§ 725.426 Applicability of the Tier I exemption.

The Tier I exemption under §725.424 applies only to a manufacturer or importer of a new microorganism that certifies that the microorganism will be used in all cases in compliance with §§725.420, 725.421, and 725.422.

§ 725.428 Requirements for the Tier II exemption.

The manufacturer or importer of a new microorganism for commercial purposes may submit to EPA a Tier II exemption request in lieu of a MCAN under subpart D of this part if all of the following conditions are met:

(a) The recipient microorganism is listed in and meets any requirements specified in §725.420.

(b) The introduced genetic material meets the criteria under §725.421.

(c) Adequate physical containment and control technologies are used. The criteria listed under §725.422 for physical containment and control technologies of facilities should be used as guidance to satisfy the Tier II exemption request data requirements listed at §725.455(d). EPA will review proposed process and containment procedures as part of the submission for a Tier II exemption under this section.

§ 725.450 Procedural requirements for the Tier II exemption.

General requirements for all submissions under this part are contained in §725.25. In addition, the following requirements apply to requests submitted under this subpart:

(a) Prenotice consultation. EPA strongly suggests that for a Tier II exemption, the submitter contact the Agency for a prenotice consultation regarding eligibility for the exemption.

(b) When to submit the Tier II exemption request. Each person who is eligible to submit a Tier II exemption request under this subpart must submit the request at least 45 calendar days before the person intends to commence manufacture or import.

(c) Contents of the Tier II exemption request. Each person who submits a request under this subpart must provide the information described in §§725.428 and 725.455, as well as information known to or reasonably ascertainable by the person that would permit EPA to determine that use of the microorganism, under the conditions specified in the request, will not present an unreasonable risk of injury to health or the environment.

(d) Recordkeeping. Each person who submits a request under this subpart must comply with the recordkeeping requirements of §725.65. In addition, the submitter should maintain records which contain information that verifies compliance with the following:

(1) The certifications made in the request.

(2) All the eligibility criteria for the Tier II exemption request including the criteria for the recipient microorganism, the introduced genetic material, the physical containment and control technologies.

§ 725.455 Information to be included in the Tier II exemption request.

The submitter must indicate clearly that the submission is a Tier II exemption request for a microorganism instead of the MCAN under subpart D of this part and must submit the following information:

(a) Submitter identification. (1) The name and headquarters address of the submitter.

(2) The name, address, and office telephone number (including area code) of the principal technical contact representing the submitter.

(b) Microorganism identity information. (1) Identification (genus, species, and strain) of the recipient microorganism. Genus, species designation should be substantiated by a letter from a culture collection or a brief summary of the results of tests conducted for taxonomic identification.

(2) Type of genetic modification and the function of the introduced genetic material.

(3) Site of insertion.

(4) Certification of compliance with the introduced genetic material criteria described in §725.421.

(c) Production volume. Production volume, including total liters per year, and the maximum cell concentration achieved during the production process.
§ 725.470  EPA review of the Tier II exemption request.

General procedures for review of all submissions under this part are contained in §§725.28 through 725.60. In addition, the following procedures apply to EPA review of Tier II exemption requests submitted under this subpart:

(a) Length of the review period. The review period for the request will be 45 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete request, or the date EPA determines the request is complete under §725.33, unless the Agency extends the review period for good cause under §725.56.

(b) Criteria for review. EPA will review the request to determine that the new microorganism complies with §725.428 and that its manufacture, processing, use, and disposal as described in the request will not present an unreasonable risk of injury to health or the environment.

(c) EPA decision regarding the Tier II exemption request. A decision concerning a request under this subpart will be made by the Administrator, or a designee.

(d) Determination that the microorganism is ineligible for a Tier II review. (1) EPA may determine that the manufacturer or importer is not eligible for Tier II review, because the microorganism does not meet the criteria under §725.428 or the Administrator, or a designee, decides that there is insufficient information to determine that the conditions of manufacture, processing, use, or disposal of the microorganism as described in the request will not present an unreasonable risk to health or the environment.

(2) If the Agency makes this determination, the Administrator, or a designee will notify the manufacturer or importer by telephone, followed by a letter, that the request has been denied. The letter will explain reasons for the denial.

(e) Approval or denial of the Tier II exemption request. (1) No later than 45 days after EPA receives a request, the Agency will either approve or deny the request.

(2) In approving a request, EPA may impose any restrictions necessary to ensure that the microorganism will not present an unreasonable risk of injury to health and the environment as a result of general commercial use.

(f) EPA may seek to enjoin the manufacture or import of a microorganism in violation of this subpart, or act to seize any microorganism manufactured or imported in violation of this section or take other actions under the authority of sections 7 or 17 of the Act.