

## § 154.21

has been prepared, the date, the subject, participants, and person who requested the meeting. The index will also list any document included in the docket by its title, its source, its recipient, and the date it was received or provided by the Agency.

(f) *Access to the docket.* (1)(i) For each chemical in Special Review, the docket shall be available for public inspection and copying and its index kept current and made available to the public on request. The docket and index for any pesticide for which the Agency has issued a pre-Special Review notification under § 154.21 will only be made available for public inspection and copying following issuance of a proposed decision not to start a Special Review under § 154.23, a Notice of Special Review under § 154.25(c), or as otherwise specified in § 154.34.

(ii) The docket and index will be available at the Program Management and Support Division, in Rm. 236, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m. Monday through Friday, excluding legal holidays.

(2) Information contained in the docket shall not be disclosed to the public to the extent that FIFRA or any other statute or regulation (including, but not limited to, 5 U.S.C. 552(b)(3) or (4)) prohibits its disclosure.

(3) The Agency will distribute a compendium of indices for new materials in the public docket by mail, on a monthly basis, to those members of the public who have specifically requested such material. The Agency will announce the availability of docket indices both annually in the FEDERAL REGISTER and in each FEDERAL REGISTER Notice concerning pre-Special Review or Special Review for specific pesticides. The Agency may also periodically require parties on the mailing list to renew their previous request for such materials.

### Subpart B—Procedures

#### § 154.21 Preliminary notification to registrants and applicants for registration.

(a) *Preliminary notification.* If the Administrator decides that he may initiate a Special Review of a pesticide

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use, he shall send written notice by certified mail to the affected registrant(s) and applicant(s) setting forth his decision and a general description of the information which supports it.

(b) *Comment opportunity.* Registrant(s) and applicant(s) will be allowed 30 days from the receipt of notification to respond in writing to dispute the validity of the Agency's conclusions or to present information in response to the notification.

#### § 154.23 Proposed decision not to initiate a Special Review.

If the Administrator proposes not to initiate a Special Review after having given notice under § 154.21, he shall issue a proposed decision for publication in the FEDERAL REGISTER. The proposal shall include a description of the concerns which were the original basis for placement of the pesticide in pre-Special Review status and the Agency's rationale for its proposed decision, announce the availability of a public docket, and provide a period generally not less than 30 days for submission of comments. A notice under § 154.25(b) may not be published unless it has been preceded by a notice under this section. A proposal under this section shall not be based on the benefits of use of a pesticide product.

#### § 154.25 Public announcement of final decision whether to initiate a Special Review.

(a) The Administrator shall evaluate the available information and the comments received in response to the notice under § 154.21 and any notice issued under § 154.23, and shall issue for publication in the FEDERAL REGISTER a notice under paragraph (b) or (c) of this section.

(b) If the Administrator determines after having given notice under § 154.21 not to initiate a Special Review, he shall issue his decision for publication in the FEDERAL REGISTER with a statement of reasons.

(c) If the Administrator determines after having given notice under § 154.21 that one or more of the risk criteria set forth in § 154.7 have been satisfied, the Agency shall issue a notice for publication in the FEDERAL REGISTER which shall include:

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(1) Identification of the pesticide uses for which a Special Review has been initiated and an identification of the criteria which have been satisfied.

(2) A brief discussion of the Agency's reasons for determining that the criteria have been satisfied.

(3) A statement indicating that EPA has established a docket for the Special Review, the contents of the docket, the location of the docket, and the times during which the docket will be available for inspection and copying.

(4) An invitation to all interested persons to submit further information concerning the risks and benefits associated with each use of the pesticide subject to the Special Review.

(5) A brief description of the Special Review process and a statement that registrants and applicants bear an affirmative burden of supporting registration of a pesticide product.

(6) A date by which information in response to the Agency's request for further information must be submitted.

(d) In his discretion, the Administrator may request that the Scientific Advisory Panel hold a public meeting to review the scientific issues related to the Special Review.

### § 154.26 Comment opportunity.

After issuance of a Notice of Special Review that applies to a use of a pesticide product (or category of products), any person may submit to the Agency any information, argument, or both, pertinent to:

(a) Whether the use of a pesticide product satisfies any of the §154.7 risk criteria, with respect to the composition, labeling, packaging, and restrictions on use of the product as currently registered.

(b) Whether the use of a pesticide product would satisfy any of the §154.7 risk criteria if its composition, labeling, packaging, and restrictions on use were approved in accordance with an application for registration or amended registration pending before the Agency. For further information see §154.27(b).

(c) Whether any risks posed by the use or proposed use of the product that satisfy the §154.7 risk criteria are unreasonable, taking into account the

economic, social, and environmental costs and benefits of the use of the product.

(d) What regulatory action, if any, the Agency should take with respect to the use of the product.

### § 154.27 Meetings with interested persons.

(a) In the Special Review process, to assure openness and responsiveness, no person or party outside of government will be afforded special or preferential access to Agency Special Review decisionmakers or to the Agency's Special Review process. At the same time, however, Agency personnel are free to meet and otherwise communicate with persons or parties outside of government, including registrants and manufacturers, users, trade unions, environmental groups and other interested persons, to obtain information, exchange views, explore factual and substantive positions, or discuss regulatory options concerning Special Review decisions.

(b) Meetings between EPA and any person or party outside of government will not result in undue delay in reaching Special Review decisions. During such meetings, the Agency will not commit to take any particular action concerning a pending decision. The Agency may receive and consider information and recommendations from persons or parties outside of government; however, the Agency will make the final administrative decision on a wholly independent basis and in accordance with law.

(c) Any interested person may ask to meet with Agency officials to discuss factual information available to the Agency, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding a pesticide which is or may be the subject of a Special Review. If, at its discretion, the Agency holds such meetings with any person outside of government concerning a use of a pesticide product, the Agency will prepare and file in the docket a memorandum of such meeting, meeting the requirements specified in §154.15(b)(7).

(d) Meetings described in this section may include meetings held after