

Environmental Protection Agency

§ 154.15

Validated test means a test determined by the Agency to have been conducted and evaluated in a manner consistent with accepted scientific procedures.

[73 FR 75595, Dec. 12, 2008]

§ 154.5 Burden of persuasion in determinations under this part.

In making determinations under this part the Administrator shall be guided by the principle that the burden of persuasion that a pesticide product is entitled to registration or continued registration for any particular use or under any particular set of terms and conditions of registration is always on the proponent(s) of registration.

§ 154.7 Criteria for initiation of Special Review.

(a) The Administrator may conduct a Special Review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):

(1) May pose a risk of serious acute injury to humans or domestic animals.

(2) May pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based upon:

(i) Effects demonstrated in humans or experimental animals.

(ii) Known or predicted levels of exposure of various groups of humans.

(iii) The use of appropriate methods of evaluating data and relating such data to human risk.

(3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.

(4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary

of Commerce under the Endangered Species Act of 1973, as amended.

(5) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act as a critical habitat for any endangered or threatened species.

(6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

(b) In making any determination that a pesticide use satisfies one of the criteria for issuance of a Special Review specified by paragraph (a) of this section, the Administrator shall consider available evidence concerning 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) responding to any notice furnished under §154.21 or §154.23 or submitted at any time during the Special Review process by any person outside of government.

(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, or, in meetings, with the participants who wish to assert a claim of confidentiality.

(2) To assert a claim of confidentiality for all or any part of a written submission concerning a Special Review, the submitter must furnish three copies of the material. Two copies must be complete, with claimed confidential business information clearly marked in the text. Items in the document that are claimed confidential should be numbered consecutively throughout the text. The third copy must have the claimed confidential business information excised from the text without closing up or paraphrasing the remaining text. The deletions should be consecutively numbered to correspond to the numbering of the complete copies. Each copy must be marked on the cover as to whether it contains claimed confidential business information.

(3) Any written material concerning a Special Review received by the Agency that is not marked as confidential will be deemed to be nonconfidential, and may be made available through the public docket or otherwise disclosed without prior notice to the submitter.

(d) *Placement of materials in the docket.* Any memorandum identified under paragraph (b)(7) of this section shall be placed in the docket within 10 working days of the subject meeting. Materials identified under paragraph (b)(8) of this section shall be placed in the docket within 10 working days of receipt by the Office of Pesticide Programs, or within 15 working days of receipt by the Office of Pesticide Programs if the submitter has asserted a confidential business information claim concerning the submittal. Materials identified under paragraph (b)(9) of this section shall be placed in the docket within 15 working days of transmittal to such person or party outside of government.

(e) *Index.* The Agency shall prepare and maintain a current index of all materials included in the docket. The index will include a list identifying, for

each meeting between Agency personnel and a person or party outside of government for which a memorandum 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 OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c).

(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.

[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 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