AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(3) Send the proposed notices and analysis to the Secretary of Agriculture and the Scientific Advisory Panel for comment, as provided by the Act.

(4) Send the Notice of Preliminary Determination and the other notices and analysis prepared under this section to all registrants and applicants for registration of products that are subject to the Special Review.

(c) *Publication.* The Agency shall issue the Notice of Preliminary Determination for publication in the FEDERAL REGISTER.

§ 154.33 Notice of Final Determination.

(a) *Publication and notice to registrants and applicants.* The Administrator shall prepare a Notice of Final Determination after the close of the comment period on a Notice of Preliminary Determination. As necessary, the Administrator shall also prepare Notices of Intent to Cancel, Notices of Denial, Notices of Intent to Hold a Hearing under FIFRA section 6(b)(2), or Notices of Intent to Change Classification.

(b) *Contents.* The Notice of Final Determination shall include:

(1) For each pesticide use subject to the Notice of Preliminary Determination, the Agency's final determination with respect to each use, along with a discussion of the reasons for the determination.

(2) Any comments submitted by the Secretary of Agriculture or the Scientific Advisory Panel, and the responses of the Administrator to these comments.

(3) The response of the Administrator to any significant public comments submitted on the Notice of Preliminary Determination.

(4) Instructions to registrants, applicants for registration, and other interested persons concerning the procedures which will be used to implement any regulatory action which the Administrator has decided upon, including instructions concerning how to request hearings, if hearings are available as of right under the Act or have been made available by the Administrator under the Act.

(5) The location of the docket under § 154.15 and the times during which the docket will be available for inspection and copying.

(c) *Publication and notification of registrants and applicants.* The Notice of Final Determination and any Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification shall be published in the FEDERAL REGISTER. If the Administrator issues a Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification, such notice, along with the Notice of Final Determination, also shall be sent by certified mail to all affected registrants and applicants.

§ 154.34 Expedited procedures.

(a) The Agency may elect to issue a Notice of Special Review and a Notice of Preliminary Determination simultaneously; or, to initiate cancellation, suspension, or denial proceedings concerning a pesticide or any of its uses without first conducting a Special Review or issuing a Notice of Preliminary Determination.

(b) If the Agency elects to issue a simultaneous Notice of Special Review and Notice of Preliminary Determination, the Agency will make the docket for that decision available for public inspection no more than 3 months after the Agency privately notifies the registrant of its risk concerns pursuant to § 154.21(a).

§ 154.35 Finality of determinations.

(a) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in paragraph (c) of this section, if:

(1) The application proposes registration of a product for a use which earlier had been the subject of a notice under § 154.21(a);

(2) After the Administrator issued the notice, he determined not to initiate a Special Review, because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for a Special Review; and

(3) The application for registration or amended registration now proposes that the terms and conditions which served as the basis of the earlier determination be eliminated, or be modified in a way which might increase the risk which was the subject of the notice under §154.21(a).

(b) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in paragraph (c) of this section, if:

(1) The application proposed registration of a product for a use which earlier had been the subject of a Notice of Special Review issued under §154.25;

(2) After the Administrator issued that Notice, he determined not to issue a notice under FIFRA section 3(c)(6) or 6(b) because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for issuance of a notice under FIFRA section 3(c)(6) or 6(b); and

(3) The application for registration or amended registration now proposes that the terms and conditions of registration which served as the basis for the earlier determination now be eliminated or be modified in a way which might increase the risk which was the subject of the Notice of Special Review.

(c) An application to which paragraph (a) or (b) of this section applies may not be approved until:

(1) The Administrator issues a notice for publication in the FEDERAL REGISTER which describes why the application is subject to the provisions of this section, states that the Administrator proposes to approve the application and his reasons, solicits public comment on whether the application should be approved, and provides a period not less than 30 days for comments to be submitted; and

(2) If any substantive comments are submitted in response to the notice, the Administrator issues a second notice for publication in the FEDERAL REGISTER responding to the comments.

PART 155—REGISTRATION STANDARDS AND REGISTRATION REVIEW

Subpart A [Reserved]

Subpart B—Docketing and Public Participation Procedures

Sec.
155.23 Definitions.
155.25 Schedule.
155.27 Agency review of data.
155.30 Meetings and communications.
155.32 Public docket.
155.34 Notice of availability.

Subpart C—Registration Review Procedures

155.40 General.
155.42 Registration review cases.
155.44 Establish schedules for registration review.
155.46 Deciding that a registration review is complete and additional review is not needed.
155.48 Data Call-In.
155.50 Initiate a pesticide's registration review.
155.52 Stakeholder engagement.
155.53 Conduct of a pesticide's registration review.
155.56 Interim registration review decision.
155.57 Registration review decision.
155.58 Procedures for issuing a decision on a registration review case.

AUTHORITY: 7 U.S.C. 136a and 136w.

SOURCE: 50 FR 49001, Nov. 27, 1985, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Docketing and Public Participation Procedures

§155.23 Definitions.

For the purposes of this part, *confidential business information* means trade secrets or confidential commercial or financial information under FIFRA sec. 10(b) or 5 U.S.C. 552(b) (3) or (4).

§155.25 Schedule.

EPA will issue annually in the FEDERAL REGISTER a notice listing the pesticides (or groups of pesticides) for