

transfer under laboratory and relevant environmental conditions.

(iv) A description of anticipated involvement in biogeochemical or biological cycling processes, involvement in rate limiting steps in mineral or nutrient cycling, or involvement in inorganic compounds cycling (such as possible sequestration or transformation of heavy metals).

(e) *Byproducts*. A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new microorganism.

(f) *Total production volume*. The estimated maximum amount of the new microorganism intended to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any consecutive 12-month period during the first 3 years of production. This estimate may be by weight or volume and should include an estimation of viability (i.e., viable cells per unit volume or colony forming units per unit dry weight).

(g) *Use information*. A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new microorganism in the formulation for each commercial or consumer use.

(h) *Worker exposure and environmental release*. (1) For sites controlled by the submitter:

(i) The identity of sites where the new microorganism will be manufactured, processed, or used. For purposes of this section, the site for a person who imports a new microorganism is the site of the operating unit within the person's organization which is directly responsible for importing the new microorganism and which controls the import transaction. The import site may in some cases be the organization's headquarters office in the United States.

(ii) A process description of each manufacture, processing, and use operation, which includes a diagram of the major unit operations and conversions, the identity and entry point of all feedstocks, and the identity of any possible points of release of the new microorganism from the process, including a description of all controls, including en-

gineering controls, used to prevent such releases.

(iii) Worker exposure information, including worker activities, physical form of process streams which contain the new microorganism to which workers may be exposed, the number of workers, and the duration of activities.

(iv) Information on release of the new microorganism to the environment, including the quantity and media of release and type of control technology used.

(v) A narrative description of the intended transport of the new microorganism, including the means of transport, containment methods to be used during transport, and emergency containment procedures to be followed in case of accidental release.

(vi) Procedures for disposal of any articles, waste, clothing, or other equipment involved in the activity, including procedures for inactivation of the new microorganism, containment, disinfection, and disposal of contaminated items.

(2) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new microorganism, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new microorganism will occur, the number of workers exposed and the duration of exposure; procedures for transport of the new microorganism and for disposal, including procedures for inactivation of the new microorganism; and control measures which limit worker exposure and environmental release.

**§ 725.160 Submission of health and environmental effects data.**

(a) *Test data on the new microorganism in the possession or control of the submitter*. (1) Except as provided in § 725.25(h), and in addition to the information required by § 725.155(d)(3), each MCAN must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new microorganism or any microbial mixture or article containing the new

microorganism, or any combination of such activities. This includes test data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed above.

(2) A full report or standard literature citation must be submitted for the following types of test data:

- (i) Health effects data.
- (ii) Ecological effects data.
- (iii) Physical and chemical properties data.
- (iv) Environmental fate characteristics.
- (v) Monitoring data and other test data related to human exposure to or environmental release of the new microorganism.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a MCAN, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected, significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the MCAN review period ends, the person must submit the study, report, or test, as specified in paragraph (a)(3)(i) of this section, to the address listed in § 725.25(c) within 10 days of receiving it, but no later than 5 days before the end of the review period. If the test or experiment is completed during the last 5 days of the review period, the submitter must immediately inform its EPA contact for that submission by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this sec-

tion, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within 10 days of the request, but no later than 5 days before the end of the review period.

(6) All test data described under paragraph (a) of this section are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new microorganism that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in § 725.25(h), and in addition to the information required by § 725.155(c)(3), any person who submits a MCAN must describe the following data, including any data from a health and safety study of a microorganism, if the data are related to effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the microorganism, of any microbial mixture or article containing the new microorganism, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the microorganism.

(2) Data that must be described include data concerning the new microorganism in a pure culture or formulated form as used or as intended to be used in one of the activities listed in paragraph (b)(1) of this section.

(3) The description of data reported under paragraph (b) of this section must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

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(ii) If the data are not available in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described in paragraph (b) of this section are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the MCAN is submitted.

### § 725.170 EPA review of the MCAN.

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of MCANs submitted under this subpart:

(a) Length of the review period. The MCAN review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete MCAN, or the date EPA determines the MCAN is complete under § 725.33, unless the Agency extends the period under section 5(c) of the Act and § 725.56.

(b) Notice of expiration of MCAN review period. (1) EPA will notify the submitter that the MCAN review period has expired or that EPA has completed its review of the MCAN. Expiration of the review period does not constitute EPA approval or certification of the new microorganism, and does not mean that EPA may not take regulatory action against the microorganism in the future.

(2) After expiration of the MCAN review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the microorganism even if the submitter has not received notice of expiration.

(3) Early notification that EPA has completed its review does not permit commencement of manufacture or import prior to the expiration of the 90-day MCAN review period.

(c) No person submitting a MCAN in response to the requirements of this subpart may manufacture, import, or process a microorganism subject to this subpart until the review period, in-

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cluding all extensions and suspensions, has expired.

### § 725.190 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new microorganism for nonexempt, commercial purposes for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement (NOC) of manufacture or import.

(b) *When to report.* (1) If manufacture or import for nonexempt, commercial purposes begins on or after May 27, 1997, the submitter must submit the NOC to EPA no later than 30 calendar days after the first day of such manufacture or import.

(2) If manufacture or import for nonexempt, commercial purposes began or will begin before May 27, 1997, the submitter must submit the NOC by May 27, 1997.

(3) Submission of an NOC prior to the commencement of manufacture or import is a violation of section 15 of the Act.

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claimed microorganism identity confidential in the MCAN, and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and resubstantiated in accordance with § 725.85(b). Otherwise, EPA will list the specific microorganism identity on the public Inventory.

(d) *Where to submit.* NOCs should be submitted to the address listed in § 725.25(c).

## Subpart E—Exemptions for Research and Development Activities

### § 725.200 Scope and purpose.

(a) This subpart describes exemptions from the reporting requirements under subpart D of this part for research and development activities involving microorganisms.

(b) In lieu of complying with subpart D of this part, persons described in