

and use of containment and inactivation controls for a particular microbial pesticide shall take into account the following:

(i) Factors relevant to the microbial pesticide's ability to survive in the environment.

(ii) Potential routes of release in air, solids, and liquids; in or on waste materials and equipment; in or on people (including maintenance and custodial personnel); and in or on other organisms such as insects and rodents.

(iii) Procedures for transfer of materials between facilities.

(iv) Plans for routine or emergency clean-up and test termination.

(2) For purposes of paragraph (e)(1) of this section, EPA will presume that compliance with the containment provisions of the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules" (51 FR 16958, May 7, 1986) constitutes selection and use of adequate containment and inactivation controls.

(3) The selection of containment and inactivation controls shall be approved by an authorized official of the organization that is conducting the test prior to commencement of the test.

(4) Records shall be developed and maintained describing the selection and use of the containment and inactivation controls, including contingency plans for emergency clean-up and test termination, that will be used during the test. These records shall be available for inspection at the test facility. In addition, these records shall be submitted to EPA at EPA's request and within the time frame specified in EPA's request.

(5) Subsequent to any EPA review of the containment/inactivation controls selected under paragraph (e)(1) of this section, changes to the controls necessary to prevent unreasonable adverse effects must be made upon EPA request. Failure to comply with EPA's request shall result in automatic revocation of the exemption from the requirement to submit a Notification.

**§ 172.46 Submission of a notification.**

(a) *When to submit a Notification.* A Notification shall be submitted for approval at least 90 days prior to the initiation of the proposed test.

(b) *Where to submit a Notification.* A Notification shall be submitted to the Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and clearly marked "ATTN: Biotechnology Notification Review."

(c) *How to format a Notification.* A Notification submitted under this section must comply with the following procedures, but is not required to comply with the format and other provisions governing submission of data in §§ 158.32 and 158.33 of this chapter. However, because data submitted with the Notification may subsequently be used to support other regulatory actions (e.g., used in EUP or registration applications), it is recommended that such data comply with EPA requirements in §§ 158.32 and 158.33 of this chapter.

(1) Each Notification must be accompanied by a transmittal document that clearly identifies the EPA action supported as a Biotechnology Notification Review.

(2) Five copies of each Notification must be submitted to EPA.

(3) Any claims of confidentiality for information submitted in the Notification must be made as described in paragraph (d) of this section.

(d) *How to make confidential business information (CBI) claims in a Notification.* Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as CBI, a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a Notification (See part 2, subpart B of this chapter). To assert such a claim, the submitter must comply with the following procedures:

(1) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time will be considered a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of the Act, with no further notice to the submitter.

(2) Of the five copies of the Notification required by paragraph (c) of this section, four copies must be complete

with the information that is claimed confidential clearly marked in the manner described in §2.203(b) of this chapter. All information claimed as confidential must be deleted from the fifth copy, but it must be otherwise complete. The first page of the fifth copy must be marked "Contains no information claimed as confidential." EPA may include the fifth copy in a public file without further notice. EPA will consider incomplete a Notification containing information claimed as CBI that is not submitted in accordance with this paragraph and will suspend the review period on the Notification until such procedures are followed.

(3) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter should refer to §2.204(e)(4) of this chapter for points to address in the substantiation. If such comments are themselves claimed confidential and are marked confidential when submitted to EPA, they will be treated as such in accordance with §2.205(c) of this chapter. EPA will consider incomplete all Notifications containing information claimed as CBI that are not accompanied by substantiation, and will suspend the review period on such Notifications until the required substantiation is provided.

(4) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent and by means of the procedures set forth in section 10 of the Act, in this subpart, and in part 2 of this chapter.

**§ 172.48 Data requirements for a notification.**

This section identifies the data and information to be included in each Notification. When specific information is not submitted, an explanation of why it is not practical or necessary to provide the information is to be provided.

(a) The identity of the microorganism which constitutes the microbial pesticide including:

(1) Summary of data supporting the taxonomic designation and its interpretation.

(2) Means and limit of detection using sensitive and specific methods (e.g., note the use of any markers that are used to distinguish the introduced population from native microorganisms). Introduction into the microbial pesticide of a unique genetic marker is encouraged.

(b) Description of the natural habitat of the parental strain of the microbial pesticide including information on:

(1) Physical and chemical features important to growth and survival of the parental strain.

(2) Biological features of the parental strain that would have an impact on the microbial pesticide (e.g., presence of phages that infect the microorganism).

(3) Competitors.

(c) Information on the host range of the microbial pesticide, if any, with an assessment of infectivity and pathogenicity to nontarget organisms.

(d) Information on survival and the ability of the microbial pesticide to increase in numbers (biomass) in the environment (e.g., in the environment into which the microbial pesticide will be introduced, and in substantially different environments that may be in the immediate vicinity). These data may be derived from the scientific literature or from tests conducted in a laboratory or other containment facility.

(e) The identity of possible transmission vectors (e.g., insects).

(f) Data on relative environmental competitiveness compared to the parental strain of the microbial pesticide.

(g) Description of the methods used to genetically modify the microbial pesticide.

(h) The identity and location of the gene segments that have been rearranged or inserted/deleted (host source, nature, and, for example, base sequence data, or restriction enzyme map of the genes).

(i) Information on the control region of the genes, and a description of the new traits or characteristics that are expressed.

(j) Data on potential for genetic transfer and exchange with other organisms and on genetic stability of any inserted sequences in the microbial pesticide.