

### Subpart E—Exemptions for Research and Development Activities

#### § 725.200 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this part for research and development activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in § 725.205 may submit a TSCA Experimental Release Application (TERA) for research and development activities involving microorganisms or otherwise comply with this subpart.

(c) Exemptions from part 725 are provided at §§ 725.232, 725.234, and 725.238.

(d) Submission requirements specific for TERAs are described at § 725.250.

(e) Data requirements for TERAs are set forth in §§ 725.255 and 725.260.

(f) EPA review procedures specific for TERAs are set forth in §§ 725.270 and 725.288.

(g) Subparts A through C of this part apply to any submission under this subpart.

#### § 725.205 Persons who may report under this subpart.

(a) Commercial research and development activities involving new microorganisms or significant new uses of microorganisms are subject to reporting under this part unless they qualify for an exemption under this part.

(b) Commercial purposes for research and development means that the activities are conducted with the purpose of obtaining an immediate or eventual commercial advantage for the researcher and would include:

(1) All research and development activities which are funded directly, in whole or in part, by a commercial entity regardless of who is actually conducting the research. Indications that the research and development activities are funded directly, in whole or in part, may include, but are not limited to:

(i) Situations in which a commercial entity contracts directly with a university or researcher; or

(ii) Situations in which a commercial entity gives a conditional grant where the commercial entity holds patent

rights, or establishes a joint venture where the commercial entity holds patent or licensing rights; or

(iii) Any other situation in which the commercial entity intends to obtain an immediate or eventual commercial advantage for the commercial entity and/or the researcher.

(2) Research and development activities that are not funded directly by a commercial entity, if the researcher intends to obtain an immediate or eventual commercial advantage. Indications that the researcher intends to obtain an immediate or eventual commercial advantage may include, but are not limited to:

(i) The research is directed toward developing a commercially viable improvement of a product already on the market; or

(ii) The researcher has sought or is seeking commercial funding for the purpose of developing a commercial application; or

(iii) The researcher or university has sought or is seeking a patent to protect a commercial application which the research is developing; or

(iv) Other evidence that the researcher is aware of a commercial application for the research and has directed the research toward developing that application.

(c) Certain research and development activities involving microorganisms subject to jurisdiction under the Act are exempt from reporting under this part. A person conducting research and development activities which meet the conditions for the exemptions described in §§ 725.232, 725.234, or 725.238 is exempt from TERA reporting under this subpart.

(d) A microorganism is not exempt from reporting under subpart D of this part if any amount of the microorganism, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development.

(e) Quantities of the inactivated microorganism, or mixtures or articles containing the inactivated microorganism, remaining after completion of research and development activities may be disposed of as a waste in accordance with applicable Federal, State, and local regulations.

## 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

**§ 725.235**

**40 CFR Ch. I (7-1-12 Edition)**

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 do one of the following:

(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,

## Environmental Protection Agency

## § 725.239

importer, or processor to whom the substance is distributed, the identity of the microorganism, the amount distributed, and copies of the notifications required.

(2) For all other research conducted in accordance with § 725.234, a person who manufactures, imports, or processes a microorganism under this section, must maintain the following records:

(i) Records describing selection and use of containment and/or inactivation controls required by § 725.234(d)(3) and certification by an authorized official required by § 725.234(d)(2) for each microorganism.

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

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

(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 microorganism, the amount distributed, and copies of the notifications required under paragraph (b)(2) of this section.

### § 725.238 Activities conducted outside a structure.

(a) *Exemption.* (1) Research and development activities involving intentional testing in the environment of certain microorganisms listed in § 725.239 may be conducted without prior review by EPA if all of the conditions of this section and § 725.239 are met.

(2) The research and development activity involving a microorganism listed in § 725.239 must be conducted by, or directly under the supervision of, a technically qualified individual, as defined in § 725.3.

(b) *Certification.* To be eligible for the exemption under this section, a manufacturer or importer must submit to EPA prior to initiation of the activity a document signed by an authorized official containing the following information:

(1) Name, address, and telephone number of the manufacturer or importer.

