

ARIZONA—SO<sub>2</sub>—Continued

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
T1S, R14½E .....	.....	.....	.....	X
T1S, R15E .....	.....	.....	.....	X
T2N, R13E <sup>1</sup> .....	.....	.....	X	.....
T2N, R16E .....	.....	.....	X	.....
T1N, R16E .....	.....	.....	X	.....
T1S, R13E <sup>1</sup> .....	.....	.....	X	.....
T1S, R16E .....	.....	.....	X	.....
T2S, R14E <sup>1</sup> .....	.....	.....	X	.....
T2S, R15E .....	.....	.....	X	.....
* * * * *				

<sup>1</sup>Only that portion in Gila County.

\* \* \* \* \*  
 [FR Doc. E7-996 Filed 1-23-07; 8:45 am]  
 BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2006-0667; FRL-8110-3]

**Spiromesifen; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation revises a tolerance for combined residues of spiromesifen in or on vegetables, fruiting, group 8 and establishes tolerances for inadvertent or indirect combined residues in or on oat (grain, forage, hay, straw). Interregional Research Project No. 4 (IR-4) and Bayer CropScience (respectively) 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 January 24, 2007. Objections and requests for hearings must be received on or before March 26, 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-2006-0667. 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:** Thomas C. Harris, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9423; e-mail address: [harris.thomas@epa.gov](mailto:harris.thomas@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-2006-0667 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 March 26, 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-2006-0667, 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 September 13, 2006 (71 FR 54057) (FRL-8091-7), 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 5E6901) by Interregional Research Project No. 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201, Princeton, NJ 08540. The petition requested that 40 CFR 180.607 be amended by revising a tolerance for combined residues of the insecticide/miticide spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on vegetable, fruiting, crop group 8 from 0.30 to 0.45 parts per million (ppm). The same notice also announced the filing of a pesticide petition (PP 6F7039) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. That petition requested that 40 CFR 180.607 be amended by establishing a tolerance for inadvertent or indirect combined residues of the insecticide/miticide spiromesifen (2-

oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on oat, forage; oat, fodder; and oat, straw at 0.25 ppm and in or on the food commodity oat, grain at 0.03 ppm. The notice included summaries of the petitions prepared by Bayer CropScience, the registrant. Comments were received on the notice of filing from one private citizen. EPA's response to these comments is discussed in Unit IV.C.

Based on the EPA analysis of the residue chemistry and toxicological databases, petition PP 6F7039 was subsequently revised to express the oat tolerances as inadvertent or indirect combined residues of the insecticide/miticide spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on oat, forage at 0.20 ppm; oat, grain at 0.03 ppm; oat, hay at 0.25 ppm; and oat, straw at 0.25 ppm.

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 \* \* \*."

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 FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm> and <http://www.epa.gov/fedrgstr/EPA-PEST/2003/July/Day-30/p19357.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of the insecticide/miticide spiromesifen and its enol metabolite, in or on vegetable, fruiting, crop group 8 at 0.45 ppm and the inadvertent or indirect combined residues of the insecticide/miticide spiromesifen and its enol metabolite, in or on oat, forage at 0.20 ppm; oat, grain at 0.03 ppm; oat, hay at 0.25 ppm; and oat, straw at 0.25 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 toxic effects caused by spiromesifen 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 in Unit III.A. of the final rule published in the **Federal Register** of April 27, 2005 (70 FR 21631) (FRL-7705-1) at <http://www.epa.gov/fedrgstr/EPAFR-CONTENTS/2005/April/Day-27/contents.htm>.

### 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 and 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 spiromesifen used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 27, 2005 (70 FR 21631) (FRL-7705-1) at <http://www.epa.gov/fedrgstr/EPAFR-CONTENTS/2005/April/Day-27/contents.htm>.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.607) for the combined residues of spiromesifen, in or on a variety of raw agricultural commodities. In addition, tolerances have been established for combined residues on several livestock (cattle, goat, horse, sheep) commodities which feed on these raw agricultural commodities and for inadvertent or indirect combined residues on some rotational crop (alfalfa, barley, sugar beet, wheat) commodities. Risk assessments were conducted by EPA to assess dietary exposures from spiromesifen 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 spiromesifen. Therefore, a quantitative acute dietary exposure assessment is unnecessary.

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 assessments: (1) Established/recommended tolerances for all plant and livestock except the leafy-green and leafy-Brassica vegetable subgroups; (2) EPA calculated residues of concern (parent and metabolites) for the leafy-green and leafy-Brassica vegetable subgroup; (3) 100% crop treated (CT) information for all proposed and existing uses; and (4) DEEM™ Version 7.81 default processing factors for all commodities.

The metabolism studies show that the hydroxymethyl metabolite is formed along with the enol metabolite only in the leafy-green and leafy-Brassica vegetable subgroups. EPA determined that these two metabolites along with the spiromesifen should be included in the chronic dietary risk assessment for these crops. Residue data are unavailable for the 4-hydroxymethyl metabolite; to account for this metabolite in the risk assessment, the recommended tolerance levels for these crops was multiplied by a correction factor of 1.3X, where 1.3 = metabolites in risk assessment (ppm) / metabolites in tolerance expression (ppm).

iii. *Cancer.* A cancer exposure assessment was not performed because spiromesifen is classified as “not likely to be carcinogenic to humans.”

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for spiromesifen 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 spiromesifen. 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>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentrations in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of spiromesifen for chronic exposures are estimated to be 11 ppb for surface water and 28 ppb for ground water. Drinking water estimates were incorporated directly into the DEEM-FCID™ using the estimated drinking water concentration generated by the SCI-GROW (version 2.3) model of 28 ppb.

