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) (Pub. L. 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).

VIII. 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: November 18, 2010.

G. Jeffrey Herndon,

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. In § 180.910, add alphabetically the following inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5).	For use in post-harvest applications; Not to exceed 15% by weight in pesticide formulations.	Surfactants.
* * *	* * *	*

[FR Doc. 2010–29992 Filed 11–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0136; FRL–8850–9]

Spiroxamine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiroxamine, [(8-(1,1-dimethylethyl)-*N*-ethyl-*N*-propyl-1, 4-dioxaspiro[4,5]decane-2-methanamine)], including its metabolites and degradates in or on artichoke, globe, import at 0.7 parts per million (ppm) asparagus, import at 0.05 ppm; and vegetables, fruiting, crop group 8, import at 1.2 ppm. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 1, 2010. Objections and requests for hearings must be received on or before January 31, 2011, 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–2010–0136. 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–9096; *e-mail address: gibson.tamue@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 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://www.gpoaccess.gov/ecfr.*

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–2010–0136 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 January 31, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0136, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 24, 2010 (75 FR 14154) (FRL–8815–6), 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 9E7564) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, North Carolina 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide spiroxamine, (8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine) and its metabolites containing the N-ethyl-N-propyl-1,2-dihydroxy-3-aminopropane moiety, calculated as parent equivalent, in or on artichoke, globe at 0.7 parts per million (ppm); asparagus at 0.05 ppm and vegetable, fruiting, group 8 at 1.2 ppm. That notice 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.

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 spiroxamine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spiroxamine 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 adverse effects caused by spiroxamine 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 "Spiroxamine: Human Health Risk Assessment for Spiroxamine on Imported Artichoke, Asparagus and Fruiting Vegetables (Corp Group 8)," pp. 33–36 in docket ID number EPA–HQ–OPP–2010–0136.

Spiroxamine has low acute oral and inhalation toxicity and is not irritating to the eye. However, spiroxamine is a skin sensitizer when tested in guinea pigs and is a severe dermal irritant. Spiroxamine subchronic studies show the target organ of toxicity is the liver. These studies were characterized by slight to mild hepatotoxicity, with associated elevation in liver enzymes. Mucous membranes of the esophagus and forestomach were keratinized and hyperplastic as a result of the strong irritant properties of spiroxamine. Administration of spiroxamine in long-term studies in the dog resulted in hepatocytomegaly, cataracts, and liver discoloration. In the rat, it resulted in an increased mortality in females, decreased body weights and body weight gains in both sexes, and increased esophageal hyperkeratosis in both sexes, while in the mouse, chronic administration resulted in uterine nodules, hyperplasia in the adrenal gland of males, hyperkeratosis in the esophagus, forestomach, and tongue of females, and acanthosis in the pinnae and tails of females. Developmental effects in rats entailed delayed ossification which may be considered secondary to decreased body weight. Treatment-related developmental effects

were not seen in rabbits. There was no evidence of increased susceptibility of the young animals following exposure to spiroxamine in any developmental toxicity studies in the data base. There was evidence of mild spiroxamine-induced neurotoxicity characterized by piloerection and slight to moderate gait incoordination, and functional observational battery (FOB) effects of decreased forelimb grip strength and foot splay in males in the acute neurotoxicity study. No neuropathology was seen in either the acute or subchronic toxicity studies in rats and no neurotoxicity was detected in the subchronic study. Spiroxamine has no carcinogenic potential, as indicated in both the rat and the mouse carcinogenicity studies. In addition, spiroxamine has no mutagenicity potential, based on several *in vivo* and *in vitro* studies.

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 spiroxamine used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPIROXAMINE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute Dietary (General population, including infants and children.	NOAEL = 10 mg/kg/day.	UF_A = 10X ..... UF_H = 10X FQPA = 1X	aRfD = 0.1 mg/kg/day. aPAD = 0.1 mg/kg/day	Acute Neurotoxicity in Rats. LOAEL = 30 mg/kg based on clinical signs (piloerection and slight to moderate gait in coordination) and FOB effects (decreased forelimb grip strength and foot splay) in males on Day 0–1.
Acute Dietary (females 13–49 years old).	No hazard identified.			
Chronic Dietary—general population, including infants and children.	NOAEL = 2.5 mg/kg/day.	UF_A = 10X ..... UF_H = 10X FQPA = 1X	cRfD = 0.025 mg/kg/day. cPAD = 0.025 mg/kg/day	Chronic Oral Toxicity Study in Dogs. LOAEL = 28.03/25.84 mg/kg/day M/F based on hepatocytomegaly, cataracts and decreased albumin in males and females; liver discoloration and decreased triglycerides in females; and increased alanine aminotransferase in males.
Short-term (1–30 days) Incidental Oral.	No residential uses are proposed.			
Intermediate Term (1–6 months) Incidental Oral.	No residential uses are proposed.			
Short-term (1–30 days) Dermal	NOAEL 5 mg/kg/day	UF_A = 10X ..... UF_H = 10X FQPA = 1X	LOC = ... MOE ≤ 100	Prenatal Toxicity study in Rats (Dermal). The maternal LOAEL (systemic) is 20 mg/kg/day based on decreased body weight gains.
Intermediate term (1–6 months) Dermal.	NOAEL 5 mg/kg/day	UF_A = 10X ..... UF_H = 10X FQPA = 1X	LOC = ... MOE ≤ 100	Prenatal Toxicity study in Rats (Dermal). The maternal LOAEL (systemic) is 20 mg/kg/day based on decreased body weight gains.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPIROXAMINE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Short term (1–30 days) Inhalation	NOAEL = 23.6 mg/kg/day.	UF_A = 10X ..... UF_H = 10X FQPA = 1X	LOC = ... MOE ≤ 100	28-day Inhalation Toxicity Study in Rats. LOAEL = 0.518 mg/L = 140.5 mg/kg/day based on decreased body weights and body weight gains, increased incidences of clinical signs of toxicity and dermal irritation, thymic atrophy and toxicity to the skin, respiratory system and liver.
Intermediate term (1–6 months) Inhalation.	NOAEL = 23.6 mg/kg/day.	UF_A = 10X ..... UF_H = 10X FQPA = 1X	LOC = ... MOE ≤ 100	28-day Inhalation Toxicity Study in Rats. LOAEL = 0.518 mg/L = 140.5 mg/kg/day based on decreased body weights and body weight gains, increased incidences of clinical signs of toxicity and dermal irritation, thymic atrophy and toxicity to the skin, respiratory system and liver.
Cancer (oral, dermal, inhalation)	Classification: Not likely to be carcinogenic to humans based on negative genotoxicity and carcinogenicity in long term cancer studies in rats and mice.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spiroxamine, EPA considered exposure under the petitioned-for tolerances as well as all existing spiroxamine tolerances in 40 CFR 180.602. EPA assessed dietary exposures from spiroxamine 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. Such effects were identified for spiroxamine. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance levels residues and 100 percent crop-treated (PCT) for the requested uses for spiroxamine.

