

## Environmental Protection Agency

## § 721.25

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

at least 90 calendar days before commencing manufacture, import, or processing of a chemical substance identified in subpart E of this part for a significant new use. The submitter must comply with any applicable requirement of section 5(b) of the Act, and the notice must include the information and test data specified in section 5(d)(1) of the Act. The notice must be submitted on EPA Form 7710–25, and must comply with the requirements of part 720 of this chapter, except to the extent that they are inconsistent with this part 721.

(b) If two or more persons are required to submit a significant new use notice for the same chemical substance and significant new use identified in subpart E of this part, they may submit a joint notice to EPA. Persons submitting a joint notice must individually complete the certification section of part I of the required notification form. Persons who are required to submit individually, but elect to submit jointly, remain individually liable for the failure to submit required information which is known to or reasonably ascertainable by them and test data in their possession or control.

(c) EPA will process the notice in accordance with the procedures of part 720 of this chapter, except to the extent they are inconsistent with this part.

(d) Any person submitting a significant new use notice in response to the requirements of this part 721 shall not manufacture, import, or process a chemical substance identified in subpart E of this part for a significant new use until the notice review period, including all extensions and suspensions, has expired.

[53 FR 28360, July 27, 1988, as amended at 60 FR 16311, Mar. 29, 1995; 75 FR 787, Jan. 6, 2010]

**§ 721.30 EPA approval of alternative control measures.**

(a) In certain sections of subpart E of this part, significant new uses for the identified substances are described as the failure to establish and implement programs providing for the use of either: specific measures to control worker exposure to or release of substances which are identified in such sections, or alternative measures to control worker exposure or environ-

mental release which EPA has determined provide substantially the same degree of protection as the specified control measures. Persons who manufacture, import, or process a chemical substance identified in such sections and who intend to employ alternative measures to control worker exposure or environmental release must submit a request to EPA for a determination of equivalency before commencing manufacture, import, or processing involving the alternative control measures.

(b) Persons submitting a request for a determination of equivalency to EPA under this part must submit the request to EPA via CDX using e-PMN software in the manner set forth in 40 CFR 720.40(a)(2)(i). See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software. Support documents related to these requests must be submitted in the manner set forth in 40 CFR 720.40(c). A request for a determination of equivalency must contain:

- (1) The name of the submitter.
- (2) The specific chemical identity of the substance.
- (3) The citation for the specific section in subpart E of this part which pertains to the substance for which the request is being submitted.
- (4) A detailed description of the activities involved.
- (5) The specifications of the alternative worker exposure control measures or environmental release control measures.
- (6) An analysis justifying why such alternative control measures provide substantially the same degree of protection as the specific control measures identified in the specific section in subpart E of this part which pertains to the substance for which the request is being submitted.
- (7) The data and information described in § 720.50 (a) and (b) of this chapter unless such data and information have already been submitted to the Office of Pollution Prevention and Toxics, EPA.

(c) Requests for determinations of equivalency will be reviewed by EPA within 45 days. Determinations under this paragraph will be made by the Director, Office of Pollution Prevention