are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

Applicant means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

1. An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.
2. A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.
3. An application for an experimental use permit under FIFRA sec. 5.
4. A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).
5. A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.

Registration includes a new registration, amended registration and reregistration, unless stated otherwise.

§ 158.5 Applicability.

(a) The requirements of this part apply to the following submissions:
1. An application for new or amended registration under FIFRA sec. 3 or 24.
2. An application for experimental use permit under FIFRA sec. 5.
3. A submission of data or information to support the continuation of a registration under FIFRA sec. 3, 4, or 24.
4. A petition to establish, modify or revoke a tolerance or exemption from a tolerance under FFDCA sec. 408.

(b) The information specified in this part must be furnished with each submission described in paragraph (a) of this section if it has not been submitted previously, or if any previous submission is not accurate or complete.

§ 158.30 Flexibility.

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

§ 158.32 Format of data submissions.

(a) General. (1) All data submitted under this part must be formatted in accordance with this section.

(b) Transmittal document. Each submission in support of a regulatory action must be accompanied by a transmittal document, which includes:

1. Identity of the submitter.
2. The transmittal date.
3. Identification of the regulatory action with which the submission is associated, e.g., the registration or petition number.

(c) Individual documents. Unless otherwise specified by the Agency, each
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§ 158.33 Confidential data.

(a) Definitions. For the purposes of this section:

(1) Registered or previously registered pesticide means any pesticide containing an active ingredient contained in a product that is, or has ever been, an active ingredient in a product registered under sec. 3 of FIFRA. A registered pesticide that is the subject of an application for a new use falls within the category of “registered or previously registered pesticide.”

(2) Safety and efficacy information means information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism.

(b) Applicability. (1) This section applies to information submitted pursuant to this part. It supplements the general confidentiality procedures in 40 CFR part 2, subpart B, including FIFRA confidentiality procedures at 40 CFR 2.307. To the extent that provisions in this section conflict with those in 40 CFR part 2, subpart B, the provisions in this section take precedence. The provisions of 40 CFR 2.308 do not apply to information to which this section applies. In addition to complying with the requirements of this section, any confidentiality claims for information subject to 40 CFR part 174 (plant-incorporated protectants) must be substantiated at the time of submission as described in §174.9 of this chapter.

(2) FFDCA sec. 408(i) protects confidentiality information submitted in connection with an application for a tolerance or exemption to the same extent as FIFRA sec. 10. References in this section to FIFRA sec. 10 are deemed to apply equally to information submitted pursuant to FFDCA sec. 408, pursuant to the authority in sec. 408(1).

(c) Method of asserting business confidentiality claims—(1) Claim required. Information to which this section applies (and which is submitted on or after the effective date of this regulation) will be deemed as not subject to a confidentiality claim unless a claim for that information is made in accordance with the procedures specified in this paragraph. Information not subject to a confidentiality claim may be made available to the public without further notice, subject to the requirements of FIFRA sec. 10(g).