

Environmental Protection Agency

§ 716.5

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144. For the purpose of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.

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

Listed mixture means any mixture listed in § 716.120.

Manufacture means to manufacture for commercial purposes.

Manufacture for commercial purposes means: (1) To produce, with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things such "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

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

(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts and impurities. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

Manufacturer means a person who 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.

Person includes any individual, 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.

Process means to process for commercial purposes.

Process for commercial purposes means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

Propose to manufacture, import, or process means that a person has made a management decision to commit financial resources toward the manufacture, importation, or processing of a substance or mixture.

Substance means chemical substance as defined at section 3(2)(A) of TSCA, 15 U.S.C. 2602(2)(A).

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

§ 716.5 Persons who must report.

(a) Except as provided in paragraphs (b) and (c) of this section, only those persons described in this section are required to report under this part. Persons who must report include manufacturers (including importers) who fall within the North American Industry Classification System (NAICS) (in effect as of January 1, 1997) Subsector 325 (chemical manufacturing and allied products) or Industry Group 32411 (petroleum refineries), who:

(1) In the 10 years preceding the effective date on which a substance or mixture is added to § 716.120, either had proposed to manufacture (including import), or had manufactured (including imported) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in § 716.65.

(2) As of the effective date on which a substance or mixture is added to § 716.120, and who propose to manufacture (including import), or who are manufacturing (including importing) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in § 716.65.

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(3) After the effective date on which a substance or mixture is added to §716.120, and who propose to manufacture (including import) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in §716.65.

(b) A rule promulgated under the authority of 15 U.S.C. 2607(d) may require that any person who does not fall within NAICS (in effect as of January 1, 1997) Subsector 325 or Industry Group 32411, and who had proposed to manufacture (including import) or process, had manufactured (including imported) or processed, proposes to manufacture (including import) or process, or is manufacturing (including importing) or processing a substance or mixture listed in §716.120 must report under this part.

(c) Processors and persons who propose to process a substance or mixture otherwise subject to the reporting requirements imposed by this part are not subject to this part unless EPA specifically states otherwise in a particular notice or rule promulgated under the authority of 15 U.S.C. 2607(d).

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§716.10 Studies to be reported.

(a) In general, health and safety studies, as defined in §716.3, on any substance or listed mixture listed in §716.120, that are unpublished are reportable, i.e., must be submitted or listed. However, this requirement has limitations according to the nature of the material studied, so that:

(1) All studies of substances and listed mixtures are reportable. However, in the case of physical and chemical properties, only those studies listed in §716.50 must be submitted.

(2) Studies of mixtures known to contain substances or listed mixtures listed in §716.120 are reportable except for studies of physical and chemical properties and the studies exempted at §716.20(a)(6) (i) through (vi).

(3) Studies of substances or listed mixtures that a person who is reporting has manufactured, imported, or processed or proposed to manufacture, import, or process only as impurities are not generally reportable under §716.20(a)(9).

(4) Underlying data, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies do not have to be submitted initially. EPA may request underlying data later under §716.40.

(b) [Reserved]

§716.20 Studies not subject to the reporting requirements.

(a) Excluding paragraph (a)(3) of this section, the following types of studies are exempt from the copy and list submission requirements of §§716.30 and 716.35.

(1) Studies which have been published in the scientific literature.

(2) Studies previously submitted to the EPA Office of Pollution Prevention and Toxics. These studies are limited to section 8(e) submissions, studies submitted during section 4 proceedings, studies submitted with premanufacture notices or significant new use notices, and studies submitted “for your information” (FYI submissions) in support of EPA’s TSCA Existing Chemicals Program. Studies which have been initiated pursuant to a TSCA section 4(a) test rule, for which the person has submitted a letter of intent to conduct testing in accordance with the provisions of §790.25 of part 790 of this chapter, are exempt from the list submission requirements of §716.35.

(3) Except for those studies described in paragraph (a)(2) of this section, studies previously submitted to any Federal agency with no claims of confidentiality are exempt only from the copy submission requirements of §716.30, and must be listed in accordance with the provisions of §716.35.

(4) Studies conducted or initiated by or for another person who is subject to, and who will report the studies under §§716.30 and 716.35.

(5) Studies of chemical substances which are not on the TSCA Chemical Substances Inventory. This exemption applies only to those substances within categories listed under §716.120(c).

(6) The following types of studies when the subject of the study is a mixture known to contain a substance or listed mixture listed under §716.120.

(i) Acute oral toxicity studies.

(ii) Acute dermal toxicity studies.