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manufactured, processed, or distributed in commerce in violation of section 5 of the Act or this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 of the Act is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this part may be subject to penalties calculated as if they never filed their submissions.

(g) EPA may seek to enjoin the manufacture or processing of a microorganism in violation of this part or act to seize any microorganism manufactured or processed in violation of this part or take other actions under the authority of section 7 of the Act (15 U.S.C. 2606) or section 17 of the Act (15 U.S.C. 2616).

§ 725.75 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this part, to verify that information required by EPA under this part is true and correct, and to audit data submitted to EPA under this part.

Subpart C—Confidentiality and Public Access to Information

§ 725.80 General provisions for confidentiality claims.

(a) A person may assert a claim of confidentiality for any information submitted to EPA under this part. However,

(1) Any person who asserts a claim of confidentiality for portions of the specific microorganism identity must provide the information as described in § 725.85.

(2) Any person who asserts a claim of confidentiality for a use of a microorganism must provide the information as described in § 725.88.

(3) Any person who asserts a claim of confidentiality for information contained in a health and safety study of a microorganism must provide the information described in § 725.92.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1) When a person submits any information under this part, including any attachments, for which claims of confidentiality are made, the claim(s) must be asserted by circling the specific information which is claimed and marking the page on which that information appears with an appropriate designation such as “trade secret,” “TSCA CBI,” or “confidential business information.”

(2) If any information is claimed confidential, the person must submit two copies of the document including the claimed information.

(i) One copy of the document must be complete. In that copy, the submitter must mark the information which is claimed as confidential in the manner prescribed in paragraph (b)(1) of this section.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the review period does not begin to run until EPA receives the second copy, in accordance with § 725.33.

(iv) Any information contained within the copy submitted under paragraph (b)(2)(ii) of this section which has been in the public file for more than 30 days will be presumed to be in the public domain, notwithstanding any assertion of confidentiality made under this section.

(3) 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.

(c) Any person asserting a claim of confidentiality under this part must substantiate each claim in accordance with the requirements in § 725.94.

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(d) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and part 2 of this title.

(e) If a submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

§ 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 resubstantiate 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 spe-

cific 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*

for general commercial use—(1) *Maintaining claim.* Any claim of confidentiality under paragraph (a) of this section is applicable only until the microorganism 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 Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement 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 confidential 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 under paragraph (b) of this section.

(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 manufacture or import the microorganism the fact that the particular microorganism is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by § 725.12.

(iv) Provide a detailed written substantiation 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 denied 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 microorganism 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 confidential Inventory.

(iii) Upon receipt of a request described 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 information required under paragraph (b)(3)(iii) of this section within 10 calendar days of receipt of a request by EPA under paragraph (b) of this section 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

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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 does provide the information requested, EPA will review the response. 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.

§ 725.88 Uses of a microorganism.

(a) *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 § 725.85(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.

§ 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 incom-

plete 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.

(2) 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 institution? How substantial would the harmful effects of disclosure be? What is the causal relationship between the disclosure and the harmful effects?

(ii) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported for general commercial use by anyone?

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

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

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or point in time, indicate that event or time period. Explain why the information should remain confidential until such point.

(2) Briefly describe any physical or procedural restrictions within the company or institution relating to the use and storage of the information claimed as confidential. What other steps, if any, apply to use or further disclosure of the information?

(3) Has the information claimed as confidential been disclosed to individuals outside of the company or institution? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

(4) Does the information claimed as confidential appear, or is it referred to, in any of the following questions? If the answer is yes to any of these questions, indicate where the information appears and explain why it should nonetheless be treated as confidential.

(i) Advertising or promotional materials for the microorganism or the resulting end product?

(ii) Material safety data sheets or other similar materials for the microorganism or the resulting end product?

(iii) Professional or trade publications?

(iv) Any other media available to the public or to competitors?

(v) Patents?

(vi) Local, State, or Federal agency public files?

(5) Has EPA, another Federal agency, a Federal court, or a State made any confidentiality determination regarding the information claimed as confidential? If so, provide copies of such determinations.

(6) For each type of information claimed confidential, describe the harm to the company's or institution's competitive position that would result if this information were disclosed. Why would this harm be substantial? How could a competitor use such information? What is the causal connection between the disclosure and harm?

(7) If EPA disclosed to the public the information claimed as confidential, how difficult would it be for the competitor to enter the market for the resulting product? Consider such constraints as capital and marketing cost,

specialized technical expertise, or unusual processes.

(d) *Microorganism identity and production method.* If confidentiality claims are asserted for the identity of the microorganism or information on how the microorganism is produced, the following questions must be answered:

(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 as defined in § 725.3 are not required to submit a notice to EPA. Persons who manufacture, import, or process a microorganism 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) If a person contracts with a manufacturer to produce or process a new microorganism and the manufacturer produces or processes the microorganism exclusively for that person, and that person specifies the identity of the microorganism, and controls the total amount produced and the basic technology for the plant process, then that person must submit the MCAN. If it is unclear who must report, EPA should be contacted 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.

(4) EPA will hold the principal importer, or the importer that EPA determines must submit the MCAN when there is no principal importer under paragraph (b)(2) of this section, liable for complying with this part, for completing the MCAN, and for the completeness and truthfulness of all information which it submits.

(c) *Manufacturers, importers, or processors of microorganisms for a significant new use.* MCAN submission is required for any person who intends to manufacture, import, or process for commercial purposes a microorganism identified as having one or more significant new