(d) Data requirements for TME applications are set forth in § 725.355.

(e) EPA review procedures specific for TMEs are set forth in § 725.370.

(f) Subparts A through C of this part apply to any submission under this subpart.

§ 725.305 Persons who may apply under this subpart.

A person identified in this section may apply for a test marketing exemption. EPA may grant the exemption if the person demonstrates that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. A person may apply under this subpart for the following test marketing activities:

(a) A person who intends to manufacture or import for commercial purposes a new microorganism.

(b) A person who intends to manufacture, import, or process for commercial purposes a microorganism identified in subpart M of this part for a significant new use.

§ 725.350 Procedural requirements for this subpart.

General requirements for all submissions under this part are contained in subparts A through C of this part. In addition, the following requirements apply to applications submitted under this subpart:

(a) *Prenotice consultation.* EPA strongly suggests that for a TME, the applicant contact EPA for a prenotice consultation regarding eligibility for a TME.

(b) *When to submit a TME application.* Each person who is eligible to apply for a TME under this subpart must submit the application at least 45 calendar days before the person intends to commence the test marketing activity.

(c) *Recordkeeping.* Each person who is granted a TME must comply with the recordkeeping requirements of § 725.65. In addition, any person who obtains a TME must retain documentation of compliance with any restrictions imposed by EPA when it grants the TME. This information must be retained for 3 years from the final date of manufacture or import under the exemption.

§ 725.355 Information to be included in the TME application.

(a) To review a TME application, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test marketing activity. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the person on the microorganism and the test marketing activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will demonstrate that the microorganism will not present an unreasonable risk of injury to health or the environment as a result of the test marketing. The TME application must be in writing and must include at least the information described in paragraphs (b), (c), (d), and (e) of this section.

(b) When specific information is not submitted, an explanation of why such information is not available or not applicable must be included.

(c) Persons applying for a TME must submit the submitter identification and microorganism identity information required for MCANs in § 725.155(c), (d)(1), and (d)(2).

(d) Persons applying for a TME must submit phenotypic and ecological characteristics information required in § 725.155(d)(3) as it relates directly to the conditions of the proposed test marketing activity.

(e) Persons applying for a TME must also submit the following information about the proposed test marketing activity:

(1) *Proposed test marketing activity.* (i) The maximum quantity of the microorganism which the applicant will manufacture or import for test marketing.

(ii) The maximum number of persons who may be provided the microorganism during test marketing.

(iii) The maximum number of persons who may be exposed to the microorganism as a result of test marketing, including information regarding duration and route of such exposures.

(iv) A description of the test marketing activity, including its duration and how it can be distinguished from full-scale commercial production and research and development activities.