

PART 716—HEALTH AND SAFETY DATA REPORTING

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

SOURCE: 51 FR 32726, Sept. 15, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 716.1 Scope and compliance.

(a) This subpart sets forth requirements for the submission of lists and copies of health and safety studies on chemical substances and mixtures selected for priority consideration for testing rules under section 4(a) of the Toxic Substances Control Act (TSCA) and on other chemical substances and mixtures for which EPA requires health and safety information in fulfilling the purposes of TSCA.

(b) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this subpart. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 716.3 Definitions.

The definitions in section 3 of TSCA apply to this subpart. In addition, the following definitions are provided for the purposes of this subpart:

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

Co-product means a chemical substance produced for a commercial purpose during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

Copy of study means the written presentation of the purpose and methodology of a study and its results.

EPA means the United States Environmental Protection Agency.

Health and safety study or *study* means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other studies of a chemical substance or mixture, and any test performed under TSCA.

(1) It is intended that the term *health and safety study* be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included. Chemical identity is part of, or underlying data to, a health and safety study.

(2) Examples are:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatotoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic

toxicity tests, critical life-stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; structure/activity relationships; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

Import means to import for commercial purposes.

Import for commercial purposes means to import with the purpose of obtaining an immediate or eventual commercial advantage for the importer, and includes the importation of any amount of a chemical substance or mixture. If a chemical substance or mixture containing impurities is imported for commercial purposes, then those impurities are also imported for commercial purposes.

Importer means any person who imports a chemical substance, including a chemical substance as a part of a mixture or article, into the customs territory of the United States and includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf (as defined in 19 CFR 1.11). Importer also includes, as appropriate:

- (1) The consignee.
- (2) The importer of record.
- (3) The actual owner, if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20.
- (4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accord-

ance 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.

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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.

(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).

[63 FR 15773, Apr. 1, 1998]

§ 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