

§ 173.9

(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.
- 174.1 Scope and purpose.
- 174.3 Definitions.
- 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Subpart B—Exemptions

- 174.21 General qualifications for exemptions.
- 174.25 Plant-incorporated protectant from sexually compatible plant.

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

- 174.71 Submission of information regarding adverse effects.

40 CFR Ch. I (7–1–18 Edition)

Subparts E–F [Reserved]

Subpart G—Labeling Requirements [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

- 174.500 Scope and purpose.
- 174.501 *Bacillus thuringiensis* Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.
- 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.
- 174.504 *Bacillus thuringiensis* Cry1F protein; exemption from the requirement of a tolerance.
- 174.505 *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.
- 174.506 *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.
- 174.507 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.
- 174.508 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.
- 174.509 *Bacillus thuringiensis* Cry3A protein; exemption from the requirement of a tolerance.
- 174.510 *Bacillus thuringiensis* Cry1Ac protein in all plants; exemption from the requirement of a tolerance.
- 174.511 *Bacillus thuringiensis* Cry1Ab protein in all plants; exemption from the requirement of a tolerance.
- 174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.
- 174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.
- 174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic

Environmental Protection Agency

§ 174.3

- Virus; exemption from the requirement for a tolerance.
- 174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.
- 174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.
- 174.517 *Bacillus thuringiensis* Cry9C protein in corn; exemption from the requirement of a tolerance.
- 174.518 *Bacillus thuringiensis* Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.
- 174.519 *Bacillus thuringiensis* Cry2Ab2 protein; exemption from the requirement of a tolerance.
- 174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.
- 174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.
- 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.
- 174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.
- 174.525 *E. coli* B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.
- 174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.
- 174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.
- 174.529 *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN-IR67B-1 in cotton; exemption from the requirement of a tolerance.
- 174.530 *Bacillus thuringiensis* Cry2Ae protein in cotton; exemption from the requirement of a tolerance.
- 174.531 Coat protein of plum pox virus; exemption from the requirement of a tolerance.
- 174.532 *Bacillus thuringiensis* eCry3.1Ab protein in corn; exemption from the requirement of a tolerance.
- 174.533 *Glycine max* Herbicide-Resistant Acetolactate Synthase (GM-HRA) inert ingredient; exemption from the requirement of a tolerance.
- 174.534 VNT1 protein; exemption from the requirement of a tolerance.
- 174.535 Spinach Defensin proteins; temporary exemption from the requirement of a tolerance.
- 174.536 *Bacillus thuringiensis* mCry51Aa2 protein in cotton; temporary exemption from the requirement of a tolerance.

- 174.537 HPPD-4 protein; exemption from the requirement of a tolerance.
- 174.538 *Bacillus thuringiensis* Cry14Ab-1 protein in soybean; temporary exemption from the requirement of a tolerance.
- 174.539 Cry51Aa2.834_16 protein; exemption from the requirement of a tolerance.

Subpart X—List of Approved Inert Ingredients

- 174.700 Scope and purpose.
- 174.705 Inert ingredients from sexually compatible plant.

Subparts Y–Z [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 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 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.

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 cycle (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 information 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

§ 174.21

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 §§ 174.507 through 174.508, 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 § 174.705. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

[66 FR 37814, July 19, 2001, as amended at 72 FR 20434, Apr. 25, 2007]

§ 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]

40 CFR Ch. I (7–1–18 Edition)

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 subpart 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

Environmental Protection Agency

§ 174.505

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

§ 174.500 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 food commodities.

[72 FR 20434, Apr. 25, 2007]

§ 174.501 *Bacillus thuringiensis* Vip3Aa protein in corn and cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa proteins in or on corn or cotton are exempt from the requirement of a tolerance when used as plant-incorporated protectants in or on the food and feed commodities of corn; corn, field; corn, sweet; corn, pop; and cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[73 FR 45624, Aug. 6, 2008]

§ 174.502 *Bacillus thuringiensis* Cry1A.105 protein; exemption from the requirement of a tolerance.

(a) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on the food and feed commodities of corn; corn, field, flour; corn, field, forage; corn, field, grain; corn, field, grits; corn, field, meal; corn, field, refined oil; corn, field, stover; corn, sweet, forage; corn, sweet, kernel plus cob with husk removed; corn, sweet, stover; and corn, pop, grain and corn, pop, stover are exempt from the requirement of a tolerance when the *Bacillus thuringiensis* Cry1A.105 protein is used as a plant-incorporated protectant in these food and feed corn commodities.

(b) Residues of *Bacillus thuringiensis* Cry1A.105 protein in or on soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of soybean.

[74 FR 39543, Aug. 7, 2009, as amended at 80 FR 25950, May 6, 2015]

§ 174.504 *Bacillus thuringiensis* Cry1F protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in the food and feed commodities of corn, field; corn, sweet; corn, pop; cotton; and soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn, field; corn, sweet; corn, pop; cotton, and soybean.

