by a certified applicator, and he maintains the records required in this subsection. Each restricted use pesticide retail dealer shall maintain records at each individual dealership of each transaction where a restricted use pesticide was made available to an uncertified person for use by a certified applicator. Records of each such transaction shall be maintained for a period of 24 months after the date of the transaction, and shall include the following information:

(A) The name and address of the residence or principal place of business of the uncertified person to whom the restricted use pesticide is made available for use by a certified applicator.

(B) The name and address of the residence or principal place of business of the certified applicator who will use the restricted use pesticide.

(C) The certified applicator's certification number, the State (or other governmental unit) that issued his certification document, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(D) The product name, EPA registration number, and the State special local need registration number, granted under section 24(c) of the FIFRA (if any) on the label of the pesticide.

(E) The quantity of the pesticide made available for use in the transaction.

(F) The date of the transaction.

(G) At the time of each transaction, EPA recommends that the dealer obtain the information required in paragraph (g)(2)(ii) (A) through (C) of this section and assure himself that the restricted use pesticide is made available for use by a certified applicator by examining one of the following sets of documents:

(*1*) The original of the certified applicator's certification document, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(*2*) A photocopy or facsimile of the certified applicator's certification document, together with a statement signed by the certified applicator authorizing the uncertified person to purchase the restricted use pesticide on his behalf, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(*3*) A photocopy or facsimile of the certified applicator's certification document, together with a copy of a signed contract or agreement, between the uncertified person to whom the restricted use pesticide is being made available for use and the identified certified applicator, which provides for the use of the restricted use pesticide by the identified certified applicator, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(3) *Availability of required records.* Each pesticide dealer shall, upon request of any officer or employee of EPA duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and copy all records required to be maintained under this section.

(4) *Failure to comply.* Any person who fails to comply with the provisions of this rule may be subject to civil or criminal sanctions, under section 14 of the Act, or 18 U.S.C. 1001. Violations include failure to submit or falsification of any report required under this paragraph, failure to maintain or falsification of records as required under this section, and making available for use any pesticide classified for restricted use to a person who is not a certified commercial applicator other than in accordance with these regulations and section 3(d) of the amended FIFRA or rules promulgated thereunder.

[43 FR 24837, June 8, 1978, as amended at 48 FR 29855, June 29, 1983; 48 FR 53974, Nov. 29, 1983; 49 FR 17759, Apr. 25, 1984; 58 FR 34203, June 23, 1993; 77 FR 39642, July 5, 2012]

PART 172—EXPERIMENTAL USE PERMITS

Subpart A—Federal Issuance of Experimental Use Permits

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AUTHORITY: 7 U.S.C. 136c, 136w. Section 172.4 is also issued under 31 U.S.C. 9701.

SOURCE: 40 FR 18782, Apr. 30, 1975, unless otherwise noted.

Subpart A—Federal Issuance of Experimental Use Permits

§ 172.1 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

Act means the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

Applicant means any person who applies for an experimental use permit pursuant to section 5 of the Act.

Cooperator means any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.

Experimental animals means individual animals or groups of animals, regardless of species, intended for use and used solely for research purposes. The term does not include animals intended to be used for any food purposes

Participant means any person acting as a representative of the permittee and responsible for making available for use, or supervising the use or evaluation of, an experimental use pesticide to be applied at a specific application site.

Permittee means any applicant to whom an experimental use permit has been granted.

Value for pesticide purposes means that characteristic of a substance or mixture of substances which produces an efficacious action on a pest.

[73 FR 75599, Dec. 12, 2008]

§ 172.2 General.

(a) Pursuant to section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 983), and except as herein provided by §172.3, any person wishing to accumulate information necessary to register under section 3 of the Act and the regulations thereunder (1) a pesticide not registered with this Agency or (2) a registered pesticide for a use not previously approved in the registration of the pesticide may apply to the Administrator at any time for an experimental use permit.

(b) Pesticides under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

§ 172.3 Scope of requirement.

(a) An experimental use permit (EUP) is generally required for testing of any unregistered pesticide or any registered pesticide being tested for an unregistered use. However, as described in paragraph (b) of this section, certain of such tests are presumed not to involve unreasonable adverse effects and, therefore, do not require an EUP.

(b) Except as provided in subpart C of this part or as specifically determined by the Environmental Protection Agency (EPA), it may be presumed that EUPs are not required when:

(1) The experimental use of the pesticide is limited to:

(i) Laboratory or greenhouse tests,

(ii) Limited replicated field trials as described in paragraph (c) of this section to confirm such tests, or

(iii) Other tests as described in paragraph (c) of this section whose purpose is only to assess the pesticide's potential efficacy, toxicity, or other properties.

(2) The producer, applicator, or any other person conducting the test does not expect to receive any benefit in pest control from the pesticide's use.

(c) For purposes of paragraphs (b)(1)(ii) and (b)(1)(iii) of this section, the following types of experimental tests are presumed not to need an EUP:

(1) A small-scale test involving use of a particular pesticide that is conducted on a cumulative total of no more than 10 acres of land per pest, except that:

(i) When testing for more than one target pest occurs at the same time and in the same locality, the 10 acre limitation shall encompass all of the target pests.

(ii) Any food or feed crops involved in, or affected by, such tests (including, but not limited to, crops subsequently grown on such land which may reasonably be expected to contain residues of the tested pesticides) shall be destroyed or consumed only by experimental animals unless an appropriate tolerance or exemption from a tolerance has been established under the Federal Food, Drug, and Cosmetic Act (FFDCA) for residues of the pesticide.

(2) A small-scale test involving the use of a particular pesticide that is conducted on a cumulative total of no more than 1 surface acre of water per pest, except that:

(i) When the testing for more than one target pest occurs at the same time and in the same locality, the 1 acre limitation shall encompass all of the target pests.

(ii) Waters which are involved in or affected by such tests are not used for irrigation purposes, drinking water supplies, or body contact recreational activities.

(iii) Testing shall not be conducted in any waters which contain or affect fish, shellfish, plants, or animals taken for recreational or commercial purposes and used for food or feed, unless an appropriate tolerance or exemption from a tolerance has been established under the FFDCA for residues of the pesticide.

(3) Animal treatment tests involving the use of a particular pesticide that are conducted only on experimental animals which will not be used for food or feed, unless an appropriate tolerance or an exemption from a tolerance has been established for animal products and byproducts under the FFDCA for residues of the pesticide.

(d) The examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section are not all-inclusive and do not preclude testing in larger areas or larger numbers of units if the intended use meets the criteria of paragraph (a) of this section. However, tests which do not come within the examples in paragraphs (c)(1), (c)(2), and (c)(3) of this section, absent a specific determination by EPA to the contrary, require an EUP. Persons intending to conduct tests who are uncertain whether the testing may be conducted without a permit may submit a request for determination to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b). Such a request shall include the information listed in §172.4(b)(1)(ii) and (b)(1)(iii) and in the case of an unregistered product, the information in §172.4(b)(3)(i).

(e) Notwithstanding paragraphs (b) through (d) of this section, EPA may, on a case-by-case basis, require that certain testing of a particular pesticide or class of pesticides be carried out under an EUP, if it is determined that such EPA oversight is warranted. If EPA determines that an EUP is required, it will notify the developer of the pesticide of the need for an EUP and provide opportunity for comment or objections before imposing the requirement.

(f) No EUP is required for a substance or mixture of substances being put through tests for the sole purpose of gathering data required for approval of such substance or mixture under the FFDCA (21 U.S.C. 301 *et seq.*) as:

(1) A ''new drug'' (21 U.S.C. sec. 321(p) and sec. 355).

(2) A ''new animal drug'' (21 U.S.C. sec. 321(w) and sec. 360(b)), or

(3) An ''animal feed'' (21 U.S.C. sec. 321 (x)) containing a ''new animal drug'' (21 U.S.C. sec. 360(b)).

(g) Paragraph (f) of this section shall not apply when a purpose of such test is to accumulate information necessary to register a pesticide under section 3 of the Act.

[59 FR 45611, Sept. 1, 1994, as amended at 71 FR 35546, June 21, 2006; 73 FR 75599, Dec. 12, 2008]

§ 172.4 Applications.

(a) *Time for submission.* An application or request for amendment to an existing permit shall be submitted as far as possible in advance of the intended date of shipment or use to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

(b) *Contents of applications*—(1) *General requirements.* (i) The name and address of the applicant;

(ii) The registration number of the product, if registered;

(iii) The purpose or objectives of the proposed testing; a description in detail of the proposed testing program including test parameters; a designation of the pest organism(s) involved; the amount of pesticide product proposed for use; the crops, fauna, flora, sites, modes, dosage rates, and situation of application on or in which the pesticide is to be used; the States in which the proposed program will be conducted; the number of acres, number of structural sites, or number of animals by State to be treated or included in the area of experimental use; the proposed dates or period(s) during which the testing program is to be conducted; and the manner in which supervision of the program will be accomplished;

(iv) The name, street address, telephone number, and qualifications of all participants in the program (whether or not in the employ of the applicant). A permit must be amended to add or change participants;

(v) The name and street address of all cooperators, if available at the time an application is submitted or as soon thereafter as available;

(vi) A description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine toxicity and effects in or on target organisms at the site of application; and to determine phytotoxicity and other forms of toxicity or effects on nontarget plants, animals, and insects at or near the site of application; and to determine adverse effects on the environment;

(vii) The proposed method of storage and disposition of any unused experimental use pesticide and its containers; and

(viii) Such other additional pertinent information as the Administrator may require.

