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1**ATTACHMENT 2**

Health and Safety Data Reporting

40 CFR 716

TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

PART 716 - HEALTH AND SAFETY DATA REPORTING

Sec. 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.

Sec. 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; dermatoxicity; 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 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 Sec. 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.).

Sec. 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 Sec.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 Sec.716.65.

(2) As of the effective date on which a substance or mixture is added to Sec. 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 Sec.716.65.

(3) After the effective date on which a substance or mixture is added to Sec. 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 Sec. 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 Sec. 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]

Sec. 716.10 Studies to be reported.

(a) In general, health and safety studies, as defined in Sec. 716.3, on any substance or listed mixture listed in Sec. 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 Sec. 716.50 must be submitted.

(2) Studies of mixtures known to contain substances or listed mixtures listed in Sec. 716.120 are reportable except for studies of physical and chemical properties and the studies exempted at Sec. 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 Sec. 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 Sec. 716.40.

(b) [Reserved]

Sec. 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 Sections 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 Sec. 790.25 of part 790 of this chapter, are exempt from the list submission requirements of Sec. 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 Sec. 716.30, and must be listed in accordance with the provisions of Sec. 716.35.

(4) Studies conducted or initiated by or for another person who is subject to, and who will report the studies under Sections 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 Sec. 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 Sec. 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 Sec. 716.120.

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

(9) Studies on a substance or listed mixture listed under Sec. 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 Sec. 716.30.

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

(2) For the specified chemicals in Sec. 716.120(d) under the category "Siloxanes," acute oral, dermal, and inhalation toxicity studies and primary eye and dermal irritation studies.

(3) For the listed chemicals under Sec. 716.120(d) in the category "OSHA Chemicals in Need of Dermal Absorption Testing," studies on ecological effects.

(4) For the chemicals listed at Sec. 716.120 with a special exemption referencing this paragraph, studies on mixtures containing the listed substance at levels below 1 percent of the mixture, except when a purpose of the study includes the investigation of the effects of the listed substance at levels below 1 percent.

(5) Rulemaking proceedings that add substances and mixtures to Sec. 716.120 will specify the types of health and/or environmental effects studies that must be reported and will specify the chemical grade/purity requirements that must be met or exceeded in individual studies. Chemical grade/purity requirements will be specified on a per chemical basis or for a category of chemicals for which reporting is required.

[51 FR 32726, Sept. 15, 1986, as amended at 58 FR 47649, Sept. 10, 1993; 58 FR 68315, Dec. 27, 1993; 60 FR 34884, July 5, 1995; 63 FR 15773, Apr. 1, 1998]

Sec. 716.25 Adequate file search.

The scope of a person's responsibility to search records is limited to records in the location(s) where the required information is typically kept, and to records kept by the person or the person's individual employee(s) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals. Persons are not required to search for reportable information dated before January 1, 1977, to comply with this subpart unless specifically required to do so in a rule.

[63 FR 15773, Apr. 1, 1998]

Sec. 716.30 Submission of copies of studies.

(a)(1) Except as provided in Sections 716.5, 716.20, and 716.50, persons must send to EPA copies of any health and safety studies in their possession for the substances or mixtures listed in Sec. 716.120. Persons are responsible for submitting copies on only the substances or listed mixtures which they: Have manufactured, imported, or processed or proposed to manufacture, import, or process (including as known byproducts) within the 10 years preceding the effective date for reporting on the substances or listed mixtures; manufacture, import, or process on the effective date for reporting on the substances or listed mixtures; and propose to manufacture, import, or process following the effective date for reporting on the substances or listed mixtures. Persons who list studies as ongoing or initiated under Sec. 716.35(a) (1) and (2) must submit them when they are completed.

(2) [Reserved]

(b) Submissions under paragraph (a) of this section must be identified either on the face of the study or otherwise by the applicable chemical name and CAS number (if any) listed in Sec.

