

Environmental Protection Agency

§ 721.45

(d) Failure or refusal to permit entry or inspection, as required by section 11 of the Act, is a violation of section 15(4) of the Act.

(e) Violators of the Act or of this part may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. The submission of false or misleading information in connection with the requirement of any provision of this part may subject persons to penalties calculated as if they never filed a notice.

(f) Under the authority of sections 7 and 17 of the Act, EPA may:

(1) Seek to enjoin the manufacture, import, or processing of a chemical substance in violation of this part.

(2) Act to seize any chemical substance which is being manufactured, imported, or processed in violation of this part.

(3) Take any other appropriate action.

[53 FR 28361, July 27, 1988]

§ 721.40 Recordkeeping.

Any person subject to the requirements of this part must retain documentation of information contained in that person's significant new use notice. This documentation must be maintained for a period of 5 years from the date of the submission of the significant new use notice.

[53 FR 28361, July 27, 1988]

§ 721.45 Exemptions.

The persons identified in § 721.5 are not subject to the notification requirements of § 721.25 for a chemical substance identified in subpart E of this part, unless otherwise specified in a specific section in subpart E, if:

(a) The person has applied for and has been granted an exemption for test marketing the substance for a significant new use identified in subpart E of this part in accordance with section 5(h)(1) of the Act and § 720.38 of this chapter.

(b) The person manufactures, imports, or processes the substance for a significant new use identified in subpart E of this part in small quantities solely for research and development in accordance with § 721.47.

(c) The person has applied for and been granted an exemption under section 5(h)(5) of the Act.

(d) The person manufactures, imports, or processes the substance only as an impurity.

(e) The person manufactures, imports, or processes the substance only as a byproduct which is used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.

(f) The person imports or processes the substance as part of an article.

(g) The person manufactures or processes the substance solely for export and, when distributing the substance in commerce, labels the substance in accordance with section 12(a)(1)(B) of the Act.

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§ 721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, § 721.5 applies and § 721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

(1) EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.

(2) EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E

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of this part which identifies the substance.

(i) The person is operating under the terms of a consent order issued under section 5(e) of the Act applicable to that person. If a provision of such section 5(e) order is inconsistent with a specific significant new use identified in subpart E of this part, abiding by the provision of the section 5(e) order exempts the person from submitting a significant new use notice for that specific significant new use.

[53 FR 28361, July 27, 1988]

§721.47 Conditions for research and development exemption.

(a) A person who manufactures, imports, or processes a chemical substance identifies in subpart E of this part for a significant new use identified in subpart E of this part is not subject to the notification requirements of §721.25 if the following conditions are met:

(1) The person manufactures, imports, or processes the substance for the significant new use in small quantities solely for research and development.

(2) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer, importer, or processor must review and evaluate the following information to determine whether there is reason to believe there is any risk to health which may be associated with the chemicals substance:

(i) Information in its possession or control concerning any significant ad-

verse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer, importer, or processor by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under section 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer, importer, or processor has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph (b)(2), a laboratory is defined as a contained research facility where relatively small quantities of chemical substances are used on a pro-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual).

(c)(1) The manufacturer, importer, or processor must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer, importer, or processor has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer, importer, or processor distributes a chemical substance manufactured, imported, or processed under this section to persons