(2) Location, estimated duration, and planned start date of the test.

(3) Certification of the following:

(i) Compliance with the conditions of the exemption specified for the microorganism in § 725.239.

(ii) If state and/or local authorities have been notified of the activity, evidence of notification.

(c) *Recordkeeping.* Persons who conduct research and development activities under this section must comply with the recordkeeping requirements of § 725.65 and retain documentation that supports their compliance with the requirements of this section and the specific requirements for the microorganism listed in § 725.239.

### § 725.239 Use of specific microorganisms in activities conducted outside a structure.

(a) *Bradyrhizobium japonicum.* To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Bradyrhizobium japonicum*:

(1) *Characteristics of recipient microorganism.* The recipient microorganism is limited to strains of *Bradyrhizobium japonicum*.

(2) *Modification of traits.* (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in § 725.421(c).

(ii) The introduced genetic material must consist only of the following components:

(A) The structural gene(s) of interest, which have the following limitations:

(1) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.

(2) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium*.

(B) The regulatory sequences permitting the expression of solely the gene(s) of interest.

**§ 725.250**

(C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(D) The vector nucleotide sequences needed for vector transfer.

(E) The vector nucleotide sequences needed for vector maintenance.

(3) *Limitations on exposure.* (i) The test site area must be no more than 10 terrestrial acres.

(ii) The technically qualified individual must select appropriate methods to limit the dissemination of modified *Bradyrhizobium japonicum*.

(b) *Rhizobium meliloti.* To qualify for an exemption under this section, all of the following conditions must be met for a test involving *Rhizobium meliloti*:

(1) *Characteristics of recipient microorganism.* The recipient microorganism is limited to strains of *Rhizobium meliloti*.

(2) *Modification of traits.* (i) The introduced genetic material must meet the criteria for poorly mobilizable listed in § 725.421(c) of this part.

(ii) The introduced genetic material must consist only of the following components:

(A) The structural gene(s) of interest, which have the following limitations:

(1) For structural genes encoding marker sequences, the gene is limited to the *aadH* gene, which confers resistance to the antibiotics streptomycin and spectinomycin.

(2) For traits other than antibiotic resistance, the structural gene must be limited to the genera *Bradyrhizobium* and *Rhizobium*.

(B) The regulatory sequences permitting the expression of solely the gene(s) of interest.

(C) Associated nucleotide sequences needed to move genetic material, including linkers, homopolymers, adaptors, transposons, insertion sequences, and restriction enzyme sites.

(D) The vector nucleotide sequences needed for vector transfer.

(E) The vector nucleotide sequences needed for vector maintenance.

(3) *Limitations on exposure.* (i) The test site area must be no more than 10 terrestrial acres.

(ii) The technically qualified individual must select appropriate methods

**40 CFR Ch. I (7-1-12 Edition)**

to limit the dissemination of modified *Rhizobium meliloti*.

**§ 725.250 Procedural requirements for the TERA.**

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to TERAs submitted under this subpart:

(a) When to submit the TERA. Each person who is eligible to submit a TERA under this subpart must submit the TERA at least 60 calendar days before the person intends to initiate the proposed research and development activity.

(b) Contents of the TERA. Each person who submits a TERA under this subpart must provide the information and test data described in §§ 725.255 and 725.260. In addition, the submitter must supply sufficient information to enable EPA to evaluate the effects of all activities for which approval is requested.

(c) A person may submit a TERA for one or more microorganisms and one or more research and development activities, including a research program.

(d) EPA will either approve the TERA, with or without conditions, or disapprove it under procedures established in this subpart.

(e) The manufacturer, importer, or processor who receives a TERA approval must comply with all terms of the approval, as well as conditions described in the TERA, and remains liable for compliance with all terms and conditions, regardless of who conducts the research and development activity. Any person conducting the research and development activity approved under the TERA must comply with all terms of the TERA approval, as well as the conditions described in the TERA.

