

**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 supersede the regulations found in parts 150 through 180 of this chapter to the extent that the regulations conflict. Unless otherwise superseded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.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 produced 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 the production of a substance; and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

*Genome* means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

*In a living plant* means inside the living plant, on the surface of the living plant, or as an exudate from the living plant.

*Inert ingredient*, means any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient.