

## Environmental Protection Agency

## § 725.190

(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.

(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, including 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).