

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

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

(e) Persons applying for a TERA must also submit the following information about the proposed research and development activity:

(1) *A detailed description of the proposed research and development activity.*

(i) The objectives and significance of the activity and a rationale for testing the microorganisms in the environment.

(ii) Number of microorganisms released (including viability per volume if applicable) and the method(s) of application or release.

(iii) Characteristics of the test site(s), including location, geographical, physical, chemical, and biological features, proximity to human habitation or activity, and description of site characteristics that would influence dispersal or confinement.

(iv) Target organisms (if the microorganism(s) to be tested has an intended target), including identification of each target organism and anticipated mechanism and result of interaction.

(v) Planned start date and duration of each activity.

(vi) If State and/or local authorities have been notified of the activity, evidence of notification.

(2) *Information on monitoring, confinement, mitigation, and emergency termination procedures.* (i) Confinement procedures for the activity, access and security measures, and procedures for routine termination of the activity.

(ii) Mitigation and emergency procedures.

(iii) Measures to detect and control potential adverse effects.

(iv) Name of principal investigator and chief of site personnel responsible for emergency procedures.

(v) Personal protective equipment, engineering controls, and procedures to be followed to minimize dispersion of

the microorganism(s) by people, machinery, or equipment.

(vi) Procedures for disposal of any articles, waste, clothing, machinery, or other equipment involved in the experimental release, including methods for inactivation of the microorganism(s), containment, disinfection, and disposal of contaminated items.

#### § 725.260 Submission of health and environmental effects data.

Each TERA must contain all available data concerning actual or potential effects on health or the environment of the new microorganism that are in the possession or control of the submitter and a description of other data known to or reasonably ascertainable by the submitter that will permit a reasoned evaluation of the planned test in the environment. The data must be reported in the manner described in § 725.160(a)(3) and (b)(3).

#### § 725.270 EPA review of the TERA.

General procedures for review of all submissions under this part are contained in §§ 725.28 through 725.60. In addition, the following procedures apply to EPA review of applications submitted under this subpart:

(a) *Length of the review period.* (1) The review period for the TERA will be 60 days from the date the Document Control Officer for the Office of Pollution Prevention and Toxics receives a complete TERA, or the date EPA determines the TERA is complete under § 725.33, unless EPA finds good cause for an extension under § 725.56.

(2) A submitter shall not proceed with the research and development activity described in the TERA unless and until EPA provides written approval of the TERA. A submitter may receive early approval if a review is completed in less than 60 days.

(b) *EPA decision regarding proposed TERA activity.* (1) A decision concerning a TERA under this subpart will be made by the Administrator, or a designee.

(2) If EPA determines that the proposed research and development activity for the microorganism does not present an unreasonable risk of injury to health or the environment, EPA will notify the submitter that the TERA is