

Environmental Protection Agency

§ 174.71

§ 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 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 protect-

ant 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.

EFFECTIVE DATE NOTE: At 72 FR 20434, Apr. 25, 2007, § 174.21 was amended in paragraph (b) by revising the reference “§§ 174.475 through 174.479” to read “§§ 174.507 through 174.508;” and in paragraph (c) by revising the reference “§§ 174.485 through 174.490” to read “§ 174.705”, effective July 24, 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]

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

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part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

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

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

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

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

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

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

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

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

Subparts E–F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I [Reserved]

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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.

EFFECTIVE DATE NOTE: At 72 FR 20434, Apr. 25, 2007, §174.451 was redesignated as §174.500 and revised, effective July 24, 2007. For the convenience of the user, the revised text is set forth as follows:

§ 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.

§ 174.452 *Bacillus thuringiensis* Vip3Aa19 protein in cotton; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa19 protein in cotton are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant (PIP) in the food and feed commodities of cotton; vegetative-insecticidal protein in cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit (EUP) 67979–EUP–7, which is being issued in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),