

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(D) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.30 of this chapter, with respect to times for submission;

(ii) Section 158.32 of this chapter, with respect to format of submission;

(iii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made;

(iv) Section 158.34 of this chapter, with respect to flagging for potential adverse effects; and

(v) Section 160.12 of this chapter, if applicable, with respect to a statement of whether studies were conducted in accordance with the Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of the Federal Food, Drug and Cosmetic Act (FFDCA). If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with part 180 of this chapter.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995]

§ 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be mailed to the Registration Division (TS-767C), U.S. Environmental Protection Agency, Washington, DC 20460. Persons who wish to hand-deliver applications should contact the Registration Division to determine the location for delivery.

Subpart D [Reserved]