

**§ 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 Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b), Attention: 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 sec-

tion 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.

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

**§ 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

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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.

(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.

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(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:

(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