(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]

Subpart B—Docketing and Public Participation Procedures

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

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 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 closing up or paraphrasing the remaining text. The deletions should be consecutively numbered to correspond to the numbering of the complete copies. Each copy must be marked on the cover as to whether it contains claimed confidential business information.

(3) Any written material received by the Agency that is not marked as confidential will be deemed to be nonconfidential, and may be made available through the public docket or otherwise

disclosed without prior notice to the submitter.

(d) *Memorandum of meeting.* For each meeting with a person or party outside of government, the Agency will prepare, based on notes taken at the meeting, a memorandum of the meeting. The memorandum will be prepared within 10 working days of the meeting and will include all of the following information:

(1) The date and time of the meeting.

(2) The name of the person who requested the meeting.

(3) The names and affiliations of the participants.

(4) The subject matter of the meeting.

(5) A full and accurate description of all significant positions taken, facts presented, and arguments made by each participant (except that any discussion of claimed confidential business information will be identified in meeting notes, and referenced in the memorandum).

(6) Identification of all documents, proposals, or other materials (other than information claimed to be confidential business information) distributed or exchanged at the meeting.

(7) The name of the person who prepared the memorandum.

[50 FR 49001, Nov. 27, 1985, as amended at 58 FR 34203, June 23, 1993]

§ 155.32 Public docket.

(a) *When created.* (1) A docket will be created for each Registration Standard under development when the Agency begins review of data for the Registration Standard or upon publication of the notice described in § 155.25 setting out the list and sequence of Registration Standards, whichever is earlier. The Agency will announce in its annual schedule notice the dockets that are available for Registration Standards under development.

(2) If the Agency notifies registrants privately in accordance with 40 CFR 154.21 that one or more risk criteria set forth in 40 CFR 154.7 (leading to a special review) may have been exceeded, that notification and any subsequent communications concerning that notification will be placed in a separate docket pertaining to possible special review in accordance with the provisions of § 154.15.

(b) *Contents of docket.* The docket will contain, within the time frames indicated, all of the following documents and information (except that information claimed to be confidential business information will not be included):

(1) An index of its contents (refer to paragraph (c) of this section).

(2) A copy of each comment received in response to the notice described in § 155.25 that pertains to a pesticide for which the notice indicated a Registration Standard was under development (within 10 working days after receipt by the Agency, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(3) A copy of each memorandum of a meeting between the Agency and persons or parties outside of government, prepared in accordance with § 155.30(d) (within 10 working days after the meeting).

(4) A copy of each document, comment, item of correspondence or other written material concerning the Registration Standard submitted to the Agency by any person or party outside of government, whether in a meeting or separately (within 10 working days after receipt, or 15 working days if the submitter has asserted a confidential business information claim concerning the material).

(5) A copy of each document, proposal, or other item of written material concerning the Registration Standard provided by the Agency to any person or party outside of government (within 15 working days after the item is made available to such person or party).

(6) A copy of the Registration Standard;

(7) With respect to a Registration Standard for which the Agency has determined that a substantially complete chronic health and teratology data base exists, a copy of the FEDERAL REGISTER notice concerning availability of a proposed Registration Standard, and a copy of each comment received in response to that notice (within 10 working days after receipt by the Agency, or 15 working days if the submitter has

asserted a confidential business information claim concerning the material).

(8) A copy of the FEDERAL REGISTER notice announcing the issuance of the Registration Standard (within 10 working days after the publication of the notice).

(c) *Index of the docket.* The Agency will establish and keep current an index to the docket for each Registration Standard. The index will include, but is not limited to:

(1) A list of each meeting between the Agency and any person or party outside of government, containing the date and subject of the meeting, the names of participants and the name of the person requesting the meeting.

(2) A list of each document in the docket by title, source or recipient(s), and the date the document was received or provided by the Agency.

(d) *Availability of docket and indices.* (1) The Agency will make available to the public for inspection and copying the docket and index for any Registration Standard.

(2) The Agency will establish and maintain a mailing list of persons who have specifically requested that they receive indices for Registration Standard dockets. On a quarterly basis, EPA will distribute the indices of new materials placed in the public docket to these persons. Annually, EPA will require that persons on the list renew their requests for inclusion on the list.

(3) The Agency will issue annually in the FEDERAL REGISTER (in conjunction with the annual schedule notice specified in § 155.25) a notice announcing the availability of docket indices.

(4) Each FEDERAL REGISTER notice of availability of a Registration Standard will announce the availability of the docket index for that Standard.

§ 155.34 Notice of availability.

(a) The Agency will issue in the FEDERAL REGISTER a notice announcing the issuance and availability of Registration Standard which:

(1) Concerns a previously unregistered active ingredient; or

(2) Concerns a previously registered active ingredient, and the Registration Standard states that registrants will be required (under FIFRA section 3(c)(2)(B)) to submit chronic health (including, but not limited to, chronic feeding, oncogenicity and reproduction) or teratology studies.

(b) Interested persons may submit comments concerning any Registration Standard described by paragraph (a) of this section at any time.

(c) The Agency will issue in the FEDERAL REGISTER a notice announcing the availability of, and providing opportunity for comment on, each proposed Registration Standard which concerns a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A—General Provisions

Sec.

Subparts B–J [Reserved]

Subpart K—Worker Protection Statements

AUTHORITY: 7 U.S.C. 136–136y.

Subpart A—General Provisions

§ 156.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom