

cranberry by removing the expiration date "12/31/06" and adding in its place "12/31/09."

**§ 180.371 [Amended]**

■ 4. In § 180.371, in the table to paragraph (b), amend the entries blueberry and citrus by removing the expiration date "6/30/07" and adding in its place "12/31/09."

**§ 180.442 [Amended]**

■ 5. In § 180.442, in the table to paragraph (b), amend the entries orchardgrass, forage and orchardgrass, hay by removing the expiration date "6/30/07" and adding in its place "12/31/09."

**§ 180.527 [Amended]**

■ 6. In § 180.527, in the table to paragraph (b), amend the entries cattle, fat; cattle, kidney; cattle, meat; cattle, meat byproducts; goat, fat; goat, kidney; goat, meat; goat, meat byproducts; hog, fat; hog, kidney; hog, meat; hog, meat byproducts; horse, fat; horse, kidney; horse, meat; horse, meat byproducts; sheep, fat; sheep, kidney; sheep, meat; sheep, meat byproducts; wheat, forage; wheat, grain; wheat, hay; and wheat, straw by removing the expiration date "6/30/07" and adding in its place "12/31/09."

**§ 180.561 [Amended]**

■ 7. In § 180.561, in the table to paragraph (b), amend the entries onion, dry bulb and onion, green by removing the expiration date "6/30/07" and adding in its place "12/31/09."

**§ 180.567 [Amended]**

■ 8. In § 180.567, in the table to paragraph (b), amend the entry ginseng by removing the expiration date "12/31/06" and adding in its place "12/31/09."

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0536; FRL-8107-7]

**Fluroxypyr; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of fluroxypyr in or on onion, bulb; garlic, bulb; and shallot, bulb. The Interregional Research Project Number 4 (IR-4) requested these tolerances under

the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective December 20, 2006. Objections and requests for hearings must be received on or before February 20, 2007, 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-2005-0536. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers;

commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides 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 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 the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2005-0536 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 on or before February 20, 2007.

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 your copies, identified by Docket ID number EPA-HQ-OPP-2005-0536, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of April 21, 2006 (71 FR 20661) (FRL-8065-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6775) by IR-4, 500 College Road East, Suite 201 West, Princeton, NJ 08540. The petition requested that 40 CFR 180.535 be amended by establishing tolerances for combined residues of the herbicide fluroxypyr, 1-methylheptyl ester [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid, in or on garlic and shallot (bulb), and onion (dry bulb) at 0.03 parts per million (ppm). The notice included a summary of the petition prepared by Dow AgroSciences, the registrant. Comments on the notice of filing were received from one private citizen. EPA's response to these comments is discussed in Unit IV.C.

Section 408(b)(2)(A)(i) of FFDCFA 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 FFDCFA 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 4 residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCFA 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. \* \* \*

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCFA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCFA, 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, consistent with section 408(b)(2) of FFDCFA, for tolerances for combined residues of fluroxypyr on onion, bulb; garlic, bulb; and shallot, bulb at 0.03 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

### 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 toxic effects caused by fluroxypyr 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>. Docket ID number EPA-HQ-OPP-2005-0536, Fluroxypyr Field Corn Human Health Risk Assessment, pages 12-15.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/pesticides/health/human.htm>.

A summary of the toxicological endpoints for fluroxypyr used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov). Docket ID number EPA-HQ-OPP-2005-0536, Fluroxypyr Field Corn Human Health Risk Assessment, page 13; and Fluroxypyr Dry Bulb Onion Human Health Risk Assessment, pages 17-18.

### C. Exposure Assessment

1. Dietary exposure from food and feed uses. Tolerances have been established (40 CFR 180.535) for the combined residues of fluroxypyr, in or on the following raw agricultural commodities: Barley, corn, grain, oat, sorghum, and wheat. Tolerances are also established for cattle, goat, hog, horse, sheep, and milk. Additionally, time limited tolerances are established in 40 CFR 180.535(b) in or on corn and onion. Risk assessments were conducted by EPA to assess dietary exposures from fluroxypyr in food as follow:

i. *Acute exposure.* There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate an acute-dietary risk to the U.S. general population or to the subpopulation females 13-50 years old. Therefore, an acute aggregate exposure assessment was not performed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII); and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessment: An unrefined, Tier 1 chronic dietary-exposure assessment was conducted for all supported fluroxypyr food uses. In this assessment, tolerance level residues

and 100% crop treated (CT) was assumed for all crops included in the analysis. The assumptions result in highly conservative dietary exposure estimates.

iii. *Cancer.* A cancer dietary assessment was not conducted since fluroxypyr has been classified as “not likely” to be carcinogenic.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fluroxypyr in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of fluroxypyr. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/index.htm>.

