

to, and the copying of, such records by EPA officials.

[68 FR 887, Jan. 7, 2003]

§ 710.3 Definitions.

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

(a) The following terms will 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* will 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 will 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) The following definitions also apply to this part:

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

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/her authority to carry out his/her functions, or any other person who will by operation of law be authorized to carry out such functions.

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.

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

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.

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 (1) of this definition.

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.

EPA means the U.S. Environmental Protection Agency.

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/her behalf (as defined in 19 CFR 1.11).

Impurity means a chemical substance which is unintentionally present with another chemical substance.

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.

Manufacture means to manufacture, produce, or import for commercial purposes.

Manufacture or import "for commercial purposes" means to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, for example, the manufacture or import of any amount of a chemical substance or mixture:

(1) For commercial distribution, including for test marketing, or

(2) For use by the manufacturer, including use for product research and development, or as an intermediate.

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 chem-

ical 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.

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

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.

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.

Process "for commercial purposes" means to process:

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

(2) For use as an intermediate.

Processor means any person who processes a chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way will 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 will be the business address of the importer.

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 lbs. (454 kg) annually will be presumed to be manufactured, imported, or processed for research and development purposes. 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.

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.

Technically qualified individual means a person:

(1) Who because of his/her 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/her supervision,

(2) Who is responsible for enforcing appropriate 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 this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical sub-

stance, 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.

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

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§ 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 § 710.3(d), 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, will 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:

(1) Any substance which is not considered a “chemical substance” as provided in subsection 3(2)(B) of the Act and in the definition of “chemical substance” in § 710.3(d);

(2) Any mixture as defined in § 710.3(d);

NOTE: A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term “mixture” includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.