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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0038; FRL-9374-3]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiromesifen in or on tea, dried. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0038, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Jennifer Gaines, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5967; email address: *Gaines.Jennifer@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0038 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0038, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 4, 2012 (77 FR 20334-20337) (FRL-9340-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7924) by Bayer CropScience, P.O. Box12014, 2 T.W. Alexander Dr., Research Triangle Park, N.C. 27709. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for residues of 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), in or on tea, dried at 50 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has changed the tolerance for tea, dried from 50 ppm to 40 ppm. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** 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 spiromesifen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spiromesifen 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.

Spiromesifen was classified as having low acute toxicity via the oral, dermal and inhalation routes of exposure. It was neither an eye nor dermal irritant, but showed moderate potential as a skin contact sensitizer. In short- and long-term animal toxicity

tests, the critical effects observed were loss of body weight, adrenal effects (discoloration, decrease in fine vesticulation, and the presence of cytoplasmic eosinophilia in zona fasciculata cells), thyroid effects (increased thyroid stimulating hormone, increased thyroxine binding capacity, decreased T3 and T4 levels, colloidal alteration and thyroid follicular cell hypertrophy), liver effects (increased alkaline phosphatase, alanine transaminase (ALT) and decreased cholesterol, and triglycerides), and spleen effects (atrophy, decreased spleen cell count, and increased macrophages). There were no developmental or reproductive effects of concern following oral administration of spiromesifen in rats or rabbits. EPA concluded that spiromesifen is not likely to be carcinogenic to humans based on a lack of evidence of cancer in bioassays in rats and mice. There were no *in vivo* or *in vitro* mutagenic effects in mutagenicity testing with spiromesifen. Spiromesifen is not considered a neurotoxic chemical based on the chemical's mode of action and the available data from multiple studies, including acute and subchronic neurotoxicity studies.

Specific information on the studies received and the nature of the adverse 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 at http://*www.regulations.gov* in document "Spiromesifen: Human-Health Risk Assessment for Request for Tolerance without U.S. Registration in/on Tea." at pages 20 to 24 in docket ID number EPA-HQ-OPP-2012-0038.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk

posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for spiromesifen used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Spiromesifen for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	Not applicable	None	An endpoint of concern attributable to a single dose was not identified. An aRfD was not established.
Chronic dietary (All populations)	NOAEL= 2.2 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.022 mg/kg/day cPAD = 0.022 mg/kg/day	2-generation reproduction study in rats. The parental systemic LOAEL = 8.81 mg/kg/day based on significantly decreased

			spleen weight (absolute and relative in parental females and F_1 males) and significantly decreased growing ovarian follicles in females.
Dermal short-term (1 to 30 days) and Intermediate-term (1 to 6 months)	None	None	No dermal, systemic, or developmental concerns.
Inhalation short-term (1 to 30 days) and Intermediate-Term (1 to 6 months)	Inhalation (or oral) study NOAEL= 21.1 mg/kg/day (inhalation absorption rate = 100%) HEC = 0.06 mg/L HED = 1.42 mg/kg/bw/day	LOC for MOE = 30 (3X interspecies and 10X intraspecies extrapolations)	Subchronic (30-day) inhalation toxicity study in rats & 5-day inhalation toxicity study in rats. LOAEL (5-day) = 134.2 mg/kg/day based on the clinical signs (tremors, clonic-tonic convulsions, reduced activity, bradypnea, labored breathing, vocalization, avoidance reaction, giddiness, piloerection, limp, emaciation, cyanosis, squatted posture, apathy, salivation, gross pathology (dark red areas or foci in the lungs, bloated stomachs, and pale liver), and decreased spleen weights.
Cancer (Oral, dermal, inhalation)	Spiromesifen has been classified as "not likely to be carcinogenic to humans."		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). HEC = human human-equivalent concentration. HED = human human-equivalent dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spiromesifen, EPA considered exposure under the petitioned-for tolerances as well as all