716.120(a) (1) and (2), and must be accompanied by a cover letter containing the name, job title, address and telephone number of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made. In the cover letter, submitters must identify any impurity or additive known to have been present in the substance or listed mixtures as studied unless its presence is specifically noted in the study itself. The cover letter accompanying a study submitted by a trade association must also state that the submission is to satisfy reporting requirements under this part.

(c) Copies of health and safety studies and the accompanying cover letters must be submitted, preferably by certified mail, to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting).

[51 FR 32726, Sept. 15, 1986, as amended at 52 FR 20084, May 29, 1987; 52 FR 44828, Nov. 20, 1987; 53 FR 12523, Apr. 15, 1988; 60 FR 34463, July 3, 1995; 63 FR 15773, Apr. 1, 1998]

Sec. 716.35 Submission of lists of studies.

(a) Except as provided in Sections 716.5, 716.20, and 716.50, persons subject to this rule must send lists of studies to EPA for each of the listed substances or listed mixtures (including as a known byproduct) in Sec. 716.120 which they are manufacturing, importing, or processing, or which they propose to manufacture (including import) or process.

(1) Ongoing studies. As of the date a person becomes subject to this part, a list of ongoing health and safety studies being conducted by or initiated for them, noting for each entry: The beginning date of the study, the purpose of the study, the types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study.

(2) Initiated studies. After the date a person becomes subject to this part, a list of studies initiated by or for them, noting for each entry: The beginning date of the study, the purpose of the study, the types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study.

(3) Studies which are known but without possession of copies. As of the date a person becomes subject to this part, a list of unpublished health and safety studies known to them of which they do not have copies. The name and address of any person known to them to possess a copy of the unpublished study must accompany each entry on the list. For purposes of this section only, an unpublished study will be considered to be "known to" a person, if the study can be discovered by a file search in accordance with Sec. 716.25.

(4) Studies previously sent to Federal agencies without confidentiality claims. A list of unpublished studies which have been sent to a Federal Agency with no claims of confidentiality. The submission must for each study: Identify the study by title, state the name and address to whom the study was sent, and the month and year in which the study was submitted. Any study identified will be treated as if it were submitted under section 8(d) and will be available for

public disclosure under section 14(b) of TSCA. Persons subject to this requirement may submit either a list of unpublished health and safety studies previously submitted to any Federal agency without claims of confidentiality in accordance with Sec. 716.35(a)(4), or copies of each such study in accordance with Sec. 716.30.
(b) Submission under paragraph (a) of this section must be identified either on the face of the study or otherwise by the applicable chemical name and CAS number (if any) listed in Sec. 716.120(a) (1) and (2), and must be accompanied by a cover letter containing the name, job title, address and telephone numbers of the submitting official, and the name and address of the manufacturing or processing establishment on whose behalf the submission is made.

(c) Lists of health and safety studies should be submitted, preferably by certified mail, to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: 8(d) Health and Safety Reporting Rule (Notification Reporting).

[51 FR 32726, Sept. 15, 1986, as amended at 52 FR 20084, May 29, 1987; 52 FR 44828, Nov. 20, 1987; 53 FR 12523, Apr. 15, 1988; 53 FR 46746, Nov. 18, 1988; 60 FR 34463, July 3, 1995; 63 FR 15774, Apr. 1, 1998]

Sec. 716.40 EPA requests for submission of further information.

EPA may, by letter, request a person to submit or make available for review the following information after the initial reporting under Sections 716.30 and 716.35. If the requested submissions are not made, EPA may subpoena them under section 11 of TSCA, 15 U.S.C. 2610.

(a) Submission of underlying data of the kind described in Sec. 716.10(a)(4) by persons who submit copies of studies under Sec. 716.30 or list studies under Sec. 716.35(a)(1) or Sec. 716.35(a)(2).

(b) Submission of preliminary reports of ongoing studies by persons who list the studies under Sec. 716.35(a)(1) or Sec. 716.35(a)(2).