(f) Recordkeeping. Persons submitting a TERA must comply with the recordkeeping requirements of § 725.65. In addition, the following requirements apply to TERAs:

(1) Each person submitting a TERA under this part must retain documentation of information contained in the TERA for a period of 3 years from the date that the results of the study are submitted to the Agency.

## Environmental Protection Agency

## § 725.260

(2) Summaries of all data, conclusions, and reports resulting from the conduct of the research and development activity under the TERA must be submitted to the EPA address identified in § 725.25(c) within 1 year of the termination of the activity.

### § 725.255 Information to be included in the TERA.

(a) To review a TERA, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test in the environment. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the submitter on the microorganism(s) and the research and development activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will be useful for EPA's risk assessment. The TERA must be in writing and must include at least the information described in the following paragraphs.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TERA, must include the submitter identification and microorganism identity information required for MCANs in § 725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TERA must submit phenotypic and ecological characteristics information required in § 725.155(d)(3) as it relates directly to the conditions of the proposed research and development activity.

(e) Persons applying for a TERA must also submit the following information about the proposed research and development activity:

(1) *A detailed description of the proposed research and development activity.*

(i) The objectives and significance of the activity and a rationale for testing the microorganisms in the environment.

(ii) Number of microorganisms released (including viability per volume if applicable) and the method(s) of application or release.

(iii) Characteristics of the test site(s), including location, geographical, physical, chemical, and bio-

logical features, proximity to human habitation or activity, and description of site characteristics that would influence dispersal or confinement.

(iv) Target organisms (if the microorganism(s) to be tested has an intended target), including identification of each target organism and anticipated mechanism and result of interaction.

(v) Planned start date and duration of each activity.

(vi) If State and/or local authorities have been notified of the activity, evidence of notification.

(2) *Information on monitoring, confinement, mitigation, and emergency termination procedures.* (i) Confinement procedures for the activity, access and security measures, and procedures for routine termination of the activity.

(ii) Mitigation and emergency procedures.

(iii) Measures to detect and control potential adverse effects.

(iv) Name of principal investigator and chief of site personnel responsible for emergency procedures.

(v) Personal protective equipment, engineering controls, and procedures to be followed to minimize dispersion of the microorganism(s) by people, machinery, or equipment.

(vi) Procedures for disposal of any articles, waste, clothing, machinery, or other equipment involved in the experimental release, including methods for inactivation of the microorganism(s), containment, disinfection, and disposal of contaminated items.

### § 725.260 Submission of health and environmental effects data.

Each TERA must contain all available data concerning actual or potential effects on health or the environment of the new microorganism that are in the possession or control of the submitter and a description of other data known to or reasonably ascertainable by the submitter that will permit a reasoned evaluation of the planned test in the environment. The data must be reported in the manner described in § 725.160(a)(3) and (b)(3).

**§ 725.270 EPA review of the TERA.**

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of applications submitted under this subpart:

(a) *Length of the review period.* (1) The review period for the TERA will be 60 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete TERA, or the date EPA determines the TERA is complete under § 725.33, unless EPA finds good cause for an extension under § 725.56.

(2) A submitter shall not proceed with the research and development activity described in the TERA unless and until EPA provides written approval of the TERA. A submitter may receive early approval if a review is completed in less than 60 days.

(b) *EPA decision regarding proposed TERA activity.* (1) A decision concerning a TERA under this subpart will be made by the Administrator, or a designee.

(2) If EPA determines that the proposed research and development activity for the microorganism does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter that the TERA is approved and that the submitter can proceed with the proposed research and development activity described in the TERA.

(3) EPA may include requirements and conditions in its approval of the TERA that would be stated in the TERA approval under paragraph (c) of this section.

(4) If EPA concludes that it cannot determine that the proposed research and development activity described in the TERA will not present an unreasonable risk of injury to health or the environment, EPA will deny the TERA and will provide reasons for the denial in writing.

(c) *TERA approval.* (1) A TERA approval issued by EPA under this section is legally binding on the TERA submitter.

(2) When EPA approves a TERA, the submitter must conduct the research and development activity only as described in the TERA and in accordance

with any requirements and conditions prescribed by EPA in its approval of the TERA.

