

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1151, to read as follows:

**§ 180.1151 Phosphinothricin acetyltransferase and the genetic material necessary for its production (plasmid vector pCIB3064) in corn; exemption from the requirement of a tolerance.**

Phosphinothricin acetyltransferase and the genetic material necessary for its production (plasmid vector pCIB3064) in corn is exempt from the requirement of a tolerance when used as a plant pesticide inert ingredient in the raw agricultural commodities of field corn, sweet corn, and popcorn. "Genetic material necessary for its production" means the genetic materials which comprise genetic material encoding the phosphinothricin acetyltransferase and its regulatory regions. "Regulatory regions" are the genetic materials that control the expression of the genetic material encoding the phosphinothricin acetyltransferase, such as promoters, terminators, and enhancers.

[FR Doc. 95-20010 Filed 8-15-95; 8:45 am]  
BILLING CODE 6560-50-F

**40 CFR Parts 180 and 185**

[PP 2F4055 and FAP 5H5719/R2151; FRL-4966-3]

RIN 2070-AB78

**Deltamethrin; Pesticide Tolerance and Food Additive Regulation**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This document establishes time-limited tolerances for residues of the pyrethroid deltamethrin in or on the raw agricultural commodity (RAC) cottonseed at 0.04 part per million (ppm) and the processed food cottonseed oil at 0.2 ppm. The Hoechst-Roussel Agri-Vet Co. requested this tolerance and food additive regulation in petitions submitted pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

**EFFECTIVE DATE:** This regulation becomes effective August 16, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 2F4055 and FAP 5H5719/R2151], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections

shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 2F4055 and FAP 5H5719/R2151]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the **Federal Register** of March 11, 1992 (57 FR 8659), which announced that Hoechst-Roussel Agri-Vet Co. (HRAVC) had submitted pesticide petition (PP) 2F4055 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a regulation to permit residues of the insecticide deltamethrin (*S*)- $\alpha$ -cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-(2-2-dibromovinyl)-2,2-

dimethyl-cyclopropanecarboxylate and its major metabolites, *trans*-deltamethrin [(*S*)- $\alpha$ -cyano-*m*-phenoxybenzyl-(1*R*,3*S*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylate] and *alpha-R*-deltamethrin [(*R*)- $\alpha$ -cyano-*m*-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on cottonseed at 0.02 ppm. After evaluation of metabolism, residue, and cottonseed processing data, EPA concluded that the tolerance proposed for cottonseed should be increased to 0.04 ppm and that a food additive regulation permitting residues of 0.20 ppm in cottonseed oil was necessary. HRAVC submitted a food additive petition to EPA requesting that the Administrator, pursuant to section 409(b) of FFDCA establish a regulation permitting residues of deltamethrin on the food commodity cottonseed oil at 0.2 ppm and amended the initial notice of filing to reflect an increase in tolerance for cottonseed to 0.04 ppm. Notice of these changes was published in the **Federal Register** of March 15, 1995 (60 FR 13979).

No comments were received in response to the notices of filing.

Tolerances of 0.2 ppm and 1.0 ppm had been previously established for the combined residues of deltamethrin and its major metabolite *trans*-deltamethrin on tomatoes imported from Mexico under 40 CFR 180.435 and tomato products (concentrated) under 40 CFR 185.1580, respectively. Based upon the review of plant metabolism data, EPA has determined that the residue to be regulated is deltamethrin and its metabolites *trans*-deltamethrin and *alpha-R*-deltamethrin. Regulation of this additional metabolite will be reflected in the tolerance expression.

Because pyrethroids are toxic to fish and other aquatic organisms, the Agency is concerned about adverse impacts on aquatic ecosystems related to this use of the pyrethroids. In November 1990, the Agency and five registrants of pyrethroid cotton insecticides (collectively, the Pyrethroid Working Group (PWG)) in collaboration with the National Cotton Council agreed to interim risk-reduction measures designed to reduce the potential for exposure of aquatic habitats of concern to pyrethroids applied to cotton. The interim risk reduction measures included user surveys to assess current pyrethroid use practices on cotton, label changes aimed at reducing the aquatic environmental exposure to pyrethroids, and a program of data generation to estimate the effectiveness of the steps taken. As part of this interim risk-

reduction program, the Agency agreed to extend the registration and tolerances of these cotton pyrethroids to November 15, 1993, and November 15, 1994, respectively. The registrations and time-limited tolerances on cottonseed were extended once again to November 15, 1996, and November 15, 1997, respectively (see the **Federal Register** of February 22, 1995 (60 FR 9784)). These extensions were granted to allow time for submission and evaluation of additional environmental effects data. In order to evaluate effects of pyrethroid on fish and aquatic organisms and its fate in the environment, additional data were required to be collected and submitted during the period of conditional registration. Such requirements included a sediment bioavailability and toxicity study and a small-plot runoff study that must be submitted to the Agency by July 1, 1996.

To be consistent with the conditional registration and extension of pyrethroids on cottonseed, the Agency is issuing a conditional registration for deltamethrin on cotton with an expiration date of November 15, 1996, and establish a time-limited tolerance on cottonseed and cottonseed oil with an expiration date of November 15, 1997, to cover residues expected to result from use during the period of conditional registration.

With respect to the use of deltamethrin on cotton, the Agency concluded that use of deltamethrin would not cause a significant increase in the risk of adverse effects to the environment. This conclusion was premised mainly on the following:

1. The short period of time the registration would be in effect before the Agency completes its final regulatory and risk reviews of cotton use of the pyrethroids.

