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 terminted, 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.