

§ 154.21

(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.

[50 FR 49015, Nov. 27, 1985, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

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 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 A notice under § 154.25(b) may not be published unless it has been preceded by a notice under this section.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 sec-

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tion 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:

(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.