butyl, R-(+)-n-butyl-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionate, plus cyhalopfop acid, R-(+)-2-(4(4-cyano-2-fluorophenoxy)-phenoxy)propionic acid) and the di-acid metabolite, (2R)-4-[4-(1-carboxyethoxy)phenoxy]-3-fluorobenzoic acid, in or on rice, grain and rice, wild, grain at 0.03 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 27, 2009.

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 180.576 is amended by revising the table in paragraph (a) to read as follows:

§ 180.576 Cyhalofop-butyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
Rice, grain	0.03
Rice, wild, grain	0.03

* * * * *

[FR Doc. E9–7990 Filed 4–7–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0272; FRL–8406–6]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined 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), calculated as the parent compound equivalents, in or on pop corn grain and stover. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this regulation establishes tolerances for sweet corn, kernel, stover, and forage; and berry, lowgrowing, subgroup 13G. Interregional Research Project No. 4 (IR-4) requested these tolerances under the FFDCA. Additionally, the existing tolerance for strawberry is being deleted because it is superseded by the tolerances established for low growing berry subgroup 13–07G. Also, the tolerances for milk fat and meat byproducts of cattle, goats, horses, and sheep are being increased.In addition, this action establishes time-limited tolerances for the combined 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), calculated as the parent compound equivalents, in or on soybean commodities in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of spiromesifen on soybeans to control spider mites. The time-limited tolerances expire and are revoked on December 31, 2011.

DATES: This regulation is effective April 8, 2009. Objections and requests for hearings must be received on or before June 8, 2009, 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–2008–0272. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: 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; e-mail address: *gaines.jennifer@epa.gov*. Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: *conrath.andrea@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document?

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0272 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 8, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0272, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of May 16, 2008 (73 FR 28462) (FRL–8361–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7340) by Interregional Research Project Number 4 (IR-4), Rutgers, The State University of NJ, 500 College Road East, Suite 201 W. Princeton, NJ 08540. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for combined residues of the insecticide 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 corn, sweet, kernel plus cob with husks removed at 0.02 parts per million (ppm); corn, sweet, forage at 6.0 ppm, corn, sweet, stover at 7.0 ppm, berry and small fruit, low growing berry, subgroup 13–07G at 2.0 ppm and delete existing tolerance for strawberry at 2.0 ppm since residues of spiromesifen on strawberry will be covered by the tolerance proposed for berry and small fruit, low growing berry, subgroup. That notice referenced a summary of the petition prepared by IR-4 the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

In the **Federal Register** of November 5, 2008 (73 FR 65851) (FRL–8385–1), 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 8F7338) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for combined residues of the insecticide 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 pop corn grain at 0.02 ppm and pop corn stover at 1.5 ppm. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerances on corn, sweet, forage; corn, sweet, stover; and berry and small fruit, low growing berry, subgroup 13–07G. The Agency has also determined from the residue data on the new uses that the tolerances for meat, byproducts of cattle, goats, horses, and sheep, and milk, fat need to be raised. The reason for these changes are explained in Unit IV.D.

EPA is also establishing time-limited tolerances for residues of spiromesifen in or on soybean at 0.02 ppm; soybean, forage at 30 ppm; and soybean, hay at 86 ppm. These tolerances expire and are revoked on December 31, 2011. The Agency is establishing these time-limited tolerances in response to a specific exemption request under FIFRA section 18 on behalf of the Delaware Department of Agriculture for emergency use of spiromesifen on soybeans to control spider mites.

According to the applicant, decreasing effectiveness of the available controls, coupled with season-long dry weather conducive to mite development, led to spider mite levels in soybean fields that were well above levels which would cause crop damage leading to significant economic losses. In the most heavily infested areas, significant yield losses of 50–70% were expected. Thus the applicant requested use of spiromesifen to address this emergency pest situation.

As part of its assessment of the emergency exemption request, EPA assessed the potential risks presented by the residues of spiromesifen in or on these soybean commodities. In doing so, EPA considered the safety standard in section 408 (b) (2) of the FFDCA, and EPA decided that the necessary time-limited tolerances under section 408 (1) (6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these time-limited tolerances without notice and opportunity for public comment as provided in section 408 (1) (6) of the FFDCA. Although, these time-limited tolerances expire and are revoked on December 31, 2011, under section 408 (1) (5) of the FFDCA, residues of the pesticide not in excess of the amount specified in the tolerances remaining in or on soybeans, soybean hay, or soybean forage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data, or other relevant information on this pesticide indicates that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether spiromesifen meets EPA's registration requirements for use on soybean or whether a permanent tolerance for this use would be appropriate. Under this circumstance, EPA does not believe that the time-limited tolerances serve as a basis for registration of spiromesifen by a State for special local needs under FIFRA section 24(c). Nor do the time-limited tolerances serve as the basis for any State other than Delaware to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for spiromesifen, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined 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), calculated as the parent compound equivalents, on corn, sweet, forage at 6.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.02 ppm; corn, sweet, stover at 7.0 ppm; pop corn grain at 0.02 ppm; pop corn stover at 1.5 ppm; soybean at 0.02 ppm; soybean, forage at 30 ppm; soybean, hay at 86 ppm; and berry and small fruit, low growing berry, subgroup 13-07G at 2.0 ppm. In addition, the available residue chemistry, toxicology or occupational databases supports the tolerances for milk, fat at 0.25 ppm; and meat, byproducts of cattle, goats, horses, and sheep at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