(c) Submission of copies of studies by persons listed under Sec. 716.35(a)(3) as possessing them.

Sec. 716.45 How to report on substances and mixtures.

Section 716.120 lists substances and mixtures, in order by Chemical Abstract Service Registry Number and by alphabetical order. Studies of listed substances and listed mixtures shall be reported as follows:

(a) When a substance is individually listed under Sec. 716.120(a), studies of the substance and studies of mixtures known to contain the substance must be reported as studies of that substance.

(b) When two or more substances are listed as a mixture under Sec. 716.120(b), studies of the listed mixture and studies of any mixture known to contain the listed mixture must be reported as studies of the listed mixture.

(c) Studies of the following preparations of a substance must be reported as studies of the substance itself, not as studies of mixtures known to contain the substance.
(1) The substance in aqueous solution.

(2) The substance containing a small amount of an additive, such as a stabilizer, emulsifier, or other chemical added for purposes of maintaining the integrity or physical form of the substance.

(3) The substance of the grade/purity specified in each rule promulgated under 15 U.S.C. 2607(d).

[51 FR 32726, Sept. 15, 1986, as amended at 63 FR 15774, Apr. 1, 1998]

Sec. 716.50 Reporting physical and chemical properties.

Studies of physical and chemical properties must be reported under this subpart if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the following properties:

(a) Water solubility.

(b) Adsorption/desorption on particulate surfaces, e.g., soil.

(c) Vapor pressure.

(d) Octanol/water partition coefficient.

(e) Density/relative density (specific gravity).

(f) Particle size distribution for insoluble solids.

(g) Dissociation constant.

(h) Degradation by photochemical mechanisms -- aquatic and atmospheric.

(i) Degradation by chemical mechanisms -- hydrolytic, reductive, and oxidative.

(j) Degradation by biological mechanisms -- aerobic and anaerobic.

Sec. 716.55 Confidentiality claims.

(a)(1) Section 14(b) of TSCA provides that EPA may not withhold from disclosure, on the grounds that they are confidential business information, health and safety studies of any substance or mixture that has been offered for commercial distribution (including for test marketing purposes and for use in research and development), any substance or mixture for which testing is required under TSCA section 4, or any substance for which notice is required

under TSCA section 5, except to the extent that disclosure of data from such studies would reveal --
(i) Processes used in the manufacturing, importing, or processing of the substance or mixture, or

(ii) The portion of a mixture comprised by any of the substances in the mixture.

(2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because disclosure would reveal a confidential process or quantitative mixture composition should briefly state the basis of the claim, e.g., by saying "reveals confidential mixture proportion data," and clearly identify the material subject to the claim.

(3) Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company. This information will not be subject to the disclosure requirements of section 14(b) of TSCA.

(4) Information other than company name or address, financial statistics, and product codes used by a company, which is contained in a study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), will be considered confidential by EPA as provided in Title 5, United States Code, section 552(b)(6).

(b) To assert a claim of confidentiality for data contained in a submitted document, the respondent must submit two copies of the document:

(1) One copy must be complete. In that copy, the respondent must indicate what data, if any, are claimed as confidential by bracketing or underlining the specific information. Each page containing data claimed as confidential must also contain a brief statement for the basis of the claim as well as a label such as "confidential," "proprietary," or "trade secret."

(2) The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted. The second copy will be immediately subject to public disclosure.

(3) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of his or her receipt of this notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

(c) If no claim of confidentiality accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

Sec. 716.60 Reporting schedule.

(a) General requirements. Except as provided in Sec. 716.5 and paragraphs (b) and (c) of this section, submissions under Sections 716.30 and 716.35 must be postmarked on or before 60 days

after the effective date of the listing of a substance or mixture in Sec. 716.120 or within 60 days of proposing to manufacture (including import) or process a listed substance or listed mixture (including as a known byproduct) if first done after the effective date of the substance or mixture being listed in Sec. 716.120.

