production and consumption of CFCs, EPA is making this action effective immediately to ensure continued availability of CFCs for medical devices.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Exports, Imports, Ozone, Reporting and recordkeeping requirements.

Dated: June 5, 2008.

Stephen L. Johnson,

Administrator.

■ 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

■ 2. Section 82.8 is amended by revising the table in paragraph (a) to read as follows:

§ 82.8 Grants of essential use allowances and critical use allowances.

(a) * * *

TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2008

Company	Chemical	2008 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	27.0

* * * * *

[FR Doc. E8–13088 Filed 6–10–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1021; FRL–8365–6]

Flutolanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective June 11, 2008. Objections and requests for hearings must be received on or before August 11, 2008, 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–2007–1021. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 (7505P), 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*.

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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–1021 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before August 11, 2008.

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–2007–1021, 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'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 March 12, 2008 (73 FR 13225) (FRL–8354–6), 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 0F6159) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.484 be amended by establishing tolerances for indirect or inadvertent residues of the fungicide flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide, and its metabolite, M-4, desisopropyl flutolanil *N*-(3-hydroxyphenyl)-2-(trifluromethyl)benzamide, expressed as 2-(trifluoromethyl) benzoic acid and calculated as flutolanil, in or on soybean forage at 9.0 parts per million (ppm), soybean hay at 2.0 ppm, soybean seed at 0.20 ppm, wheat bran at 0.3 ppm, wheat forage at 2.0 ppm, wheat grain at 0.10 ppm, wheat hay at 1.0 ppm, and wheat straw at 0.30 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*. One comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised all proposed tolerances except for soybean seed. The reasons for these changes are explained in Unit IV.D.

The time-limited tolerances exemptions for rice, grain; rice, straw; rice, bran; and rice, hulls are removed from 40 CFR 180.484 because the expiration date of December 31, 2000 has passed.

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 the petitioned-for tolerances for indirect or inadvertent 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 soybean forage at 8.0 ppm, soybean hay at 2.5 ppm, soybean seed at 0.20 ppm, wheat forage at 2.5 ppm, wheat grain at 0.05 ppm, wheat hay at 1.2 ppm, wheat straw at 0.20 ppm, and wheat bran at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

The toxicology studies conducted on flutolanil demonstrate few or no biologically significant toxic effects. Liver effects in rats included increases in absolute and relative liver weight in the absence of clinical chemistry and/or histopathology findings. In dogs, there was an elevation in alkaline phosphatase and cholesterol levels together with dose-related increases in absolute and relative liver weights, slightly enlarged livers, and an increase in severity of glycogen deposition. The increased liver weights are considered to be an adaptive response to flutolanil treatment and not an adverse effect. Based on the lack of evidence of carcinogenicity and the lack of evidence of mutagenicity, flutolanil is classified as ''not likely to be carcinogenic to humans''.

Flutolanil is not neurotoxic, and it is not a developmental or reproductive toxicant. No maternal, reproductive, or developmental toxicity was observed at the limit dose. There was no evidence for increased susceptibility of rat or rabbit fetuses to *in utero* exposure or rat pups to post-natal exposure to flutolanil. No toxic effects were observed in studies in which flutolanil was administered by the dermal route of exposure at the limit dose.

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 can be found at *http://www.regulations.gov* in the document ''Flutolanil, Human Health Risk Assessment. Requests for Inadvertent or Indirect Tolerances for use on soybean, wheat, corn and cotton, November 27, 2007'' beginning on page 7 in docket ID number EPA–HQ–OPP–2007–1021.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for

derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 shown in the following table.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUTOLANIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)			No appropriate toxicological endpoint attributable to a single exposure (dose) was identified from the oral toxicity studies including developmental toxicity studies in rats and rabbits.
Chronic dietary (all populations)	NOAEL = 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.5 mg/kg/day cPAD = 0.5 mg/kg/day	2–year chronic study in dogs, MRID no. 40342922 LOAEL = 250 mg/kg/day based on increased incidence of clinical toxic signs (emesis, salivation, and soft stool)
Cancer (oral, dermal, inhalation)	''Not likely to be carcinogenic to humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to flutolanil and metabolites, 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 United States Department of Agriculture (USDA) 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that tolerance-level residues were used for all crops.

iii. *Cancer*. Flutolanil has been classified as ''Not likely to be Carcinogenic to Humans'' therefore a cancer dietary exposure assessment was not performed.

