

**§ 173.8**

rescind be withdrawn and that the rescission proceeding be terminated.

(c) If, following the close of the hearing, the Presiding Officer finds that the State has not corrected the deficiencies in its program, the Presiding Officer shall issue a decision recommending that the State's primary enforcement responsibility for pesticide use violations be rescinded in whole or in part.

(d) The recommended decision of the Presiding Officer shall become final Agency action forty-five (45) days after its service upon the parties and without further proceedings unless (1) an appeal to the Administrator is taken from it by a party to the proceeding, or (2) the Administrator elects, sua sponte, to review the recommended decision.

**§ 173.8 Final order.**

(a) If the State does not request a hearing within the sixty-day time period and the Administrator has not issued an order withdrawing the notice of intent to rescind, the Administrator shall issue a final order as soon as practicable after the time for public comment on the notice of intent to rescind has elapsed. The final order shall either withdraw the notice of intent to rescind and terminate the proceeding or rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(b) If a hearing has been held and the Presiding Officer has made a recommended decision, then either the Office of Enforcement or the State may appeal the recommended decision to the Administrator or the Administrator may elect to review the recommended decision on his own initiative.

(c) After an appeal or sua sponte review the Administrator shall issue a final order terminating the rescission proceeding or rescinding, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(d) In no event may the Administrator issue his final decision sooner than ninety (90) days after service of the notice of intent to rescind on a State.

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(e) Any final order, or a recommended decision which becomes a final order under §173.7(c), shall be published in the FEDERAL REGISTER.

**§ 173.9 Judicial review.**

The State may appeal an order rescinding, in whole or in part, its primary enforcement responsibility for pesticide use violations to the appropriate federal court pursuant to section 16 of FIFRA.

**PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT INCORPORATED PROTECTANTS**

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## Environmental Protection Agency

## § 174.3

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AUTHORITY: 7 U.S.C. 136-136y; 21 U.S.C. 346a and 371.

SOURCE: 66 FR 37814, July 19, 2001, unless otherwise noted.

### Subpart A—General Provisions

#### § 174.1 Scope and purpose.

The characteristics of plant-incorporated protectants such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment distinguish them from traditional chemical pesticides. Therefore, plant-incorporated protectants are subject to some different regulatory requirements and procedures than traditional chemical pesticides. This part sets forth regulatory requirements, criteria, and procedures applicable to plant-incorporated protectants under FIFRA and FFDCA. When applied to plant-incorporated protectants, the definitions and regulations in this part supercede the regulations found in parts 150 through 180 of this chapter to the extent that the regulations conflict. Unless otherwise superceded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.

#### § 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following terms have the meaning set forth in this section.

*Active ingredient* means a pesticidal substance that is intended to be pro-

duced and used in a living plant, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance.

*Administrator* means the Administrator of the United States Environmental Protection Agency or his/her delegate.

*Bridging crosses between plants* means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

*Cell fusion* means the fusion *in vitro* of two or more cells or protoplasts.

*Conventional breeding* of plants means the creation of progeny through either: The union of gametes, i.e., syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

*EPA* means the United States Environmental Protection Agency.

*Exudate* means a substance gradually discharged or secreted across intact cellular membranes or cell walls and present in the intercellular spaces or on the exterior surfaces of the plant.

*FFDCA* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

*FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*).

*Food* includes articles used for food or drink by humans or other animals.

*Food plant* means a plant which either in part or *in toto*, is used as food.

*Genetic material necessary for the production* means both: Genetic material that encodes a substance or leads to