existing spiromesifen tolerances in 40 CFR 180.607. EPA assessed 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 food consumption data from the USDA 1994-1996 and 1998 Cumulative Survey of Food Intake by Individuals, CSFII. As to residue levels in food, EPA assumed tolerance-level residues for all commodities except for the leafy-green and leafy-*Brassica* vegetable subgroups (4A, 4B, and 5B), spearmint and peppermint tops and oil, and tea. For these commodities, residues were also based on tolerance levels; however, a correction factor was applied to the tolerance levels to account for BSN 2060-4-hydroxymethyl metabolites of spiromesifen included in the risk assessment for these commodities. The additional metabolites, BSN 2060-4-hydroxymethyl and BSN 2060-4-hydroxymethyl-glucoside, were observed in the metabolism studies of lettuce only, comprising 21% of the total radioactive residues. Since the toxicity of the BSN 2060-4-hydroxymethyl metabolites is expected to be comparable to the parent compound, it was included in the risk assessment for leafy crops (including tea, subgroups 4A, 4B, and 5B and spearmint and peppermint tops and oil). To account for this additional exposure, the recommended tolerance level was multiplied by a correction factor of 1.3X, where 1.3 = (Metabolites in Risk Assessment)/(Metabolites in Tolerance Expression; concentrations

from the lettuce metabolism study). Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors and 100 percent crop treated were assumed.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that spiromesifen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for spiromesifen. As discussed in Unit III.C.1.ii., for the leafy-greens and leafy *Brassica* greens subgroups (4A, 4B, and 5B) and spearmint and peppermint tops and oil, and tea, the residue values were adjusted upward to account for the metabolite BSN 2060-4-hydroxymethyl (free and conjugated).

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spiromesifen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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 Provisional Cranberry Model and Screening Concentration in Ground Water (SCI-GROW) models the estimated drinking water concentrations (EDWCs) of spiromesifen for chronic exposures for non-cancer assessments are estimated to be 188 ppb for surface water and 86 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 188 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). Spiromesifen is currently registered for the following uses that could result in residential exposures: Indoor and outdoor uses for the control of mites and whiteflies on ornamental plants in and around areas such as parks, golf courses, recreational areas, and residential and commercial buildings. EPA assessed residential exposure using the following assumptions: Residential handler inhalation exposure was assessed for adults mixing/loading/applying spiromesifen using handheld equipment to ornamentals. Details for the residential risk exposure and risk assessment are contained in the EPA public docket EPA-HQ-OPP-2012-0038 at *http://www.regulations.gov* in document "Spiromesifen: Human-Health Risk Assessment for Request for Tolerance without U.S. Registration in/on Tea" on pp.15-19.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

http://www.epa.gov/pesticides/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf

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

EPA has not found spiromesifen to share a common mechanism of toxicity with 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 assumed that spiromesifen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rats or rabbits following *in utero* and/or postnatal exposure to spiromesifen. In the prenatal developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, developmental toxicity to the offspring occurred at equivalent or higher doses than parental toxicity.

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 spiromesifen is complete.

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

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spiromesifen in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spiromesifen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term

risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spiromesifen from food and water will utilize 78% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spiromesifen is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, spiromesifen is not expected to pose a short-term risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, spiromesifen is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spiromesifen is not expected to pose a cancer risk to humans.

6. *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 spiromesifen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography/tandem mass spectroscopy (HPLC/MS/MS)/Method BS001-P09-01 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; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for spiromesifen in/on dried tea.

C. Response to Comments

There were no comments received.

D. Revisions to Petitioned-For Tolerances

Based on the analysis of the data supporting the petition, EPA has revised the proposed tolerance for tea, dried from 50 ppm to 40 ppm. EPA revised this tolerance level based on the highest-average field trial residue level and a processing factor for black tea.

V. Conclusion

Therefore, tolerances are established for residues of 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), in or on tea, dried at 40 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction

Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq*.).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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 4, 2013.

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. In §180.607, the table in paragraph (a)(1) is amended by adding, alphabetically, the commodity "Tea, dry" to read as follows:

§180.607 Spiromesifen; tolerances for residues.

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

Commodity	**Parts per million**
* * * * * * *	
Tea, dry	40
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[FR Doc. 2013-00728 Filed 01/15/2013 at 8:45 am; Publication Date: 01/16/2013]