

(e) If the Agency meets with any person or party outside of government concerning a pending Special Review decision, the Agency will not issue a final Special Review decision until 30 days after inclusion of a memorandum concerning that meeting in the public docket. During those 30 days, any person or party may submit written comments to the Agency regarding the subject matter of the meeting in question. The Agency may issue a final Special Review decision without allowing this 30-day period if expedited action is necessary to protect public health or the environment, or if the Agency has invited other parties with potentially opposing viewpoints to the meeting in question (e.g., registrants, users, labor, and environmental groups).

(f) The Agency may decline to meet subsequently with any person or party who asserts unreasonable confidential business information claims pursuant to §154.15(c) for the purpose of circumventing the docketing procedures described in §154.15(b).

§ 154.29 Informal public hearings.

(a) *Timing.* At any time after issuance of a Notice of Special Review and prior to issuance of a Notice of Final Determination, the Administrator may conduct an informal public hearing to gather relevant information or otherwise assist Agency decisionmaking.

(b) FEDERAL REGISTER notice. The Administrator shall issue a notice for publication in the FEDERAL REGISTER of any informal public hearing to be held under this section. The notice shall contain the following information:

(1) The time, date, and place of the hearing.

(2) A brief description of the procedures governing participation in the hearing by interested persons.

(3) The issues to be considered at the hearing.

(c) *Transcript.* A verbatim transcript of the hearing shall be prepared and filed in the public docket.

§ 154.31 Notices of Preliminary Determination.

The Administrator shall prepare a Notice of Preliminary Determination

after the close of the comment period on a Notice of Special Review.

(a) *Contents of notice.* The Notice of Preliminary Determination shall respond to all significant comments submitted in response to the Notice of Special Review. For each use of a pesticide product that was the subject of the Notice of Special Review, the Notice of Preliminary Determination shall also include, as appropriate:

(1) A determination whether the use satisfies any of the risk criteria set forth in §154.7, and a discussion of the reasons for the determination.

(2) A determination of whether any changes in the composition, packaging, labeling, or restrictions on use of a pesticide product that were proposed in an application for new or amended registration submitted after issuance of the Notice of Special Review would reduce the risk so that the use no longer would satisfy any of the risk criteria in §154.7.

(3) If the use satisfies any of the risk criteria set forth in §154.7, a determination of whether the adverse effects posed by the use are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product, and a discussion of reasons for the determination.

(4) If the use is determined to pose an unreasonable adverse effect, a statement of the regulatory action, if any, which the Agency intends to initiate with respect to the use, and a discussion of the reasons for initiating that regulatory action.

(5) A statement that the Administrator is requesting comments from the Secretary of Agriculture and the Scientific Advisory Panel on the notices and analysis specified in paragraph (b) of this section, and that the notices and analysis are available on request.

(6) Instructions to interested persons on how to submit comments (including the deadline for submission of comments).

(7) The location of the docket under §154.15 and the times during which the docket will be available for inspection and copying.

(b) *Referral to Secretary of Agriculture and Scientific Advisory Panel.* If the Administrator proposes to cancel, deny,

Environmental Protection Agency

§ 154.35

or change the classification of the registration of a pesticide product which is the subject of a Special Review, or to hold a hearing under FIFRA section 6(b)(2) on whether to take any of those actions, he shall:

(1) Prepare a proposed form of a Notice of Intent to Cancel, a Notice of Intent to Deny Registration, a Notice of Intent to Hold a Hearing, and/or a Notice of Intent to Change Classification, as appropriate.

(2) Prepare an Agricultural Impact Analysis, analyzing the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

(3) Send the proposed notices and analysis to the Secretary of Agriculture and the Scientific Advisory Panel for comment, as provided by the Act.

(4) Send the Notice of Preliminary Determination and the other notices and analysis prepared under this section to all registrants and applicants for registration of products that are subject to the Special Review.

(c) *Publication.* The Agency shall issue the Notice of Preliminary Determination for publication in the FEDERAL REGISTER.

§ 154.33 Notice of Final Determination.

(a) *Publication and notice to registrants and applicants.* The Administrator shall prepare a Notice of Final Determination after the close of the comment period on a Notice of Preliminary Determination. As necessary, the Administrator shall also prepare Notices of Intent to Cancel, Notices of Denial, Notices of Intent to Hold a Hearing under FIFRA section 6(b)(2), or Notices of Intent to Change Classification.

(b) *Contents.* The Notice of Final Determination shall include:

(1) For each pesticide use subject to the Notice of Preliminary Determination, the Agency's final determination with respect to each use, along with a discussion of the reasons for the determination.

(2) Any comments submitted by the Secretary of Agriculture or the Scientific Advisory Panel, and the responses of the Administrator to these comments.

(3) The response of the Administrator to any significant public comments submitted on the Notice of Preliminary Determination.

(4) Instructions to registrants, applicants for registration, and other interested persons concerning the procedures which will be used to implement any regulatory action which the Administrator has decided upon, including instructions concerning how to request hearings, if hearings are available as of right under the Act or have been made available by the Administrator under the Act.

(5) The location of the docket under § 154.15 and the times during which the docket will be available for inspection and copying.

(c) *Publication and notification of registrants and applicants.* The Notice of Final Determination and any Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification shall be published in the FEDERAL REGISTER. If the Administrator issues a Notice of Intent to Cancel, Notice of Denial, Notice of Intent to Hold a Hearing, or Notice of Intent to Change Classification, such notice, along with the Notice of Final Determination, also shall be sent by certified mail to all affected registrants and applicants.

§ 154.34 Expedited procedures.

(a) The Agency may elect to issue a Notice of Special Review and a Notice of Preliminary Determination simultaneously; or, to initiate cancellation, suspension, or denial proceedings concerning a pesticide or any of its uses without first conducting a Special Review or issuing a Notice of Preliminary Determination.

(b) If the Agency elects to issue a simultaneous Notice of Special Review and Notice of Preliminary Determination, the Agency will make the docket for that decision available for public inspection no more than 3 months after the Agency privately notifies the registrant of its risk concerns pursuant to § 154.21(a).

§ 154.35 Finality of determinations.

(a) The Administrator will not approve an application for registration or amended registration of a pesticide