

ICR 2311.02 -- Attachment B-2

Title 40: Protection of Environment

[PART 162—STATE REGISTRATION OF PESTICIDE PRODUCTS](#)

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

Authority: 7 U.S.C. 136v, 136w.

Source: 46 FR 2014, Jan. 7, 1981, unless otherwise noted.

§ 162.150 General.

(a) *Scope.* This subpart sets forth regulations governing the registration by any State of pesticide products, or uses thereof, formulated for distribution and use within the State to meet special local needs under sec. 24(c) of the Act. It also sets forth regulations governing the exercise by the Administrator of the power to disapprove specific State registrations and to suspend a State's registration authority under sec. 24(c). Unless otherwise indicated, any reference herein to registrations issued by a State includes amendments of registrations issued by States.

(b) *Applicability.* This subpart applies only to State registration authority granted by sec. 24(c) of FIFRA. It does not apply to any authority granted, or procedures established, by State law with respect to registration, licensing, or approval required for use within the State of federally registered pesticide products.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988; 60 FR 32097, June 19, 1995]

§ 162.151 Definitions.

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this subpart, the following terms shall apply:

Federally registered means currently registered under section 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 by the Secretary of Agriculture or under FIFRA by the Administrator.

Manufacturing-use product means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after reformulation or repackaging.

New product means a pesticide product which is not a federally registered product.

Pest problem means:

- (1) A pest infestation and its consequences, or
- (2) Any condition for which the use of plant regulators, defoliant, or desiccants would be appropriate.

Product or pesticide product means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

Similar composition means a pesticide product which contains only the same active ingredient(s), or combinations of active ingredients, and which is in the same toxicity category, as defined in §156.62 of this chapter, as a federally registered pesticide product.

Similar product means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

Similar use pattern means a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under part 156 of this chapter, and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

Special local need means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

State or State lead agency means the State agency designated by the State to be responsible for registering pesticides to meet special local needs under section 24(c) of the Act.

[73 FR 75597, Dec. 12, 2008]

§ 162.152 State registration authority.

(a) *Statutory limitations.* In accordance with sec. 24(c) of the Act, each State is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

- (1) There is a special local need for the use within the State;
- (2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 *et seq.*), if the use is a food or feed use;
- (3) Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and
- (4) The registration is in accord with the purposes of FIFRA.

(b) *Types of registrations* —(1) *Amendments to federal registrations.* (i) Subject to the provisions of paragraphs (a) and (b)(1)(ii) through (iv) of this section, States may register any new use of a federally registered pesticide product.

(ii) A State may register any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended, or cancelled by the Administrator, provided that the State may register a use not considered by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.

(iii) Except as provided in paragraph (a)(3) of this section, a State may register any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant, provided that a State may register such a use only after the State has consulted with appropriate EPA personnel.

(iv) A State may not register an amendment to a federally registered manufacturing-use product.

(2) *New products.* (i) Subject to the provisions of paragraph (a) and subparagraphs (b)(2) (ii) and (iii) of this section, a State may issue registrations to meet special local needs for the following types of new end-use products:

(A) A product which is identical in composition to a federally registered product, but which has differences in packaging, or in the identity of the formulator.

(B) A product which contains the same active and inert ingredients as a federally registered product, but in different percentages.

(C) Subject to the requirements of paragraph (b)(2)(ii) of this section, a product containing a new combination of active, or active and inert, ingredients.

(ii) A State may register a new product only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product.

(iii) A State may not register a new manufacturing-use product.

(iv) A State may register any use of a new product containing an ingredient described in paragraph (a)(3) of this section, if the new product registration is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily cancelled without a prior notice of intent to cancel by the Administrator. However, a formulation or use of such a new product which was not considered by the Administrator during such proceedings, or which was not the subject of a notice of intent to cancel, may be registered by a State only after the State consults with appropriate EPA personnel regarding the registration application.

(c) *Effect of State registration.* (1) A State registration issued under FIFRA sec. 24(c) which meets the conditions described in paragraphs (a) and (b) of this section, and which is not disapproved by the Administrator under §162.154, shall be considered a federal registration, but shall authorize distribution and use only within that State. Accordingly, such registrations are subject to all provisions of FIFRA which apply to currently registered products, including provisions for cancellation and suspension of registrations, and reregistration of products.

