

Environmental Protection Agency

§ 162.153

§ 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.

(6) *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.

(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:

(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.

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§ 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