(2) *Requirement for tolerance.* If the experimental use pesticide is to be used in such a manner that any residue can reasonably be expected to result in or on food or feed, the applicant must:

(i) Submit evidence that a tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug, and Cosmetic Act; or

(ii) Submit a petition proposing establishment of a tolerance or an exemption from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act; or

(iii) Certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment. The method of such destruction or disposition shall be provided in the application for the permit.

(3) *Additional requirements for unregistered pesticide products.* (i) A complete confidential statement of composition for the formulation to be tested giving the name and percentage by weight of each ingredient, active and inert;

(ii) Chemical and physical properties of each active ingredient of the formulation to be tested, including, but not limited to, the manufacturing or laboratory processes and analytical methods suitable for determining the active ingredients in the formulation;

(iii) Appropriate date, if available, on the rate of decline of residues on the treated crop or environmental site or other information for determination

regarding entry of persons into treated areas; and

(iv) Results of toxicity tests and other data relevant to the product's potential for causing injury to the users or other persons who may be exposed, including any available epidemiological information as to man.

(c) *Fees.* The payment of fees for experimental use permits shall apply as specified in subpart U of part 152 of the chapter.

[40 FR 18782, Apr. 30, 1975, as amended at 53 FR 19115, May 26, 1988; 71 FR 35546, June 21, 2006; 73 FR 75599, Dec. 12, 2008]

§ 172.5 The permit.

(a) *Issuance.* The Experimental Use Permit shall be issued when the Administrator determines that the conditions of section 5 of the Act, and the regulations thereunder, have been met subject to such terms and conditions as the Administrator determines are warranted.

(b) *Duration.* Permits will be effective for a specified period of time, normally one year, depending upon the crop or site to be tested and the requirements of the testing program submitted. The applicant should propose a suitable duration of the permit commensurate with the program submitted. Permits and associated temporary tolerances may be renewed, extended, or amended upon request if circumstances warrant.

(c) *Limitations.* The quantity of a pesticide allowed by a permit may be less than requested if it is determined that the available information on efficacy, toxicity or other hazards, the need for data, or the adequacy of program supervision does not justify the quantity of the pesticide requested. Other limitations may also be placed in the permit if necessary for the protection of the public health and the environment.

(d) *Additions.* With respect to an experimental use pesticide containing any chemical or combination of chemicals not included in any previously registered pesticides, the Administrator may require that additional studies be conducted during the permit period to gather data to support the establishment of tolerances and/or registration. To the extent practicable, the applicant will be notified of any such requirements before or at the time an experimental use permit is issued.

(e) *Maintenance of records.* All producers of pesticides produced pursuant to an experimental use permit shall maintain records in accordance with part 169.

§ 172.6 Labeling.

(a) *Contents.* Except as provided by paragraph (b) of this section, all pesticides shipped or used under an experimental use permit shall be labeled with directions and conditions for use which shall include the following:

(1) The prominent statement, ''For Experimental Use Only'';

(2) The Experimental Use Permit number;

(3) The statement, ''Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program'';

(4) The name, brand, or trademark;

(5) The name and address of the permittee, producer, or registrant;

(6) The net contents;

(7) An ingredient statement;

(8) Warning or caution statements;

(9) Any appropriate limitations on entry of persons into treated areas;

(10) The establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and

(11) The directions for use, except that the Administrator may approve the use of the experimental program as labeling provided that such program is to be distributed with the product.

(b) *Supplemental labeling.* In the case of a registered pesticide, the Administrator may, at his discretion, permit a pesticide to be used under an experimental use permit with supplemental labeling as approved by him.

§ 172.7 Importation of technical material.

Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an Experimental Use Permit has been requested if the application for such permit states that such importation will occur.

§ 172.8 Program surveillance and reporting of data.

(a) The permittee shall supervise the test program and evaluate the results of testing at each site of application. It will further be the responsibility of the permittee to report immediately to the Administrator, or to any person designated by him, any adverse effects from use of, or exposure to, the pesticide.

