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## **Title 40 —Protection of Environment**

### **Chapter I —Environmental Protection Agency**

#### **Subchapter E —Pesticide Programs**

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## PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

**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 Unless otherwise superseded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.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.

**Gene**, and other grammatical variants such as “genic,” means a unit of heritable genetic material that is comprised of the genetic material necessary for the production of a substance.

**Genetic engineering** means the modification of the genome of an organism using recombinant, synthesized, or amplified nucleic acids or other techniques excluded from the definition of conventional breeding.

**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.

**Loss-of-function plant-incorporated protectant** means a plant-incorporated protectant in which the genetic material of a native gene is modified to result in a pesticidal effect through the reduction or elimination of the activity of that gene. For purposes of loss-of-function plant-incorporated protectants, the active ingredient and pesticidal substance are one and the same and are defined as the genetic material that has been modified to create the pesticidal trait (*i.e.*, modification of the sequence of nucleic acids). Loss-of-function plant-incorporated protectants do not include instances where the reduction or elimination of the activity of the modified native gene results in the intentional increase of activity of another pesticidal gene.

**Native allele** means a variant of a native gene that is identified in the genetic diversity of plants sexually compatible with the recipient plant.

**Native gene** means a gene that is identified in the recipient plant or source plants that are sexually compatible with the recipient plant. It does not include genes introduced through genetic engineering from a source organism that is not sexually compatible with the source plant.

**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 plants must be capable of forming a viable zygote 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.

[66 FR 37814, July 19, 2001, as amended at 88 FR 34776, May 31, 2023]

## § 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 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 the exemption criteria in paragraphs (a) through (d) of this section. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

- (a) The active ingredient of the plant-incorporated protectant meets the exemption 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 active ingredient of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (21 U.S.C. 321 *et seq.*) as listed in subpart W of this part, or no tolerance would otherwise be required.
- (c) Any inert ingredient that is part of the plant-incorporated protectant is listed as an approved inert ingredient in subpart X of this part.
- (d) For plant-incorporated protectants listed in the subparagraphs below, the exemption applies only if the developer is compliant with the general recordkeeping requirements specified in § 174.73 per sections 8 and 9 of FIFRA, 7 U.S.C. 136f and 136g, and only after compliance with the relevant eligibility determination procedures specified in § 174.90:
  - (1) Plant-incorporated protectant created through genetic engineering from a sexually compatible plant.
  - (2) Loss-of-function plant-incorporated protectant.

[88 FR 34776, May 31, 2023]

### **§ 174.25 Active ingredient of a plant-incorporated protectant from a sexually compatible plant created through conventional breeding.**

The active ingredient 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.
- (c) The genetic material is transferred from the source plant to the recipient plant only through conventional breeding.

[66 FR 37814, July 19, 2001, as amended at 88 FR 34777, May 31, 2023]

### **§ 174.26 Active ingredient of a plant-incorporated protectant created through genetic engineering from a sexually compatible plant.**

The active ingredient is exempt if the conditions in paragraphs (a) and (b) of this section are met.



- (a) The active ingredient is characteristic of the population of plants sexually compatible with the recipient plant and is created through genetic engineering from either an insertion of a native gene into the recipient plant as specified in paragraph (a)(1) of this section or a modification of an existing native gene in the recipient plant as specified in paragraph (a)(2) of this section.
  - (1) **Insertion.** A native gene is inserted into the genome of the recipient plant and produces a pesticidal substance identical in sequence to the pesticidal substance identified in the source plant. The regulatory regions inserted as part of the native gene must be identical in nucleic acid sequence to those regulatory regions of the native gene identified in the source plant.
  - (2) **Modification.** The existing native gene is modified to match corresponding polymorphic sequence(s) in a native allele of that gene using a single source plant as a template.
- (b) This exemption does not apply until the requirements in § 174.21(d) have been met.