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

Spiromesifen shows 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 contact sensitizer in a Magnusson and Kligman maximization assay. In short-term and long-term animal toxicity tests, the critical effects observed were loss of body weight, adrenal effects (discoloration, decrease in fine vesiculation, and the presence of cytoplasmic eosinophilia in zona fasciculata cells), thyroid effects (increased thyroid stimulating hormone, increased thyroxine binding capacity, decreased T_3 and T_4 levels, colloidal alteration and thyroid follicular cell hypertrophy), liver effects (increased alkaline phosphatase, ALT and decreased cholesterol, triglycerides), and spleen effects (atrophy, decreased spleen cell count, and increased macrophages). Spiromesifen shows no significant developmental or reproductive effects, is not likely to be carcinogenic based on bioassays in rat and mouse, and lacks *in vivo* and *in vitro* mutagenic effects. 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 Proposed Section 3 Uses on Pop Corn, Sweet Corn, Low-Growing Berry Subgroup; and Section 18 Emergency Exemption Use on Soybean*, pages 17–25 in docket ID number EPA–HQ–OPP–2008–0272 and memo, D300469, February 17, 2005.

B. Toxicological Endpoints

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

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

A summary of the toxicological endpoints for spiromesifen used for human risk assessment can be found at *http://www.regulations.gov* in document *Spiromesifen: Human-Health Risk Assessment for Proposed Section 3 Uses on Pop Corn, Sweet Corn, Low-Growing Berry Subgroup; and Section 18 Emergency Exemption Use on Soybean*, page 25 in docket ID number EPA–HQ–OPP–2008–0272.

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 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 and 5B). The tolerance values for leafy vegetables were adjusted upward to account for the metabolite BSN 2060-4-hydroxymethyl (free and conjugated), which is a residue of concern in leafy vegetables for risk assessment purposes only. EPA used data from the metabolism studies to create a tolerance-equivalent value for the parent spiromesifen and the BSN 2060-4-hydroxymethyl metabolite to estimate residues in leafy vegetables. DEEM 7.81 default processing factors and 100 percent crop treated (PCT) were assumed for all commodities.

iii. *Cancer*. Due to no evidence of carcinogenic effects in the submitted rat and mouse cancer studies, spiromesifen has been classified as ''not likely to be carcinogenic to humans.'' Therefore, an exposure assessment to evaluate cancer risk was not performed.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for spiromesifen. Tolerance level residues were used for all food commodities except for the leafy-green and leafy-Brassica vegetable subgroups (4A and 5B). For these subgroups, the residue values were adjusted to account for the metabolite BSN 2060-4-hydroxymethyl (free and conjugated), which is a residue of concern in leafy vegetables for risk assessment purposes only. 100 PCT was assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring 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, 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*.

Parent spiromesifen is not likely to persist in the environment as it readily undergoes both biotic and abiotic degradation; however, its primary degradate BSN2060-enol is expected to persist. While parent spiromesifen strongly sorbs to sediment and is not likely to be mobile, its major degradates, BSN2060-enol and BSN2060-carboxy, do not sorb to sediment and are expected to leach into ground water. Spiromesifen has limited solubility in water (130 µg/L at 25°C) and in some cases has been reported to have a practical solubility of 40 to 50 µg/L. The pesticide degrades primarily through aerobic soil metabolism and hydrolysis; however, in clear shallow water it will ready undergo photolysis. Field studies indicate that spiromesifen readily dissipates with field dissipation half-lives ranging from 2 to 10 days.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spiromesifen for chronic exposure are 188 parts per billion (ppb) for surface water and 86 ppb for ground water. For chronic dietary risk assessment, the water concentration of value 188 ppb was used to assess the contribution to drinking water. Modeled estimates of drinking water concentrations were

directly entered into the dietary exposure model.

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 any specific use patterns that would result in residential exposure.

