(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

Subpart C—Registration Review Procedures

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

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.

Subpart C—Registration Review Procedures

SOURCE: 71 FR 45732, Aug. 9, 2006, unless otherwise noted.

§155.40 General.

(a) *Purpose.* These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

(1) Among other things, FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment. Registration review is intended to ensure that each

pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.

(2) If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA.

(b) *Applicability*. This subpart applies to every pesticide product registered under FIFRA section 3 as well as all pesticide products registered under FIFRA section 24(c). It does not apply to products whose sale or distribution is authorized under FIFRA section 5 or section 18.

(c) *Limitations*. (1) At any time, the Agency may undertake any other review of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing, scheduled, or not yet scheduled registration review.

(2) When the Agency determines that new data or information are necessary for a pesticide's registration review, it will require such data under FIFRA section 3(c)(2)(B).

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75595, Dec. 12, 2008]

§ 155.42 Registration review cases.

(a) *Establishing registration review cases*. A registration review case will be composed of one or more active ingredients and all the products containing such ingredient(s). The Agency may group related active ingredients into a registration review case when the active ingredients are so closely related in chemical structure and toxicological profile as to allow common use of some or all required data for hazard assessment.

(1) *Existing pesticides*. The Agency will assign each pesticide registered on or before the effective date of this regulation to a registration review case.

(2) New pesticides. The Agency will assign each pesticide registered after the effective date of this regulation to an existing registration review case or to a new registration review case.

(3) A pesticide product that contains multiple active ingredients will belong to the registration review cases for each of its active ingredients.

(b) *Modifying registration review cases*. New data or information may suggest that a registration review case should be modified. The Agency may modify a registration review case in the following ways:

(1) Add a new active ingredient to a registration review case. The Agency may determine that a new active ingredient is chemically and toxicologically similar to active ingredients in an existing registration review case and should be grouped with the ingredients in the existing registration review case.

(2) Split a registration review case into two or more registration review cases. For example, new data or information may suggest that active ingredients in a registration review case are not as similar as previously believed and that they belong in two or more separate registration review cases.

(3) Move an ingredient from one registration review case to another. For example, new data or information might suggest that an ingredient should not be grouped with the other ingredients in the registration review case and that it belongs in a different registration review case.

(4) Merge two or more registration review cases into a single registration review case. For example, new data or information might suggest that the active ingredients in two or more registration review cases should be grouped together for registration review.

(5) Delete an active ingredient from a registration review case. For example, the Agency will remove the ingredient from the case if the registrations of all products containing an active ingredient in a registration review case are canceled.

(c) *Closing a registration review case*. The Agency will close a registration review case if all products in the case are canceled.

(d) *Establishing a baseline date for a registration review case*. For the purpose of scheduling registration reviews, the Agency will establish a baseline date for each registration review case. In general, the baseline date will be the date of initial registration of the oldest pesticide product in the case or the date of reregistration, whichever is

later. For the purpose of these procedures, the date of reregistration is the date on which the Reregistration Eligibility Decision or Interim Reregistration Decision was signed, whichever date the Agency determines to be more appropriate based on the comprehensiveness of the review.

(1) The Agency generally will not change the baseline date for a registration review case when it modifies a case by adding or deleting ingredients or products.

(2) When the Agency splits a registration review case into two or more cases, the new case(s) generally will have the baseline date of the original registration review case.

(3) When the Agency merges two or more registration review cases into a single case, the Agency generally will use the earliest baseline date as the baseline date for the new case.

(e) *Announcing registration review cases and baseline dates.* The Agency will maintain a list of registration review cases, including baseline dates, on its website.

§ 155.44 Establish schedules for registration review.

The Agency will develop schedules for registration review that are generally based on the baseline date of the registration review case or on the date of the latest registration review of the registration review case. The Agency may also take into account other factors, such as achieving process efficiencies by reviewing related cases together, when developing schedules for registration review. The Agency will maintain schedules for the current year and at least two subsequent years on its website.

§ 155.46 Deciding that a registration review is complete and additional review is not needed.

