(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.