[88 FR 34777, May 31, 2023]

### § 174.27 Active ingredient of a loss-of-function plant-incorporated protectant.

The active ingredient is exempt if the following conditions are met:

- (a) The genetic material of a native gene is modified using genetic engineering to result in a pesticidal effect through the reduction or elimination of the activity of that gene; and
- (b) This exemption does not apply until the requirements in § 174.21(d) have been met.

[88 FR 34777, May 31, 2023]

## 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 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 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]

### § 174.73 General recordkeeping requirements for exemptions.

For 5 years, starting with the effective date of a plant-incorporated protectant exemption, any person who is required to submit documentation for the determination of eligibility for a plant-incorporated protectant listed under § 174.21(d) must do both of the following:

- (a) Maintain documentation of either the request for EPA confirmation or the letter of self-determination (or both, if applicable) along with all supporting documentation for the specific exemption listed in subpart E of this part.
- (b) Make the documentation outlined in paragraph (a) of this section available to EPA upon request.

[88 FR 34777, May 31, 2023]

## Subpart E—Exemption Eligibility Determination Process and Requirements

**Source:** 88 FR 34777, May 31, 2023, unless otherwise noted.

### § 174.90 Determining eligibility.

- (a) **Options for determining eligibility.** As required in §§ 174.21(d) and 174.541(c), the developer must notify EPA to be eligible for exemption. Available notification options differ by plant-incorporated protectant. The developer must do at least one of the following:
  - (1) **EPA confirmation.** Unless permitted in paragraph (a)(2) of this section, a developer must submit a request for EPA confirmation of eligibility in accordance with § 174.93. Any developer may submit a request for EPA confirmation of eligibility in accordance with § 174.93.
  - (2) **Self-determination.** A developer may submit a letter of self-determination in accordance with § 174.91 if the plant-incorporated protectant qualifies for exemption as one of the following:
    - (i) A loss-of-function plant-incorporated protectant eligible for exemption under § 174.27.
    - (ii) [Reserved]

- (b) **Where to submit a request for EPA confirmation or letter of self-determination.** A request for EPA confirmation of eligibility or a letter of self-determination must be submitted electronically.
- (c) **Claims of confidentiality.** Any claims of confidentiality for information submitted in the request for EPA confirmation or a letter of self-determination must be made in accordance with the procedures outlined in § 174.9.
- (d) **Overlapping determinations of eligibility.** If a plant-incorporated protectant is eligible for a self-determination option, a developer may elect to submit a letter of self-determination as well as a request for EPA confirmation of eligibility concurrently or at a later time. If the developer so elects, the letter of self-determination will remain in effect while EPA evaluates the request for confirmation of eligibility.
- (e) **Revisiting eligibility determination.** If, at any time after EPA issues a confirmation of eligibility or the letter of self-determination is submitted, EPA becomes aware of information indicating that a plant-incorporated protectant no longer meets the criteria for exemption (e.g., adverse effects reports submitted under § 174.71) or that the self-determination was incorrect, EPA will generally notify the submitter in writing of EPA's intention to initiate a review of eligibility for exemption and may request additional information from the submitter in order to evaluate that eligibility for exemption. Upon conclusion of its review, EPA will notify the submitter in writing of its determination as to whether the plant-incorporated protectant meets the exemption criteria and any actions that will be required should the plant-incorporated protectant be found to not meet the exemption criteria. Under those circumstances, the plant-incorporated protectant may be considered to be noncompliant with FIFRA and subject to possible enforcement by EPA. At any time, if EPA finds or has reason to believe that a plant-incorporated protectant's non-compliance with FIFRA requires immediate action, EPA may take such action, including enforcement, without first informing the submitter of an eligibility review.
- (f) **Extension of exemption.** An exemption can be extended in one of two ways. First, if the exempted plant-incorporated protectant is moved through conventional breeding to other plants, the exemption is extended to the subsequent plant-incorporated protectant. Second, to extend the exemption of the plant-incorporated protectant to subsequent genetic engineering events in other plants, the following exemption-specific criteria apply:
  - (1) **Plant-incorporated protectant created through genetic engineering from a sexually compatible plant.** An exemption extends to a plant-incorporated protectant when that plant-incorporated protectant is genetically engineered by the submitter into another variety of that same plant species, the substance produced is identical to the substance produced in the original recipient plant, and no new modifications were made to the regulatory regions.
  - (2) **Loss of function plant-incorporated protectant.** An exemption extends to a plant-incorporated protectant when that plant-incorporated protectant is genetically engineered by the submitter into another variety of that same plant species and the same native gene is targeted to create the loss-of-function PIP.
- (g) **No duplication necessary.** A developer is not required to submit duplicative requests for eligibility determination or self-determination under both §§ 174.541(c) and 174.21(d), if it has already been submitted for purposes of determining eligibility under § 174.21(d).

