

§ 154.3

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.

40 CFR Ch. I (7–1–10 Edition)

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

Environmental Protection Agency

§ 154.15

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