

Environmental Protection Agency

§ 725.25

microorganism. If necessary, EPA will compare this information to the information requested for the confidential microorganism under § 725.85(b)(3)(iii).

(e) In order for EPA to make a conclusive determination of the microorganism's status, the proposed manufacturer, importer, or processor must show a *bona fide* intent to manufacture, import, or process the microorganism and must provide sufficient information to establish identity unambiguously. After sufficient information has been provided, EPA will inform the manufacturer, importer, or processor whether the microorganism is subject to this part and if so, which sections of this part apply.

(f) If the microorganism is found on the confidential version of the Inventory, in § 725.239 or in subpart M of this part, EPA will notify the person(s) who originally reported the microorganism that another person (whose identity will remain confidential, if so requested) has demonstrated a *bona fide* intent to manufacture, import, or process the microorganism and therefore was told that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part.

(g) A disclosure to a person with a *bona fide* intent to manufacture, import, or process a particular microorganism that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part will not be considered a public disclosure of confidential business information under section 14 of the Act.

(h) EPA will answer an inquiry on whether a particular microorganism is subject to this part within 30 days after receipt of a complete submission under paragraph (b) of this section.

§ 725.17 Consultation with EPA.

Persons may consult with EPA, either in writing or by telephone, about their obligations under this part. Written consultation is preferred. Written inquiries should be sent to the following address: Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, ATTN: Biotechnology Notice Consultation. Persons wishing to con-

sult with EPA by telephone should call (202) 554-1404; hearing impaired TDD (202) 554-0551 or e-mail: TSCA-Hotline@epamail.epa.gov.

Subpart B—Administrative Procedures

§ 725.20 Scope and purpose.

This subpart describes general administrative procedures applicable to all persons who submit MCANs and exemption requests to EPA under section 5 of the Act for microorganisms.

§ 725.25 General administrative requirements.

(a) *General.* (1) Each person who is subject to the notification provisions of this part must complete, sign, and submit a MCAN or exemption request containing the information as required for the appropriate submission under this part. Except as otherwise provided, each submission must include all referenced attachments. All information in the submission (unless certain attachments appear in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) In addition to specific information required, the submitter should submit all information known to or reasonably ascertainable by the submitter that would permit EPA to make a reasoned evaluation of the human health and environmental effects of the microorganism and any microbial mixture or article that may contain the microorganism.

(b) *Certification.* Persons submitting MCANs and exemption requests to EPA under this part, and material related to their reporting obligations under this part, must attach the following statement to any information submitted to EPA. This statement must be signed and dated by an authorized official of the submitter:

I certify that to the best of my knowledge and belief: The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in this submission is complete and truthful as of the date of submission. I am including