Environmental Protection Agency § 725.94

§ 725.94 Substantiation requirements.
(a) Claims applicable to the period prior to commencement of manufacture or import for general commercial use—(1) MCAN, TME, Tier I certification, and Tier II exemption request requirements. Any person who submits a MCAN, TME, Tier I certification, or Tier II exemption request should strictly limit confidentiality claims to that information which is confidential and proprietary to the business.
(i) If any information in the submission is claimed as confidential business information, the submitter must substantiate each claim in accordance with the requirements of §725.85(a).
(ii) If the submitter does not provide written substantiation as required in paragraph (a)(1)(i) of this section, the submission will be considered incomplete and the review period will not begin in accordance with §725.33.
(2) TERA requirements. Any person who submits a TERA, should strictly limit confidentiality claims to that information which is confidential and proprietary to the business. If any information in such a submission is claimed as confidential business information, the submitter must have available for each of those claims, and agree to furnish to EPA upon request, written answers to the questions in paragraphs (d) and (e) of this section.
(b) Claims applicable to the period after commencement of manufacture or import for general commercial use. (1) If a submitter claimed portions of the microorganism identity confidential in the MCAN and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and substantiated at the time the Notice of Commencement (NOC) is submitted under §725.190. Otherwise, EPA will list the specific microorganism identity on the public Inventory.
(ii) The submitter must substantiate the claim for confidentiality of the microorganism identity by answering all of the questions in paragraphs (c), (d), and (e) in this section. In addition, the following questions must be answered:
(i) What harmful effects to the company’s or institution’s competitive position, if any, would result if EPA publishes on the Inventory the identity of the microorganism? How could a competitor use such information given the fact that the identity of the microorganism otherwise would appear on the TSCA Inventory with no link between the microorganism and the company or

confidentiality in accordance with §725.80.

(b) Microorganism identity—(1) Claims applicable to the period prior to commencement of manufacture or import for general commercial use. A claim of confidentiality for the period prior to commencement of manufacture or import for general commercial use for the specific identity of a microorganism for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under §725.85(a). The submitter must substantiate each claim in accordance with the requirements of §725.94(a).

(2) Claims applicable to the period after commencement of manufacture or import for general commercial use. To maintain the confidential status of the specific identity of a microorganism for which a health and safety study was submitted after commencement of manufacture or import for general commercial use, the claim must be reasserted and substantiated in conjunction with a claim under §725.85(b). The submitter must substantiate each claim in accordance with the requirements of §725.94(b).

(c) Denial of confidentiality claim. EPA will deny a claim of confidentiality for microorganism identity under paragraph (b) of this section, unless:
(1) The information would disclose processes used in the manufacture or processing of a microorganism.
(2) The microorganism identity is not necessary to interpret a health and safety study.
(d) Use of generic names. When EPA discloses a health and safety study containing a microorganism identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the microorganism by the generic name selected under §725.85.

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(1) Has the microorganism or method of production been patented in the U.S. or elsewhere? If so, why is confidentiality necessary?

(2) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? What is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

(3) For each additional type of information claimed as confidential, explain what harm would result from disclosure of each type of information if the identity of the microorganism were to remain confidential.

(e) Health and safety studies of microorganisms. If confidentiality claims are asserted for information in a health or safety study of a microorganism, the following questions must be answered:

(1) Would the disclosure of the information claimed confidential reveal: confidential process information, or information unrelated to the effects of the microorganism on health and the environment. Describe the causal connection between the disclosure and harm.

(2) Does the company or institution assert that disclosure of the microorganism identity is not necessary to interpret any health and safety studies
which have been submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

§ 725.95 Public file.
All information submitted, including any health and safety study of a microorganism and other supporting documentation, will become part of the public file for that submission, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, unless such materials are claimed confidential. Any of the nonconfidential material described in this subpart will be available for public inspection in the TSCA Public Docket Office, Rm. NE-B607, 401 M St., SW., Washington, DC, between the hours of noon to 4 p.m., Monday through Friday, excluding legal holidays.

Subpart D—Microbial Commercial Activities Notification Requirements

§ 725.100 Scope and purpose.
(a) This subpart establishes procedures for submission of a notice to EPA under section 5(a) of the Act for persons who manufacture, import, or process microorganisms for commercial purposes. This notice is called a Microbial Commercial Activity Notice (MCAN). It is expected that MCANs will in general only be submitted for microorganisms intended for general commercial use. Persons who manufacture, import, or process a microorganism in small quantities solely for research and development activities that do not fit the definition of small quantities solely for research and development may nonetheless qualify for more limited reporting requirements in Subpart E, including the TERA which can be used for review of research and development involving environmental release.
(b) Persons subject to MCAN submission are described in §725.105.
(c) Exclusions and exemptions specific to MCAN submissions are described in §725.110.
(d) Submission requirements applicable specifically to MCANs are described at §725.150.
(e) Data requirements for MCANs are set forth in §§725.155 and 725.160.
(f) EPA review procedures specific to MCANs are set forth in §725.170.
(g) Subparts A through C of this part apply to any MCAN submitted under this subpart.

§ 725.105 Persons who must report.
(a) Manufacturers of new microorganisms. (1) MCAN submission is required for any person who intends to manufacture for commercial purposes in the United States a new microorganism. Exclusions are described in §725.110.
(2) When several persons are involved in an import transaction, the MCAN must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the MCAN.
(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a MCAN.
(b) Importers of new microorganisms. (1) MCAN submission is required for a person who intends to import into the United States for commercial purposes a new microorganism. Exclusions are described in §725.110.
(2) When several persons are involved in an import transaction, the MCAN must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the MCAN for that transaction.
(3) Except as otherwise provided in paragraph (b)(4) of this section, the provisions of this subpart D apply to each person who submits a MCAN for a new microorganism which such person intends to import for a commercial purpose. In addition, each importer must comply with paragraph (b)(4) of this section.