2. HRAVC's commitment to agree to the terms and conditions stipulated by the Agency for continued registration of current cotton pyrethroid products. These conditions include aquatic risk mitigation language for the cotton use labeling and conditional registration subject to an Agency determination of aquatic risk.

3. The total number of treated acres of cotton is essentially the same and the registration of new pyrethroid on cotton, such as deltamethrin, would result in no significant increase in the number of acres treated. Instead, it would result in only changes in market share, i.e., the percentage of acres that are treated with any particular cotton pyrethroid.

Residues remaining in or on the above commodities after expiration of these tolerances will not be considered actionable if the pesticide is legally

applied during the term of and in accordance with provisions of conditional registration.

The scientific data submitted in support of these petitions and other relevant material have been evaluated. The toxicology data considered in support of these tolerances include:

1. Chronic 2-year feeding in dogs with a systemic NOEL greater than 40 ppm (highest dose treated (HDT)).

2. A 24-month chronic feeding/carcinogenicity study in rats with a systemic NOEL of 20 ppm (1 mg/kg/day) and LEL of 50 mg/kg/day based on decreased body weight. No carcinogenic effects were observed in the study.

3. A carcinogenicity study in mice in which no evidence of carcinogenicity was noted up to and including 100 ppm (HDT).

4. An oral development toxicity study in rats with a developmental NOEL of 11 mg/kg/day (highest dose tested). The maternal NOEL was 3.3 mg/kg/day with the LEL of 7 mg/kg/day based on one death and excessive salivation. An oral developmental toxicity study in rabbits with a maternal NOEL of 10 mg/kg/day and a maternal LEL of 25 mg/kg/day based on decreased defecation. The developmental NOEL was 25 mg/kg/day with a developmental LEL of 100 mg/kg/day based on statistically significant increase in fetal incidence of unossification of pubic bone and tail bone. These skeletal variations were not considered to be statistically significant.

5. A three-generation reproduction study in rats noted no parental or fetal effects up to and including 50 ppm (HDT).

6. A metabolism study in rats demonstrates that deltamethrin is relatively well absorbed and excreted. Urine and fecal excretions were almost complete at 48 hours post dose.

7. Mutagenicity tests included a reverse mutation Ames assay, a structural chromosomal aberration assay in Chinese hamster ovary (CHO) cells, and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

A chronic dietary exposure/risk assessment was performed for deltamethrin using a reference dose (RfD) of 0.01 mg/kg bwt/day based on a NOEL of 1.00 mg/kg bwt/day from a 2-year rat feeding study with an uncertainty factor of 100. The end-point effect of concern was decreased body weight. The Theoretical Maximum Residue Contribution from established tolerances utilizes 3.7% of the RfD for the U.S. population and 7.3% in children ages 1 to 6 years old, the subgroup with the highest estimated exposure to deltamethrin residues. The

use on cotton does not contribute any more to the dietary exposure for the general population of children ages 1 to 6 years. Generally speaking, EPA has no cause for concern if total residue contribution for published tolerances is less than the RfD. EPA concludes that the chronic dietary risk of deltamethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

The nature of the deltamethrin residue in plants and animals for this use is adequately understood. The residues of concern are combined residues of deltamethrin and its metabolites *trans*-deltamethrin and *alpha-R*-deltamethrin. There is no reasonable expectation of secondary residues in eggs, meat, milk, or poultry from the proposed use as delineated in 40 CFR 180.6(a)(3).

An adequate analytical method involving gas-liquid chromatography is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration, and published in the Pesticide Analytical Manual, Vol. II (PAM II).

There are currently no actions pending against the continued registration of this chemical.

The pesticide is considered useful for the purposes for which it is sought and capable of achieving its intended physical or technical effect. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health and that use of the pesticide in accordance with the tolerance established by amending 40 CFR part 185 would be safe. Therefore, the tolerances and food additive regulations are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the

requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 2F4055 and FAP 5H5719/R2151] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 2F4055 and FAP 5H5719/R2151], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements, or establishing or raising food additive regulations do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

**List of Subjects in 40 CFR Parts 180 and 185**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 27, 1995.

**Daniel M. Barolo,**  
Director, Office of Pesticide Programs.

Therefore, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

**PART 180—[AMENDED]**

- 1. In part 180:
  - a. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 346a and 371.

- b. By revising § 180.435, to read as follows:

**§ 180.435 Deltamethrin; tolerances for residues.**

A tolerance is established for residues of the insecticide deltamethrin [(S)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and its major metabolites, *trans*-deltamethrin [(S)-alpha-cyano-m-phenoxybenzyl(1R,3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *alpha*-R-deltamethrin [(R)-alpha-cyano-m-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration date
Cottonseed .....	0.04	Nov. 15, 1997
Tomatoes .....	0.2	None

**PART 185—[AMENDED]**

- 2. In part 185:
  - a. The authority citation for part 185 continues to read as follows:
    - Authority:** 21 U.S.C. 346a and 348.
  - b. By revising § 185.1580, to read as follows:

**§ 185.1580 Deltamethrin.**

Tolerances are established for residues of the insecticide deltamethrin [(S)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and its major metabolites, *trans*-deltamethrin [(S)-alpha-cyano-m-phenoxybenzyl(1R,3S)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *alpha*-R-deltamethrin [(R)-alpha-cyano-m-phenoxybenzyl-(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on the following food commodities:

Commodity	Parts per million	Expiration date
Cottonseed oil ...	0.2	Nov. 15, 1997
Tomato (products) concentrated .....	1.0	None