

§ 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.

(d) *Process and containment information.* (1) A description of the process including the following:

(i) Identity and location of the manufacturing site(s).

(ii) Process flow diagram illustrating the production process, including downstream separations, and indicating the containment envelope around the appropriate equipment.

(iii) Identities and quantities of feedstocks.

(iv) Sources and quantities of potential releases to both the workplace and environment, and a description of engineering controls, inactivation procedures, and other measures which will reduce worker exposure and environmental releases.

(v) A description of procedures which will be undertaken to prevent fugitive emissions, i.e. leak detection and repair program.

(vi) A description of procedures/safeguards to prevent and mitigate accidental releases to the workplace and the environment.

(2) Certification of those elements of the containment criteria described in § 725.422 with which the manufacturer is in compliance, including stating by number the elements with which the manufacturer is in full compliance.

(e) The site of waste disposal and the type of permits for disposal, the permit

numbers and the institutions issuing the permits.

(f) The certification statement required in § 725.25(b). Certification of submission of test data is not required for the Tier II exemption.

§ 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.

(3) If the request is denied, the manufacturer or importer may submit the information necessary to constitute a MCAN under subpart D of this part.

(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.

(g) A manufacturer or importer may only proceed after receipt of EPA approval.

Subparts H–K [Reserved]

Subpart L—Additional Procedures for Reporting on Significant New Uses of Microorganisms

§ 725.900 Scope and purpose.

(a) This subpart describes additional provisions governing submission of MCANs for microorganisms subject to significant new use rules identified in subpart M of this part.

(b) Manufacturers, importers, and processors described in § 725.105(c) must submit a MCAN under subpart D of this part for significant new uses of microorganisms described in subpart M of this part, unless they are excluded under §§ 725.910 or 725.912.

(c) Section 725.920 discusses exports and imports.

(d) Additional recordkeeping requirements specific to significant new uses of microorganisms are described in § 725.950.

(e) Section 725.975 describes how EPA will approve alternative means of complying with significant new use requirements designated in subpart M of this part.