(2) A State may require, as a condition of distribution or use of a pesticide product within the State, that the pesticide product be registered under State law as well as under FIFRA. Neither FIFRA sec. 24(c) nor §§162.150–162.156 affects a State's right under its own law to revoke, suspend, cancel, or otherwise affect such a registration issued under State law. However, the federal registration, whether issued under FIFRA sec. 3 or 24(c), is not affected by such a State action.

[46 FR 2014, Jan. 7, 1981, as amended at 73 FR 75597, Dec. 12, 2008]

§ 162.153 State registration procedures.

(a) *Application for registration.* States shall require all applicants for registration to submit the following information:

(1) Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.

(2) The name of the pesticide product, and, if the application is for an amendment to a federally registered product, the EPA registration number of that product.

(3) A copy of proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of:

(i) For a new product, a copy of the complete proposed labeling; or,

(ii) For an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product.

(4) The complete formula of the product, if the application is for a new product registration.

(5) Any other information which is required to be reviewed prior to registration under this section.

(b) *Special local need determination.* In reviewing any application for registration, the State shall determine whether there is a special local need for the registration. Situations which a State may consider as not involving a special local need may include, but are not limited to, applications for registrations to control a pest problem present on a nationwide basis, or for use of a pesticide product registered by other States on an interregional or nationwide basis.

(c) *Unreasonable adverse effects determination.* (1) Prior to issuing a registration in the following cases, the State shall determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices:

(i) For use of a product which has a composition not similar to any federally registered product.

(ii) For use of a project involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition.

(iii) For use of a product for which other uses of the same product, or of a product with a similar composition, have had registration denied, disapproved, suspended, or cancelled by the Administrator.

(2) Determinations required by paragraph (c)(1) of this section shall be based on data and criteria consistent with those sections of part 152 of this chapter, applicable to the type of product or use under consideration. Such determinations may also involve consideration of the effect of the anticipated classification of the product or use under paragraph (g) of this section.

(d) *Efficacy determination.* Prior to registration of any use of a product for public health purposes—that is, a use which could result in substantial harm to the public health if the product does not perform its intended function, the State shall determine that the product warrants the claims made for it in the registration application. Such determinations shall be based on criteria specified in applicable sections of part 152 of this chapter and on any additional criteria established by the State.

(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practical after a registration is issued in order to verify compliance with this paragraph.

(2) For a new product, the State must, as a condition of the registration, require that the product be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria of §156.10 of this chapter. New product labeling must all contain:

(i) A statement identifying the State where registration is to be valid.

(ii) The special local need registration number assigned by the State.

(3) Except as provided in paragraph (e)(4) of this section, as a condition for a registration of an additional use of a federally registered product, the State must require that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid.

(ii) Directions for use to meet the special local need which satisfy the criteria of §156.10(i) of this chapter.

(iii) The trade name of the product.

(iv) The name and address of the section 24(c) registrant.

(v) The EPA registration number of the federally registered product.

(vi) The special local need registration number assigned by the State.

(vii) A statement prohibiting use of the product in a manner inconsistent with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product and accompanying supplemental labeling.

(4) When a federally registered product is already in the stream of commerce at the time the State issues a registration for an additional use of that product, the State must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph (e)(3) of this section, is made available to purchasers and users of the product within 45 days of the date on which the State approves the final printed supplemental labeling.

(5) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

(f) *Packaging and coloration standards.* All products registered by a State must meet all appropriate packaging standards prescribed by the Administrator under sec. 25(c)(3) of FIFRA. State registered products must also meet all appropriate standards for coloration, or discoloration, established by regulation under sec. 25(c) of FIFRA, including the standards contained in subpart H of part 153 of this chapter. Prior to issuing any registration, the State shall determine that the product will conform to these requirements.

(g) *Classification.* (1) As part of the registration of any product or use, a State shall classify the product or use as a restricted use pesticide if:

(i) The product is identical or similar in composition to a federally registered product:

(A) For which all federally registered uses have been classified as restricted by the Administrator; or

(B) For which a use similar to the State registered use has been classified as restricted by the Administrator; or

(ii) The State registered product or use meets the criteria for classification as a restricted use pesticide under the applicable provisions of §152.170 of this chapter.

