

the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### IV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

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

Dated: March 26, 2010.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

#### § 180.628 [Amended]

■ 2. In § 180.628, amend the table in paragraph (d) by revising the expiration/revocation dates "4/10/10" to read "4/10/14," each time it appears.

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**BILLING CODE 6560-50-S**

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2009-0553; FRL-8817-9]

#### Flutolanil; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of flutolanil in or on cotton and soybean. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 7, 2010. Objections and requests for hearings must be received on or before June 7, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0553. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-

4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Lisa Jones, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9424; e-mail address: [jones.lisa@epa.gov](mailto:jones.lisa@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

##### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those

objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0553 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 7, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0553, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Tolerance

In the **Federal Register** of September 4, 2009 (74 FR 45848) (FRL-8434-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7542) by Nichino America, Inc., 4550 New Linden Hill Rd., Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.484 be amended by establishing tolerances for residues of the fungicide flutolanil, (*N*-(3-(1-methylethoxy) phenyl)-2-(trifluoromethyl) benzamide) and its metabolite, M-4, desisopropylflutolanil (*N*-(3-hydroxyphenyl)-2-(trifluoromethyl) benzamide), expressed as 2-trifluoromethyl benzoic acid and

calculated as flutolanil, in or on cotton at 0.05 parts per million (ppm) and in or on soybean at 0.05 ppm. That notice referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

EPA has modified the proposed tolerance expression to: "residues of flutolanil, (*N*-(3-(1-methylethoxy) phenyl)-2-(trifluoromethyl) benzamide), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flutolanil and its metabolites converted to 2-(trifluoromethyl) benzamide and calculated as flutolanil." Based on review of the data supporting the petition, EPA has also modified the proposed tolerances to be established under paragraph (a), *General*, for flutolanil at 40 CFR 180.484 as follows: Soybean, seed, 0.20 ppm; soybean, forage, 8.0 ppm; soybean, hay, 2.5 ppm; cotton, undelinted seed, 0.20 ppm and cotton, gin byproducts, 0.20 ppm. Additionally, the following tolerances will be removed from paragraph (d), *Indirect or inadvertent residues*, for flutolanil as redundant: Soybean, seed 0.20 ppm; soybean, forage, 8.0 ppm and soybean hay, 2.5 ppm. The reasons for these changes are explained in Unit IV.D.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for flutolanil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flutolanil follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Specific information on the studies received and the nature of the adverse effects caused by flutolanil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of June 11, 2008, (73 FR 33013) (FRL-8365-6). The complete toxicological profile for flutolanil can be found at <http://www.regulations.gov> on pages 7 through 12 in the document "Flutolanil, Human Health Risk Assessment: Requests for Inadvertent or Indirect Tolerances for Use on Soybean, Wheat, Corn and Cotton" in docket ID number EPA-HQ-OPP-2007-1021.

### B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level-generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) and a safe margin of exposure (MOE). For non-threshold

risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for flutolanil used for human risk assessment is discussed in Unit III, *Aggregate Risk Assessment and Determination of Safety*, of the final rule published in the **Federal Register** of June 11, 2008 (73 FR 33013) (FRL–8365–6).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flutolanil, EPA considered exposure under the petitioned-for tolerances as well as all existing flutolanil tolerances in 40 CFR 180.484. EPA assessed dietary exposures from flutolanil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for flutolanil; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, the chronic dietary analysis included tolerance level residues, 100 percent crop treated estimates and processing factors (default).

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight-of-the-evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is

utilized. Based on the lack of evidence of carcinogenicity in two rodent studies and the lack of evidence of mutagenicity, flutolanil is not expected to pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flutolanil. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flutolanil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flutolanil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

The Agency used the First Approximation Rice Model (FARM) to estimate pesticide concentrations in surface water after applying flutolanil on rice and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use Generic Expected Environmental Concentrations (GENEEC) (a Tier 1 model) before using Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) (a Tier 2 model) for a screening-level assessment for surface water, but given the unique hydrological issues arising from pesticide application to rice paddies, EPA used the FARM rather than GENEEC or PRZM/EXAMS for surface water estimates.

Based on the SCI-GROW model, and the FARM (to estimate pesticide concentrations in surface water after applying flutolanil on rice) the estimated environmental concentrations (EECs) of flutolanil for acute exposures are estimated to be 3.8 parts per billion (ppb) for surface water and 0.34 ppb for ground water. The EEC for peak acute exposure is estimated to be 11.6 ppb for surface water. The EECs for chronic exposures are estimated to be 3.8 ppb for surface water and 0.34 ppb for ground water.

For chronic dietary risk assessment, the water concentration of value 3.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-

occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Flutolanil is currently registered for the following uses that could result in residential exposures: Turf grass and ornamental plants. EPA assessed residential exposure using the following assumptions: Although residential (non-occupational) exposure exists, a quantitative exposure assessment was not conducted since no toxicological endpoint attributable to acute, short-term or intermediate-term exposure have been identified and the current use pattern does not indicate chronic or long-term exposure (6 or more months of continuous exposure) potential. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found flutolanil to share a common mechanism of toxicity with any other substances, and flutolanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flutolanil does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different

additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure or rat pups to post-natal exposure to flutolanil. Flutolanil is not a developmental or reproductive toxicant. No maternal, reproductive, or developmental toxicity was observed at the limit dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for flutolanil is complete except for acute and subchronic neurotoxicity and immunotoxicity studies. Recent changes to 40 CFR part 158 make acute and subchronic neurotoxicity testing (OPPTS Test Guideline 870.6200), and immunotoxicity testing (OPPTS Test Guideline 870.7800) required for pesticide registration. However, the available data for flutolanil do not suggest that the compound produces hematological or thymus/spleen organ effects indicative of immunotoxicity. Further, there is no evidence of neurotoxicity in any study in the toxicity database for flutolanil. Therefore, EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a NOAEL lower than the NOAEL of 50 milligrams/kilogram/day (mg/kg/day) already established for flutolanil. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that flutolanil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that flutolanil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to flutolanil in drinking water. Residential exposure does not pose a concern for flutolanil because (1) chronic residential exposure is not expected; and (2) although short-term or intermediate-term residential exposure may occur, no

