

§ 725.17

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 consult 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.

40 CFR Ch. I (7–1–10 Edition)

(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 with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 CFR 725.160 or 725.260.

(c) *Where to submit information under this part.* MCANs and exemption requests, and any support documents related to these submissions, may only be submitted in a manner set forth in this paragraph.

(1) *Paper-based submissions.* MCANs and exemption requests, and any support documents related to these submissions, may be submitted on paper on or before April 6, 2011. All paper-based submissions must be generated using e-PMN reporting software and be completed through the finalization step of the software, and e-PMN software must be used to print the biotechnology notice submission to be sent to EPA. Paper notices must be submitted either via U.S. mail to the Document Control Office (DCO) (7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or submitted via courier to the Environmental Protection Agency, OPPT Document Control Office (DCO), EPA East Bldg., 1201 Constitution Ave., NW., Rm. 6428, Washington, DC 20004.

(2) *Submissions on optical disc—*(i) MCANs and exemption requests may be submitted as electronic files on optical disc on or before April 6, 2012. MCANs and exemption requests submitted as electronic files on optical disc must be