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(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.


§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.

PART 173—PROCEDURES GOVERNING THE RESCISSION OF STATE PRIMARY ENFORCEMENT RESPONSIBILITY FOR PESTICIDE USE VIOLATIONS

Sec.
173.1 Applicability.
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173.4 Informal conference and settlement.
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§ 173.1 Applicability.
These procedures govern any proceeding to rescind a State’s primary enforcement responsibility for pesticide use violations conducted under section 27(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. 136 et seq.

§ 173.2 Definitions.
For purposes of this part:
(a) Administrator means the Administrator of the United States Environmental Protection Agency or his delegate.
(b) Notice of intent to rescind means a notice to a State issued under § 173.3 which initiates a proceeding to rescind the State’s primary enforcement responsibility for pesticide use violations.
(c) State means the agency or agencies primarily responsible for enforcing pesticide use laws or regulations within the State or jurisdiction undergoing rescission proceedings.
(d) Party to the proceeding shall mean the State or the Agency’s Office of Enforcement.
(e) Presiding Officer means an attorney appointed by the Administrator to conduct the rescission proceeding. The Presiding Officer shall be an employee or representative of the Agency and shall not have had prior direct connection with the specific proceeding except in circumstances where subsequent hearings are in order.

§ 173.3 Initiation of rescission proceedings.
(a) Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out such responsibility, or cannot carry out such responsibility due to the lack of adequate legal authority, the Administrator shall notify the State in writing of his intent to rescind its primary enforcement responsibility, in whole or in part, by serving upon the State a notice of intent to rescind.
(b) The notice of intent to rescind shall:
(1) Specify those aspects of the State’s pesticide use enforcement program determined to be inadequate;
(2) Specify the facts which underlie the findings contained in the rescission notice;
(3) Have attached thereto copies of any relevant documents discoverable under the Federal Rules of Civil Procedure and the Freedom of Information Act which contain data relied upon by the Administrator in making his decision to issue the notice;
(4) Have attached thereto a copy of this part; and
(5) Be sent to the State by certified mail, return receipt requested.
(c) The State may respond in writing to the findings specified in the notice of intent to rescind.

§ 173.4 Informal conference and settlement.
(a) After receipt of a notice of intent to rescind, the State may request that an informal conference be held between appropriate State and EPA officials to discuss the findings made in the notice of intent to rescind. The informal conference shall then be held in the State. If the Administrator finds, on the basis of information submitted by the State at the conference, that the deficiencies specified in the notice did not exist or were corrected by the State, the Administrator shall issue an order withdrawing the notice of intent to rescind and terminating the rescission proceeding.
(b) At any time after receipt of a notice of intent to rescind and before the issuance of a final order, the State and EPA may resolve the issues raised in the notice by agreement. Any settlement agreement shall be in writing and signed by the parties and shall:
(1) Detail the deficiencies found in the State program;
(2) Specify the steps the State has taken or will take to remedy the deficiencies; and
(3) Set forth a precise schedule for each remedial action yet to be initiated.
(c) If a written agreement is signed by the parties, the Administrator shall issue an order withdrawing the notice of intent to rescind and terminating the rescission proceeding. If the State
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§ 173.8 Final order.

(a) If the State does not request a hearing within the sixty-day time period and the Administrator has not issued an order withdrawing the notice of intent to rescind, the Administrator shall issue a final order as soon as

§ 173.7 Hearing and recommended decision.

(a) The Presiding Officer shall:
(1) Conduct a fair and impartial hearing, without unnecessary delay;
(2) Ensure that the facts are fully elicited; and
(3) Consider all evidence, comment, and argument which is submitted by persons who will be affected by the outcome of the proceeding and which is not irrelevant, immaterial, unduly repetitious, or otherwise unreliable or of little probative value. The Presiding Officer may require any prospective witness to make available, in advance of the hearing, a brief summary of his or her testimony.

(b) If, following the close of the hearing, the Presiding Officer finds that the State has corrected, or has agreed in writing to correct, the deficiencies specified in the notice of intent to rescind or has shown that such deficiencies do not exist, the Presiding Officer shall issue a decision recommending that the notice of intent to rescind be withdrawn and that the rescission proceeding be terminated.

(c) If, following the close of the hearing, the Presiding Officer finds that the State has not corrected the deficiencies in its program, the Presiding Officer shall issue a decision recommending that the State's primary enforcement responsibility for pesticide use violations be rescinded in whole or in part.

(d) The recommended decision of the Presiding Officer shall become final Agency action forty-five (45) days after its service upon the parties and without further proceedings unless (1) an appeal to the Administrator is taken from it by a party to the proceeding, or (2) the Administrator elects, sua sponte, to review the recommended decision.

§ 173.6 Publication of the notice; scheduling the hearing.

(a) If the Administrator has not issued an order terminating the rescission proceeding within sixty (60) days after service of the notice of intent to rescind upon the State, the Administrator shall publish the notice of intent to rescind in the Federal Register. The Administrator may modify the original notice of intent to rescind before its publication by deleting those deficiencies listed in the original notice which have been corrected or which were shown not to have existed. The public may submit comments upon the matters specified in the published notice of intent to rescind within the time specified therein.

(b) Concurrently with the publication of the notice of intent to rescind, the Administrator shall schedule a hearing in the State if one has been requested by the State. The date, time, and location of the hearing shall be published in the Federal Register along with the notice of intent to rescind.

(c) If a hearing is requested and the Administrator has not issued an order terminating the rescission proceeding, the Administrator shall provide for a hearing as scheduled. Representatives of the State, EPA, and the public may present evidence at the hearing. The Administrator shall appoint a Presiding Officer who shall preside over the hearing and make a recommended decision regarding the adequacy of the State's pesticide use enforcement program. The Administrator, after consultation with the State, may prescribe additional procedures governing the conduct of the hearing.

(d) If a termination order is issued or the hearing is rescheduled after the notice of intent to rescind is published in the Federal Register, such order or notice rescheduling the hearing shall also be published in the Federal Register.

§ 173.5 Request for hearing.

A State may request a hearing before a Presiding Officer not later than sixty (60) days after receipt of a notice of intent to rescind.
practicable after the time for public comment on the notice of intent to rescind has elapsed. The final order shall either withdraw the notice of intent to rescind and terminate the proceeding or rescind, in whole or in part, the State’s primary enforcement responsibility for pesticide use violations.

(b) If a hearing has been held and the Presiding Officer has made a recommended decision, then either the Office of Enforcement or the State may appeal the recommended decision to the Administrator or the Administrator may elect to review the recommended decision on his own initiative.

(c) After an appeal or sua sponte review the Administrator shall issue a final order terminating the rescission proceeding or rescinding, in whole or in part, the State’s primary enforcement responsibility for pesticide use violations.

(d) In no event may the Administrator issue his final decision sooner than ninety (90) days after service of the notice of intent to rescind on a State.

(e) Any final order, or a recommended decision which becomes a final order under §173.7(c), shall be published in the FEDERAL REGISTER.

§ 173.9 Judicial review.

The State may appeal an order rescinding, in whole or in part, its primary enforcement responsibility for pesticide use violations to the appropriate federal court pursuant to section 16 of FIFRA.

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

Subpart A—General Provisions

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174.511 Bacillus thuringiensis Cry1Ab protein in all plants; exemption from the requirement of a tolerance.