

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

Subpart B—Exemptions

§ 174.21 General qualifications for exemptions.

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

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

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

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

§ 174.25 Plant-incorporated protectant from sexually compatible plant.

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

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

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

Subpart C—Registration Procedures and Requirements [Reserved]

Subpart D—Monitoring and Recordkeeping

§ 174.71 Submission of information regarding adverse effects.

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under 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

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

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

Subparts E–F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I [Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L–T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V [Reserved]

Subpart W—Tolerances and Tolerance Exemptions

§ 174.451 Scope and purpose.

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

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

Bacillus thuringiensis VIP3A protein and the genetic material necessary for its production is temporarily exempt from the requirement of a tolerance when used as a vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. Genetic material necessary for its production means the genetic material which comprise genetic encoding the VIP3A protein and its regulatory re-

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gions. Regulatory regions are the genetic material, such as promoters, terminators, and enhancers, that control expression of the genetic material encoding the VIP3A protein. This temporary exemption from the requirement of a tolerance expires May 1, 2007.

[71 FR 24586, Apr. 26, 2006]

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

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

[69 FR 58284, Sept. 30, 2004]

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

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