

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

40 CFR Parts 180 and 185

[PP 4F4342 and FAP 4H5711/R2153; FRL-4966-8]

RIN 2070-AB78

Flutolanil; Pesticide Tolerances**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule establishes tolerances for combined residues of flutolanil (*N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide) and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil in or on peanut nutmeats at 0.5 part per million (ppm), peanut hulls at 5.0 ppm, peanut hay at 15.0 ppm, meat, meat byproducts (mbyp) and milk of cattle, goats, hogs, horses, and sheep at 0.05 ppm, fat of cattle, goats, hogs, horses, and sheep at 0.10 ppm, liver of cattle, goats, hogs, horses, and sheep at 2.0 ppm, kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm, and poultry (including turkeys) meat, mbyp, fat, and eggs at 0.05 ppm; and in or on the processed food commodity peanut meal at 1.0 ppm when present therein as a result of application of the fungicide to growing crops. AgrEvo USA Co. submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish a maximum permissible level for residues of the fungicide.

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

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4342 and FAP 4H5711/R2153], 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 any 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 document number [PP 4F4342 and FAP 4H5711/R2153]. 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: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6226; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of February 8, 1995 (60 FR 7540), which announced that AgrEvo USA Co. had submitted pesticide petitions (PP) 4F4342 and 4H5711 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), establish tolerances for combined residues of flutolanil (*N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide) and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil in or on peanut nutmeats at 0.5 part per million (ppm), peanut hulls at 5.0 ppm, peanut hay at 15.0 ppm, meat, mbyp, and milk of cattle, goats, hogs, horses, and sheep at 0.05 ppm, fat of cattle, goats, hogs, horses, and sheep at 0.10 ppm, liver of cattle, goats, hogs, horses, and sheep at 2.0 ppm, kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm, and poultry meat, mbyp, fat and eggs (including turkeys) at 0.05 ppm; and in or on the processed food commodity peanut meal at 1.0 ppm, when present therein as a result of application of the fungicide to growing crops.

There were no comments received in response to the notice of filing. The

scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. Several acute toxicity studies that place technical flutolanil in Toxicity Category III (Caution). Data show minimal-to-slight irritation to the eye.

2. A 90-day rat feeding study with a systemic no-observed-effect level (NOEL) of 37 mg/kg/day for males and 44 mg/kg/day for females and a systemic lowest-effect-level (LEL) of 299 mg/kg/day for males and 339 mg/kg/day for females based on increased absolute and relative liver weights in both the 299-mg/kg/day males and the 339-mg/kg/day females and the 1,512-mg/kg/day males and the 1,743-mg/kg/day females, along with a slight decrease in body weight in the 1,512-mg/kg/day males.

3. A 90-day oral study in dogs with a systemic NOEL of 80 mg/kg/day and a systemic LEL of 400 mg/kg/day based on enlarged livers and increased glycogen deposition in the livers of both males and females. High-dose (2,000 mg/kg/day) males and females showed increased alkaline phosphatase levels and cholesterol thyroid/parathyroid organ weights.

4. A 2-year feeding/carcinogenicity study in rats with a systemic NOEL of 86.9 mg/kg/day for males and 103.1 mg/kg/day for females and a systemic LEL of 460.5 mg/kg/day for males and 535.8 mg/kg/day for females based on reduced body weight and body weight gain in males along with decreased and absolute relative weights in females. Flutolanil was not carcinogenic under the conditions of this study.

5. A carcinogenicity study in mice with a systemic NOEL of 735 mg/kg/day for males and 1,168 mg/kg/day for females and a systemic lowest-observed-effect level (LEL) of 13,333 mg/kg/day for males and 1,839 mg/kg/day for females based on body weight gains in the high-dose females which were significantly lower than those of controls during the first 24 weeks of treatment. There were no effects of biological importance on survival, clinical signs, food intake, hematology, gross pathology, or histopathology. Flutolanil was not carcinogenic under the conditions of this study.

6. A 2-year oral feeding study in dogs with a systemic NOEL of 50 mg/kg/day for males and females and a systemic LEL of 250 mg/kg/day based on increased incidence of clinical signs (emesis, salivation, soft stools, lower body weight gains and decreased food consumption in the 250- and 1,250-mg/kg group males and females).

7. A rat developmental toxicity study with a maternal NOEL of 1,000 mg/kg/day (limit dose) and a developmental toxicity NOEL of 1,000 mg/kg/day (limit dose). Developmental toxicity was not observed at any dose level.

8. A rabbit developmental toxicity study with a maternal NOEL of 40 mg/kg/day and a maternal LEL of 200 mg/kg/day based on increased resorptions in the 200- and 1,000-mg/kg group. A developmental NOEL of 40 mg/kg/day, and a developmental LEL of 200 mg/kg/day were based on increased resorptions in the 200- and 1,000-mg/kg/day group.

9. A two-generation rat reproduction study with a parental toxicity NOEL of 1,936 mg/kg/day (limit dose) and a reproductive toxicity NOEL of 1,936 mg/kg/day (limit dose).