(b) The permittee shall submit the following reports to the Registration Division during the experimental program.

(1) [Reserved]

(2) A final report shall be submitted within 180 days after the expiration of the permit, unless a request for extension of time is approved, and shall include:

(i) All data gathered during the testing program; field notes need not be submitted but must be maintained and submitted upon request;

(ii) A description of the disposition of any pesticide containers and any unused pesticides including amounts disposed of and the method and site of disposition; and

(iii) The method of disposition of affected food and/or feed.

The data under paragraph (b)(2)(i) of this section above may be submitted as part of an application for registration submitted within 180 days after the expiration of the permit, provided that the final report shall include a statement that such application has been made, and the date of such application.

(c) In addition to the reporting requirements provided for elsewhere in this part, in the case of any meat-producing animals or birds that receive a direct treatment or application of any experimental use pesticide, the name and location of the packing plant where the animals will be processed shall be sent to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC 20250, at least 10 days before the animals are to be shipped for slaughter. This requirement may be waived, on request, by the USDA. These provisions do not exempt treated food-producing animals and their products from compliance with other applicable inspection requirements.

(d) Failure to submit required reports may constitute grounds for revocation of the permit.

(e) For the purpose of supervising the use of experimental use pesticides, the Agency may require the permittee or any participant to give reasonable advance notification of the intended dates, times, and sites on which such experimental use pesticide will be applied.

(f) The permittee or participants in the experimental use program will permit any authorized representative of the Agency, upon presentation of official identification, entry, at any reasonable time, to any premises involved in the testing program to inspect and to determine whether there has been compliance with the terms and conditions of the permit.

[40 FR 18782, Apr. 30, 1975, as amended at 60 FR 32097, June 19, 1995]

§ 172.9 Renewals.

Applications for renewal of experimental use permits and temporary tolerances, to provide for additional testing, shall be submitted prior to expiration of the permit. Requirements for renewals are the same as for applications under § 172.4, except that information previously submitted may be incorporated by reference.

§ 172.10 Refusals to issue and revocation.

(a) *Refusal.* At any time that the Administrator determines that an experimental use permit is not justified, or that the issuance of such a permit would cause unreasonable adverse effects on the environment, or that for any other reason provided for under the law a permit shall not be issued, he shall notify the applicant in writing.

(b) *Revocation.* The Administrator may revoke an experimental use permit if he finds that its terms or conditions are being violated or that its terms or conditions are inadequate to avoid unreasonable adverse effects on the environment, or if new evidence is obtained which demonstrates that the tolerance will be inadequate to protect the public health, or for failure to meet any other provision of this part 172. The Administrator will notify the permittee in writing of such revocation.

The permittee shall notify all participants of such revocation as soon as possible after he receives notice of revocation. The revocation of a permit shall not preclude the Administrator from initiating civil or criminal sanctions for the violations of the permit conditions or otherwise as authorized by law.

(c) *Hearing.* In the event that an applicant for an experimental use permit wishes to contest the refusal to issue an experimental use permit, or an experimental use permittee wishes to contest the revocation of any such permit, he shall, within twenty days after receipt of notice of such refusal or revocation, file with the Administrator a written request for an opportunity to confer with the Administrator or his designee. Within twenty days after such conference, the applicant or permittee will be notified of the Administrator's final decision.

§ 172.11 Publication.

(a) *Notice of receipt of an experimental use permit application.* The Administrator shall publish notice in the FEDERAL REGISTER of receipt of an application for an experimental use permit upon finding that issuance of the experimental use permit may be of regional or national significance. This notice shall include:

(1) The active ingredients,
(2) Use pattern(s),
(3) Quantity of pesticide,
(4) Total acreage,
(5) Location of area of application,
(6) A statement soliciting comments from any interested persons regarding the application.

(b) *Public hearing.* The Administrator may hold a public hearing, and publish notice in the FEDERAL REGISTER of the date and location of the hearing, when he determines that there is sufficient interest in the application to warrant a hearing, based upon the comments received in response to the Notice of Receipt of an Application, or that a hearing would otherwise be in the public interest.

(c) *Issuance of experimental use permit.* The Administrator shall give prompt notice in the FEDERAL REGISTER of the issuance of an experimental use permit. The notice shall include:

(1) The active ingredients,
(2) Use pattern(s),
(3) Quantity of pesticide,
(4) Total acreage,
(5) Location of area of application,
(6) A statement indicating where the experimental use permit is available for public inspection.

Subpart B—State Issuance of Experimental Use Permits

SOURCE: 44 FR 41787, July 18, 1979, unless otherwise noted.

