

(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.