10. Mutagenicity studies included: An Ames Assay which was negative; Chromosome Aberration studies which showed flutolanil induced chromosomal aberrations in cultured Chinese hamster lung cells in the presence of metabolic activation; reverse data which showed that flutolanil did not cause an increase in revertant colonies using *Salmonella* and *E. coli* strains; micronucleus assay data which indicated that flutolanil, up to a dose of 10 gm/kg, did not induce micronuclei in the bone marrow erythrocytes of male and female mice; unscheduled DNA synthesis (UDS) data which showed that flutolanil did not induce UDS because the test compound failed to induce a genotoxic response in the *in vitro* assay; and lymphoma mutation test data which showed that flutolanil was found to be nonmutagenic in the Mammalian Cell Gene Mutation Assay.

The Reference Dose (RfD) used in the analysis is 0.2 mg/kg bwt/day, based on an LEL of 63.7 mg/kg bwt/day from a three generation rat reproductive study with an uncertainty factor of 300 that demonstrated decreased body weight gains and increased liver weights at the high dose of 661.8 mg/kg. Flutolanil is classified as a group E carcinogen, showing no evidence of cancer in rats or mice. The Theoretical Maximum Residue Contribution (TMRC) from the current action is estimated at 0.000810 mg/kg bwt/day and utilizes less than 1 percent of the RfD for the general population of the lower 48 States. The TMRCs for the most highly exposed subgroups, children (1 to 6 years old) is 0.003577 mg/kg bwt/day (1.8% of the RfD).

As the first food use of this chemical, tolerances for flutolanil have yet to be published in the CFR. Tolerance level residues and 100-percent-crop- treated assumptions were made for the proposed commodities. Anticipated

residues and percent crop treated information were not available for this analysis.

The residue analytical method will not be forwarded to FDA for publication at this time. This method is available for limited distribution from Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232. It has the following disclaimer: The method is for use only by experienced chemists who have demonstrated knowledge of the principles of trace organic analysis; and have proven skills and abilities to run a complex residue analytical method obtaining accurate results at the part-per-billion level. Users of this method are expected to perform additional method validation prior to using the method for either monitoring or enforcement. The method can detect gross misuse.

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

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR parts 180 and 185 will protect the public health. Therefore, the tolerances 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 4F4342 and FAP 4H5711/R2153] (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 Rm. 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 4F4342 and 4H5711/R2153], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

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The official record for this rulemaking, 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 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 Part 180

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

Dated: July 31, 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 adding new § 180.484, to read as follows:

§ 180.484 Flutolanil (N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide); tolerances for residues.

Tolerances are established for residues of flutolanil, N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolites converted to 2-

(trifluoromethyl) benzoic acid and calculated as flutolanil in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, kidney	1.00
Cattle, liver	2.00
Cattle, mby	0.05
Cattle, meat	0.05
Cattle, milk	0.05
Eggs	0.05
Goats, fat	0.10
Goats, kidney	1.00
Goats, liver	2.00
Goats, mby	0.05
Goats, meat	0.05
Goats, milk	0.05
Hogs, fat	0.10
Hogs, kidney	1.00
Hogs, liver	2.00
Hogs, mby	0.05
Hogs, meat	0.05
Hogs, milk	0.05
Horses, fat	0.10
Horses, kidney	1.00
Horses, liver	2.00
Horses, mby	0.05
Horses, meat	0.05
Horses, milk	0.05
Peanuts	0.5
Peanut hay	15.0
Peanut hulls	5.0
Poultry (including turkeys), fat	0.05
Poultry (including turkeys), mby	0.05
Poultry (including turkeys), meat	0.05
Sheep, fat	0.10
Sheep, kidney	1.00
Sheep, liver	2.00
Sheep, meat	0.05
Sheep, mby	0.05
Sheep, milk	0.05

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 adding new § 185.3385, to read as follows:

§ 185.3385 Flutolanil (N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide).

A food additive regulation is established permitting the combined residues of the insecticide flutolanil, N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil in or on the following processed food commodity:

Commodity	Parts per million
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Commodity	Parts per million
Peanut meal	1.0

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BILLING CODE 6560-50-F

40 CFR Parts 180 and 185

[OPP-300389A; FRL-4967-9]

RIN 2070-AB78

Sodium Propionate, Methoprene, and Heliothis zea NPV; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: For each of the pesticides subject to the actions listed in this rule, EPA has completed the reregistration process and issued a Reregistration Eligibility Document (RED). In the reregistration process, all information to support a pesticide's continued registration is reviewed for adequacy and, when needed, supplemented with new scientific studies. Based on the RED tolerance assessments for the pesticide chemicals subject to this rule, EPA is taking the following tolerance actions: amending the exemptions from the requirement of a tolerance for methoprene; revoking exemptions for sodium propionate; and making wording changes to the exemption from the requirement of a tolerance for *Heliothis zea* NPV. With this rule to amend the exemptions from the requirement of tolerances for methoprene, the Agency is correcting its position in the RED, which stated that the exemptions should be revoked. The Agency believes that exemptions from the requirement of tolerances for these uses are appropriate.

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

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP-300389A], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests 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