Refined (Tier II) surface water concentrations were developed for fluroxypyr with the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model, using an index reservoir scenario for the aerial application of fluroxypyr on rangeland and permanent grass pastures. The model assumes that fluroxypyr is applied at the maximum label rate (0.5 lb ae/acre). The estimated annual average environmental concentration of fluroxypyr in surface water is 3.3 parts per billion (ppb).

For the ground water estimated concentration, the Tier I Screening Concentration in Ground Water (SCI-GROW) model predicts that fluroxypyr will be found at relatively small concentrations when the herbicide is applied at the maximum recommended application rate of 0.5 lbs ae/acre. The estimate is 0.042 ppb (0.042 µg/L). This conservative estimate is a default value generated by the SCI-GROW model.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of fluroxypyr for surface water are estimated to be 3.3 ppb, and 0.04 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM-FCID™). For chronic dietary risk assessment, the annual average concentration of 3.3 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).

Fluroxypyr (Vista™) is registered for application to residential turfgrass and recreational sites such as golf courses, parks, and sports fields. The proposed label does not prohibit homeowners from mixing/loading/applying Vista™.

Residential handlers may receive short-term dermal and inhalation exposure to fluroxypyr when mixing, loading and applying the formulations. Adults and children may be exposed to fluroxypyr residues from dermal contact with turf during post-application activities. Toddlers may also receive short and intermediate-term oral exposure from incidental ingestion during post-application activities.

In conducting the short and intermediate-term aggregate risk assessments, the Agency made the following conservative assumptions.

- Incidental oral and inhalation exposures for the aggregate residential handler scenario included children and adults (U.S. population subgroup).

- Incidental oral exposure from treated areas included infants and children (up to age 12) for the aggregate post-application scenario.

- Inhalation exposure resulting from residential application included youth (age 13–19 years old), and the adult population subgroups.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluroxypyr and any other substances and fluroxypyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluroxypyr has 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 the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common

mechanism on EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

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

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There was no evidence (quantitative/qualitative) of increased susceptibility following in utero exposure to the acid and the ester in rats and rabbits, or following prenatal and/or postnatal exposure to the acid form in rats.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- The toxicity database for fluroxypyr is complete.

- There was no evidence of neurotoxicity or neuropathology in the available studies.

- There was no evidence (quantitative/qualitative) of increased susceptibility following pre and/or postnatal exposure.

- The chronic dietary food exposure assessment utilizes tolerance level residue estimates and assumes 100% CT for all commodities. This assessment is not likely to underestimate exposure/risk.

- The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

- The residential exposure assessment was conducted using standard assumptions based on carefully reviewed data.

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

1. *Acute risk.* There were no toxic effects attributable to a single dose. An endpoint of concern was not identified for any population subgroup. Therefore, fluroxypyr 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 fluroxypyr from food and water will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year old, and 1.4% of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of fluroxypyr is not expected.

3. *Short and intermediate-term risk.* Short and intermediate-term aggregate exposures are likely to result from exposure to fluroxypyr residues from food, drinking water, and residential pesticide uses. High-end estimates are used for residential exposure, while average values are used for food and drinking water. Short and intermediate-term risk assessments are required for adults (residential handler inhalation exposure scenario), in addition to infants and children (residential post-application oral exposure scenario).

Using the exposure assumptions described for non-dietary short and intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs from 4,400 to 54,000 (adults 50+ years old). The MOEs are 8,300 and 4,400 for the U.S. population, and children 1–2 years old (the most highly exposed subgroup), respectively.

