

§ 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 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 58 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 re-

quired 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 need-

ed. Based on conclusions concerning the product’s composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(iii) Product composition data, including certified limits of components, are used to determine whether a product is “identical or substantially similar” to another product or “differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment” (FIFRA sec. 3(c)(7)(A)). In nearly every case, this determination involves a comparison of the composition of an applicant’s product with that of currently registered products.

(2) *Certified limits.* Certified limits required by § 158.175 are used in two ways. First, the Agency considers the certified limits in making the registration determination required by sections 3(c)(5), 3(c)(7) and 3(d) of the Act and making other regulatory decisions required by the Act. Second, the Agency may collect commercial samples of the registered products and analyze them for the active ingredient(s), inert ingredients, or impurities determined by the Agency to be toxicologically significant. If, upon analysis the composition of such a sample is found to differ from that certified, the results may be used by the Agency in regulatory actions under FIFRA sec. 12(a)(1)(C) and other pertinent sections.

(3) *Nominal concentration.* The nominal concentration required by § 158.155 is the amount of active ingredient that is most likely to be present in the product when produced. Unlike the certified limits, which are the outer limits