(2) [Reserved]

(h) *Notification and submission of data.* (1) Within ten working days from the date a State issues, amends, or revokes a registration, the State shall notify EPA, in writing, of the action. Notification of State registrations, or amendments thereto, shall include the effective date of the registration or amendment, a confidential statement of the formula of any new product, and a copy of the draft labeling reviewed and approved by the State, provided that labeling previously approved by the Administrator as part of a federal registration need not be submitted.

(2) Notification of State registrations or amendments shall be supplemented by the State sending to EPA a copy of the final printed labeling approved by the State within 60 days after the effective date of the registration or amendment.

(3) Notification of revocation of a registration by a State shall indicate the effective date of revocation, and shall state the reasons for revocation.

(4) The Administrator or his designee may request, when appropriate, that a State submit to EPA any data used by the State to determine that unreasonable adverse effects will not be caused when the State registers any use described in paragraph (c)(1) of this section. Within 15 working days of receipt of such a request from EPA, the State shall submit two copies of the requested data.

(i) *Federal Register publication.* The Administrator shall publish in the Federal Register, on a regular basis, a summary of all State registrations made under sec. 24(c) during a previous reporting period established by the Administrator. For each product or use registered, the notice shall indicate:

(1) The name of the product.

(2) The name of the registrant.

(3) The registered use(s) of the product.

(4) The effective date of the State registration.

(5) If the registration is for an additional use of a federally registered product, whether the State registration involves a changed use pattern.

(j) *Electronic reporting under State registration of pesticide products for special local needs.* States that choose to receive electronic documents under the regulations pertaining to state registration of pesticides to meet special local needs, must ensure that the requirements of 40 CFR Part 3—(Electronic reporting) are satisfied by their state procedures for such registrations.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988; 60 FR 32097, June 19, 1995; 70 FR 59888, Oct. 13, 2005; 73 FR 75597, Dec. 12, 2008]

§ 162.154 Disapproval of State registrations.

(a) *General disapprovals.* (1) Except as provided in paragraph (b) of this section, the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have both a similar composition and a similar use pattern; provided that the Administrator may not disapprove such a registration solely because of a lack of essentiality. Grounds for disapproval of State registrations not involving similar products may include, but are not limited to:

(i) Probable creation of unreasonable adverse effects on man or the environment by the registered use.

(ii) Refusal of the registering State to submit information supporting the registration as required by §162.153(h).

(iii) Failure of information submitted by the State to support the State's decision to issue the registration under standards established by §162.153.

(2) Prior to disapproval of any State registration under this paragraph, the Administrator shall notify the registering State, in writing, of the Administrator's intent to disapprove, and of the reasons for disapproval. The notice of intent will provide a reasonable time, not less than ten days from the date the notice is received by the State, for the State to respond, and will invite the State to consult with the Administrator or his designee. If the grounds for disapproval are based on actions or omissions by the State, the notice will, if possible, also provide the State with a reasonable amount of time in which to take corrective action, not to exceed the time allowed for disapproval under paragraph (c) of this section.

(3) The registering State may, within ten days of receipt of a notice of intent to disapprove, request that the Administrator, or his designee, consult with appropriate State officials prior to the Administrator's final decision on disapproval. The Administrator will consider any relevant information presented at such a consultation, or in any other timely and appropriate fashion, in deciding whether to withdraw the notice of intent to disapprove.

(b) *Special disapprovals.* (1) The Administrator may disapprove any State registration, including a registration for a similar product, at any time, if the Administrator determines that use of the product under the State registration:

(i) Would constitute an imminent hazard.

(ii) May result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a *et seq.*).

(2) If the Administrator disapproves a registration under this paragraph, the Administrator shall provide the registering State with written notification of disapproval, in accordance with paragraph (c) of this section, as soon thereafter as practicable. Such notification will specify the grounds for disapproval and invite the State to comment on the decision.

(3) If requested by the State within ten days of its receipt of a notice of disapproval, the Administrator, or his designee, will consult with appropriate State officials. The Administrator may consider any information presented at such a consultation, or in any other appropriate fashion, in determining whether the disapproval should be rescinded.

