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Title 40 —Protection of Environment

Chapter I —Environmental Protection Agency

Subchapter E —Pesticide Programs

Part 154 Special Review Procedures

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PART 154—SPECIAL REVIEW PROCEDURES

Authority: 7 U.S.C. 136a, d, and w.

Source: 50 FR 49015, Nov. 27, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 154.1 Purpose and scope.

- (a) **Purpose.** The purpose of the Special Review process is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment, in accordance with sections 3(c)(6) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The process is intended to ensure that the Agency assesses risks that may be posed by pesticides, and the benefits of use of those pesticides, in an open and responsive manner. The issuance of a Notice of Special Review means that the Agency has

determined that one or more uses of a pesticide may pose significant risks and that, following completion of the Special Review process, the Agency expects to initiate formal proceedings seeking to cancel, deny, reclassify, or require modifications to the registration of the product(s) in question unless it has been shown during the Special Review that the Agency's initial determination was erroneous, that the risks can be reduced to acceptable levels without the need for formal proceedings, or that the benefits of the pesticide's use outweigh the risks. Following completion of the Special Review process, a pesticide in question may be returned to the registration process.

- (b) **Scope.** This part sets forth the substantive standards for initiating a Special Review of a pesticide product and the procedures for initiating and conducting the Special Review.

§ 154.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, as used in this part, the following terms shall apply:

Act or FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Administrator means the Administrator of the Environmental Protection Agency or any officer or employee thereof to whom authority has been delegated to act for the Administrator.

Confidential business information means trade secrets or confidential commercial or financial information under FIFRA section 10(b) or 5 U.S.C. 552(b)(3) or (4).

Other significant evidence means factually significant information that relates to the uses of the pesticide and its adverse risk to man or to the environment but does not include evidence based only on misuse of the pesticide unless such misuse is widespread and commonly recognized practice.

Person means an applicant, registrant, manufacturer, pesticide user, environmental group, labor union, or other individual or group of individuals interested in pesticide regulation.

Pesticide use means a use of a pesticide (described in terms of the application site and other applicable identifying factors) that is included in the labeling of a pesticide product which is registered, or for which an application for registration is pending, and the terms and conditions (or proposed terms and conditions) of registration for the use.

Terms and conditions of registration means the terms and conditions governing lawful sale, distribution, and use approved in conjunction with registration, including labeling, use classification, composition, and packaging.

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

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§ 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 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.

§ 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 issuance of a Notice of Special Review with any registrant who proposes to change voluntarily the composition, packaging, and labeling, or other terms and conditions of registration of his pesticide product in a way which he believes would reduce the risks of use of the product so that it would no longer meet or exceed the risk criteria of § 154.7. Meetings for this purpose will be most helpful and productive for both registrants and the Agency if they are requested by registrants shortly after the issuance of the Notice of Special Review.
- (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, 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 product except by use of the procedures specified in paragraph (c) of this section, if:
 - (1) The application proposes registration of a product for a use which earlier had been the subject of a notice under § 154.21(a);
 - (2) After the Administrator issued the notice, he determined not to initiate a Special Review, because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for a Special Review; and
 - (3) The application for registration or amended registration now proposes that the terms and conditions which served as the basis of the earlier determination be eliminated, or be modified in a way which might increase the risk which was the subject of the notice under § 154.21(a).
- (b) The Administrator will not approve an application for registration or amended registration of a pesticide product except by use of the procedures specified in paragraph (c) of this section, if:
 - (1) The application proposed registration of a product for a use which earlier had been the subject of a Notice of Special Review issued under § 154.25;
 - (2) After the Administrator issued that Notice, he determined not to issue a notice under FIFRA section 3(c)(6) or 6(b) because of a proposal by an applicant for registration or amended registration to change the terms and conditions of registration of the product in a way which would reduce the risk sufficiently to eliminate the need for issuance of a notice under FIFRA section 3(c)(6) or 6(b); and
 - (3) The application for registration or amended registration now proposes that the terms and conditions of registration which served as the basis for the earlier determination now be eliminated or be modified in a way which might increase the risk which was the subject of the Notice of Special Review.
- (c) An application to which paragraph (a) or (b) of this section applies may not be approved until:
 - (1) The Administrator issues a notice for publication in the FEDERAL REGISTER which describes why the application is subject to the provisions of this section, states that the Administrator proposes to approve the application and his reasons, solicits public comment on whether the application should be approved, and provides a period not less than 30 days for comments to be submitted; and

- (2) If any substantive comments are submitted in response to the notice, the Administrator issues a second notice for publication in the FEDERAL REGISTER responding to the comments.