

Environmental Protection Agency

§ 152.118

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.

(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)(D)(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 ex-

clusive 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 section to that exclusive use data submitter.

§ 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.