

§ 154.5

been conducted and evaluated in a manner consistent with accepted scientific procedures

§ 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.

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(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