

(a) Refer to subparts C and D (§§158.150 through 158.740). These subparts describe the data requirements, including data tables for each subject area. The corresponding subdivisions in the Pesticide Assessment Guidelines are listed in §158.108.

(b) Select the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label. Selection of the appropriate general use pattern(s) will usually be obvious. However, unique or ambiguous cases will arise occasionally. These situations may be clarified by reference to the Use Pattern Index presented in the appendix to the Data Requirements for Registration. The applicant can look up a specific use pattern in appendix A and it will be cross referenced to the appropriate general use patterns to be used in each Data Requirement table.

(c) Proceed down the appropriate general use pattern column in the table and note which tests (listed along the left hand side of the table) are required ("R"), conditionally required ("CR") or usually not required ("—"). After reading through each data requirement table, the applicant will have a complete list of required and conditionally required data for the pesticide product and the substance to be tested in developing data to meet each requirement. The data EPA must have available to review the registration of a specific product consists of all the data designated as required for that product and all the applicable data designated as conditionally required for that product.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15993, May 4, 1988]

#### § 158.101 Required vs. conditionally required data.

(a) Data designated as "required" ("R") for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern unless the data requirement has been waived under §158.45 for that particular product or unless the product is covered by a specific exception set forth in a note accompanying the requirement.

(b) Data designated as "conditionally required" ("CR") for products with a given general use pattern are needed by

EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the corresponding notes accompanying the data requirements table. As indicated in the notes, the determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (e.g., tier testing). Applicants must evaluate each applicable note to determine whether or not conditionally required data must be submitted as indicated by the conditions and criteria specified in the accompanying notes unless the Agency has granted a waiver request submitted by the registrant in accordance with §158.45.

(c) For certain of the required or conditionally required data, the "R" or "CR" designations and are enclosed in brackets (*i.e.*, [R], [CR]). The brackets designate those data that are required or conditionally required to support a product when an experimental use permit is being sought. In all other situations (*i.e.*, other than support of an experimental use permit), the brackets have no meaning and the designations R and CR are equivalent to [R] and [CR], respectively.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 34203, June 23, 1993]

#### § 158.102 Distinguishing between what data are required and what substance is to be tested.

(a) Readers should be careful to distinguish between what data are required and what substance is to be tested, as specified in this part and in each corresponding section of the guidelines. Each data requirement table specifies whether a particular data requirement is required to support the registration of manufacturing-use products, end-use products, or both. The test substance column specifies which substance is to be subjected to testing. Thus, the data from a certain kind of study may be required to support the registration of each end-use product, but the test substance column may state that the particular test shall be performed using, for example, the technical grade of the active ingredient(s) in the end-use product.

(b) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no inert ingredients are identical in composition to each other and to the technical grade of the active ingredient (TGAI) from which they were derived, and therefore, the data from a test conducted using any one of these as the test substance (e.g., TGAI) is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances (*i.e.*, MP or EP).

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

**§ 158.108 Relationship of Pesticide Assessment Guidelines to data requirements.**

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 Road, Springfield, VA 22161 (703-487-4650). The following Subdivisions of the Pesticide Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D	Product Chemistry .....	PB83-153890	§§ 158.150-158.190
E	Hazard Evaluation: Wildlife and Aquatic Organisms .....	PB83-153908	§ 158.490
F	Hazard Evaluation: Humans and Domestic Animals .....	PB83-153916	§ 158.340
G	Product Performance .....	PB83-153924	§ 158.640
I	Experimental Use Permits .....	PB83-153932	§§ 158.20-158.740
J	Hazard Evaluation: Nontarget Plants .....	PB83-153940	§ 158.540
K	Reentry Protection .....	PB85-120962	§ 158.390
L	Hazard Evaluation: Nontarget Insect .....	PB83-153957	§ 158.590
M	Biorational Pesticides .....	PB83-153965	§§ 158.690-158.740
N	Environmental Fate .....	PB83-153973	§ 158.290
O	Residue Chemistry .....	PB83-153961	§ 158.240
R	Spray Drift Evaluation .....	PB84-189216	§ 158.440

[53 FR 15993, May 4, 1988]

**Subpart C—Product Chemistry Data Requirements**

SOURCE: 53 FR 15993, May 4, 1988, unless otherwise noted.

**§ 158.150 General.**

(a) *Applicability.* This subpart describes the product chemistry data that are required to support the registration of each pesticide product. The information specified in this subpart must be submitted with each application for new or amended registration or for reregistration, if it has not been submitted previously or if the previously submitted information is not complete and accurate. References in this subpart to the “applicant” include the registrant if the information is required for a registered product.

(b) *Purpose*—(1) *Product composition.* (i) Data on product composition are needed to support the conclusions expressed in the statement of formula.

These data include information on the starting materials, production or formulating process, possible formation of impurities, results of preliminary analysis of product samples, a description of analytical methods to identify and quantify ingredients and validation data for such methods. In addition, an applicant is required to certify the limits for ingredients of his product.

(ii) Product composition data are compared to the composition of materials used in required testing under subpart D of this part. This comparison indicates which components of a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product’s composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.