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40 CFR Ch. I (7-1-00 Edition)

§ 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

Subpart A [Reserved]

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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

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which Registration Standards are currently being developed. The list will include pesticides for which a Registration Standard is scheduled for issuance within the next year, and the approximate sequence of issuance. The list may also include pesticides for which a Registration Standard will be under development during the upcoming year, but which are not scheduled for issuance until the succeeding year. The notice will invite comment and submission of information on the individual pesticides on the list.

§ 155.27 Agency review of data.

EPA will independently (or using the services of disinterested contractors or consultants) review available data in preparation for the development of a Registration Standard, and will be responsible for the drafting of the Registration Standard based on such data reviews. The Agency will not permit registrants to prepare, or assist in the preparation of, data reviews or other Registration Standard documents. The Agency may, however, meet with registrants to discuss its pending reviews, decisions, or documents, in accordance with the meeting procedures in § 155.30, and the docketing procedures in § 155.32.

§ 155.30 Meetings and communications.

EPA personnel may, upon their own initiative or upon request of any interested person or party, meet or communicate with persons or parties outside of government concerning a Registration Standard under development. Such meetings or communications will conform to the following policies and procedures:

(a) *Purpose.* Meetings and communications may be for the purpose of receiving and considering information, exchanging views, exploring factual and substantive positions, discussing regulatory options or for any other purpose deemed appropriate by the Agency in its deliberations concerning development of a Registration Standard. The Agency will not commit to take any particular action concerning a Registration Standard under development during discussions with any person or party outside of government.

The Agency will make its final administrative decision on a wholly independent basis, and in accordance with law.

(b) *Meetings with persons or parties outside of government.* Requests by responsible persons or parties outside of government to meet with Agency personnel concerning a Registration Standard under development should be directed in writing to the Registration Division. Reasonable requests will ordinarily be granted on a timely basis. EPA will decide the time and place of such meetings, and the Agency personnel who will attend. EPA may decline to meet with persons or parties who assert unreasonable claims of confidential business information for the purpose of circumventing the docketing procedures in § 155.32. EPA may also decline to meet if the number or frequency of meetings would delay unduly the issuance of the Registration Standard. Further, no person or party outside government will be accorded special or preferential access to Agency pesticide decisionmaking or to the Agency's decisional process.

(c) *Information submitted to the Agency concerning a Registration Standard under development.* (1) Information, comments, data, or other written material submitted to the Agency at any time concerning a Registration Standard under development may be claimed by the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter, or, in meetings, with the participants from outside of government who wish to assert a claim of confidentiality.

(2) To assert a claim of confidentiality for all or any part of a written submission concerning a Registration Standard under development, the submitter must furnish three copies of the material. Two copies must be complete, with claimed confidential business information clearly marked in the text. Items in the document that are claimed confidential should be numbered consecutively throughout the document. The third copy must have the claimed confidential business information excised from the text without