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 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 adverse 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 not in its employ, the manufacturer, importer, or processor must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer, importer, or processor.

(d) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, State, and local regulations, to the extent the disposal activity is not identified as a significant new use for the substance in subpart E of this part, or

(2) Used for a commercial purpose, to the extent the use is not identified as a significant new use of the substance in subpart E of this part.

(e)(1) Persons who manufacture, import, or process a chemical substance under this section must retain the following records:

(i) Copies of or citations to information reviewed and evaluated under paragraph (b)(1) of this section to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under paragraph (c)(1) of this section including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under paragraph (b)(2) of this section.

(iv) The names and addresses of any persons other than the manufacturer, importer, or processor to whom the substance is distributed, the identity of the substance, the amount distributed, and copies of the notifications required under paragraph (c)(2) of this section.

(2) [Reserved]

[53 FR 28361, July 27, 1988, as amended at 58 FR 34204, June 23, 1993]

Subpart B—Certain Significant New Uses

SOURCE: 54 FR 31308, July 27, 1989, unless otherwise noted.

§ 721.50 Applicability.

This subpart B identifies certain significant new uses of chemical substances identified in subpart E of this part. The provisions of this subpart B