relevant adverse effects were identified for dermal or incidental oral or inhalation exposure related to residential use. These assessments will not underestimate the exposure and risks posed by flutolanil.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute Risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, flutolanil is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flutolanil from food and water will utilize 2% of the cPAD for children between 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flutolanil is not expected.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no short- or intermediate-term adverse effect was identified, flutolanil is not expected to pose a short-term or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* EPA has classified flutolanil as "not likely" to be a human carcinogen.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flutolanil residues.

## **IV. Other Considerations**

### *A. Analytical Enforcement Methodology*

An adequate enforcement methodology, (Method AU/95R/04), a common moiety Gas Chromatography/Mass Spectrometry (GC/MS) method which determines residues of flutolanil and metabolites as 2-trifluoromethyl benzoic acid (2-TFBA) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### *B. International Residue Limits*

Codex maximum residue limits (MRLs) are established for residues of flutolanil in rice commodities at 1–10 ppm, and in livestock commodities at 0.05–0.2 ppm. No Canadian or Mexican MRLs have been established. No Codex MRLs are established for soybean, cotton seed, or sugar beet commodities.

### *C. Response to Comments*

One comment was received from a private citizen objecting to the establishment of tolerances for flutolanil. The commenter criticized EPA's reliance on toxicology testing on animals. The Agency has received, and responded to, similar comments from this commenter on numerous previous occasions. Refer to the **Federal Register** issues of June 30, 2005 (70 FR 37686), January 7, 2005 (70 FR 1354), October 28, 2004 (FR 69 63096) for the Agency's response to these objections.

### *D. Revisions to Petitioned-For Tolerances*

The Agency is establishing tolerances that are greater than the proposed tolerance for soybean seed and cotton seed because the enforcement analytical method has not been validated at a level below 0.20 ppm, and the greater tolerance value is needed to accommodate indirect residues from soybean rotational crops. Additional tolerances are established for cotton gin byproducts, as the radiolabeled seed treatment study revealed residues on cotton gin trash, and soybean hay to accommodate the seed treatment use and the inadvertent residue from soybean as a rotational crop.

EPA is revising the tolerance expression in §180.484 to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of flutolanil not specifically mentioned; and that compliance with the specified tolerance levels is to be determined by measuring only the

specific compounds mentioned in the tolerance expression. The tolerance definition previously read “residues of the fungicide flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil.” It is being changed to “residues of flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, including its metabolites and degradates, in or on the commodities. Compliance with the tolerance levels is to be determined by measuring only flutolanil and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil.”

Finally, the inadvertent residue, rotational crop tolerances previously established for soybean forage and soybean hay encompass the use on soybean as a seed treatment. Therefore the tolerances established under paragraph (d), *Indirect or inadvertent residues*, for soybean, seed at 0.20 ppm; soybean, forage at 8.0 ppm, and soybean hay at 2.5 ppm are being revoked since the same tolerance values are being established under paragraph (a), *General*.

## V. Conclusion

Therefore, tolerances are established for residues of flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, including its metabolites and degradates, in or on cotton, undelinted seed at 0.20 ppm; soybean, seed at 0.20 ppm; soybean, forage at 8.0 ppm; soybean, hay at 2.5 ppm; cotton, gin byproducts at 0.20 ppm. Compliance with the tolerance levels is to be determined by measuring only flutolanil and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil.

## VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

*Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

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

Dated: March 26, 2010.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.484 is amended as follows:

- a. Revise the section heading.
- b. Revise the introductory text of paragraph (a).
- c. Add alphabetically entries to the table in paragraph (a) for cotton, gin byproducts; cotton, undelinted seed; soybean forage; soybean, hay; and soybean, seed.
- d. Revise paragraph (d).

### § 180.484 Flutolanil; tolerances for residues.

(a) *General.* Tolerances are established for residues of flutolanil, *N*-(3-(1-methylethoxy) phenyl)-2-(trifluoromethyl)benzamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flutolanil and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil, in or on the following commodities:

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts ...	0.20
Cotton, undelinted seed	0.20
* * *	* *
Soybean, forage .....	8.0
Soybean, hay .....	2.5
Soybean, seed .....	0.20

\* \* \* \* \*

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of

flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only flutolanil and its metabolites converted to 2-(trifluoromethyl) benzoic acid and calculated as flutolanil, in or on the following commodities.

Commodity	Parts per million
Wheat, bran .....	0.20
Wheat, forage .....	2.5
Wheat, grain .....	0.05
Wheat, hay .....	1.2
Wheat, straw .....	0.20

\* \* \* \* \*

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0673; FRL-8817-4]

#### Pendimethalin; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the current tolerance for combined residues of pendimethalin and its metabolite, expressed as pendimethalin equivalents, in or on alfalfa forage. BASF Corporation requested this tolerance amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 7, 2010. Objections and requests for hearings must be received on or before June 7, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0673. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Jim Tompkins, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5697; e-mail address: [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those

objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0673 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 7, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0673, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### II. Petition for Tolerance

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL-8801-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7576) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.361 be amended by increasing the tolerance for the combined residues of the herbicide pendimethalin, [N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine], and its metabolite 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on alfalfa, forage from 3.0 parts per million (ppm) to 3.5 (ppm). That notice referenced a summary of the petition