Environmental Protection Agency

§ 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.


(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 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 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
§ 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.