

Environmental Protection Agency

§ 725.270

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 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.