

Environmental Protection Agency

§ 152.118

(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.

(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 appli-

cant'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 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.

§ 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.

(b) Within 30 days after registration, the Agency will make available for public inspection, upon request, the materials required by subpart E to be submitted with an application. Materials that will be publicly available include an applicant's list of data requirements, the method used by the applicant to demonstrate compliance for each data requirement, and the applicant's citations of specific studies in the Agency's possession if applicable.

(c) Except as provided by FIFRA sec. 10, within 30 days after registration, the data on which the Agency based its decision to register the product will be made available for public inspection, upon request, in accordance with the procedures in 40 CFR part 2.

Subpart G—Obligations and Rights of Registrants

SOURCE: 53 FR 15983, May 4, 1988, unless otherwise noted.

§ 152.122 Currency of address of record and authorized agent.

(a) The registrant must keep the Agency informed of his current name and address of record. If the Agency's good faith attempts to contact the registrant are not successful, the Agency will issue in the FEDERAL REGISTER a

notice of intent to cancel all products of the registrant under FIFRA sec. 6(b). The registrant must respond within 30 days requesting that the registrations be maintained in effect, and providing his name and address of record. If no response is received, the cancellations will become effective at the end of 30 days without further notice to the registrant. The Agency may make provision for the sale and distribution of existing stocks of such products after the effective date of cancellation.

(b) The registrant must also notify the Agency if he changes his authorized agent.

§ 152.125 Submission of information pertaining to adverse effects.

If at any time the registrant receives or becomes aware of any factual information regarding unreasonable adverse effects of the pesticide on the environment that has not previously been submitted to the Agency, he shall, in accordance with FIFRA sec. 6(a)(2), provide such information to the Agency, clearly identified as FIFRA 6(a)(2) data.

[53 FR 15975, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 152.130 Distribution under approved labeling.

(a) A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency.

(b) A registrant may distribute or sell a product under labeling bearing any subset of the approved directions for use, provided that in limiting the uses listed on the label, no changes would be necessary in precautionary statements, use classification, or packaging of the product.

(c) Normally, if the product labeling is amended on the initiative of the registrant, by submission of an application for amended registration, the registrant may distribute or sell under the previously approved labeling for a period of 18 months after approval of the revision, unless an order subsequently issued by the Agency under FIFRA sec. 6 or 13 provides otherwise. However, if paragraph (d) of this section applies to the registrant's product, the time frames established by the Agency in