

(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.

(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 of the range of the product’s ingredients and thus are present only in a small proportion of the products, the nominal concentration is the amount that typically is expected to result from the applicant’s production or formulating process. The nominal concentration together with production process information is used to gauge the acceptability of the certified limits presented by the applicant. The nominal concentration is used by the Agency as the basis for enforceable certified limits if the applicant has chosen not to specify certified limits of his own (thereby agreeing to abide by the standard limits in §158.175).

(4) *Physical and chemical characteristics.* (1) Data on the physical and chemical characteristics of pesticide active ingredients and products are used to

confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product. For example, data that indicate significant changes in production or formulation might indicate the need for additional information on product composition.

(ii) Certain information (e.g., color, odor, physical state) is needed for the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills. Physicians, hospitals, and poison control centers also request this information to aid in their identification of materials implicated in poisoning episodes.

(iii) Certain physical and chemical data are used directly in the hazard assessment. These include stability, oxidizing and reducing action, flammability, explosibility, storage stability, corrosion, and dielectric breakdown voltage. For example, a study of the corrosion characteristics of a pesticide is needed to evaluate effects of the product formulation on its container. If the pesticide is highly corrosive, measures can be taken to ensure that lids, liners, seams or container sides will not be damaged and cause the contents to leak during storage, transport, handling, or use. The storage stability study provides data on change (or lack of change) in product composition over time. If certain ingredients decompose, other new chemicals are formed whose toxicity and other characteristics must be considered.

(iv) Certain data are needed as basic or supportive evidence in initiating or evaluating other studies. For example, the octanol/water partition coefficient is used as one of the criteria to determine whether certain fish and wildlife toxicity or accumulation studies must be conducted. Vapor pressure data are needed, among other things, to determine suitable reentry intervals and other label cautions pertaining to worker protection. Data on viscosity and miscibility provide necessary information to support acceptable labeling for tank mix and spray applications.