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.*).

[51 FR 32726, Sept. 15, 1986, as amended at 78 FR 72826, Dec. 4, 2013]

§ 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 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.

(iii) Acute inhalation toxicity studies.

(iv) Primary eye irritation studies.

(v) Primary dermal irritation studies.

(vi) Dermal sensitization studies.

(vii) Physical and chemical properties.

If the substance or listed mixture is an impurity, no reporting is required (see paragraph (a)(9) of this section).

(7) Analyzed aggregations of monitoring data based on monitoring data acquired more than 5 years preceding the date the substance or listed mixture was added to the list under § 716.120.

(8) Analyzed aggregations of monitoring data on mixtures known to contain one or more substances or listed mixtures listed in § 716.120, when the monitoring data are not analyzed to determine the exposure or concentration levels of the substances or listed mixture listed under § 716.120.

(9) Studies on a substance or listed mixture listed under § 716.120 that the person who is reporting has manufactured, imported, or processed or proposed to manufacture, import, or process only as an impurity. When reporting of such studies is to be required, that reporting will be separately proposed in the FEDERAL REGISTER.

(10) Studies of chemical substances or listed mixtures previously submitted by trade associations in accordance with the provisions of § 716.30.

(b) The following types of studies on substances or listed mixtures listed under § 716.120 are exempt from the copy and list submission requirements of §§ 716.30 and 716.35.

(1) For the listed ureaformaldehyde resins (CAS Nos. 9011–05–6 and 68611–64–3), studies on agronomic plant growth or damage which demonstrate only that the resins stimulate plant growth or cause plant damage when applied as a fertilizer.