[79 FR 8295, Feb. 12, 2014]

§ 174.505 *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]

§ 174.506

§ 174.506 *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins 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.

[72 FR 20434, Apr. 25, 2007]

§ 174.507 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. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.508 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. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.509 *Bacillus thuringiensis* Cry3A protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3A protein are exempted from the requirement of a tolerance when used

40 CFR Ch. I (7–1–18 Edition)

as a plant-incorporated protectant in potatoes.

[72 FR 20435, Apr. 25, 2007]

§ 174.510 *Bacillus thuringiensis* Cry1Ac protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ac protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.511 *Bacillus thuringiensis* Cry1Ab protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ab protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.

Residues of Coat Protein of Potato Virus Y are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant-incorporated protectant Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus; exemption from the requirement for a tolerance.

Residues of Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus are exempt from the requirement of a tolerance when

Environmental Protection Agency

§ 174.524

used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Papaya Ringspot Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Cucumber Mosaic Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.517 *Bacillus thuringiensis* Cry9C protein in corn; exemption from the requirement of a tolerance.

The plant-incorporated protectant *Bacillus thuringiensis* Cry9C protein in corn is exempted from the requirement of a tolerance for residues, only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

[72 FR 20435, Apr. 25, 2007]

§ 174.518 *Bacillus thuringiensis* Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3Bb1 protein in corn are exempt 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.

[72 FR 20435, Apr. 25, 2007]

§ 174.519 *Bacillus thuringiensis* Cry2Ab2 protein; exemption from the requirement of a tolerance.

(a) Residues of *Bacillus thuringiensis* Cry2Ab2 protein in or on corn or cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn,

sweet; corn, pop; and cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts.

(b) Residues of *Bacillus thuringiensis* Cry2Ab2 protein in or on soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of soybean.

[80 FR 25604, May 5, 2015]

§ 174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.

Residues of the neomycin phosphotransferase II (NPTII) enzyme are exempted from the requirement of a tolerance in all food commodities when used as a plant-incorporated protectant inert ingredient.

[72 FR 20435, Apr. 25, 2007]

§ 174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.

Residues of the Phosphinothricin Acetyltransferase (PAT) enzyme are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.

Residues of the CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase enzyme in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.

Residues of the Glyphosate Oxidoreductase GOX or GOXv247 enzyme in all plants are exempt from the requirement of a tolerance when used

§ 174.525

as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.525 *E. coli* B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.

Residues of *E. coli* B-D-glucuronidase enzyme are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.

Residues of the Hygromycin B phosphotransferase (APH4) enzyme in all plants are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in cotton.

[72 FR 20435, Apr. 25, 2007]

§ 174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.

Residues of the phosphomannose isomerase (PMI) enzyme in plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.529 *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN-IR67B-1 in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN-IR67B-1 are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in cotton; cotton, undelinted seed; cotton, refined oil; cotton, meal; cotton, hay; cotton, hulls; cotton, forage; and cotton, gin byproducts.

[73 FR 40764, July 16, 2008]

40 CFR Ch. I (7-1-18 Edition)

§ 174.530 *Bacillus thuringiensis* Cry2Ae protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ae protein in or on the food and feed commodities of cotton; cotton, undelinted seed; cotton, gin byproducts; cotton, forage; cotton, hay; cotton, hulls; cotton, meal; and cotton, refined oil, are exempt from the requirement of a tolerance when *Bacillus thuringiensis* Cry2Ae protein is used as a plant-incorporated protectant in cotton.

[77 FR 6475, Feb. 8, 2012]

§ 174.531 Coat protein of plum pox virus; exemption from the requirement of a tolerance.

Residues of the coat protein of plum pox virus in or on the food commodities of fruit, stone, Group 12; and almond, are exempt from the requirement of a tolerance in these food commodities when expressed by the plant-incorporated protectant, coat protein gene of plum pox virus, and used in accordance with good agricultural practices.

[75 FR 29435, May 26, 2010]

§ 174.532 *Bacillus thuringiensis* eCry3.1Ab protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when *Bacillus thuringiensis* eCry3.1Ab protein in corn is used as a plant-incorporated protectant.

[77 FR 47291, Aug. 8, 2012]

§ 174.533 *Glycine max* Herbicide-Resistant Acetolactate Synthase (GM-HRA) inert ingredient; exemption from the requirement of a tolerance.

Residues of *Glycine max* herbicide-resistant acetolactate synthase (GM-HRA) enzyme in or on the food and feed commodities of soybean are exempt from the requirement of a tolerance

Environmental Protection Agency

§ 174.705

when used as a plant-incorporated protectant inert ingredient.

[78 FR 9321, Feb. 8, 2013]

§ 174.534 VNT1 protein; exemption from the requirement of a tolerance.

Residues of VNT1 protein in potato are exempt from the requirement of a tolerance when the *Rpi-vnt1* gene that express the VNT1 protein is used as a plant-incorporated protectant in potato.

