Environmental Protection Agency

both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide.

§ 154.10 Petitions to begin the Special Review process.

The Administrator may evaluate a pesticide use under the criteria of §154.7 either on his own initiative, or at the suggestion of any interested person.

§ 154.15 Docket for the Special Review.

(a) Establishment of the docket. When the Agency first notifies registrants privately that it is considering issuance of a Notice of Special Review for a pesticide, it shall establish a docket concerning that particular pesticide.

(b) Contents of the docket. For each pre-Special Review or Special Review, the docket shall contain:
   (1) The Notice of Special Review, any Notice of Preliminary Determination, and any Notice of Final Determination.
   (2) Any notice issued under §154.21 or §154.23.
   (3) Any documents (other than information claimed to be confidential business information) referred to by the Agency in those notices as relied upon by the Agency in reaching its determination.
   (4) Copies of all written comments or materials (other than information claimed to be confidential business information) submitted to the Agency concerning a Special Review decision provided to the Agency by a person or party outside of government (other than information claimed to be confidential business information).
   (5) Any written response to the Notice of Preliminary Determination from the Secretary of Agriculture or the Scientific Advisory Panel.
   (6) A transcript of all public meetings held by the Scientific Advisory Panel or conducted by the Agency for the purpose of gathering information.
   (7) A memorandum describing each meeting between Agency personnel and any person or party outside of government which concerns a pending pre-Special Review or Special Review decision. Each such memorandum shall be based on notes taken at the meeting and shall specify the date and time of the meeting, the participants and their affiliations, who requested the meeting, the subject matter of the meeting, and the person who prepared the memorandum. Except for information claimed to be confidential business information, each memorandum shall describe fully and accurately all significant positions taken, arguments made, and facts presented by each participant in the meeting, and shall identify all documents, proposals, or other materials distributed or exchanged at the meeting. Any discussion of claimed confidential business information shall be identified in meeting notes and referenced in the memorandum.
   (8) All comments, correspondence, or other materials concerning a pending pre-Special Review or Special Review decision provided to the Agency by a person or party outside of government (other than information claimed to be confidential business information).
   (9) All documents, proposals, or other materials concerning a pending pre-Special Review or Special Review decision, provided by the Agency to any person or party outside of government (other than information claimed to be confidential business information).

(c) Assertion of confidential business information claims. (1) Information, comments, data, or other written material submitted to the Agency concerning a Special Review may be claimed by the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter to be confidential business information. The burden of identifying claimed confidential business information rests with the submitter to be confidential business information. 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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