§ 172.20 Scope.

This subpart sets forth regulations governing State issuance of experimental use permits pursuant to section 5(f) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). It also sets forth regulations governing authorization by the Administrator of State experimental use permit programs.

§ 172.21 Definitions.

Terms used in this subpart shall have the meaning set forth in FIFRA and in § 172.1.

Designated State agency means the State agency designated by State law or other authority to be responsible for registering pesticides to meet special local needs.

Public or private agricultural research agency or educational institution means any organization engaged in research pertaining to the agricultural use of pesticides, or any educational institution engaged in pesticide research. Any research agency or educational institution whose principal function is to promote, or whose principal source of income is directly derived from, the sale or distribution of pesticides (or their active ingredients) does not come within the meaning of this term.

[73 FR 75599, Dec. 12, 2008]

§ 172.22 General.

(a) Experimental use permits are not required under this rule in those situations described in § 172.3 of subpart A pertaining to Federal experimental use permits.

(b) Subpart B is not applicable to experimental use permits issued by a

State, as required by State law, to a permittee who already holds a valid Federal experimental use permit issued under subpart A for the same purpose, or who is not required to obtain a permit under this rule.

(c) Pesticide products used under experimental use permits may not be sold or distributed other than through participants, and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit.

(d) Establishments in which pesticide products under State experimental use permits are produced shall be registered as required by 40 CFR 167.2(a) and producers of such products shall maintain books and records as required by 40 CFR 169.2.

(e) Pesticide products and their containers used under this rule must also be packaged, stored, transported, used, and disposed of in accordance with all applicable Federal laws and regulations, including the Resource Conservation and Recovery Act of 1976 as amended (Pub. L. 94–580; 90 Stat. 2795; 42 U.S.C. 6901 *et seq.*) (RCRA), and rules thereunder.

§ 172.23 State plans.

(a) *Submission.* (1) A State may, by submitting a State plan, request the Administrator to authorize the designated State agency to issue experimental use permits under section 5(f) of FIFRA.

(2) A State shall request authorization to issue experimental use permits by having the Governor or Chief Executive Officer or his designated agent submit a State plan in writing to the Administrator.

(b) *Contents.* A State plan shall include—

(1) A designation of the State agency responsible for the administration of the State experimental use permit program.

(2) An opinion of the State attorney general or the legal counsel of the designated State agency that the State has the requisite legal authorities as set forth in paragraph (c)(1)(i) of this section, accompanied by copies of the applicable State laws and regulations.

(3) A description of procedures that the designated State agency will follow:

(i) To review experimental use permit applications, to ensure that experimental use permits will be issued in accordance with the terms and conditions of the authorization, FIFRA, and this subpart; and

(ii) To supervise use pursuant to the permits, and to ensure that permits are used in accordance with their terms and conditions, FIFRA, and this subpart.

(c) *Criteria for EPA acceptance of State plan.* (1) The Administrator shall grant authorization to issue experimental use permits if the State plan establishes that the designated State agency—

(i) Has adequate legal authority under State law to implement the plan, including authority:

(A) To issue experimental use permits, subject to limitations necessary for the protection of public health and the environment;

(B) To supervise the use of a pesticide pursuant to an experimental use permit, as provided in §172.25(c);

(C) To deny an experimental use permit if it determines that a permit is not justified, or that the issuance of the permit would cause unreasonable adverse effects on the environment;

(D) To amend or revoke an experimental use permit, if the designated State agency finds that:

(*1*) The terms and conditions of the permit are being violated, or are inadequate to avoid unreasonable adverse effects on the environment;

(*2*) Any required tolerance under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) has been revoked by EPA, or any exemption from the requirement for tolerance has been withdrawn by EPA; or

(*3*) A failure by the permittee or any cooperator to meet any other provision of FIFRA or this subpart has occurred;

(E) To enter, by consent or by warrant or by other legal means, in connection with an experimental use permit, a permittee's or cooperator's premises at reasonable times in order to sample or inspect any pesticides used or property treated, to inspect any equipment or records kept, or to

observe any activities conducted, as necessary to enforce compliance with State law, the terms of the permit, and this subpart;

(F) To comply in all other respects with the requirements of this subpart, including labeling requirements; and

(ii) Utilizes procedures for the review of each permit which are adequate to ensure that the State program will be administered in accordance with the purposes of FIFRA and this subpart.

(2) After receiving a State plan, EPA shall publish a FEDERAL REGISTER notice announcing the fact and inviting interested parties to comment thereon.