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 to *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 and no additional immunotoxicity of neurotoxicty testing is required. The rationale is described in this Unit:

a. Because spleen effects were seen in several toxicity studies, the registrant pursued specialized immunotoxicity studies in rats and mice that were both negative. These studies satisfy the revised part 158 requirement for immunotoxicity testing. In addition, the endpoints selected for the risk assessment are considered protective of any possible immunotoxic effects.

b. There is no concern for 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) at high doses (134 and 536 milligrams/kilogram/day (mg/kg/day), respectively). These effects were neither reflected in neurohistopathology nor in other studies. Because these effects were not observed in the acute and subchronic neurotoxicity studies, they were not considered reproducible. Thus, based on the chemical's mode of action and the available data from multiple studies, the chemical is not considered neurotoxic.

ii. There is no evidence that spiromesifen results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. A developmental neurotoxicity study is not required.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to spiromesifen in drinking water. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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, an acute aggregate exposure assessment was not conducted.

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 77% of the cPAD for (all infants <1 year old) the population group receiving the greatest exposure.

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

Spiromesifen is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to spiromesifen through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Spiromesifen has been classified as ''not likely to be carcinogenic to humans.'' 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, 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/mass spectroscopy (HPLC/MS/MS)/Method 00631/M001) 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*.

B. International Residue Limits

No Codex, Canadian, or Mexican MRLs have been established for residues of spiromesifen and its metabolites on the requested crops.

C. Response to Comments

One comment was received from a private citizen who opposed the authorization to sell to any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated in the **Federal Register** of January 7, 2005 (70 FR 1349) (FRL–7691–4.)

D. Revisions to Petitioned-For Tolerances

1. Corn, sweet, forage; corn, sweet, stover; corn, pop, grain; corn, pop, stover; and berry, lowgrowing, subgroup 13G: Using the North American Free Trade Agreement (NAFTA) Maximum Residue Limit (MRL) Tolerance Harmonization Workgroup methodology for evaluating field trial data, the Agency determined that the following modifications to the requested tolerances should be made: Corn, sweet, forage proposed at 6.0 ppm should be 17 ppm; and corn, sweet, stover proposed at 7.0 ppm should be 12 ppm. Additionally, the terminology should be corrected for berry and small fruit, low growing berry, subgroup 13-07G.2.

2. Meat, byproducts of cattle, goats, horses, and sheep; milk, fat: The Agency has also determined from the residue data on the new uses, the newly calculated maximum reasonable dietary burden for dairy cattle, and the reside data from an available ruminant feeding study, it is appropriate to raise the tolerances for meat, byproducts of cattle, goats, horses, and sheep to 0.20 ppm; and to raise the tolerance for milk, fat to 0.25 ppm.

V. Conclusion

Therefore, tolerances are established for combined residues of insecticide 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 corn, sweet, kernel plus cob with husks removed at 0.02 ppm; corn, sweet, forage at 17 ppm; corn, sweet, stover at 12 ppm; berry and small fruit; berry, lowgrowing, subgroup 13G at 2.0 ppm and delete existing tolerance for strawberry at 2.0 ppm since residues of spiromesifen on strawberry will be covered by the tolerance proposed for berry and small fruit, low growing berry, subgroup. In addition, this regulation establishes time-limited tolerances for residues of spiromesifen and its enol metabolite, in or on soybeans at 0.02 ppm; soybean, forage at 30 ppm; and soybean, hay at 86 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 30, 2009.

Daniel J. Rosenblatt,

Acting 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 as follows:

■ i. In paragraph (a)(1), in the table, by removing the commodity strawberry and alphabetically adding the following commodities;

■ ii. In paragraph (a)(2), in the table, by revising the tolerance level for cattle, meat byproducts; goat, meat by products; horse, meat byproducts; milk, fat; and sheep, meat byproducts; and

■ iii. By adding paragraph (b).

The amendments read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Berry and small fruit, low growing berry, subgroup 13-07G	2.0
* * * * *	
Corn, pop, grain	0.02
Corn, pop, stover	4.0
Corn, sweet, forage	17
Corn, sweet, kernel plus cob with husks removed	0.02
* * * * *	
Corn sweet, stover	12
* * * * *	

(2) * * *

Commodity	Parts per million
* * * * *	
Cattle, meat byproducts	0.20
* * * * *	
Goat, meat byproducts	0.20
* * * * *	
Horse, meat byproducts	0.20
* * * * *	
Milk, fat	0.25
* * * * *	
Sheep, meat byproducts	0.20

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for combined 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), calculated as the parent compound equivalents in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Soybean, seed	0.02	12/31/11
Soybean, forage	30	12/31/11
Soybean, hay	86	12/31/11

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