Environmental Protection Agency

§ 725.92

claim of confidentiality under paragraph (b) of this section, EPA will examine the generic microorganism name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular microorganism, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the identity of the microorganism to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity of the microorganism. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA’s chosen generic name on the public Inventory. If the submitter’s proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter’s proposed generic name is not acceptable, EPA will notify the submitter of EPA’s choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§ 725.92 Data from health and safety studies of microorganisms.

(a) Information other than specific microorganism identity. Except as provided in paragraph (b) of this section, EPA will deny any claim of confidentiality with respect to information included in a health and safety study of a microorganism, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a microorganism.

(2) Information which is not in any way related to the effects of a microorganism on health or the environment, such as, the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of 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).
§ 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 by submitting written answers to the questions in paragraphs (c), (d), and (e) of this section at the time the person submits the information.

(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.

(b) Termination of confidentiality claim. 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.

(c) General questions. The following questions must be answered in detail for each confidentiality claim:

(i) For what period of time is a claim of confidentiality being asserted? If the claim is to extend until a certain event