§ 174.479 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]

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.

§ 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.

Subparts Y–Z [Reserved]
§ 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 either has requested an emergency 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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§ 177.1 Scope and applicability.
(a) This part establishes procedures for the establishment, modification, or revocation by the Administrator of food additive regulations under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348, for food additives which may result in pesticide residues in or on processed food or otherwise affect the characteristics of such food.

(b) Part 178 of this chapter contains procedures for filing objections and requests for hearings under FFDCA section 409(f) on food additive regulations or petition denials issued under this part. Part 179 of this chapter contains rules governing formal evidentiary hearings under FFDCA section 409(f).

(c) Part 180 of this chapter contains regulations establishing tolerances, or exemptions from the necessity for a tolerance, for pesticide residues on raw agricultural commodities under FFDCA section 408. If the use of a pesticide chemical in the production, storage, or transportation of a raw agricultural commodity (RAC) in conformity with such a tolerance or exemption results in the presence of a pesticide residue in or on processed food made from the RAC, FFDCA section 402(a)(2)(C) provides that such pesticide residue shall not be deemed unsafe for the purposes of FFDCA section 409 (despite the absence of a food additive regulation regarding such residue on the processed food) if the residue in or on the RAC has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the RAC. However, a food additive regulation would be required if the level of the pesticide residue in the processed food when ready to eat exceeded the level permitted in the “parent” RAC by the tolerance established under FFDCA section 408. In addition, if a pesticide residue in or on a processed food results from the application of a pesticide during or after processing, the food would be unsafe.