

§ 154.35

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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 reg-

istration 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

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.

AUTHORITY: 7 U.S.C. 136 through 136y.

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

Subpart A [Reserved]