

records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for whichever of the following periods is longest:

(1) In the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor holds any research or marketing permit to which the study is pertinent.

(2) A period of at least 5 years following the date on which the results of the study are submitted to the EPA in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens, samples of test, control, or reference substances, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by §160.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by §160.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by §160.63 (b) and (c), shall be retained for the length

of time specified in paragraph (b) of this section.

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.

(i) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

PART 162—STATE REGISTRATION OF PESTICIDE PRODUCTS

Subparts A–C [Reserved]

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Subpart E [Reserved]

Subparts A–C [Reserved]

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

AUTHORITY: 7 U.S.C. 136v, 136w.

Environmental Protection Agency

§ 162.152

SOURCE: 46 FR 2014, Jan. 7, 1981, unless otherwise noted.

§ 162.150 General.

(a) *Scope.* This subpart sets forth regulations governing the registration by any State of pesticide products, or uses thereof, formulated for distribution and use within the State to meet special local needs under sec. 24(c) of the Act. It also sets forth regulations governing the exercise by the Administrator of the power to disapprove specific State registrations and to suspend a State's registration authority under sec. 24(c). Unless otherwise indicated, any reference herein to registrations issued by a State includes amendments of registrations issued by States.

(b) *Applicability.* This subpart applies only to State registration authority granted by sec. 24(c) of FIFRA. It does not apply to any authority granted, or procedures established, by State law with respect to registration, licensing, or approval required for use within the State of federally registered pesticide products.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988; 60 FR 32097, June 19, 1995]

§ 162.151 Definitions.

Unless otherwise indicated, terms used in this subpart have the meanings set forth in FIFRA and in subpart A of this part. In addition, as used in this subpart, the following terms have the meanings set forth below:

(a) *Federally registered* means currently registered under sec. 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (Pub. L. 86-139; 73 Stat. 286; June 25, 1947) by the Secretary of Agriculture or under FIFRA by the Administrator.

(b) *Manufacturing-use product* means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after re-formulation or repackaging.

(c) *New product* means a pesticide product which is not a federally registered product.

(d) *Pest problem* means (1) a pest infestation and its consequences, or (2) any condition for which the use of plant

regulators, defoliants, or desiccants would be appropriate.

(e) *Product or pesticide product* means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

(f) *Similar composition* refers to a pesticide product which contains only the same active ingredient(s), or combination of active ingredients, and which is in the same category of toxicity, as a federally registered pesticide product.

(g) *Similar product* means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

(h) *Similar use pattern* refers to a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under § 156.10(h) of this chapter, and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

(i) *Special local need* means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

(j) *State or State lead agency* as used in this subpart means the State agency designated by the State to be responsible for registering pesticides to meet special local needs under sec. 24(c) of the Act.

[46 FR 2014, Jan. 7, 1981, as amended at 53 FR 15999, May 4, 1988]

§ 162.152 State registration authority.

(a) *Statutory limitations.* In accordance with sec. 24(c) of the Act, each State is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

(1) There is a special local need for the use within the State;

(2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 *et seq.*), if the use is a food or feed use;