Environmental Protection Agency

§ 725.85 Microorganism identity.

(a) Claims applicable to the period prior to commencement of manufacture or import for general commercial use—(1) When to make a claim. (i) A person who submits information to EPA under this part may assert a claim of confidentiality for portions of the specific microorganism identity at the time of submission of the information. This claim will apply only to the period prior to the commencement of manufacture or import for general commercial use.

(ii) A person who submits information to EPA under this part must reassert a claim of confidentiality and substantiate the claim each time the information is submitted to EPA. For example, if a person claims certain information confidential in a TERA submission and wishes the same information to remain confidential in a subsequent TERA or MCAN submission, the person must reassert and substantiate the claim in the subsequent submission.

(2) Assertion of claim. (i) A submitter may assert a claim of confidentiality only if the submitter believes that public disclosure prior to commencement of manufacture or import for general commercial use of the fact that anyone is initiating research and development activities pertaining to the specific microorganism or intends to manufacture or import the specific microorganism for general commercial use would reveal confidential business information. Claims must be substantiated in accordance with the requirements of §725.94(a).

(ii) If the submission includes a health and safety study concerning the microorganism and if the claim for confidentiality with respect to the specific identity is denied in accordance with §725.92(c), EPA will deny a claim asserted under paragraph (a) of this section.

(3) Development of generic name. Any person who asserts a claim of confidentiality for portions of the specific microorganism identity under this paragraph must provide one of the following items at the time the submission is filed:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(4) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential identity of the particular microorganism. The name should reveal the specific identity to the maximum extent possible. The generic name will be subject to EPA review and approval.

(4) Determination by EPA. (i) Any person who intends to assert a claim of confidentiality for the specific identity of a new microorganism may seek a determination by EPA of an appropriate generic name for the microorganism before filing a submission. For this purpose, the person should submit to EPA:

(A) The specific identity of the microorganism.

(B) A proposed generic name(s) which is only as generic as necessary to protect the confidential identity of the new microorganism. The name(s) should reveal the specific identity of the microorganism to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(5) Use of generic name. If a submitter claims microorganism identity as confidential under paragraph (a) of this section, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the Federal Register notice described in §725.40 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) Claims applicable to the period after commencement of manufacture or import
§ 725.85

40 CFR Ch. 1 (7–1–14 Edition)

for general commercial use—(1) Maintain-
ing claim. Any claim of confidentiality under paragraph (a) of this section is applica-
able only until the microorgan-

ism is manufactured or imported for general commercial use and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the microorganism identity when the microorganism is added to the Inven-
tory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commence-
ent of manufacture required under §725.190.

(i) A submitter may not claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use unless the submitter claimed the microorganism identity confidential under paragraph (a) of this section in the MCAN submitted for the microorganism.

(ii) A submitter may claim the microorganism identity confidential for the period after commencement of manufacture or import for general commercial use if the submitter did not claim the microorganism identity confidential under paragraph (a) of this section in any TERA submitted for the microorganism, but subsequently did claim microorganism identity con-
fidential in the MCAN submitted for the microorganism.

(2) Assertion of claim. (i) A person who believes that public disclosure of the fact that anyone manufactures or imports the microorganism for general commercial use would reveal confidential business information may assert a claim of confidentiality in accordance with this paragraph.

(ii) If the notice includes a health and safety study concerning the new microorganism, and if the claim for confidentiality with respect to the microorganism identity is denied in accordance with §725.92(c), EPA will deny a claim asserted under paragraph (b) of this section.

(3) Requirements for assertion. Any person who asserts a confidentiality claim for microorganism identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a bona fide intent to manu-

facture or import the microorganism the fact that the particular microorgan-

ism is included on the confidential Inven-
tory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available and agree to furn-

ish to EPA upon request the taxo-
nomic designations and supplemental information required by §725.12.

(iv) Provide a detailed written sub-

stantiation of the claim, in accordance with the requirements of §725.94(b).

(4) Denial of claim. If the submitter does not meet the requirements of paragraph (b) of this section, EPA will deny the claim of confidentiality.

(5) Acceptance of claim. (i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the microorganism identity as part of a health and safety study has been de-

 nied in accordance with part 2 of this title or §725.92.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a bona fide intent to manufacture or import a microorgan-

ism which is described by a generic name on the public Inventory may submit an inquiry to EPA under §725.15(b) to determine whether the particular microorganism is included on the confi-

dential Inventory.

(iii) Upon receipt of a request de-

scribed in §725.15(b), EPA may require the submitter who originally asserted confidentiality for a microorganism to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the in-

formation required under paragraph (b)(3)(iii) of this section within 10 cal-

endar days of receipt of a request by EPA under paragraph (b) of this sec-

tion will constitute a waiver of the original submitter’s confidentiality claim. In this event, EPA may place the specific microorganism identity on the public Inventory without further notice to the original submitter.

(6) Use of generic name on the public Inventory. If a submitter asserts a
Environmental Protection Agency

§ 725.92

(a) **Uses of a microorganism.**

(1) **Assertion of claim.** A person who submits information to EPA under this part on the categories or proposed categories of use of a microorganism may assert a claim of confidentiality for this information.

(b) **Requirements for claim.** A submitter that asserts such a claim must:

1. Report the categories or proposed categories of use of the microorganism.

2. Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the Federal Register notice described in §725.40.

(c) **Generic use description.** The person must submit the information required by paragraph (b) of this section by describing the uses as precisely as possible, without revealing the information which is claimed confidential, to disclose as much as possible how the use may result in human exposure to the microorganism or its release to the environment.

§ 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 §725.83(a). The submitter must substantiate each claim in accordance with the requirements of §725.94(a).