(d) If a termination order is issued or the hearing is rescheduled after the notice of intent to rescind is published in the FEDERAL REGISTER, such order or notice rescheduling the hearing shall also be published in the FEDERAL REGISTER.

§ 173.7 Hearing and recommended decision.

(a) The Presiding Officer shall:

(1) Conduct a fair and impartial hearing, without unnecessary delay;

(2) Ensure that the facts are fully elicited; and

(3) Consider all evidence, comment, and argument which is submitted by persons who will be affected by the outcome of the proceeding and which is not irrelevant, immaterial, unduly repetitious, or otherwise unreliable or of little probative value. The Presiding Officer may require any prospective witness to make available, in advance of the hearing, a brief summary of his or her testimony.

(b) If, following the close of the hearing, the Presiding Officer finds that the State has corrected, or has agreed in writing to correct, the deficiencies specified in the notice of intent to rescind or has shown that such deficiencies do not exist, the Presiding Officer shall issue a decision recommending that the notice of intent to rescind be withdrawn and that the rescission proceeding be terminated.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shall issue a decision recommending that the State's primary enforcement responsibility for pesticide use violations be rescinded in whole or in part.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.

(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

Subpart A—General Provisions

Sec.

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 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.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Nucleic acids means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil; polymers of the deoxyribose-5′-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3′-5′ phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5′-monophosphates of uracil, cytosine, guanine, and adenine linked by successive 3′-5′ phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.

Pesticidal substance, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose, during any part of a plant's life cyle (e.g., in the embryo, seed, seedling, mature plant).

Plant, for plant-incorporated protectants, means an organism classified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. This includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

Plant-incorporated protectant 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 production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Produce thereof, when used with respect to plants containing plant- incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains, and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not ''produce thereof'' when the residues are not intended to serve a pesticidal purpose in the produce.

Recipient plant means the living plant in which the plant-incorporated protectant is intended to be produced and used.

Recombinant DNA means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

Sexually compatible, when referring to plants, means a viable zygote is formed only through the union of two gametes through conventional breeding.

Source means the donor of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance.

Vegetative reproduction means either:

(1) In seed plants, reproduction by apomixis, or

(2) In other plants, reproduction by fragmentation, or division of the somatic body.

Wide crosses means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

§ 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, the submitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the nformation submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in §2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will

suspend any applicable review of such submissions until the required substantiation is provided.

Subpart B—Exemptions

§ 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of § 174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of the sections in §§ 174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in a crop used as food, the residues of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) as codified at §§ 174.475 through 174.479, or no tolerance would otherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at §§ 174.485 through 174.490. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

§ 174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

§ 174.71 Submission of information regarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under supart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans or other nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where the incident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide

Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[66 FR 37814, July 19, 2001, as amended at 71 FR 35546, June 21, 2006]

Subparts E–F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I [Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L–T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V [Reserved]

Subpart W—Tolerances and Tolerance Exemptions

§ 174.451 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerance for residues of plant-incorporated protectants in or on raw agricultural commodities, in food, and in animal feeds.

§ 174.452 Bacillus thuringiensis VIP3A protein and the genetic material necessary for its production; temporary exemption from the requirement of a tolerance.

Bacillus thuringiensis VIP3A protein and the genetic material necessary for its production is temporarily exempt from the requirement of a tolerance when used as a vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. Genetic material necessary for its production means the genetic material which comprise genetic encoding the VIP3A protein and its regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control expression of the genetic material encoding the VIP3A protein. This temporary exemption from the requirement of a tolerance expires May 1, 2007.

[71 FR 24586, Apr. 26, 2006]

§ 174.455 Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in cotton; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in food and feed commodities of cotton. ''Genetic material necessary for its production'' means the genetic material which comprise: Genetic material encoding the Cry1F protein and its regulatory regions. ''Regulatory regions'' are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry1F protein.

[69 FR 58284, Sept. 30, 2004]

§ 174.456 Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn.

Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn is temporarily exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of field corn, sweet corn and popcorn. Genetic material necessary for its production means the genetic material which comprise genetic material encoding the mCry3A protein and its regulatory regions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the mCry3A protein. This temporary exemption from the requirement of a tolerance will permit the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 67979–EUP–4 which is being

issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked October 15, 2007; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[71 FR 13273, Mar. 15, 2006]

§ 174.457 Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry34Ab1 and Cry35Ab1 proteins and the genetic material necessary for their production in corn are exempted from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[70 FR 55260, Sept. 21, 2005]

§ 174.475 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.

Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

[66 FR 37830, July 19, 2001]

§ 174.479 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37854, July 19, 2001]

Subpart X—List of Approved Inert Ingredients

§ 174.480 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA and FFDCA section 408 requirements and may be used in a plant-incorporated protectant listed in subpart B of this part.

§ 174.485 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:

(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

Subparts Y–Z [Reserved]

PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

Sec.

AUTHORITY: 21 U.S.C. 346a and 371.