

Environmental Protection Agency

§ 725.260

(2) Summaries of all data, conclusions, and reports resulting from the conduct of the research and development activity under the TERA must be submitted to the EPA address identified in § 725.25(c) within 1 year of the termination of the activity.

§ 725.255 Information to be included in the TERA.

(a) To review a TERA, EPA must have sufficient information to permit a reasoned evaluation of the health and environmental effects of the planned test in the environment. The person seeking EPA approval must submit all information known to or reasonably ascertainable by the submitter on the microorganism(s) and the research and development activity, including information not listed in paragraphs (c), (d), and (e) of this section that the person believes will be useful for EPA's risk assessment. The TERA must be in writing and must include at least the information described in the following paragraphs.

(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 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 bio-

logical 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).