

Environmental Protection Agency

§ 725.234

(f) A person who manufactures, imports, or processes a microorganism solely for research and development is not required to comply with the requirements of this section if:

(1) The person is manufacturing a microbial pesticide identified in § 172.45(c), or

(2) The person is manufacturing a microbial pesticide for which an Experimental Use Permit is required, pursuant to § 172.3; or

(3) The person is manufacturing a microbial pesticide for which a notification or an Experimental Use Permit is not required to be submitted.

§ 725.232 Activities subject to the jurisdiction of other Federal programs or agencies.

This part does not apply to any research and development activity that meets all of the following conditions.

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) There is no intentional testing of a microorganism outside of a structure, as structure is defined in § 725.3.

(c)(1) The person receives research funds from another Federal agency, and the funds are awarded on the condition that the research will be conducted in accordance with the relevant portions of the NIH Guidelines, or

(2) A Federal agency or program otherwise imposes the legally binding requirement that the research is to be conducted in accordance with relevant portions of the NIH Guidelines.

§ 725.234 Activities conducted inside a structure.

A person who manufactures, imports, or processes a microorganism is not subject to the reporting requirements under subpart D of this part if all of the following conditions are met:

(a) The microorganism is manufactured, imported, or processed solely for research and development activities.

(b) The microorganism is used by, or directly under the supervision of, a technically qualified individual, as defined in § 725.3. The technically qualified individual must maintain documentation of the procedures selected to comply with paragraph (d) of this sec-

tion and must ensure that the procedures are used.

(c) There is no intentional testing of a microorganism outside of a structure, as structure is defined in § 725.3.

(d) Containment and/or inactivation controls. (1) Selection and use of containment and/or inactivation controls inside a structure for a particular microorganism shall take into account the following:

(i) Factors relevant to the organism's ability to survive in the environment.

(ii) Potential routes of release in air, solids and liquids; in or on waste materials and equipment; in or on people, including maintenance and custodial personnel; and in or on other organisms, such as insects and rodents.

(iii) Procedures for transfer of materials between facilities.

(2) The technically qualified individual's selection of containment and/or inactivation controls shall be approved and certified by an authorized official (other than the TQI) of the institution that is conducting the test prior to the commencement of the test.

(3) Records shall be developed and maintained describing the selection and use of containment and/or inactivation controls, as specified in § 725.235(c). These records, which must be maintained at the location where the research and development activity is being conducted, shall be submitted to EPA upon written request and within the time frame specified in EPA's request.

(4) Subsequent to EPA review of records in accordance with paragraph (d)(3) of this section, changes to the containment/inactivation controls selected under paragraph (d)(1) of this section must be made upon EPA order. Failure to comply with EPA's order shall result in automatic loss of eligibility for an exemption under this section.

(e) The manufacturer, importer, or processor notifies all persons in its employ or to whom it directly distributes the microorganism, who are engaged in experimentation, research, or analysis on the microorganism, including the manufacture, processing, use, transport, storage, and disposal of the microorganism associated with research and development activities, of

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any risk to health, identified under § 725.235(a), which may be associated with the microorganism. The notification must be made in accordance with § 725.235(b).

§ 725.235 Conditions of exemption for activities conducted inside a structure.

(a) *Determination of risks.* To determine whether notification under § 725.234(e) is required, the manufacturer, importer, or processor must meet the conditions laid out at IV-B-4-d of the NIH Guidelines; or

(1) For research conducted in accordance with the NIH Guidelines, the manufacturer, importer, or processor must meet the conditions laid out at IV-B-4-d of the NIH Guidelines; or

(2) For all other research conducted in accordance with § 725.234, 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 microorganism:

(i) Information in its possession or control concerning any significant adverse reaction of persons exposed to the microorganism 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 microorganism.

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

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

(b) *Notification to employees and others.* (1) The manufacturer, importer, or processor must notify the persons identified in § 725.234(e) 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 be-

lieve may be associated with the microorganism, as determined under paragraph (a) of this section.

(2) If the manufacturer, importer, or processor distributes a microorganism 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 microorganism is to be used only for research and development purposes and the requirements of § 725.234 are to be met.

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

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

(c) *Recordkeeping.* (1) For research conducted in accordance with the NIH Guidelines, a person who manufactures, imports, or processes a microorganism under this section must retain the following records:

(i) Documentation that the NIH Guidelines have been adhered to. Such documentation shall include:

(A) For experiments subject to Institutional Biosafety Committee review, or notification simultaneous with initiation of the experiment, the information submitted for review or notification, along with standard laboratory records, shall satisfy the recordkeeping requirements specified in § 725.234(d)(3).

(B) For experiments exempt from Institutional Biosafety Committee review or notification simultaneous with initiation of the experiment, documentation of the exemption, along with standard laboratory records, shall satisfy the recordkeeping requirement specified in § 725.234(d)(3).

(ii) Documentation of how the following requirements are satisfied under the NIH Guidelines:

(A) Copies or citations to information reviewed and evaluated to determine the need to make any notification of risk.

(B) Documentation of the nature and method of notification of risk, including copies of any labels or written notices used.

(C) The names and addresses of any persons other than the manufacturer,