

Environmental Protection Agency

§ 158.1020

9. Tests are required on a case-by-case basis based on the results of lower tier phytotoxicity studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

10. Registrants must consult with the Agency on appropriate test protocols prior to designing the study.

Subparts H–J [Reserved]

§§ 158.700–158.900 [Reserved]

Subpart K—Human Exposure

§ 158.1000 Applicator exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA), provide adequate protection from risk under FIFRA for a particular pesticide use pattern, exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing prior to the initiation of studies.

(b) The Agency may accept surrogate exposure data estimations from other sources to satisfy applicator exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. In order to be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address applicator exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the applicator activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1010 Applicator exposure—criteria for testing.

Applicator exposure data described in paragraph (d) of this section are required based on toxicity and exposure

criteria. Data are required if a product meets, as determined by the Agency, at least one of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide.

(b) *Exposure criteria.* (1) Dermal exposure may occur during the prescribed use.

(2) Respiratory exposure may occur during the prescribed use.

§ 158.1020 Applicator exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the applicator exposure data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood crop, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food use, and indoor nonfood use. Occupational use patterns also include commercial (“for hire”) applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and residential indoor use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed pertain to pesticide products that meet the testing criteria outlined in § 158.1010. The table notes are shown in paragraph (e) of this section.