(d) *Approval, rejection, and revocation.* (1) EPA shall approve or reject the State plan within 90 days after receipt of all information necessary for final review of the plan, including copies of effective statutes and regulations which satisfy the requirements of this subpart.

(2) The Administrator may at any time revoke the authorization of a State to issue experimental use permits if he determines that the designated State agency has not complied with the requirements of this subpart or with the terms and conditions of such authorization. State experimental use permits issued prior to the revocation of authority shall remain valid until they expire or until three years from the date of revocation of the State's authority, whichever comes first, unless sooner revoked by EPA under § 172.26(c) of this subpart.

(3) Notices of approval, rejection, and revocation shall be published in the FEDERAL REGISTER, as well as the basis for such approval, rejection, or revocation.

(4) Prior to rejecting or revoking authorization, the Administrator shall notify the State in writing of his intention to take such action, along with the basis for such action, and shall afford the State the opportunity for a hearing, and time to take corrective action.

§ 172.24 State issuance of permits.

(a) *General.* Upon approval of a State plan by the Administrator under § 172.23, the designated State agency is authorized to issue, amend, renew, deny or revoke experimental use permits subject to the terms of the authorization and these regulations.

(b) *Authority.* A designated State agency may issue an experimental use permit—

(1) To any person for the purpose of gathering the data necessary to support the State registration of a pesticide to meet special local needs under section 24(c), FIFRA.

(2) To any agricultural research agency or educational institution conducting work within the State for the purpose of experimentation:

(i) Which is done within the State; and

(ii) Which is not directly intended to result in the registration of a specific pesticide product.

(3) For use of a restricted use pesticide only if the pesticide is to be used by, or under the direct supervision of, an applicator certified in accordance with section 11 of FIFRA.

(c) *Limitations.* (1) In the case of applicants who need to gather data required to register a pesticide product to meet a special local need under section 24(c) of FIFRA, a State may only issue experimental use permits for the types of pesticide products and uses which it has authority to register under section 24(c).

(2) A State may not issue an experimental use permit under § 172.24(b)(1) or § 172.24(b)(2) for any of the following:

(i) A product containing an active or inert ingredient not contained in any EPA-registered product;

(ii) A product containing an active or inert ingredient which is currently subject to an EPA cancellation or suspension of registration order, or which is currently subject to an EPA notice of intent to suspend or cancel registration because of human health, environmental or efficacy considerations; except that the State may issue a permit for such a product for a purpose or in a formulation—

(A) Which was not specifically considered in, or which is not subject to, such suspension or cancellation proceedings, after consultation with appropriate EPA officials; or

(B) Which was specifically considered during such proceedings but not suspended, cancelled, or subjected to a notice of intent to suspend or cancel;

(iii) A use of a product which has been the subject of a notice of denial of registration published in the FEDERAL REGISTER pursuant to section 3(c)(6) of FIFRA and part 154 of this chapter; or

(iv) A use of a product which may involve use in or on food or feed other than as authorized under §172.24(d), *Requirement of tolerance.*

(3) A State may not issue an experimental use permit for use of a pesticide product in an area or in an amount in excess of that necessary to accomplish the purposes for which the permit was issued under paragraph (b) of this section.

(d) *Requirement of tolerance.* If the experimental use pesticide is to be used in or on food or feed, the applicant must—

(1) Submit evidence that:

(i) A tolerance or exemption from the requirement of a tolerance has been established for residues of the pesticide in or on such food or feed under section 408 of the Federal Food, Drug and Cosmetic Act; and

(ii) The proposed program would not reasonably be expected to result in residues of the pesticide in or on such food or feed in excess of that authorized under section 408 of the Federal Food, Drug and Cosmetic Act; and

(iii) All inert ingredients in the pesticide are exempted from the requirement of a tolerance under the appropriate section of 40 CFR part 180, subpart D; or

(2) Certify that the food or feed derived from the experimental program will be destroyed or fed only to experimental animals for testing purposes, or otherwise disposed of in a manner which will not endanger man or the environment. The method of destruction or disposal shall be described in the application for the permit.

[44 FR 41787, July 18, 1979, as amended at 50 FR 49020, Nov. 27, 1985; 73 FR 75599, Dec. 12, 2008]

§172.25 Administration of State programs.

(a) *General.* State experimental use permit programs shall be consistent with the Federal experimental use permit program, as set forth in subpart A of 40 CFR part 172.

(b) *Procedures leading to issuance.* An application for an experimental use permit shall be made in writing, and shall contain sufficient information, including a confidential statement of formula for any new product, to enable the State to determine whether use pursuant to the permit would be in accordance with the purposes of FIFRA and this subpart.

