

## Environmental Protection Agency

## § 172.50

(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.

(k) A description of the proposed testing program including:

(1) The purpose or objectives of the proposed testing.

(2) Designation of the pest organisms involved (common and scientific names).

(3) The States in which the proposed program will be conducted.

(4) The exact location of the test sites (including proximity to residences and human activities, surface water, etc.).

(5) The crops, fauna, flora, geographical description of sites, modes, dosage rates, frequency, and situation of application on or in which the pesticide is to be used.

(6) The total amount of pesticide product proposed for use in the testing.

(7) The method of application.

(8) A comparison of the natural habitat of the microbial pesticide with the proposed test site.

(9) The number of acres, structural sites, or animals/plants by State, to be treated or included in the area of experimental use.

(10) Procedures to be used to protect the test area from intrusion by unauthorized individuals.

(11) The proposed dates or periods during which the testing program is to be conducted, and the manner in which supervision of the program will be accomplished.

(12) Description of procedures for monitoring the microbial pesticide within and adjacent to the test site during the test.

(13) The method of sanitation or disposal of plants, animals, soils, farm tools, machinery etc., that will be exposed to the microbial pesticide during or after the test.

(14) Means of evaluating potential adverse effects and methods of controlling the microbial pesticide if detected beyond the test area.

(1) A statement of composition for the formulation to be tested, giving:

(1) The name and percentage by weight (or other suitable units) of each ingredient, active and inert.

(2) Production methods.

(3) Extraneous microorganisms present as contaminants.

(4) Amount and potency of any toxin present.

(5) Where applicable, the number of viable microorganisms per unit weight or volume of the product or other appropriate system for designating the quantity of active ingredient.

(m) Any additional factual information regarding the potential for unreasonable adverse effects on the environment.

### § 172.50 Response to a notification.

(a) EPA will review and evaluate each Notification as expeditiously as possible and will make a determination no later than 90 days after receipt of the complete Notification; however, under no circumstances shall the proposed test proceed until the submitter has received notice from EPA of its approval of such test.

(b) For each Notification, EPA may make the following determinations:

§ 172.52

40 CFR Ch. I (7-1-06 Edition)

(1) Require additional information from the submitter to assess the proposed test adequately.

(2) Approve the proposed test.

(3) Approve the proposed test provided that the submitter makes certain modifications to the test proposal.

(4) Require an EUP for the test.

(5) Disapprove the proposed test because of the potential for unreasonable adverse effects. Such disapproval by EPA shall be considered the equivalent of denial of an EUP and the remedies for such denial provided by § 172.10 are available to the submitter.

(c) If the proposed test is approved by EPA, then the submitter shall perform the test in the same manner described in the Notification, subject to any requirements imposed under paragraph (b)(3) of this section.

**§ 172.52 Notification exemption process.**

(a) *Initiation of the exemption process.* Pesticides may be added to the list of exemptions in § 172.45(d) by rule at EPA's initiative or in response to a petition submitted in accordance with paragraph (b) of this section.

(b) *Petitions for exemption from the requirement for a Notification—(1) Who may submit a petition.* Any person may submit a petition requesting an exemption from the notification requirements of this subpart for a specific microbial pesticide or class of microbial pesticides.

(2) *Where to submit a petition.* All petitions shall be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(3) *Content of petition.* Each petition shall contain the following:

(i) Name and address of petitioner and name, address, and telephone number of a person who may be contacted for further information.

(ii) Description of the exemption requested, including the specific microbial pesticide or class of microbial pesticides to be tested under the petition for exemption.

(iii) Basis for the petitioner's contention that the specific microbial pesticide or class of microbial pesticides meet the criteria of § 172.3 for small-

scale tests of pesticides that do not require an EUP.

(iv) Discussion of the extent to which the microbial pesticide or class of microbial pesticides covered by the petition differ from microbial pesticides that are already registered or subject to an EUP under the Act.

(4) *Administrative action on a petition.* EPA will review and evaluate petitions as expeditiously as possible and may request further information from the petitioner to assess the proposed exemption adequately. No later than 180 days after the submission of a petition, or 90 days after the last submission of additional information by the petitioner, whichever is later, EPA will take one of the following actions with respect to the petition:

(i) Grant the petition and publish a notice of proposed rulemaking in the FEDERAL REGISTER for a 45-day comment period proposing the exemption requested by the petitioner.

(ii) Grant the petition and publish a notice of proposed rulemaking in the FEDERAL REGISTER for a 45-day comment period proposing an exemption under such terms and conditions as EPA deems appropriate.

(iii) Deny the petition and provide the petitioner with a written explanation of EPA's decision.

(5) *Confidential business information (CBI) claims.* To assert a claim of confidentiality, the petitioner must comply with the applicable procedures in § 172.46(d).

(6) *Supplements, amendments, and withdrawals.* The petitioner may supplement, amend, or withdraw his or her petition in writing without EPA approval at any time prior to the granting or denial of the petition under paragraph (b)(4) of this section. The withdrawal of a petition shall be without prejudice to the resubmission of the petition at a later date.

[59 FR 45612, Sept. 1, 1994, as amended at 71 FR 35546, June 21, 2006]

**§ 172.57 Submission of information regarding potential unreasonable adverse effects.**

Any person using a microbial pesticide in small-scale testing covered by this subpart who obtains information