

Environmental Protection Agency

§ 162.152

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.

Unless otherwise indicated, terms used in this subpart have the meanings set forth in FIFRA and in subpart A of this part. In addition, as used in this subpart, the following terms have the meanings set forth below:

(a) *Federally registered* means currently registered under sec. 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (Pub. L. 86-139; 73 Stat. 286; June 25, 1947) by the Secretary of Agriculture or under FIFRA by the Administrator.

(b) *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 re-formulation or repackaging.

(c) *New product* means a pesticide product which is not a federally registered product.

(d) *Pest problem* means (1) a pest infestation and its consequences, or (2) any condition for which the use of plant

regulators, defoliants, or desiccants would be appropriate.

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

(f) *Similar composition* refers to a pesticide product which contains only the same active ingredient(s), or combination of active ingredients, and which is in the same category of toxicity, as a federally registered pesticide product.

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

(h) *Similar use pattern* refers to 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 § 156.10(h) 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.

(i) *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.

(j) *State or State lead agency* as used in this subpart means the State agency designated by the State to be responsible for registering pesticides to meet special local needs under sec. 24(c) of the Act.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988]

§ 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)(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,

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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.

§ 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 § 162.153(h).

(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: