

**PART 710—INVENTORY REPORTING REGULATIONS**

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AUTHORITY: 15 U.S.C. 2607(a).

**§ 710.1 Scope and compliance.**

(a) This part establishes regulations governing reporting by certain persons who manufacture, import, or process chemical substances for commercial purposes under section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)). Section 8(a) authorizes the Administrator to require reporting of information necessary for administration of the Act and requires EPA to issue regulations for the purpose of compiling an inventory of chemical substances manufactured or processed for a commercial purpose, as required by section 8(b) of the Act. Following an initial reporting period, EPA published an initial inventory of chemical substances manufactured, processed or imported for commercial purposes. In accordance with section 8(b), EPA periodically amends the inventory to include new chemical substances which are manufactured or imported for a commercial purpose and reported under section 5(a)(1) of the Act. EPA also revises the categories of chemical substances and makes other amendments as appropriate.

(b) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under these reporting regulations. In addition, section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by

these regulations. Section 16 provides that any person who violates a provision of section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to section 17, the Government may seek judicial relief to compel submission of section 8(a) information and to otherwise restrain any violation of section 15.

NOTE: As a matter of traditional Agency policy, EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.

(c) Each person who reports under these regulations shall maintain records that document information reported under these regulations and, in accordance with the Act, permit access to, and the copying of, such records by EPA officials.

[42 FR 64572, Dec. 23, 1977, as amended at 45 FR 18375, Mar. 21, 1980; 60 FR 31921, June 19, 1995]

**§ 710.2 Definitions.**

In addition to the definitions in § 704.3 in this chapter, the following definitions also apply to this part:

(a) The following terms shall have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under such Act: *Cosmetic, device, drug, food, and food additive*. In addition, the term *food* includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 et seq.; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 et seq.; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 et seq.

(b) The term *pesticide* shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the regulations issued thereunder.

(c) The following terms shall have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 et seq., and the regulations issued thereunder: *byproduct material, source material, and special nuclear material*.

(d) *Act* means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

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(e) *Administrator* means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any other person who shall by operation of law be authorized to carry out such functions.

(f) An *article* is a manufactured item: (1) Which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which 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 §710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.

(g) *Byproduct* means a chemical substance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).

(h) *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:

- (1) Any mixture,
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide,
- (3) Tobacco or any tobacco product, but not including any derivative products,
- (4) Any source material, special nuclear material, or byproduct material,
- (5) Any pistol, firearm, revolver, shells, and cartridges, and
- (6) 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.

(i) *Commerce* means trade, traffic, transportation, or other commerce: (1) Between a place in a State and any place outside of such State, or (2)

which affects trade, traffic, transportation, or commerce described in paragraph (i)(1) of this section.

(j) *Distribute in commerce* and *distribution in commerce* when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture, mean to sell or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(k) *EPA* means the U.S. Environmental Protection Agency.

(l) *Importer* means any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the U.S. and includes:

(1) The person primarily liable for the payment of any duties on the merchandise, or

(2) An authorized agent acting on his behalf (as defined in 19 CFR 1.11).

(m) *Impurity* means a chemical substance which is unintentionally present with another chemical substance.

(n) *Intermediate* means any chemical substance:

- (1) Which is intentionally removed from the equipment in which it is manufactured, and (2) which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

NOTE: The *equipment in which it was manufactured* includes the reaction vessel in which the chemical substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

(o) *Manufacture* means to produce or manufacture in the United States or import into the customs territory of the United States.

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(p) *Manufacture or import "for commercial purposes"* means to manufacture or import:

(1) For distribution in commerce, including for test marketing purposes, or

(2) For use by the manufacturer, including for use as an intermediate.

(q) *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 that "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, after the effective date or premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and

(2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.

(r) *New chemical substance* means any chemical substance which is not included in the inventory compiled and published under subsection 8(b) of the Act.

(s) *Person* means any natural or juridical person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.

(t) *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.

(u) *Process for "commercial purposes"* means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.

(v) *Processor* means any person who processes a chemical substance or mixture.

(w) *Site* means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site shall be the business address of the importer.

(x) *Small manufacturer or importer* means a manufacturer or importer whose total annual sales are less than \$5,000,000, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a "small manufacturer or importer" with respect to any chemical substance which such person manufactured at one site or imported in quantities greater than 100,000 pounds during calendar year 1977. In the case of a company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

NOTE: The purpose of the exception to the definition is to ensure that manufacturing and importers report production volumes for all chemical substances which they manufactured at one site or imported in quantities equal to or greater than 100,000 pounds during calendar year 1977.

(y) *Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product* (hereinafter sometimes shortened to *small quantities for research and development*) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that (1) are no greater than reasonably necessary for such purposes and (2) after the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

NOTE: Any chemical substances manufactured, imported or processed in quantities less than 1,000 pounds annually shall be presumed to be manufactured, imported or processed for research and development purposes.

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No person may report for the inventory any chemical substance in such quantities unless that person can certify, that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.

(z) *State* means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(aa) *Technically qualified individual* means a person: (1) Who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision, (2) who is responsible for enforcing appropriated methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in paragraph (aa)(3) of this section may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (aa)(1) of this section.

(bb) *Test marketing* means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture or article in commerce.

(cc) *United States*, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

(dd) *Master Inventory File* means EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under sub-

part A of this part and substances reported under part 720 of this chapter for which a Notice of Commencement of Manufacture or Import has been received under §720.120 of this chapter.

(ee) *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 substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(ff) *Site-limited* means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited.

[42 FR 64572, Dec. 23, 1977, as amended at 60 FR 31921, June 19, 1995]

### §710.3 [Reserved]

### §710.4 Scope of the inventory.

(a) *Chemical substances subject to these regulations.* Only chemical substances which are manufactured, imported, or processed "for a commercial purpose," as defined in §710.2, are subject to these regulations.

(b) *Naturally occurring chemical substances automatically included.* Any chemical substance which is naturally occurring and:

(1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) Which is extracted from air by any means, shall automatically be included in the inventory under the category "Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

(c) *Substances excluded by definition or section 8(b) of TSCA.* The following substances are excluded from the inventory: