imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN or SNUN substance under the terms of this Order from the Company to the Successor in Interest.
4. Liabilities associated with Successor in Interest transfers.
 - a. The Company shall be liable for compliance with the requirements of the Consent Order until the effective date of the transfer described above.
 - b. The Successor in Interest shall be liable for compliance with the requirements of the Consent Order effective as of the date of transfer.
 - c. Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company imported, processed, used, distributed in commerce, or disposed of the PMN or SNUN substance pursuant to terms of the Consent Order.
5. If the Testing section of a Consent Order requires the Company to submit test data to EPA at a specified import volume (“test trigger”), the aggregate volume of the PMN or SNUN substance imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

Pre-Manufacturing Notice (Import Only)

This part (720.1) establishes procedures for the reporting of new chemical substances by importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices.

- 1) *Chemical substance* means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that “chemical substance” does not include:
 - a. Any mixture.
 - b. Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.
 - c. Tobacco or any tobacco product.
 - d. Any source material, special nuclear material, or byproduct material.
 - e. Any pistol, firearm, revolver, shells, or cartridges.
 - f. Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

- 2) *Importer* means any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. “Importer” includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:
 - a. The consignee.
 - b. The importer of record.
- 3) *Impurity* means a chemical substance which is unintentionally present with another chemical substance.
- 4) *Intermediate* means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.
- 5) *Inventory* means the list of chemical substances manufactured or processed in the United States that EPA Compiled and keeps current under section 8(b) of the Act.
- 6) *Manufacture* means to produce or manufacture in the United States or import into the customs territory of the United States.
- 7) *Manufacturer* means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.
- 8) *Mixture* means 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 “mixture” does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction 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, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.
- 9) *New chemical substance* means any chemical substance which is not included on the Inventory.
- 10) *Nonisolated intermediate* means any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.
- 11) *Person* means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal Government.
- 12) *Possession or control* means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner).

- 13) *Principal importer* means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.
- 14) *Process* means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.
- 15) *Processor* means any person who processes a chemical substance or mixture.
- 16) *Test data* means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.
- 17) *Support documents* means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data. The term “support documents” does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).

§ 720.22 Persons who must report.

- 1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

§ 720.40 General. Use of the notice form; electronic submissions.

- 1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.
- 2) All notices must be submitted on EPA Form 7710-25. Notices, and any support documents related to these notices, may only be submitted in a manner set forth in this paragraph.
 - a. TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710-25 using e-PMN software.
- 3) Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture of the new chemical substance for commercial purposes begins.
- 4) Where to submit a notice or support documents. For submitting notices or support documents via CDX, use the e-PMN software.
- 5) General notice requirements.
 - a. Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the person. In accordance with § 720.50, the notice must also include any test data in the person's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the person and which concern the health and environmental effects of the new chemical substance.

- b. If information is claimed as confidential pursuant to § 720.80, a person who submits a notice to EPA in the manner set forth in § 720.40(a)(2)(i), (ii), or (iii) must also provide EPA with a sanitized copy.
- 6) Agency or joint submissions.
- a. An importer may designate an agent to assist in submitting the notice. If so, only the importer, and not the agent, signs the certification form.
 - b. An importer may authorize another person, (e.g., a supplier or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. The importer should indicate in a cover letter accompanying the notice which information will be supplied by another person and must identify that other person as a joint submitter where indicated on their notice form. The other person supplying information (i.e., the joint submitter) may submit the information to EPA using either the notice form or a Letter of Support, except that if the joint submitter is not incorporated, licensed, or doing business in the United States, the joint submitter must submit the information to EPA in a Letter of Support only, not in a notice form. The joint submitter must indicate in the notice or Letter of Support the identity of the manufacturer. Any person who submits a notice form or Letter of Support for a joint submission must sign and certify the notice form or Letter of Support.

§ 720.45 Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

- 1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:
 - a. The currently correct Chemical Abstracts (CA) name for the substance, based on the Ninth Collective Index (9CI) of CA nomenclature rules and conventions, and consistent with listings for similar substances in the Inventory. For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on CA 9CI nomenclature rules and conventions). In addition, for a Class 2 substance, the notice must identify the immediate chemical precursors and reactants by specific chemical name and Chemical Abstracts Service Registry Number (CASRN), if the number is available. Tradenames or generic names of chemical precursors or reactants are not acceptable as substitutes for specific chemical names.
 - b. The currently correct CASRN for the substance if a CASRN already exists for the substance.
 - c. For a Class 1 substance and for any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable, the correct molecular formula.
 - d. For a Class 1 substance, a complete, correct chemical structure diagram; for a Class 2 substance or polymer, a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.
- 2) The person must use one of the following two methods to develop or obtain the specified chemical identity information reported under paragraphs (a) (1) and (2) of this section and must identify the method used in the notice:
 - a. Method 1. Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) of this section directly from the Chemical Abstracts Service (CAS), specifically from the CAS Registry Services Inventory Expert Service, prior to submitting a notice to EPA. A copy of the chemical identification report obtained from CAS must be submitted with the notice.
 - b. Method 2. Obtain the correct chemical identity information required by paragraphs (a) (1) and (2) from any source. The notice will be incomplete according to § 720.65(c)(1)(vi) if the person uses Method 2 and any chemical identity information is determined to be incorrect by EPA.

- 3) If an importer submitting the notice cannot provide all the information specified in paragraphs (a) (1) and (2) of this section because it is claimed as confidential by the foreign supplier of the substance, the importer must have the foreign supplier follow the procedures in paragraph (a)(3) of this section and provide the correct chemical identity information specified in paragraphs (a) (1) and (2) of this section directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The statutory review process will commence upon receipt of both the notice and the complete, correct information.
- 4) If a manufacturer cannot provide all the information specified in paragraphs (a)(1) and (2) of this section because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity of the reported substance and its proprietary reactant. In addition, the manufacturer must ensure that the supplier of the confidential reactant submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant, including the CAS number, if available, and the appropriate PMN or exemption number, if applicable. The letter of support must reference the manufacturer's name and PMN Fee Identification Number. The statutory review period will commence upon receipt of both the notice and the letter of support.
- a. The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.
 - b. Known synonyms or trade names of the new chemical substance.
 - c. A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.
 - d. The estimated maximum amount to be manufactured during the first year of production and the estimated maximum amount to be manufactured during any 12-month period during the first three years of production.
 - e. A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.
 - f. For sites controlled by the submitter:
 - i. The identity of sites where the new substance will be manufactured, processed, or used.
 - ii. A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.
 - iii. Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.
 - iv. Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.
 - g. For sites not controlled by the submitter, a description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.
 - i. Any safety data sheet already developed for the new chemical substance, including draft safety data sheets.