§ 153.125 Criteria for determination of pesticidal activity.

(a) An ingredient will be considered an active ingredient if it is contained in a pesticide product and:

1. The ingredient has the capability by itself, and when used as directed at the proposed use dilution, to function as a pesticide; or

2. The ingredient has the ability to elicit or enhance a pesticidal effect in another compound whose pesticidal activity is substantially increased due to the interaction of the compounds.

Compounds which function simply to enhance or prolong the activity of an active ingredient by physical action, such as stickers and other adjuvants, are not generally considered to be active ingredients.

(b) Normally the applicant will determine and state in his application whether an ingredient is active or inert with respect to pesticidal activity. The Agency, as part of its review of an application for registration, or in conjunction with the Registration Standard or Special Review process, may require any ingredient, to be designated as an active ingredient if the Agency finds that it meets the criteria in paragraph (a) of this section. Conversely, the Agency may determine that any ingredient designated as active by an applicant is an inert ingredient if it fails to meet those criteria.

(c) If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement. If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.

(d) Designation of a substance as a pesticidally inert ingredient does not relieve the applicant or registrant of other requirements of FIFRA with respect to labeling of inert ingredients or submission of data, or from the requirements of the Federal Food, Drug, and Cosmetic Act with respect to tolerances or other clearance of ingredients.

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(2) Products intended and labeled for use solely as at-planting or hopper box treatments.

(3) Products which are gaseous in form or are used as fumigants.

(c) EPA-approved dyes for seed treatment are listed in:

(1) Sections 180.910, 180.920, and 180.950 if an exemption from the requirement of a tolerance has been established.

(2) Section 180.2010 if EPA has determined that residues of the dye will be present, if at all, at levels that are below the threshold of regulation.

(3) Section 180.2020 if it has been determined that no tolerance or exemption from the requirement of a tolerance is needed as a result of a determination by EPA that the use is unlikely to result in residues in food/feed.


Subparts I–M [Reserved]

PART 154—SPECIAL REVIEW PROCEDURES

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.