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 EECs for chronic exposures are estimated to be 3.8 ppb for surface water and 0.34 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the

water concentration of value 3.8 ppb was used to access 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. 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.

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 (MOE) 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 neurotoxic, and it 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.

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 data bases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) 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. The level of residential exposure was not assessed as flutolanil was found to have no toxic endpoints corresponding to the duration of exposures in the residential setting. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. No appropriate endpoint attributable to a single exposure (dose) was identified from oral toxicity studies for the general population or for females aged thirteen years or older. 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 exposure to flutolanil and metabolites from food and water will utilize 1% of the cPAD for the most highly exposed population subgroup (infants less than one year old). Based on the use pattern, chronic residential exposure to residues of flutolanil is not expected.

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

Because no flutolanil toxicity from short-term or intermediate-term dermal and inhalation exposure was identified, flutolanil is not expected to pose a short-term or intermediate-term dermal or inhalation 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 common moiety high performance liquid chromatography/mass spectrometry (HPLC/MS) method (Method AU/95R/04) is available which determines residues of flutolanil and metabolites as 2-trifluoromethyl benzoic acid (2-TFBA). 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.*

B. International Residue Limits

Codex maximum residue limits (MRLs) are established for residues of flutolanil *per se* in rice commodities at 1–10 ppm, and in livestock commodities at 0.05–0.2 ppm. There are no wheat or soybean Codex MRL's.

Codex MRL's differ from established tolerances for the following commodities: Rice, grain; cattle, goat and hog kidney, and cattle, goat and hog liver. No Canadian or Mexican MRLs have been established for flutolanil.

The Agency's tolerance levels are based on analyses of the residue field trial data using EPA's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data, Standard Operating Procedure (SOP).

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 **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005) and, 69 FR 63096 (October 29, 2004) for the Agency's response to these objections.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerances should be revised as follows: Soybean, forage decreased from 9.0 ppm to 8.0 ppm; soybean, hay increased from 2.0 ppm to 2.5 ppm; wheat, forage increased from 2.0 ppm to 2.5 ppm; wheat, grain decreased from 0.1 ppm to 0.05 ppm; wheat, hay increased from 1.0 ppm to 1.2 ppm; wheat, straw decreased from 0.3 ppm to 0.20 ppm; and wheat, bran decreased from 0.3 ppm to 0.20 ppm. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

V. Conclusion

Therefore, tolerances are established for indirect or inadvertent 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 soybean, forage at 8.0 ppm, soybean, hay at 2.5 ppm, soybean, seed at 0.20 ppm, wheat, forage at 2.5 ppm, wheat, grain at 0.05 ppm, wheat, hay at 1.2 ppm, wheat, straw at 0.20 ppm, and wheat, bran at 0.20 ppm.

Additionally, expired time-limited tolerances for rice, grain; rice, straw; rice, bran; and rice, hulls are removed from 40 CFR part 180.484:

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, *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: May 29, 2008.

Lois A. 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 by removing paragraph (a)(2), removing the heading to paragraph (a)(1), redesignating paragraph (a)(1) as paragraph (a) and revising paragraph (d) to read as follows:

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

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent 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, in or on the following commodities:

Commodity	Parts per million
Soybean, forage	8.0
Soybean, hay	2.5
Soybean, seed	0.20
Wheat, bran	0.20
Wheat, forage	2.5
Wheat, grain	0.05
Wheat, hay	1.2
Wheat, straw	0.20

[FR Doc. E8–13000 Filed 6–10–08; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0535; FRL–8366–4]

Bifenthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide bifenthrin (2-methyl [1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on food commodities bushberry subgroup 13-07B; and leafy petioles subgroup 4B. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action revises previously established time-limited tolerances for residues of bifenthrin in or on orchardgrass, forage and orchardgrass, hay in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of this insecticide on orchardgrass in the State of Oregon to control western orchardgrass billbug. Residue data have been submitted indicating the need to increase the tolerances from their original level. This regulation establishes maximum permissible levels of residues of bifenthrin in these food/feed commodities. The time-limited tolerances expire and are revoked on December 31, 2009.

DATES: This regulation is effective June 11, 2008. Objections and requests for hearings must be received on or before August 11, 2008, 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–2007–0535. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–