

(2) EPA has received significant additional information during the review period.

(3) The submitter has failed to correct a submission after receiving EPA's request under § 725.32.

(4) EPA has reviewed the submission and determined that there is a significant possibility that the microorganism will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial review period.

**§ 725.60 Withdrawal of submission by the submitter.**

(a) A submitter may withdraw a submission during the review period. A statement of withdrawal must be made in writing to the address listed in § 725.25(c). The withdrawal is effective upon receipt of the statement by the Document Control Officer.

(b) If a manufacturer, importer, or processor who withdrew a submission later resubmits a submission for the same microorganism, a new review period begins.

**§ 725.65 Recordkeeping.**

(a) *General provisions.* (1) Any person who submits a notice under this part must retain documentation of information in the submission, including:

(i) Any data in the submitter's possession or control; and

(ii) Records of production volume for the first 3 years of manufacture, import, or processing.

(2) Any person who submits a notice under this part must retain documentation of the date of commencement of testing, manufacture, import, or processing.

(3) Any person who is exempt from some or all of the reporting requirements of this part must retain documentation that supports the exemption.

(4) All information required by this section must be retained for 3 years from the date of commencement of each activity for which records are required under this part.

(b) *Specific requirements.* In addition to the requirements of paragraph (a) of this section, specific recordkeeping requirements included in certain subparts must also be followed.

(1) Additional recordkeeping requirements for activities conducted inside a structure are set forth in § 725.235(h).

(2) Additional recordkeeping requirements for TERAs are set forth in § 725.250(f).

(3) Additional recordkeeping requirements for TMEs are set forth in § 725.350(c).

(4) Additional recordkeeping requirements for Tier I exemptions under subpart G of this part are set forth in § 725.424(a)(5).

(5) Additional recordkeeping requirements for Tier II exemptions under subpart G of this part are set forth in § 725.450(d).

(6) Additional recordkeeping requirements for significant new uses of microorganisms reported under subpart L of this part are set forth in § 725.850. Recordkeeping requirements may also be included when a microorganism and significant new use are added to subpart M of this part.

**§ 725.67 Applications to exempt new microorganisms from this part.**

(a) *Submission.* (1) Any manufacturer or importer of a new microorganism may request, under section 5(h)(4) of the Act, an exemption, in whole or in part, from this part by sending a Letter of Application to the Chief, New Chemicals Branch, Chemical Control Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(2) *General provisions.* The Letter of Application should provide information to show that any activities affected by the requested exemption will not present an unreasonable risk of injury to health or the environment. This information should include data described in the following paragraphs.

(i) The effects of the new microorganism on health and the environment.

(ii) The magnitude of exposure of human beings and the environment to the new microorganism.

(iii) The benefits of the new microorganism for various uses and the availability of substitutes for such uses.

(iv) The reasonably ascertainable economic consequences of granting or

denying the exemption, including effects on the national economy, small business, and technological innovation.

(3) *Specific requirements.* In addition to the requirements of paragraph (a)(2) of this section, the specific information requirements of the relevant subpart under which the exemption is sought should be met.

(i) *Exemption from MCAN reporting under subpart D.* Information requirements are set forth in §§ 725.155 and 725.160.

(ii) *Exemption from TERA reporting under subpart E.* Information requirements are set forth in §§ 725.255 and 725.260.

(iii) *Listing a recipient microorganism as eligible for exemption under subpart G.* Information regarding the following criteria should be addressed in an application to list a recipient microorganism under § 725.420:

(A) Identification and classification of the microorganism using available genotypic and phenotypic information;

(B) Information to evaluate the relationship of the microorganism to any other closely related microorganisms which have a potential for adverse effects on health or the environment;

(C) A history of safe commercial use for the microorganism;

(D) Commercial uses indicating that the microorganism products might be subject to TSCA;

(E) Studies which indicate the potential for the microorganism to cause adverse effects to health or the environment; and

(F) Studies which indicate the survival characteristics of the microorganism in the environment.

(b) *Processing of the Letter of Application by EPA—(1) Grant of the Application.* If, after consideration of the Letter of Application and any other relevant information available to EPA, the Assistant Administrator for Prevention, Pesticides and Toxic Substances makes a preliminary determination that the new microorganism will not present an unreasonable risk of injury to health or the environment, the Assistant Administrator will propose a rule to grant the exemption using the applicable procedures in part 750 of this chapter.

(2) *Denial of the application.* If the Assistant Administrator decides that the preliminary determination described in paragraph (b)(1) of this section cannot be made, the application will be denied by sending the applicant a written statement with the Assistant Administrator's reasons for denial.

(c) *Processing of the exemption—(1) Unreasonable risk standard.* Granting a section 5(h)(4) exemption requires a determination that the activities will not present an unreasonable risk of injury to health or the environment.

(i) An unreasonable risk determination under the Act is an administrative judgment that requires balancing of the harm to health or the environment that a chemical substance may cause and the magnitude and severity of that harm, against the social and economic effects on society of EPA action to reduce that harm.

(ii) A determination of unreasonable risk under section 5(h)(4) of the Act will examine the reasonably ascertainable economic and social consequences of granting or denying the exemption after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

(2) *Grant of the exemption.* The exemption will be granted if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the new microorganism will not present an unreasonable risk of injury to health or the environment.

(3) *Denial of the exemption.* The exemption will be denied if the Assistant Administrator determines, after consideration of all relevant evidence presented in the rulemaking proceeding described in paragraph (b)(1) of this section, that the determination described in paragraph (c)(2) of this section cannot be made. A final decision terminating the rulemaking proceeding will be published in the FEDERAL REGISTER.

#### § 725.70 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).