

§ 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