

Environmental Protection Agency

§ 172.45

Test or testing means any use of a microbial pesticide consistent with section 5 of the Act, including limited replicated field trials and associated activities.

Translocations of genetic material means a chromosomal configuration in which part of a chromosome becomes attached to a different chromosome, or inserts in a different location on the same chromosome.

[59 FR 45612, Sept. 1, 1994, as amended at 72 FR 61029, Oct. 26, 2007]

§ 172.45 Requirement for a notification.

(a) *Who must submit a Notification.* Notwithstanding §172.3, any person who plans to conduct small-scale testing of a type of microbial pesticide identified in paragraph (c) of this section must submit a Notification to EPA and obtain prior approval for either of the following tests:

(1) Small-scale tests that involve an intentional environmental introduction of that microbial pesticide.

(2) Small-scale tests performed in a facility without adequate containment and inactivation controls as provided in paragraph (e) of this section.

(b) *Alternative to Notification.* In lieu of a Notification, any person required to submit a Notification under paragraph (a) of this section may submit an application for an experimental use permit (EUP) to EPA for approval.

(c) *Small-scale testing that requires a Notification.* As provided in paragraph (a) of this section, and notwithstanding any other approval by any governmental entity, EPA review and approval are required prior to the initiation of any small-scale test involving either of the following microbial pesticides:

(1) Microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.

(2) Nonindigenous microbial pesticides that have not been acted upon by the U.S. Department of Agriculture (*i.e.*, either by issuing or denying a permit or determining that a permit is unnecessary; or a permit is not pending with the USDA).

(d) *Small-scale testing that does not require a Notification.* (1) Testing conducted with microbial pesticides identified in paragraph (c) of this section, but made exempt pursuant to §172.52, does not require a Notification. The following microbial pesticides (or classes of pesticides) are exempt from the notification requirement in paragraph (a) of this section:

(i) Microbial pesticides resulting from deletions or rearrangements within a single genome that are brought about by the introduction of genetic material that has been deliberately modified.

(ii) [Reserved]

(2) Testing conducted in a facility with adequate containment and inactivation controls, as provided in paragraph (e) of this section, does not require a Notification.

(e) *Selection and use of containment and inactivation controls.* (1) Selection 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 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 or 161.32 and 161.33 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