(b)(1) Submission of lists of initiated studies. Persons subject to the listing requirements of Sec. 716.35(a)(2) must inform EPA of the initiated study within 30 days of its initiation.

(2) Submission of copies of completed studies. Persons must submit copies of studies listed as ongoing or initiated under Sec. 716.35(a) (1) and (2) within 30 days of completing the study.

(c) Requests for extensions of time. Respondents who cannot meet a deadline under this section may apply for a reasonable extension of time. Requests for extensions must be in writing and addressed to the Director, Office of Pollution Prevention and Toxics (7401), U.S. Environmental Protection Agency, Room E-539, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Section 8(d) extension. Extension requests must be postmarked on or before 40 days after the effective date of the listing of a substance or mixture in Sec. 716.120. The Director of EPA's Office of Pollution Prevention and Toxics will grant or deny extension requests.

[51 FR 32726, Sept. 15, 1986, as amended at 60 FR 34464, July 3, 1995; 63 FR 15774, Apr. 1, 1998]

Sec. 716.65 Reporting period.

Unless otherwise required in a rule promulgated under 15 U.S.C. 2607(d) relating to a listed chemical substance or listed mixture [hereinafter "rule"], the reporting period for a listed chemical substance or listed mixture will terminate 60 days after the effective date on which the listed chemical substance or listed mixture is added to 40 CFR 716.120. EPA may require reporting for a listed chemical substance or listed mixture beyond the 60 day period in a rule promulgated under 15 U.S.C. 2607(d), however EPA will not extend any reporting period later than 2 years after the effective date on which a listed chemical substance or listed mixture is added to 40 CFR 716.120. After the applicable reporting period terminates, any person subject to the rule under 40 CFR 716.5 (a)(2) or (a)(3) and who has submitted to EPA lists of ongoing or initiated studies under 40 CFR 716.35 (a)(1) or (a)(2) must submit a copy of any such study within 30 days after its completion, regardless of the study's completion date.

[63 FR 15774, Apr. 1, 1998]

Sec. 716.105 Additions of substances and mixtures to which this subpart applies.

The requirements of this subpart will be extended periodically to cover additional substances and mixtures. Two procedures will be used to add substances and mixtures.

(a) Except as provided in paragraph (b) of this section, substances and mixtures will be added to Sec. 716.120 after publication in the Federal Register of a notice of proposed amendment to this subpart. There will be at least a 30-day public comment period on the notice. After consideration

of the comments, EPA will amend Sec. 716.120 by final rule to add the substances and listed mixtures.

(b) Except as provided in paragraph (c) of this section, chemical substances, mixtures, and categories of chemical substances that have been added to the TSCA section 4(e) Priority List by the Interagency Testing Committee, established under section 4 of TSCA, will be added to Sec. 716.120 but only to the extent that the total number of designated and recommended substances, mixtures and categories of chemical substances has not exceeded 50 in any 1 year. The addition of such chemical substances, mixtures, and categories of chemical substances to Sec. 716.120 will be effective 30 days after publication of a notice to that effect in the Federal Register.

(c) Prior to the effective date of an amendment under paragraph (b) of this section, the Assistant Administrator for Prevention, Pesticides and Toxic Substances may for good cause withdraw a chemical substance, mixture, or category of chemical substances from Sec. 716.120. Any information submitted showing why a chemical substance, mixture, or category of chemical substances should be withdrawn from the amendment must be received by EPA within 14 days after the date of publication of the notice under paragraph (b) of this section. If a chemical substance, mixture, or category of chemical substances is withdrawn, a Federal Register notice announcing this decision will be published no later than the effective date of the amendment under paragraph (b) of this section. Persons who wish to submit information that shows why a chemical should be withdrawn must address their comments, in writing to the Document Control Office (7407), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room G-099, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: 8(d) Auto-ITC.

[51 FR 32726, Sept. 15, 1986, as amended at 60 FR 34464, July 3, 1995]