

Environmental Protection Agency

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sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

§ 152.114 Approval of registration under FIFRA sec. 3(c)(7)—Products that contain a new active ingredient.

An application for registration of a pesticide containing an active ingredient not in any currently registered product may be conditionally approved for a period of time sufficient for the generation and submission of certain of the data necessary for a finding of registrability under FIFRA sec. 3(c)(5) if the Agency determines that:

(a) Insufficient time has elapsed since the imposition of the data requirement for those data to have been developed;

(b) All other required test data and materials have been submitted to the Agency;

(c) The criteria in § 152.112(a), (b), (d), and (f) through (h) have been satisfied;

(d) The use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment; and

(e) The registration of the pesticide product and its subsequent use during the period of the conditional registration are in the public interest.

§ 152.115 Conditions of registration.

(a) *Substantially similar products and new uses.* Each registration issued under § 152.113 shall be conditioned upon the submission or citation by the registrant of all data which are required for unconditional registration of his product under FIFRA sec. 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered. If a notice requiring submission of such data has been issued under FIFRA sec. 3(c)(2)(B) prior to the date of approval of the application, the applicant must submit or cite the data described by that notice at the time specified by that notice. The applicant must agree to these conditions before the application may be approved.

(b) *New active ingredients.* Each registration issued under § 152.114 shall be conditioned upon the applicant's agreement to each of the following conditions:

(1) The applicant will submit remaining required data (and interim reports if required) in accordance with a schedule approved by the Agency.

(2) The registration will expire upon a date established by the Agency, if the registrant fails to submit data as required by the Agency. The expiration date will be established based upon the length of time necessary to generate and submit the required data. If the studies are submitted in a timely manner, the registration will be cancelled if the Agency determines, based on the data (alone, or in conjunction with other data), that the product or one or more of its uses meets or exceeds any of the risk criteria established by the Agency to initiate a special review. If the Agency so determines, it will issue to the registrant a Notice of Intent to Cancel under FIFRA sec. 6(e), and will specify any provisions for sale and distribution of existing stocks of the pesticide product.

(3) The applicant will submit an annual report of the production of the product.

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(c) *Other conditions.* The Agency may establish, on a case-by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7).

(d) *Cancellation if condition is not satisfied.* If any condition of the registration of the product is not satisfied, or if the Agency determines that the registrant has failed to initiate or pursue appropriate action towards fulfillment of any condition, the Agency will issue a notice of intent to cancel under FIFRA sec. 6(e).

[53 FR 15980, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 152.116 Notice of intent to register to original submitters of exclusive use data.

(a) Except as provided in paragraph (c) of this section, at least 30 days before registration of a product containing an active ingredient for which a previously submitted study is eligible for exclusive use under FIFRA sec. 3(c)(1)(F)(i), the Agency will notify the original submitter of the exclusive use study of the intended registration of the product. If requested by the exclusive use data submitter within 30 days, the Agency will also provide the applicant's list of data requirements and method of demonstrating compliance with each data requirement.

(b) Within 30 days after receipt of the Agency's notice, or of the applicant's list of data requirements, whichever is later, the exclusive use data submitter may challenge the issuance of the registration in accordance with the procedures in §152.99 (b) and (c). If the Agency finds that the challenge has merit, it will issue a notice of denial of the application. The applicant may then avail himself of the hearing procedures provided by FIFRA sec. 3(c)(6). If the Agency finds that the challenge is without merit, it will deny the petition and register the applicant's product. Denial of the petition is a final Agency action.

(c) If an applicant has submitted to the Agency a certification from an exclusive use data submitter that he is aware of the applicant's application for registration, and does not object to the issuance of the registration, the Agency will not provide the 30-day notification described in paragraph (a) of this

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section to that exclusive use data submitter.

[53 FR 15980, May 4, 1988, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.117 Notification to applicant.

The Agency will notify the applicant of the approval of his application by a Notice of Registration for new registration, or by a letter in the case of an amended registration.

§ 152.118 Denial of application.

(a) *Basis for denial.* The Agency may deny an application for registration if the Agency determines that the pesticide product does not meet the criteria for registration under either FIFRA sec. 3(c)(5) or (7), as specified in §§152.112 through 152.114.

(b) *Notification of applicant.* If the Agency determines that an application should be denied, it will notify the applicant by certified letter. The letter will set forth the reasons and factual basis for the determination with conditions, if any, which must be fulfilled in order for the registration to be approved.

(c) *Opportunity for remedy by the applicant.* The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action. During this time the applicant may request that his application be withdrawn.

(d) *Notice of denial.* If the applicant fails to correct the deficiencies within the 30-day period, the Agency may issue a notice of denial, which will be published in the FEDERAL REGISTER, and which will set forth the reasons and the factual basis for the denial.

(e) *Hearing rights.* Within 30 days following the publication of the notice of denial, an applicant, or any interested person with written authorization of the applicant, may request a hearing in accordance with FIFRA sec. 6(b). Hearings will be conducted in accordance with part 164 of this chapter.

§ 152.119 Availability of material in support of registration.

(a) The information submitted to support a registration application shall be part of the official Agency file for that registration.