(c) *Labeling.* (1) New products shall bear labeling satisfying the requirements of §172.6(a), except that the prominent statement ''For Distribution and Experimental Use Only Within (State)'' shall be used in place of ''For Experimental Use Only''. The designated State agency may approve, as directions for use on labeling, the experimental program, provided such program is to be distributed with the product.

(2) The designated State agency may permit an EPA or State registered pesticide to be used under an experimental use permit with supplemental labeling as approved by the State agency. In exercising this discretion, the designated State agency shall ensure that the supplemental labeling and the registered label together satisfy the requirements of §172.6(a).

(d) *Duration.* State experimental use permits shall be issued for a specified period of time, not to exceed three years, depending upon the nature of the pest problem and the requirements of the testing program submitted. The designated State agency may renew, extend or amend the stated duration of a permit, if circumstances warrant.

(e) *Limitations.* The designated State agency shall impose such limitations in the permit as are necessary to protect health and the environment, including limitations on quantity, sites, area, disposal, and other aspects of pesticide use.

(f) *Program surveillance and reporting of data.* (1) The permittee shall supervise the test program and evaluate the results of testing at each site of application. The designated State agency shall require the permittee to report to it immediately any adverse effects resulting from use of, or exposure to, the pesticide.

(2) During the course of the program, the designated State agency shall require the permittee to submit such reports (both special and periodic) as are necessary to supervise effectively the progress of the program to prevent unreasonable adverse effects on man or the environment. The designated State agency shall also require the permittee to submit a final report at the conclusion of the program. Where applicable, such reports shall also be made available to the U.S. Department of Agriculture, Food Service and Quality Service (FSQS), as required by §172.8(c).

(g) *Disposal.* All pesticides and pesticide containers, whether disposed of during the course of a State permit or remaining at the termination of a permit, must either be:

(1) Disposed of in accordance with a disposal plan approved as part of the experimental program; or

(2) Returned to the permittee for storage or disposal in accordance with the requirements of RCRA and rules there under; or

(3) If the product is currently registered, used in accordance with the registered label.

[44 FR 41787, July 18, 1979, as amended at 60 FR 32097, June 19, 1995]

§ 172.26 EPA review of permits.

(a) *Notification of State action.* (1) Within 10 days after the issuance of an experimental use permit, the designated State agency shall notifiy EPA of the action by forwarding to the appropriate EPA Regional Office a copy of the permit, a description of the experimental program to be conducted under the terms of the permit, a copy of the approved labeling, and a copy of the confidential statement of formula for any new product.

(2) Within 10 days after amendment or revocation of an experimental use permit by a State, the designated State agency shall notify the appropriate EPA Regional Office in writing of the amendment or revocation. The notice shall include a brief explanation of the reason for the amendment or revocation. If amendments to permits include changes in the approved labeling, the designated State agency shall also forward a copy of the amended labeling.

(3) EPA shall give notice in the FEDERAL REGISTER of State issuance of experimental use permits.

(b) *Reports.* The designated State agency shall submit the following reports to EPA:

(1) An annual report covering the number of permits issued, the names and addresses of permittees, the names of the products covered by permits, and the State permit numbers issued;

(2) Reports, as requested by EPA, containing any information that EPA may determine necessary to ensure that a State has acted in compliance with provisions of FIFRA and this subpart; and

(3) Reports of any serious adverse effect(s), as soon thereafter as possible, from use of, or exposure to, a pesticide used pursuant to an experimental use permit.

(c) *Revocation by EPA.* (1) The Administrator may revoke an experimental use permit issued under this subpart if he finds:

(i) That its terms and conditions are being violated;

(ii) That its terms and conditions are inadequate to avoid unreasonable adverse effects on the environment;

(iii) That new evidence demonstrates that any tolerance upon which the permit is based will be inadequate to protect the public health, or that any exemption from the requirement for a tolerance is no longer appropriate; or

(iv) That a failure by the permittee to meet any other provisions of FIFRA or this subpart has occurred.

(2) The Administrator shall, prior to revoking a State experimental use permit, consult with the State agency which issued the permit, except in cases where continued use of the pesticide under the permit would create an imminent hazard to man or the environment.

(3) The Administrator shall notify the designated State agency, in writing, of the revocation, and the State agency shall notify the permittee, also in writing, of the revocation.

(4) The permittee shall notify all participants of the revocation within 10 days after he receives notice of revocation.

(5) The revocation of a permit shall not preclude the Administrator from

initiating civil or criminal sanctions for violations of the permit conditions or other violations, as authorized by law.

(6) If a permittee wishes to contest the revocation of a State experimental use permit, he shall, within 30 days after receipt of notice of such revocation, file with the Administrator a written request for an opportunity to confer with the Administrator or his designee. The revocation of the permit shall remain effective pending the outcome of any conference requested under this paragraph.

(7) If a permittee requests a conference under paragraph (c)(6) of this section, the Administrator shall provide the permittee:

(i) With information as to the time, place and nature of the conference, and of the matters of fact and law asserted by the Agency as grounds for the revocation action;

(ii) An opportunity to offer a written statement of facts, explanations, and arguments relevant to the revocation action;

(iii) All other procedural opportunities to which the permittee may be entitled by law.

(8) The Administrator shall notify the affected permittee and State Agency, in writing, of his final decision on the revocation matter as expeditiously as possible and shall attempt to do so within 30 days after the conclusion of a conference conducted under paragraph (c)(7). The Administrator shall also provide the permittee and the State agency with a written statement of the reasons for his decision, which shall take into account the evidence presented pursuant to paragraph (c)(7)(ii) of this section.

(9) A decision to revoke a permit under paragraph (c)(8) of this section is a final Agency action subject to judicial review as provided by law.

[44 FR 41787, July 18, 1979, as amended at 73 FR 75599, Dec. 12, 2008]

Subpart C—Notification for Certain Genetically Modified Microbial Pesticides

SOURCE: 59 FR 45612, Sept. 1, 1994, unless otherwise noted.

§ 172.43 Definitions.

Terms used in this subpart shall, with the exception of those defined below, have the meaning set forth in the Act and in §172.1.

Containment and inactivation controls means any combination of mechanical, procedural, or biological controls designed and operated to restrict environmental release of viable microorganisms from a facility.

Deliberately modified means the directed addition, rearrangement, or removal of nucleotide sequences to or from genetic material.

Introduction of genetic material means the movement of nucleotide sequences into a microorganism, regardless of the technique used.

Inversions of genetic material means the replacement of an internal section of a chromosome in the reverse orientation.

Microbial pesticide means a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaebacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

Microbial pesticides resulting from rearrangements means a microbial pesticide resulting from translocations or inversions of genetic material.

Microorganism means a bacterium, fungus, alga, virus, or protozoan.

Nonindigenous microbial pesticide means a microbial pesticide brought into one of the following geographic areas from outside that area:

(1) The continental United States, including Alaska, and the immediately adjoining countries (*i.e.*, Canada and Mexico).

(2) The Hawaiian Islands.

(3) The Caribbean Islands including Puerto Rico and the U.S. Virgin Islands.

Pesticidal property means a characteristic exhibited by a microorganism that contributes to the intentional use of the microorganism to prevent, destroy, repel, or mitigate a pest or to act as a plant regulator, defoliant, or desiccant.

Single genome means the sum total of chromosomal and extrachromosomal genetic material of an isolate and any descendants derived under axenic culture conditions from that isolate.

Small-scale test means the experimental use of a microbial pesticide in a facility such as a laboratory or greenhouse, or use in limited replicated field trials or other tests as described in §172.3(c).

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 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; 72 FR 61029, Oct. 26, 2007; 73 FR 75600, Dec. 12, 2008]

§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.

(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.

(l) 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 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 regarding potential unreasonable adverse effects on health or the environment must within 30 days of receipt of such information submit the information to EPA, unless the person has actual knowledge that EPA has been adequately informed of such information. The requirement to submit information applies both to those microbial pesticides subject to the notification requirements under §172.45(c) and those that are exempt under §172.45(d).

§172.59 Enforcement.

(a) *Imminent threat of substantial harm to health or the environment.* The use of a microbial pesticide in small-scale testing covered by this subpart (whether subject to the notification requirements of §172.45(c) or exempt under §172.45(d)) in a manner that creates an imminent threat of substantial harm to health or the environment is prohibited, and is considered a violation of section 12(a)(2)(S) of the Act.

(b) *EPA response to violations.* Under section 14 of the Act, EPA may seek civil or criminal penalties for violations of the Act. Failure to comply with the regulations in this part could result in civil or criminal penalties. Moreover, under sections 14 and 16(c) of the Act, EPA may at any time take appropriate action against violators to prevent or otherwise restrain use of a microbial pesticide in small-scale testing if it is determined that:

(1) Such use would create an imminent threat of substantial harm to health or the environment that is prohibited under paragraph (a) of this section; or

(2) The terms or conditions on which approval of the testing was granted under this subpart C are violated.