(3) Any person who fails to conduct the research and development activity as described in the TERA and in accordance with any requirements and conditions prescribed by EPA in its approval of the TERA under this section, shall be in violation of sections 5 and 15 of the Act and be subject to civil and criminal penalties under section 16 of the Act.

**§ 725.288 Revocation or modification of TERA approval.**

(a) *Significant questions about risk.* (1) If, after approval of a TERA under this subpart, EPA receives information which raises significant questions about EPA's determination that the activity does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing of those questions.

(2) The submitter may, within 10 days of receipt of EPA's notice, provide in writing additional information or arguments concerning the significance of the questions and whether EPA should modify or revoke the approval of the TERA.

(3) After considering any such information and arguments, EPA will decide whether to change its determination regarding approval of the TERA.

(i) If EPA determines that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing. To make this finding, EPA may prescribe additional conditions which must be followed by the submitter.

(ii) If EPA determines that it can no longer conclude that the activity will not present an unreasonable risk of injury to health or the environment, it will notify the submitter in writing that EPA is revoking its approval and state its reasons. In that event, the submitter must terminate the research and development activity within 48 hours of receipt of the notice in accordance with directions provided by EPA in the notice.

(b) *Evidence of unreasonable risk.* (1) If, after approval of a TERA under this

## Environmental Protection Agency

## § 725.350

subpart, EPA determines that the proposed research and development activity will present an unreasonable risk of injury to health or the environment, EPA will notify the submitter in writing and state its reasons.

(2) In the notice, EPA may prescribe additional safeguards to address or reduce the risk, or may instruct the submitter to suspend the research and development activities.

(3) Within 48 hours, the submitter must implement the instructions contained in the notice. The submitter may then submit additional information or arguments concerning the matters raised by EPA and whether EPA should modify or revoke the approval of the TERA in accordance with paragraph (a)(2) of this section.

(4) EPA will consider the information and arguments in accordance with paragraph (a)(3) of this section.

(5) Following consideration of the information and arguments under paragraph (a)(3) of this section, if EPA notifies the submitter that the R&D activity must be suspended or terminated, the submitter may resume the activity only upon written notice from EPA that EPA has approved resumption of the activity. In approving resumption of an activity, EPA may prescribe additional conditions which must be followed by the submitter.

(c) *Modifications.* If, after approval of a TERA under this subpart, the submitter concludes that it is necessary to alter the conduct of the research and development activity in a manner which would result in the activity being different from that described in the TERA agreement and any conditions EPA prescribed in its approval, the submitter must inform the EPA contact for the TERA and may not modify the activity without the approval of EPA.

### Subpart F—Exemptions for Test Marketing

#### § 725.300 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this part for test marketing activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in § 725.305 may submit an application for a test marketing exemption (TME).

(c) Submission requirements specific for TME applications are described at § 725.350.

(d) Data requirements for TME applications are set forth in § 725.355.

(e) EPA review procedures specific for TMEs are set forth in § 725.370.

(f) Subparts A through C of this part apply to any submission under this subpart.

#### § 725.305 Persons who may apply under this subpart.

A person identified in this section may apply for a test marketing exemption. EPA may grant the exemption if the person demonstrates that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. A person may apply under this subpart for the following test marketing activities:

(a) A person who intends to manufacture or import for commercial purposes a new microorganism.

(b) A person who intends to manufacture, import, or process for commercial purposes a microorganism identified in subpart M of this part for a significant new use.

#### § 725.350 Procedural requirements for this subpart.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to applications submitted under this subpart:

(a) *Prenotice consultation.* EPA strongly suggests that for a TME, the applicant contact EPA for a prenotice consultation regarding eligibility for a TME.

(b) *When to submit a TME application.* Each person who is eligible to apply for a TME under this subpart must submit the application at least 45 calendar days before the person intends to commence the test marketing activity.

(c) *Recordkeeping.* Each person who is granted a TME must comply with the recordkeeping requirements of § 725.65. In addition, any person who obtains a