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).

Spiromesifen is not registered for use on any sites that would result in residential exposure.

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 considers “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 spiromesifen and any other substances and spiromesifen 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 spiromesifen 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 website 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a Margin of Exposure (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 of increased susceptibility of rats or rabbits to *in utero* prenatal or postnatal exposure to spiromesifen. In a rat developmental toxicity study, no developmental toxicity was observed at doses up to 500 milligrams/kilograms/day (mg/kg/day) (the highest dose tested) in the presence of maternal toxicity. The rat maternal LOAEL was determined to be 70 mg/kg/day based on decreased body-weight gain and reduced food consumption. In the rabbit developmental toxicity study, there was no developmental toxicity observed at doses up to 250 mg/kg/day (the highest dose tested), but the maternal LOAEL was determined to be 35 mg/kg/day based on body weight loss and reduced food consumption. There is no qualitative and/or quantitative evidence of increased susceptibility to spiromesifen following pre/postnatal exposure in a 2-generation reproduction study in rats.

There is no concern for developmental neurotoxicity resulting from exposure to spiromesifen. Neurotoxic effects such as reduced motility, spastic gait, increased reactivity, tremors, clonic-tonic convulsions, reduced activity, labored breathing, vocalization, avoidance reaction, piloerection, limp, cyanosis, squatted posture, and salivation were observed in two studies (5-day inhalation and subchronic oral rat). However, these effects were considered as secondary, not neurotoxic, effects due to the high dosage. There was no evidence of neurotoxicity in the acute or subchronic neurotoxicity or any other studies.

3. *Conclusion.* For spiromesifen, EPA determined that the 10X safety factor to protect infants and children should be removed. A 1X safety factor is appropriate because:

- There is a complete toxicity database for spiromesifen.
- There was no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies, nor following prenatal or postnatal exposure by rats in the 2-generation reproduction study.

- There are no neurotoxicity concerns based on acute and subchronic neurotoxicity studies.

- The dietary food exposure assessment uses proposed tolerance levels or higher residues for most commodities and assumed 100% crop-treated information for all commodities. By using these screening-level

assessments, chronic exposures and risks will not be underestimated. The “higher residues” are those that were calculated using a modifying factor to account for the lack of spiromesifen-4-hydroxymethyl residue data.

- The dietary drinking water assessment (Tier 2 estimates) uses values generated by model and associated modeling parameters which are designed to provide conservative, health protective, and high-end estimates of water concentrations.

- Residential exposure is not expected, spiromesifen will be registered for agricultural and greenhouse/ornamental uses only.

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

1. *Acute risk.* As there were no toxic effects attributable to a single dose, an endpoint of concern was not identified to quantitate acute dietary risk to the general population or any subpopulation. No acute risk is expected from exposure to spiromesifen.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spiromesifen from food and water will utilize 31% of the chronic population adjusted dose (cPAD) for the U.S. population, 23% of the cPAD for all infants less than 1 year old, and 38% of the cPAD for children 1-2 years old, the most highly exposed population subgroups. There are no residential uses for spiromesifen that result in chronic residential exposure to spiromesifen. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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

Spiromesifen is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Spiromesifen 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 spiromesifen residues.

## IV. Other Considerations

### A. Analytical Enforcement Methodology

Adequate analytical enforcement methodologies, high-performance liquid chromatography (HPLC)/mass spectrometry (MS)/MS, exist and have been successfully validated by independent laboratories.

### B. International Residue Limits

There are no international residue limits for spiromesifen listed in CODEX.

### C. Response to Comments

Several comments were received from one private citizen objecting to pesticide body load, registrant profiteering, establishing tolerances, pollution by pesticides, and lack of notification when pesticides are applied to neighboring areas. The Agency has received 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 63096–63098 (October 29, 2004) for the Agency's response to these objections.

## V. Conclusion

Therefore, the tolerance is revised for combined residues of the insecticide/miticide spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on vegetable, fruiting, crop group 8 to 0.45 ppm. Also, the tolerance is established for inadvertent or indirect combined residues of the insecticide/miticide spiromesifen (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents, in or on oat, forage at 0.20 ppm; oat, grain at 0.03 ppm; oat, hay at 0.25 ppm; and oat, straw at 0.25 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) (Public Law 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 FFDCFA, 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 FFDCFA. 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: January 17, 2007.

**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 180.607 is amended in the table to paragraph (a)(1) by revising the entry for “Vegetable, fruiting group 8” and in the table to paragraph (d) by adding alphabetically commodities to read as follows:

**§180.607 Spiromesifen; tolerances for residues.**

(a) *General.* (1) \* \* \*

Commodity	Parts per million
* * * * *	* * * * *
Vegetable, fruiting, group 8 .....	0.45
* * * * *	* * * * *

(d) \* \* \*

Commodity	Parts per million
* * * * *	* * * * *
Oat, forage .....	0.20
Oat, grain .....	0.03
Oat, hay .....	0.25
Oat, straw .....	0.25
* * * * *	* * * * *

[FR Doc. E7-990 Filed 1-23-07; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**42 CFR Part 51a**

**RIN # 0906-AA70**

**Healthy Tomorrows Partnership for Children Program (HTPC)**

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Final rule.

**SUMMARY:** This Final Rule sets forth the Secretary’s proposal to require HTPC grant recipients to contribute non-Federal matching funds in years 2 through 5 of the project period equal to two times the amount of the Federal Grant Award or such lesser amount