4. *Aggregate cancer risk for U.S. population.* Fluroxypyr has been classified as “not likely” to be carcinogenic. Therefore, fluroxypyr is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to fluroxypyr residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

The gas chromatography/mass-selective detector (GC/MSD) analytical method used to determine residues of fluroxypyr in both the acid and methylheptyl ester forms is adequate to

recover residues of fluroxypyr and fluroxypyr 1–MHE in dry bulb onions. The method converts the methylheptyl ester form of fluroxypyr to the acid and results are reported as the acid equivalent. The lower limit of method validation (LLMV) for bulb onions was 0.01 ppm. Further, the method is an adaptation of a Dow AgroSciences method GRM 96.02, which has been adequately validated as an enforcement method; therefore the Agency considers the modified method to be adequate to enforce the requested tolerance.

Adequate enforcement methodology (GC/MSD) 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

There are currently no Codex, Canadian, or Mexican maximum residue limits for fluroxypyr or its metabolites in/on dry bulb onions.

##### C. Response to Comments

A private citizen of Florham Park, New Jersey submitted public comments on the fluroxypyr notice of filing. The private citizen commented on the cancer finding classification “not likely a carcinogen,” and views the statement deceptive.

*EPA's response:* The cancer classification “Not Likely to be Carcinogenic to Humans” comes from EPA's Guidelines for Carcinogen Risk Assessment. These Guidelines recommend this descriptor when the available data are considered robust for deciding that there is no basis for human hazard concern. These Guidelines were developed as part of an Agency-wide guidelines development program by a Technical Panel of the U.S. EPA's Risk Assessment Forum, which was composed of scientists from throughout the Agency. Selected drafts were peer reviewed internally by the U.S. EPA's Science Advisory Board, and by experts from universities, environmental groups, industry and other governmental agencies. The Guidelines were also subjected to several public comment periods. For additional information regarding EPA's Guidelines for Carcinogen Risk and recommended descriptor language please refer to the **Federal Register** of April 7, 2005 (70 FR 17765) (FRL–7896–1) (<http://www.epa.gov/fedrgstr/EPA-TOX/2005/April/Day-07/t6642.htm>).

The private citizen also commented on profiteers utilizing the Agency to promote poor products to the American citizens.

*EPA's response:* This comment is not germane to EPA's statutory basis for acting on fluroxypyr tolerance petition. Thus, a technical response to this comment is not required. The private citizen's comments contained no scientific data or other substantive evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to fluroxypyr from the establishment of these tolerances.

#### V. Conclusion

Therefore, the tolerances are established for combined residues of fluroxypyr, 1-methylheptyl ester [1-methylheptyl] ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate and its metabolite fluroxypyr (((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid), in or on onion, bulb; garlic, bulb; and shallot, bulb at 0.03 ppm.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCa. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the

relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: December 12, 2006.  
**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 180.535 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

**§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Garlic, bulb .....	0.03
* * * * *	*
Onion, bulb .....	0.03
Shallot, bulb .....	0.03
* * * * *	*

\* \* \* \* \*  
 [FR Doc. 06-9765 Filed 12-19-06; 8:45 am]  
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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 710**

[EPA-HQ-OPPT-2006-0981; FRL-8109-9] RIN 2070-AC61

**2006 Reporting Notice and Amendment; Partial Updating of TSCA Inventory Database; Chemical Substance Production, Processing, and Use Site Reports**

**AGENCY:** Environmental Protection Agency (EPA).  
**ACTION:** Final rule; Amendment; Notice of submission period extension.

**SUMMARY:** EPA is amending the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) regulations by extending the submission deadline for 2006 reports from December 23, 2006 to March 23, 2007. This is a one-time extension for the 2006 submission period only. The IUR requires manufacturers and importers of certain chemical substances included on the TSCA Chemical Substance Inventory to report current data on the manufacturing, processing, and use of the substances.

**DATES:** This final rule is effective December 20, 2006. The 2006 IUR submission period is extended to run from December 23, 2006 to March 23, 2007.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2006-0981. All documents in the docket are listed on the regulations.gov website. 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. The EPA Docket Center (EPA/DC) suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Rm. 3334) in the EPA West Bldg., located at 1301 Constitution Ave., NW., Washington,