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.