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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]

EFFECTIVE DATE NOTE: At 72 FR 20434, Apr. 25, 2007, §174.479 was redesignated as §174.508, effective July 24, 2007

Subpart X—List of Approved Inert Ingredients

§ 174.480 Scope and purpose.

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

EFFECTIVE DATE NOTE: At 72 FR 20434, Apr. 25, 2007, §174.480 was redesignated as §174.700 and remains in subpart X, effective July 24, 2007.

§ 174.485 Inert ingredients from sexually compatible plant.

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

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

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

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

EFFECTIVE DATE NOTE: At 72 FR 20434, Apr. 25, 2007, §174.485 was redesignated as §174.705 and remains in subpart X, effective July 24, 2007.

Subparts Y-Z [Reserved]

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PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

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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

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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 an emergency exemption, has stated its intention to issue a crisis exemption, or has issued a crisis exemption for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

§ 176.7 Information needed to establish a tolerance.

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into

account the limited duration and emergency nature of a section 18 application, and based on the available data the Agency cannot conclude that there is a reasonable certainty that no harm will result from the use proposed by the applicant or granted pursuant to a crisis exemption, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

§ 176.9 Publication of a tolerance.

(a) If EPA issues an emergency exemption or crisis exemption under FIFRA section 18, and EPA concludes that the tolerance for residues resulting from use of the pesticide under the exemption will be safe, then EPA will establish the tolerance by publishing an amendment to 40 CFR part 180 in the FEDERAL REGISTER.

(b) A tolerance under this part may be established without prior publication of a proposed tolerance or comment period.

§ 176.11 Duration of a tolerance.

(a) Tolerances issued under this part will become effective upon publication in the FEDERAL REGISTER, unless otherwise specified by the Administrator.

(b) Unless extended, tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the final rule published in FEDERAL REGISTER.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

§ 176.13 Modification of a time-limited tolerance.

If additional emergency or crisis exemptions are authorized that would extend use beyond the date originally authorized, or if EPA determines that the duration of a time-limited tolerance is insufficient to allow treated commodities to clear the channels of trade, EPA may modify the time-limited tolerance by publication of a final rule in

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the FEDERAL REGISTER. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

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Subpart C [Reserved]

Subpart D—Judicial Review

178.65 Judicial review.

178.70 Administrative record.

AUTHORITY: 21 U.S.C. 346a, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

Subpart A—General Provisions

§ 178.3 Definitions.

For the purposes of this part:

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

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Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart B—Procedures for Filing Objections and Requests for Hearing

§ 178.20 Right to submit objections and requests for a hearing.

(a) On or before the 60th day after the date of publication in the FEDERAL REGISTER of an order under part 180 of this chapter establishing, modifying, or revoking a regulation, or denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an evidentiary hearing on such objection in accordance with § 178.27

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 178.25 Form and manner of submission of objections.

(a) To be considered by the Administrator, an objection must:

- (1) Be in writing.