[82 FR 11515, Feb. 24, 2017]

§ 174.535 Spinach Defensin proteins; temporary exemption from the requirement of a tolerance.

Residues of the defensin proteins SoD2, SoD2*, SoD7, and SoD8 derived from spinach (*Spinacia oleracea* L.) in or on citrus food commodities are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in citrus plants in accordance with the terms of Experimental Use Permit No. 88232-EUP-1. This temporary exemption from the requirement of a tolerance expires on May 31, 2021.

[83 FR 24944, May 31, 2018]

§ 174.536 *Bacillus thuringiensis* mCry51Aa2 protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of the protein mCry51Aa2 in or on the food and feed commodities of cotton: Cotton, undelinted seed; cotton, gin byproducts; cotton, forage; cotton, hay; cotton, hulls; cotton, meal; and cotton, refined oil are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in cotton plants in accordance with the terms of Experimental Use Permit No. 524-EUP-108. This temporary exemption from the requirement of a tolerance expires on February 28, 2019.

[82 FR 18230, Apr. 18, 2017]

§ 174.537 HPPD-4 protein; exemption from the requirement of a tolerance.

Residues of the HPPD-4 protein, which is a modified protein derived from the 4-hydroxyphenylpyruvate

dioxygenase enzyme of *Pseudomonas fluorescens*, in or on all food commodities are exempt from the requirement of a tolerance, when the HPPD-4 protein is used as a plant-incorporated protectant inert ingredient.

[82 FR 57140, Dec. 4, 2017]

§ 174.538 *Bacillus thuringiensis* Cry14Ab-1 protein in soybean; temporary exemption from the requirement of a tolerance.

Residues of the protein Cry14Ab-1 in or on soybean are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in soybean plants in accordance with the terms of Experimental Use Permit No. 264-EUP-151. This temporary exemption from the requirement of a tolerance expires on April 1, 2020.

[82 FR 57137, Dec. 4, 2017]

§ 174.539 Cry51Aa2.834_16 protein; exemption from the requirement of a tolerance.

Residues of the Cry51Aa2.834_16 protein, which is a modified protein derived from the Cry51Aa2 protein of *Bacillus thuringiensis*, in or on cotton are exempt from the requirement of a tolerance, when the Cry51Aa2.834_16 protein is used as a plant-incorporated protectant.

[83 FR 3603, Jan. 26, 2018]

Subpart X—List of Approved Inert Ingredients

§ 174.700 Scope and purpose.

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

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

§ 174.705 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.

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

Subparts Y–Z [Reserved]

PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

Sec.

176.1 Scope and applicability.

176.3 Definitions.

176.5 Establishment of a time-limited tolerance or exemption.

176.7 Information needed to establish a tolerance.

176.9 Publication of a tolerance.

176.11 Duration of a tolerance.

176.13 Modification of a time-limited tolerance.

176.15 Effect of a tolerance.

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

SOURCE: 65 FR 64131, Oct. 25, 2000, unless otherwise noted.

§ 176.1 Scope and applicability.

This part describes the procedures and criteria under which EPA will establish time-limited tolerances and exemptions from the requirement of a tolerance for pesticide chemical residues associated with use of pesticides under emergency or crisis exemptions under FIFRA section 18. This part applies only to tolerances issued on the initiative of EPA as the result of the issuance of an emergency exemption or the declaration of a crisis exemption. This part does not cover time-limited tolerances in any other circumstances.

§ 176.3 Definitions.

The terms have the same meaning as in the Federal Insecticide, Fungicide, and Rodenticide Act section 2, and in the Federal Food, Drug, and Cosmetic

Act section 201 and § 166.3 of this chapter. In addition, the following terms are defined for the purposes of this part.

Agency means the U.S. Environmental Protection Agency.

Applicant means any entity authorized under section 18 of FIFRA to request an emergency exemption that requests such an exemption under § 166.20 of this chapter, or issues a crisis exemption under § 166.40 of this chapter.

Crisis exemption means an exemption authorized under FIFRA section 18, in accordance with §§ 166.40 through 166.53 of this chapter.

Emergency exemption means a specific, quarantine, or public health exemption authorized under FIFRA section 18 and the regulations at §§ 166.20 through 166.35 of this chapter.

EPA means the U.S. Environmental Protection Agency.

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 (7 U.S.C. 136 *et seq.*).

Tolerance means the maximum amount of a pesticide chemical residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.

Tolerance exemption means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C. 346a(c), that no tolerance is needed for a given pesticide chemical residue in or on a particular food commodity. For purposes of this part, the term “tolerance” shall include an exemption from the requirement of a tolerance.

§ 176.5 Establishment of a time-limited tolerance or exemption.

EPA will establish a time-limited tolerance for pesticide chemical residues in or on raw or processed food or feed resulting from the use of a pesticide chemical, if EPA authorizes an emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant acting under authority of FIFRA section 18 either has requested