(c) *Decision and notification of disapproval.* Except as provided in paragraph (b)(1) of this section, the Administrator will make a final decision on disapproval of a State registration, and provide written notification thereof to the State, within 90 days of the effective date of the registration; provided that, if the State does not notify the Agency of a registration within ten days of its effective date, then the Administrator will make a final decision on disapproval within 90 days of the date on which EPA receives notification of the State registration. The notice of disapproval will specify an appropriate date on which the disapproval will become effective. Disapproval may become effective immediately, or at anytime within the period allowed for the Administrator to make a final decision on disapproval. The notice of disapproval will also, when appropriate, give instructions for use or disposal of the pesticide. Each notice of disapproval will be published in the Federal Register.

(d) *Effect of disapproval.* If a registration issued by a State is disapproved by the Administrator, that registration will not be valid for any purpose under FIFRA, as of the date the disapproval becomes effective. Thereafter, distribution or sale of the pesticide, in either interstate or intrastate commerce, for uses subject to the disapproval will be a violation of sec. 12(a)(1) of FIFRA.

(e) *Rescission of disapproval.* If the Administrator determines, after consultation with the State lead agency, that a registration, previously issued by the State and disapproved by the Administrator, should not have been disapproved under FIFRA, then the Administrator shall rescind the disapproval. The Administrator shall send written notification of the rescission to the State. In addition, the Administrator shall publish notice of any rescission of disapproval in the Federal Register.

(f) *Notification of registrants.* Any State that issues a registration which has been disapproved, or which is subject to a notice of intent to disapprove, shall be responsible for notifying the affected registrant of any such notice of intent or disapproval, and of any recession of disapproval by the Administrator.

§ 162.155 Suspension of State registration authority.

(a) *General.* (1) If the Administrator finds that a State is not capable of exercising, or has failed to exercise, adequate control over its registration program, so that the State cannot ensure that registrations issued by it will be in accord with the purposes of FIFRA, then the Administrator may suspend the State's authority to register pesticides under sec. 24(c) of the Act. Registrations issued by the State after suspension of its authority will not be considered valid under FIFRA. Registrations issued by the State prior to suspension will not be affected by the suspension.

(2) The Administrator may suspend all or any part of a State's registration authority, as appropriate.

(b) *Grounds for suspension.* (1) The Administrator may suspend a State's registration authority due to lack of, or failure to exercise, adequate control by the State over its sec. 24(c) registration program. Adequate control includes, but is not limited to, all of the following:

(i) Access to appropriate scientific and technical personnel to review data and make determinations as required by §162.153.

(ii) Registration procedures satisfying §162.153.

(iii) Complete and accurate records of State registrations.

(iv) Adequate legal authority. (A) To deny, suspend, revoke, or amend a State registration when the registration is not in compliance with FIFRA, this subpart, or State law, or when necessary to prevent unreasonable adverse effects on the environment.

(B) To enter, at reasonable times, by consent, warrant, or other legal means, any establishment where pesticides are produced or held for distribution or sale, to inspect, sample, and observe whether pesticides are being produced or distributed in compliance with FIFRA, this subpart, State law, and the terms of any State registration.

(2) The Administrator may suspend a State's registration authority if the State fails to exercise the controls specified in paragraph (b)(1) of this section, or if the State refuses to correct within a reasonable time any other significant deficiencies in its regulatory program, as specified by the Administrator in a notice of intent to suspend.

(c) *Procedures for suspension.* (1) Prior to suspending the registration authority of any State, the Administrator will notify the State lead agency, in writing, of the Administrator's intent to suspend, and of the specific grounds for suspension. The notice of intent will specify whether the suspension will be complete or partial, and will provide the State an opportunity to respond and a reasonable amount of time, not less than 30 days from the date the notice is received, in which to correct the deficiencies specified in the notice. If the State does not correct the specified deficiencies within the reasonable time allowed by the notice, or if the Administrator has not withdrawn the notice of intent before that time, the notice of intent will be published in the Federal Register, and the public given an opportunity to comment thereon.

