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(other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.

(b) A device is not required to be registered under FIFRA sec. 3. The Agency has issued a policy statement concerning its authority and activities with respect to devices, which was published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51065). A device is subject to the requirements set forth in:

(1) FIFRA sec. 2(q)(1) and part 156 of this chapter, with respect to labeling;

(2) FIFRA sec. 7 and part 167 of this chapter, with respect to establishment registration and reporting;

(3) FIFRA sec. 8 and part 169 of this chapter, with respect to books and records;

(4) FIFRA sec. 9, with respect to inspection of establishments;

(5) FIFRA sec. 12, 13, and 14, with respect to violations, enforcement activities, and penalties;

(6) FIFRA sec. 17, with respect to import and export of devices;

(7) FIFRA sec. 25(c)(3), with respect to child-resistant packaging; and

(8) FIFRA sec. 25(c)(4), with respect to the Agency's authority to declare devices subject to certain provisions of the Act.

[53 FR 15990, May 4, 1988. Redesignated at 60 FR 32096, June 19, 1995]

PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

Subparts A–F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

Sec.

153.125 Criteria for determination of pesticidal activity.

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Subparts I–M [Reserved]

AUTHORITY: 7 U.S.C. 136w.

Subparts A–F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

SOURCE: 53 FR 15989, May 4, 1988, unless otherwise noted.

§ 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.

[53 FR 15989, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

Subpart H—Coloration and Discoloration of Pesticides

SOURCE: 53 FR 15990, May 4, 1988, unless otherwise noted.

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if the Administrator determines that such requirements are feasible and necessary for the protection of health and the environment. This subpart describes those pesticide products which must be colored or discolored.

[60 FR 32096, June 19, 1995]

§ 153.155 Seed treatment products.

(a) Pesticide products intended for use in treating seeds must contain an EPA-approved dye to impart an unnatural color to the seed, unless appropriate tolerances or other clearances have been established under the Federal Food, Drug and Cosmetic Act for residues of the pesticide.

(b) The following products are exempt from the requirement of paragraph (a) of this section:

(1) Products intended and labeled for use solely by commercial seed treaters, provided that the label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process.

(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.

[53 FR 15990, May 4, 1988, as amended at 66 FR 66772, Dec. 27, 2001; 69 FR 23117, Apr. 28, 2004]

Subparts I–M [Reserved]

PART 154—SPECIAL REVIEW PROCEDURES

Subpart A—General Provisions

Sec.

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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