

(2) That the person is processing the chemical substance without knowledge that the substance is identified in subpart E of this part.

(d)(1) If at any time after commencing distribution in commerce of a chemical substance identified in a specific section in subpart E of this part a person described in paragraph (a)(2) of this section has knowledge that a recipient of the substance is engaging in a significant new use of that substance designated in that section without submitting a notice under this part, the person is required to cease supplying the chemical substance to that recipient and to submit a significant new use notice for that chemical substance and significant new use, unless the person is able to document each of the following:

(i) That the person has notified the recipient and EPA enforcement authorities (at the address in paragraph (d)(1)(iii) of this section), in writing within 15 working days of the time the person develops knowledge that the recipient is engaging in a significant new use, that the recipient is engaging in a significant new use without submitting a significant new use notice.

(ii) That, within 15 working days of notifying the recipient as described in paragraph (d)(1)(i) of this section, the person received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of the applicable section in subpart E of this part and will not engage in the significant new use.

(iii) That the person has promptly provided EPA enforcement authorities with a copy of the recipient's statement of assurance described in paragraph (d)(1)(ii) of this section. The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC, 20044.

(2) If EPA notifies the manufacturer, importer, or processor that the recipient is engaging in a significant new use after providing the statement of assurance described in paragraph (d)(1)(ii) of this section and without submitting a notice under this part, the manufacturer, importer, or processor shall im-

mediately cease distribution to that recipient until the manufacturer, importer, or processor or the recipient has submitted a significant new use notice under this part and the notice review period has ended.

(3) If, after receiving a statement of assurance from a recipient under paragraph (d)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge 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.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995]

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

(a) A person who intends to manufacture (including 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 that the person has a *bona fide* intent to manufacture (including import) or process the chemical substance for commercial purposes.

(b) To establish a *bona fide* intent to manufacture (including import) or

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process a chemical substance, the person who proposes to manufacture (including import) or process the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such *bona fide* intents to manufacture (including import) or process must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A *bona fide* intent to manufacture (including import) or process must contain:

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

(2) A signed statement that the person intends to manufacture (including 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 (including 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 (including importer) or processor under paragraph (b) of this section to determine whether that person has shown a *bona fide* intent to manufacture (including import) or process the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer (including importer) or processor has shown a *bona fide* intent to manufacture (including 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 (including 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 (including 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.

[53 FR 28359, July 27, 1988, as amended at 60 FR 34464, July 3, 1995; 71 FR 33641, June 12, 2006; 80 FR 42746, July 20, 2015]

§ 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.

[53 FR 28360, July 27, 1988]

§ 721.25 Notice requirements and procedures.

(a) Each person who is required to submit a significant new use notice under this part must submit the notice