(2) If requested by the affected State lead agency within 30 days of receipt of the notice of intent to suspend, an informal consultation between appropriate State and EPA officials will be held to discuss the proposed suspension. In such a case, the Administrator shall not make a final decision on the proposed suspension until after the consultation. The Administrator shall consider all relevant information presented at the consultation, or in any other appropriate manner, in determining whether to suspend the State's authority. If the Administrator determines, on the basis of such information, that the deficiencies listed in the notice of intent no longer exist, or will be corrected in a reasonable time, then the Administrator will withdraw, in writing, the notice of intent to suspend.

(3) Within ten days of the date a notice of intent to suspend is published in the Federal Register, a State may request a public hearing to consider the proposed suspension. If a hearing is requested, the Administrator will:

(i) Schedule a public hearing to be held in that State.

(ii) Publish in the Federal Register a notice announcing the date, time, and location of the hearing.

(iii) Appoint a presiding officer who shall preside over the hearing.

(iv) Prescribe additional, appropriate procedures for the conduct of the hearing, including procedures for the presentation of relevant material evidence from the State, EPA, or members of the public who would be affected by the outcome of the hearing. Evidence may be presented in either oral or written form, at the discretion of the Administrator.

(4) Following the close of any hearing held under paragraph (c)(3) of this section, the presiding officer shall make a recommended decision that the State's authority to register pesticides under sec. 24(c) of FIFRA be suspended, in whole or in part, or that the State's authority not be suspended and that the notice of intent to suspend be withdrawn.

(5) Any recommended decision made by a presiding officer under paragraph (c)(4) of this section may be appealed to the Administrator within 30 days after its issuance by the State or by EPA. Any recommended decision which is not appealed, or which the Administrator does not review on his own initiative, will become a final Agency action 30 days after its issuance.

(6) If no hearing is requested under paragraph (c)(3) of this section, or if a recommended decision is appealed to the Administrator under paragraph (c)(5) of this section, the Administrator shall issue a final order either suspending the State's authority to register pesticides under section 24(c) of FIFRA, in whole or in part, or withdrawing the notice of intent to suspend.

(7) Any final order suspending State registration authority, issued under paragraph (c) (5) or (6) of this section, will specify the grounds therefor and an effective date for the suspension. If the suspension is merely partial, the notice of suspension will specify the types of registrations which will not be recognized as valid under sec. 24(c). All final orders issued under paragraph (c) (5) or (6) will be published in the Federal Register.

(d) *Termination of suspension.* Suspension of a State's authority will be effective for the period specified in the notice of suspension, or if no period was specified, until such time as the Administrator is satisfied that the State can and will exercise adequate control over its program. In the latter case, the Administrator will notify the State that the

suspension is terminated, or that it will be terminated on a specific date. In either case, the Administrator will publish a notice of the termination of suspension in the Federal Register.

(e) *Judicial review.* Any State whose authority to register pesticides has been finally suspended by the Administrator may seek judicial review of the Administrator's decision under sec. 16 of FIFRA, at any time prior to termination of the suspension. Such suspension shall remain in effect during the period of judicial review unless otherwise ordered by the Administrator.

§ 162.156 General requirements.

(a) *Requirements for distribution and use.* (1) Any product whose State registration has been issued in accordance with §§162.152 and 162.153 may be distributed and used in that State, subject to the following provisions of the Act and the regulations promulgated thereunder:

(i) Sec. 12(a)(1) (A) through (E), in accordance with:

(A) Sec. 2(q)(1) (A) through (G).

(B) Sec. 2(q)(2) (A) through (D).

(ii) Sec. 12(a)(2) (A) through (G) and (I) through (P).

(2) A product or use classified by a State for restricted use under §162.153(g) may be used only by, or under the direct supervision of, an applicator certified under a plan approved by EPA in accordance with sec. 4 of FIFRA.

(3) State registrations which are not issued in accordance with §162.152 (a) and (b)(2) (i), (ii) and (iii) are not authorized by section 24(c) and are not considered valid for any purposes under FIFRA. When the Administrator determines that a registration is invalid, the Administrator shall notify the registering State that the registration is invalid, and may specify the reason for the invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with sec. 7 of FIFRA and 40 CFR part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under sec. 24(c), must maintain records in accordance with the requirements imposed under sec. 8 of FIFRA and 40 CFR part 169.