

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