### § 174.91 Submitting a letter of self-determination.

To self-determine eligibility for the exemption of a plant-incorporated protectant listed under § 174.90(a)(2), a developer must comply with all of the following requirements.

- (a) **When to submit a letter of self-determination.** A letter of self-determination for an exemption must be submitted to EPA prior to engaging in any activity that would be subject to FIFRA absent an exemption.
- (b) **Contents of a letter of self-determination.** The letter of self-determination must:
  - (1) Provide the name and contact information for the submitter (including telephone number and email address), company name, or other affiliation.
  - (2) Identify the plant-incorporated protectant by providing: the identity of the recipient plant (genus and species), a unique identifier for the native gene from the National Center for Biotechnology Information (NCBI) at the National Library of Medicine of the National Institutes of Health (NLM) at the National Institutes of Health (NIH) (i.e., Entrez GeneID), the trait type (e.g., insect resistance), and cite the paragraph under § 174.90(a)(2) that indicates that the plant-incorporated protectant is eligible for self-determination.
  - (3) Complete and submit the certification statement provided in the electronic submission portal. The statement must be dated and signed by the certifying official identified in the certification statement.
- (c) **EPA response.** EPA will provide electronic confirmation of receipt immediately. Electronic confirmation of receipt shall be equivalent to written confirmation of receipt.
- (d) **Effective date of exemption.** The exemption does not apply until EPA confirms receipt of the letter of self-determination.

### § 174.93 Requesting EPA confirmation.

To request EPA confirmation of eligibility for exemption of a plant-incorporated protectant listed under § 174.21(d), a developer must comply with all of the following requirements.

- (a) **When to submit a request for EPA confirmation.** Unless the developer has received confirmation of receipt of a letter of self-determination, the request for EPA confirmation must be submitted prior to engaging in any activity that would be subject to FIFRA absent an exemption.
- (b) **Contents of a request for EPA confirmation of exemption eligibility.** The request must contain information as specified in § 174.91(b) and supporting documentation, as specified in exemption-specific sections of this subpart (e.g., § 174.95).
- (c) **EPA review and response.** Upon receipt of a request, EPA will review and evaluate the information provided to determine whether the plant-incorporated protectant meets the exemption criteria in § 174.21. EPA may require additional information to assess whether a plant-incorporated protectant meets the criteria for exemption. EPA will notify the submitter in writing of its determination. If EPA determines that the plant-incorporated protectant does not meet the criteria for exemption, EPA will notify the submitter in writing of any actions that will be required.
- (d) **Effective date of exemption.** If the plant-incorporated protectant is not already exempt pursuant to the self-determination process under § 174.91, this exemption applies once EPA notifies the submitter in writing, confirming that the plant-incorporated protectant meets the criteria for exemption.

## **§ 174.95 Documentation for an exemption for a plant-incorporated protectant created through genetic engineering from a sexually compatible plant.**

A developer requesting EPA confirmation of exemption eligibility for a plant-incorporated protectant created through genetic engineering from a sexually compatible plant pursuant to § 174.93 must submit the information in the following paragraphs to EPA. The following documentation must be maintained by a developer of a plant-incorporated protectant created through genetic engineering from a sexually compatible plant per § 174.73:

**(a) *Biology of the plant.***

- (1)** The identity of the recipient plant, including genus and species.
- (2)** If the plant-incorporated protectant was derived from a plant species other than the recipient plant species, provide the identity of the source plant including genus and species and information to support the determination that the recipient plant and the source plant are sexually compatible (e.g., through peer-reviewed literature rationale).

