

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 §161.175 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 §161.155 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 §161.175).

(4) *Physical and chemical characteristics.* (i) 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.

§ 161.153 Definitions.

The following terms are defined for the purposes of this subpart:

(a) *Active ingredient* means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as

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a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(b) *End use product* means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(c) *Formulation* means

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing use product or an end use product, or

(2) The repackaging of any registered product.

(d) *Impurity* means any substance (or group of structurally similar substances if specified by the Agency) in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

(e) *Impurity associated with an active ingredient* means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

(f) *Inert ingredient* means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(g) *Integrated system* means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

(h) *Manufacturing use product* means any pesticide product other than an

end use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

(i) *Nominal concentration* means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

(j) *Starting material* means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

(k) *Technical grade of active ingredient* means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot-plant production scale (whether or not it is ever held for sale).

§ 161.155 Product composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b) and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) must be provided.

(a) *Active ingredient*. The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with §161.175.

(2) If the source of any active ingredient in the product is not an EPA-registered product: