

Environmental Protection Agency

§ 725.29

(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.

[62 FR 17932, April 11, 1997, as amended at 75 FR 788, Jan. 6, 2010]

§ 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.

(c) Requirements specific to test marketing exemptions (TMEs) are described in §§ 725.350 and 725.355.

(d) Requirements specific to Tier I and Tier II exemptions for certain general commercial uses are described in §§ 725.424 through 725.470.

(e) Additional requirements specific to significant new uses for microorganisms are described at § 725.950.

§ 725.28 Notice that submission is not required.

When EPA receives a MCAN or exemption request, EPA will review it to determine whether the microorganism is subject to the requirements of this part. If EPA determines that the microorganism is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture, import, or processing of the microorganism and that the submission is not needed.

§ 725.29 EPA acknowledgement of receipt of submission.

(a) EPA will acknowledge receipt of each submission by sending a letter via CDX or U.S. mail to the submitter that identifies the number assigned to each MCAN or exemption request and the date on which the review period begins. The review period will begin on the date the MCAN or exemption request is received by the Office of Pollution Prevention and Toxics Document Control Officer.