

## Environmental Protection Agency

## § 725.60

(d) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

[62 FR 17932, April 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

### § 725.56 Extension of the review period.

(a) At any time during the review period, EPA may unilaterally determine that good cause exists to extend the review period specified for MCANs, or the exemption requests.

(b) If EPA makes such a determination, EPA:

(1) Will notify the submitter that EPA is extending the review period for a specified length of time and state the reasons for the extension.

(2) For MCANs, EPA may issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the review period and gives the reasons for the extension.

(c) The total period of the extension may be for a period of up to the same length of time as specified for each type of submission in § 725.50. If the initial extension is for less than the total time allowed, EPA may make additional extensions. However, the sum of the extensions may not exceed the total allowed.

(d) The following are examples of situations in which EPA may find that good cause exists for extending the review period:

(1) EPA has reviewed the submission and is seeking additional information.

(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 notice during the notice review period by submitting a statement of withdrawal in a manner set forth in this paragraph. The withdrawal is effective upon receipt of the written paper request, electronic request on optical disc, or CDX submission by EPA.

(1) *Older notices.* Statements of withdrawal for notices submitted before April 6, 2010 must be submitted on paper either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(2) *Newer notices.* For notices submitted on or after April 6, 2010, EPA will accept statements of withdrawal only if submitted in accordance with this paragraph:

(i) Statements of withdrawal may be submitted on paper on or before April 6, 2011. All paper-based statements of withdrawal must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the statement of withdrawal for submission to EPA. Paper statements of withdrawal must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(ii) Statements of withdrawal be submitted as electronic files on optical disc on or before April 6, 2012. All statements of withdrawal submitted as electronic files on optical disc must be generated using e-PMN reporting software and be completed through the finalization step of the software. Optical discs containing electronic statements of

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withdrawal must be submitted by courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(iii) Statements of withdrawal may be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such statements of withdrawal must be generated and completed using e-PMN reporting software. See 40 CFR 720.40(a)(2)(iv) for information on how to obtain e-PMN software.

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

[62 FR 17932, April 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

### § 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 TSCA section 5(h)(4), an exemption, in whole or in part, from this part by sending a Letter of Application in the manner set forth in § 725.25(c).

(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.