

(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.

§ 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 uses in subpart M of this part, and who intends either to engage in a des-

40 CFR Ch. I (7-1-07 Edition)

ignated significant new use of the microorganism or intends to distribute it in commerce. Persons excluded from reporting on significant new uses of microorganisms and additional procedures for reporting are described in subpart L of this part.

§ 725.110 Persons not subject to this subpart.

Persons are not subject to the requirements of this subpart for the following activities:

(a) Manufacturing, importing, or processing solely for research and development microorganisms that meet the requirements for an exemption under subpart E of this part.

(b) Manufacturing, importing, or processing microorganisms for test marketing activities which have been granted an exemption under subpart F of this part.

(c) Manufacturing or importing new microorganisms under the conditions of a Tier I or Tier II exemption under subpart G of this part.

§ 725.150 Procedural requirements for this subpart.

General requirements for all MCANs under this part are contained in subparts A through C of this part. In addition, the following requirements apply to MCANs submitted under this subpart:

(a) *When to submit a MCAN.* A MCAN must be submitted at least 90 calendar days prior to manufacturing or importing a new microorganism and at least 90 calendar days prior to manufacturing, importing, or processing a microorganism for a significant new use.

(b) *Section 5(b) of the Act.* The submitter must comply with any applicable requirement of section 5(b) of the Act for the submission of test data.

(c) *Contents of a MCAN.* Each person who submits a MCAN under this subpart must provide the information and test data described in §§ 725.155 and 725.160.

(d) *Recordkeeping.* Each person who submits a MCAN under this subpart must comply with the recordkeeping requirements of § 725.65.