

§716.10

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 par-

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ticular 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health and safety studies, as defined in §716.3, on any substance or listed mixture listed in §716.120, that are unpublished are reportable, i.e., must be submitted or listed.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