Environmental Protection Agency

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture, import, or process a chemical substance which is described by a generic chemical name in subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines

(b) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use without submitting a notice under this part, the manufacturer, importer, or processor must immediately cease distributing the substance to that recipient and notify EPA enforcement authorities at the address identified in paragraph (d)(1)(iii) of this section. The manufacturer, importer, or processor may not resume distribution to that recipient until any one of the following has occurred:

(i) The manufacturer, importer, or processor has submitted a significant new use notice under this part and the notice review period has ended.

(ii) The recipient has submitted a significant new use notice under this part and the notice review period has ended.

(iii) The manufacturer, importer, or processor has received notice from EPA enforcement authorities that it may resume distribution to that recipient.

(e) Any significant new use notice relating to import of a substance must be submitted by the principal importer.

§ 721.20 Exports and imports.

Persons who intend to export a chemical substance identified in subpart E of this part, or in any proposed rule which would amend subpart E of this part, are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who import a substance identified in a specific section in subpart E of this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR part 707.

§ 721.25 Notice requirements and procedures.

(a) Each person who is required to submit a significant new use notice under §710.7(e)(2)(v) of this chapter or the information requested under §20(b)(3)(ii) of this chapter.

(b) To establish a bona fide intent to manufacture, import, or process a chemical substance, the person who intends to manufacture, import, or process the chemical substance must submit the following information in writing to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, ATTN: SNUR Bonafide submissions.

(1) The specific chemical identity of the chemical substance that the person intends to manufacture, import, or process.

(2) A signed statement that the person intends to manufacture, import, or process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture, import, or process the chemical substance.

(4) An elemental analysis.

(5) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or, if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(c) If an importer or processor cannot provide all the information required in paragraph (b) of this section because it is claimed as confidential business information by the importer’s or processor’s manufacturer or supplier, the manufacturer or supplier may supply the information directly to EPA.

(d) EPA will review the information submitted by the manufacturer, importer, or processor under paragraph (b) of this section to determine whether than person has shown a bona fide intent to manufacture, import, or process the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under §710.7(e)(2)(v) of this chapter or the information requested under §20(b)(3)(ii) of this chapter.

(e) If the manufacturer, importer, or processor has shown a bona fide intent to manufacture, import, or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer, importer, or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

(f) A disclosure to a person with a bona fide intent to manufacture, import, or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

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