

**§ 156.204 Modification and waiver of requirements.**

(a) *Modification on Special Review.* If the Agency concludes in accordance with § 154.25(c) of this chapter that a pesticide should be placed in Special Review because the pesticide meets or exceeds the criteria for human health effects of § 154.7(a)(1)(2) or (6) of this chapter, the Agency may modify the personal protective equipment required for handlers or early-entry workers or both, the restricted-entry intervals, or the notification to workers requirements.

(b) *Other modifications.* The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data required by Subdivisions U or K of the Pesticide Assessment Guidelines or data from medical, epidemiological, or health effects studies. The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. A registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

**§ 156.206 General statements.**

(a) *Application restrictions.* Each product shall bear the statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." This statement shall be near the beginning of the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) *40 CFR part 170 reference statement.* (1) Each product shall bear the reference statement: "Use this product

only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170." This statement shall be placed on the product label under the heading AGRICULTURAL USE REQUIREMENTS.

(2) Each product shall bear the statement: "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling] about [use any of the following that are applicable] personal protective equipment, restricted-entry interval, and notification to workers." These statements shall be placed immediately following the reference statement required by paragraph (b)(1) of this section, or they shall be placed in the supplemental product labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(3) If the statements in paragraph (b)(2) of this section are included in supplemental labeling rather than on the label of the pesticide container, the container label must contain this statement immediately following the statement required in paragraph (b)(1) of this section: "Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard."

(4) If the statements in paragraph (b)(2) of this section are included in supplemental labeling, they must be preceded immediately by the statement in paragraph (b)(1) of this section under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(c) *Product-type identification.* (1) If the product contains an organophosphate (*i.e.*, an organophosphorus ester that inhibits cholinesterase) or an *N*-methyl carbamate (*i.e.*, an *N*-methyl carbamic acid ester that inhibits cholinesterase), the label shall so state. The statement shall be associated with

the product name or product-type identification or shall be in the STATEMENT OF PRACTICAL TREATMENT or FIRST AID section of the label.

(2) If the product is a fumigant, the label shall so state. The identification shall appear:

(i) As part of the product name; or

(ii) Close to the product name, as part of the product-type identification or as a separate phrase or sentence.

(d) *State restrictions.* Each product shall bear the statement: "For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(e) *Spanish warning statements.* If the product is classified as toxicity category I or toxicity category II according to the criteria in §156.10(h)(1), the signal word shall appear in Spanish in addition to English followed by the statement, "Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find some one to explain it to you in detail.)" The Spanish signal word "PELIGRO" shall be used for products in toxicity category I, and the Spanish signal word "AVISO" shall be used for products in toxicity category II. These statements shall appear on the label close to the English signal word.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

**§ 156.208 Restricted-entry statements.**

(a) *Requirement.* Each product with a restricted-entry interval shall bear the following statement: "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI)." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(b) *Location of specific restricted-entry interval statements.* (1) If a product has one specific restricted-entry interval applicable to all registered uses of the product on agricultural plants, the restricted-entry interval for the product shall appear as a continuation of the statement required in paragraph (a) of this section and shall appear as follows: "of X hours" or "of X days" or

"until the acceptable exposure level of X ppm or mg/m<sup>3</sup> is reached."

(2) If different restricted-entry intervals have been established for some crops or some uses of a product, the restricted-entry statement in paragraph (b)(1) of this section shall be associated on the labeling of the product with the directions for use for each crop each use to which it applies, immediately preceded or immediately followed by the words "Restricted-entry interval" (or the letters "REI").

(c) *Restricted-entry interval based on toxicity of active ingredient—(1) Determination of toxicity category.* A restricted-entry interval shall be established based on the acute toxicity of the active ingredients in the product. For the purpose of setting the restricted-entry interval, the toxicity category of each active ingredient in the product shall be determined by comparing the obtainable data on the acute dermal toxicity, eye irritation effects, and skin irritation effects of the ingredient to the criteria of §156.10(h)(1). The most toxic of the applicable toxicity categories that are obtainable for each active ingredient shall be used to determine the restricted-entry interval for that product. If no acute dermal toxicity data are obtainable, data on acute oral toxicity also shall be considered in this comparison. If no applicable acute toxicity data are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If no acute toxicity data are obtainable on the active ingredients and no toxicity category of a registered manufacturing-use product is obtainable, the toxicity category of the end-use product (corresponding to the signal word on its labeling) shall be used.

(2) *Restricted-entry interval for sole active ingredient products.* (i) If the product contains only one active ingredient and it is in toxicity category I by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 48 hours. If, in addition, the active ingredient is an organophosphorus ester that inhibits cholinesterase and that may be applied outdoors in an