The Agency may determine that there is no need to reconsider a previous decision that a pesticide satisfies the standard of registration in FIFRA. In such cases, instead of establishing a pesticide registration review case docket as described in §155.50, the Agency may propose that, based on its determination that a pesticide meets the FIFRA standard for registration, no further review will be necessary. In such circumstances, the Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the proposed decision and provide a comment period of at least 60 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a final version of the decision, an explanation of any changes to the proposed decision and its response to any comments. The date of the final notice of availability would be used as the date of the latest registration review for the purpose of scheduling subsequent registration reviews.

§ 155.48 Data Call-In.

The Agency may issue a Data Call-In notice under FIFRA section 3(c)(2)(B) at any time if the Agency believes that the data are needed to conduct the registration review. The provisions in FIFRA section 3(c)(1), (c)(2)(B), and (c)(2)(D) apply to the submission, compensation, and exemption of data required to conduct a registration review.

§ 155.50 Initiate a pesticide's registration review.

The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under §155.46, and opening it for public review.

(a) *Contents of the registration review case docket.* The Agency will place in this docket information that will assist the public in understanding the types of information and issues that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any FEDERAL REGISTER notices regarding pending registration actions, and current or pending tolerances;

(3) Risk assessment documents;

(4) Bibliographies concerning current registrations;

(5) Summaries of incident data; and

(6) Any other pertinent data or information.

(b) *Public review of the registration review case docket.* The Agency will publish a notice in the FEDERAL REGISTER announcing the availability for public review of the information described in paragraph (a) of this section and establishing a comment period of at least 60 days. During this comment period, interested persons may identify any additional information they believe the Agency should consider in the course of the registration review.

(c) *Submission of data and other information during the comment period.* The Agency may identify, either in the notice published under paragraph (b) of this section, or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review. Any person may submit data or information in response to such identification. In order to be considered during a pesticide's registration review, the submitted data or information must meet the requirements listed below.

(1) In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section. The Agency may, at its discretion, consider data or information submitted at a later date.

(2) The data or information must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

§ 155.52 Stakeholder engagement.

In addition to the public participation opportunities described in § 155.50 and § 155.53(c), the Agency may meet with stakeholders regarding a forthcoming or ongoing registration review. For example, before conducting a pesticide's registration review, the Agency may consult with registrants or pesticide users regarding the use and usage of the pesticide. The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review with regard to developing risk management options for a pesticide. The Agency may informally consult with officials of Federal, State or Tribal agencies regarding a forthcoming or ongoing registration review.

(a) *Minutes of meetings with persons outside of government.* Subject to paragraph (c) of this section, if the Agency meets with one or more individuals that are not government employees to discuss matters relating to a registration review, the Agency will place in the docket a list of meeting attendees, minutes of the meeting, and any documents exchanged at the meeting, not later than the earlier of:

(1) 45 days after the meeting; or

(2) The date of issuance of the registration review decision.

(b) *Exchange of documents or other written material.* In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged.

(c) *Confidential business information.* The Agency will identify, but not include in the docket, any confidential business information whose disclosure is prohibited by FIFRA section 10.

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75596, Dec. 12, 2008]

§ 155.53 Conduct of a pesticide's registration review.

The Agency will review data and information described in §155.50(a), (b), and (c) or submitted in response to a Data Call-In notice that it believes should be considered in the pesticide's registration review.

(a) *Assess changes since a pesticide's last review.* The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted under §155.50 or in response to a Data Call-In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under §155.50 or in response to a Data Call-In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) *Conduct new assessments as needed.* (1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it can base the new assessment on available data or information, including data or information submitted under §155.50 or in response to a Data Call-In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product's registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(c) *Public participation during a pesticide's registration review.* The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment.

(1) The Agency might not request comments on a draft risk assessment in cases where the Agency's initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, poses low risk, and/or requires little or no risk mitigation. In such cases, the Agency will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case.

(2) If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in §155.58.

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in §155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A—General Provisions

Subparts B–C [Reserved]

Subpart D—Human Hazard and Precautionary Statements

Subpart E—Environmental Hazard and Precautionary Statements

Subparts F–G [Reserved]