

Environmental Protection Agency

§ 725.25

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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 with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertain-

able by me as required by 40 CFR 725.160 or 725.260.

(c) *Where to submit information under this part.* Persons submitting MCANs and exemption requests to EPA under this part, and material related to their reporting obligations under this part, must send them to: TSCA Document Processing Center (7407), Rm. L-100, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(d) *General requirements for submission of data.* (1) Submissions under this part must include the information described in § 725.155, 725.255, 725.355, or 725.455, as appropriate, to the extent such information is known to or reasonably ascertainable by the submitter.

(2) In accordance with § 725.160 or 725.260, as appropriate, the submission must also include any test data in the submitter's possession or control and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the microorganism.

(e) *Agency or joint submissions.* (1) A manufacturer or importer may designate an agent to submit the MCAN or exemption request. Both the manufacturer or importer and the agent must sign the certification required in paragraph (b) of this section.

(2) A manufacturer or importer may authorize another person (e.g., a foreign manufacturer or supplier, or a toll manufacturer) to report some of the information required in the MCAN or exemption request to EPA on its behalf. If separate portions of a joint submission are not submitted together, the submitter must indicate which information will be supplied by another person and identify that person. The manufacturer or importer and any other person supplying the information must sign the certification required by paragraph (b) of this section.

(3) If EPA receives a submission which does not include the information required, which the submitter indicates that it has authorized another person to provide, the review period will not begin until EPA receives all of the required information.

(f) *Microorganisms subject to a section 4 test rule.* (1) Except as provided in paragraph (f)(3) of this section, if a person intends to manufacture or import a new microorganism which is subject to the notification requirements of this part, and the microorganism is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 725.160. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 725.33.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the person may not file a MCAN or TERA until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(g) *Microorganisms subject to a section 5(b)(4) rule.* (1) If a person:

(i) Intends to manufacture or import a microorganism which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and

(ii) Is not required by a rule issued under section 4 of the Act to submit test data for the microorganism before the filing of a submission, the person must submit to EPA data described in paragraph (g)(2) of this section at the time the submission is filed.

(2) Data submitted under paragraph (g)(1) of this section must be data which the person submitting the notice

believes show that the manufacture, processing, distribution in commerce, use, and disposal of the microorganism, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

(h) *Data that need not be submitted.* Specific data requirements are listed in subparts D, E, F, G, and L of this part. The following is a list of data that need not be submitted under this part:

(1) Data previously submitted to EPA. (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the new submission includes: the office or person to whom the data were submitted; the date of submission; and, if appropriate, a standard literature citation as specified in § 725.160(a)(3)(ii).

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the new submission and any claim of confidentiality, under § 725.80.

(2) Efficacy data. This part does not require submission of any data related solely to product efficacy. However, including efficacy data will improve EPA's ability to assess the benefits of the use of the microorganism. This does not exempt a person from submitting any of the data specified in § 725.160 or 725.260.

(3) Non-U.S. exposure data. This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

§ 725.27 Submissions.

Each person who is required to submit information under this part must submit the information in the form and manner set forth in the appropriate subpart.

(a) Requirements specific to MCANs are described in §§ 725.150 through 725.160.

(b) Requirements specific to TERAs are described in §§ 725.250 through 725.260.