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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

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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 viola-

tions 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

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AUTHORITY: 7 U.S.C. 136w and 136w-2.

SOURCE: 46 FR 26059, May 11, 1981, unless otherwise noted.

§ 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