**(b) *Description of the pesticidal trait and how the trait was engineered into the plant.*** Include a description of the measures that were taken to ensure that no engineering components (e.g., Cas proteins) are present in the final plant product and the measures taken to maximize the likelihood that the modification to the recipient plant is limited to the intended modification.

**(c) *Molecular characterization of the plant-incorporated protectant.*** A nucleic acid sequence comparison of the plant-incorporated protectant between the recipient plant and the comparator(s). A deduced amino acid sequence comparison is additionally required when the pesticidal substance is proteinaceous. The relevant comparator(s) for the sequence comparison(s) are determined by the type of modification:

- (1)** For § 174.26(a)(1), sequences in the source plant and in the recipient plant.
- (2)** For § 174.26(a)(2), sequences in the recipient plant before the modification, after the modification, and the sequence in the source plant. The polymorphic site(s) must be indicated.

**(d) *Information on the history of safe use of the plant-incorporated protectant.***

- (1)** If the pesticidal substance is a known allergen or mammalian toxin/toxicant (e.g., solanine), describe how conventional breeding practices are being used to ensure that it does not exceed human dietary safety levels in the recipient food plant (*i.e.*, ensure residues of pesticidal substance are not present in food at levels that are injurious or deleterious and are within the ranges of levels generally seen in plant varieties currently on the market and/or known to produce food safe for consumption).
- (2)** If the source plant is a wild relative of the recipient plant, describe why the plant-incorporated protectant is not anticipated to pose a hazard to humans or the environment (e.g., Are levels of the pesticidal substance produced in the recipient plant within the ranges of levels generally seen in plant varieties currently on the market and/or known to produce food safe for consumption? Is the pesticidal mode of action non-toxic? Does the plant-incorporated protectant lack sequence similarity to known mammalian toxins, toxicants, or allergens? Is the plant-incorporated protectant a commonly screened substance and therefore familiar to plant breeders?).

## **§ 174.96 Documentation for an exemption for a loss-of-function plant-incorporated protectant.**

A developer requesting EPA confirmation of exemption eligibility for a loss-of-function plant-incorporated protectant pursuant to § 174.93 must submit the information in the following paragraphs to EPA along with the developer's request for exemption confirmation. The following documentation must be maintained by a developer of a loss-of-function plant-incorporated protectant per § 174.73:

- (a) Biology of the plant: The identity of the recipient plant, including genus and species.
- (b) Description of the pesticidal trait that results from the loss-of-function and how the trait was engineered into the plant. Include a description of the steps that were taken to ensure that no engineering components (e.g., Cas proteins) remain in the plant and the measures taken to maximize the likelihood that the modification to the recipient plant is limited to the intended modification.

**Subpart 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 *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 of a plant-incorporated protectant from a sexually compatible plant created through conventional breeding; exemption from the requirement of a tolerance.**

Residues of a pesticidal substance 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 genetic material is transferred from the source plant to the recipient plant only through conventional breeding.
- (d) 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; 88 FR 34779, May 31, 2023]

**§ 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 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 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 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]

**§ 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 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, 2025.

[86 FR 51004, Sept. 14, 2021]

**§ 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]

**§ 174.539 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]

**§ 174.540 *Bacillus thuringiensis* Cry14Ab-1 protein; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Cry14Ab-1 protein in or on soybean food and feed commodities are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in soybean.

[85 FR 35008, June 8, 2020]

**§ 174.541 Pesticidal substance of a plant-incorporated protectant created through genetic engineering from a sexually compatible plant; exemption from the requirement of a tolerance.**

Residues of a pesticidal substance are exempt from the requirements of a tolerance if the conditions in paragraphs (a) through (c) of this section are met.

- (a) The pesticidal substance is characteristic of the population of plants sexually compatible with the recipient food plant and is created through genetic engineering from either an insertion of a native gene into the recipient food plant as specified in paragraph (a)(1) of this section or a modification of an existing native gene in the recipient food plant as specified in paragraph (a)(2) of this section.

- (1) **Insertion.** A native gene is inserted into the genome of the recipient food plant and produces a pesticidal substance identical in sequence to the pesticidal substance identified in the source plant. The regulatory regions inserted as part of the native gene must be identical in nucleic acid sequence to those regulatory regions of the native gene identified in the source plant.
- (2) **Modification.** The existing native gene is modified to match corresponding polymorphic sequence(s) in a native allele of that gene using a single source plant as a template.
- (b) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.
- (c) This exemption does not apply until the requirements in § 174.90 have been met.

[88 FR 34779, May 31, 2023]

#### **§ 174.542 *Bacillus thuringiensis* Cry1Ab/Cry2Aj protein in corn; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Cry1Ab/Cry2Aj protein in or on the food or feed commodities of corn, field; corn, sweet; and corn, pop, are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[86 FR 3830, Jan. 15, 2021]

#### **§ 174.543 G10evo-EPSPS protein in all plants; exemption from the requirement of a tolerance.**

Residues of G10evo-Enolpyruvylshikimate-3-phosphate synthase (G10evo-EPSPS) protein in or on all food or feed commodities, are exempt from the requirement of a tolerance when used as an inert ingredient in a plant-incorporated protectant.

[86 FR 3830, Jan. 15, 2021]

#### **§ 174.544 Modified potato acetolactate synthase (StmALS) in potato; exemption from the requirement of a tolerance.**

Residues of modified potato acetolactate synthase (StmALS) in potato are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient.

[88 FR 95188, Mar. 15, 2023]

#### **§ 174.545 BLB2 and AMR3 proteins in potato; temporary exemption from the requirement of a tolerance.**

Residues of BLB2 and AMR3 proteins in potato are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in potato in accordance with the terms of Experimental Use Permit No. 8917-EUP-3. This temporary exemption from the requirement of a tolerance expires on March 31, 2025.

[89 FR 31651, Apr. 25, 2024]

**§ 174.546 *Bacillus thuringiensis* Cry1B.868 and Cry1Da\_7 proteins; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Cry1B.868 and Cry1Da\_7 proteins 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 used as a plant-incorporated protectant in corn.

[89 FR 43331, May 17, 2024]

**§ 174.547 *Ophioglossum pendulum* IPD079Ea protein; exemption from the requirement of a tolerance.**

Residues of *Ophioglossum pendulum* IPD079Ea protein 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 used as a plant-incorporated protectant in corn.

[89 FR 64810, Aug. 8, 2024]

**§ 174.548 *Pseudomonas chlororaphis* IPD072Aa protein; exemption from the requirement of a tolerance.**

Residues of *Pseudomonas chlororaphis* IPD072Aa in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement when used as a plant-incorporated protectant in corn.

[89 FR 68785, Aug. 28, 2024]

**§ 174.549 *Bacillus thuringiensis* Cry1Da2 protein; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Cry1Da2 protein in or on the food and feed commodities of corn, including corn, field; corn, sweet; and corn, pop, are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[89 FR 100749, Dec. 13, 2024]

**§ 174.550 *Streptomyces sviveus* DGT-28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein; exemption from the requirement of a tolerance.**

Residues of *Streptomyces sviveus* DGT-28 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein 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 used as an inert ingredient in a plant-incorporated protectant in corn.

[89 FR 100751, Dec. 13, 2024]

**§ 174.551 *Brevibacillus laterosporus* Mpp75Aa1.1 protein; exemption from the requirement of a tolerance.**

Residues of *Brevibacillus laterosporus* Mpp75Aa1.1 protein 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 used as a plant-incorporated protectant in corn.

[89 FR 101941, Dec. 17, 2024]

**§ 174.552 *Bacillus thuringiensis* Vpb4Da2 protein; exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* Vpb4Da2 protein 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 used as a plant-incorporated protectant in corn.

[89 FR 101941, Dec. 17, 2024]

**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 FFDCA 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]**