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 and 100 PCT for the requested and currently registered uses of spiroxamine.

iii. *Cancer.* The Agency classified spiroxamine as "Not Likely to be Carcinogenic to Humans" based on the results of the carcinogenicity studies in rats and mice. Spiroxamine was determined to be non-mutagenic in bacteria, negative in an *in vivo* mammalian cytogenetics assay, and did not cause unscheduled DNA synthesis in mammalian cells *in vitro.* Accordingly, an exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for spiroxamine. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spiroxamine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spiroxamine. 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 SCI–GROW model, the estimated drinking water concentrations (EDWCs) of spiroxamine for acute exposures are estimated to be 19 parts per billion (ppb) for surface water and 0.035 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 15 ppb for surface water and 0.035 ppb for ground 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). Spiroxamine 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 spiroxamine to share a common mechanism of toxicity with any other substances, and spiroxamine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spiroxamine 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 Web site 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 concern for pre- or postnatal toxicity due to spiroxamine exposure. Delays in ossification, balanopreputial separation and vaginal patency were observed in the rat and may be secondary to decreased body weight. The latter two delays were resolved within the appropriate age range of puberty and no effects on reproductive function were observed in the multigeneration study in rats. Delayed balanopreputial separation was seen only in the presence of maternal toxicity and is not more severe than the maternal effects of decreased body weight and esophageal hyperkeratosis (due to irritation) seen at the common LOAEL of the multigeneration study. Delayed balanopreputial separation or vaginal patency does not cause concern for increased sensitivity to the young. There were no other treatment-related effects on fertility, viability or lactation indices or other reproductive parameters in either generation of the 2-generation reproductive toxicity study.

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. Except for an immunotoxicity study, the toxicity database for spiroxamine is complete. In accordance with the revised part 158 an immunotoxicity study is required. Although a test-article related structural effect on the immune system was observed in the 90-day rat inhalation study in the form of thymic atrophy accompanied by decreased platelets and consequent increased clotting time, decreased lymphocytes and increased neutrophils, these lesions were seen only when inhalation was the route of administration and at the highest dose tested of 3,000 mg/m^3 (equivalent to 141 mg/kg/day) which exceeds the limit dose of 1 mg/L (1,000 mg/m^3). These route-specific lesions are likely secondary to local (respiratory system) irritation, inflammation and injury and not attributable to frank immunotoxicity. The Agency does not believe that conducting the immunotoxicity study will result in a dose less than the POD used in this risk assessment: NOAEL = 2.5 mg/kg/day based on liver toxicity at approximately 25 mg/kg/day. Hepatotoxicity was accompanied by decreased body weight and food consumption which were also considered secondary to local (digestive system) irritation resulting in test-article related hyperkeratosis of the tongue, esophagus and stomach.

ii. There is no concern for neurotoxicity with spiroxamine. Signs of neurotoxicity were reported in the acute neurotoxicity study only. Minimal clinical signs of neurotoxicity was observed only in males at the lower dose level. However, no evidence of neurotoxicity were observed at the highest dose level in the subchronic neurotoxicity study. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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

iv. Although storage and stability sampling and analysis dates have been requested for hops, there are no residual uncertainties identified in the exposure database because there is no indication of residue degradation during frozen storage. The acute and chronic dietary exposure assessments were performed based on 100 PCT and tolerance-level residues. Conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spiroxamine in drinking water. Residential exposures are not expected. These assessments will not underestimate exposures and risks posed by spiroxamine.

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 population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer 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 appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to spiroxamine will occupy 36% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spiroxamine from food and water will utilize 40% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no proposed or existing residential uses for spiroxamine. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spiroxamine 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).

Spiroxamine is not registered for any use patterns that would result in residential exposure. Therefore, there is no potential for short-term risk to spiroxamine.

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).

Spiroxamine is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, there is no potential for intermediate-term risk to spiroxamine.

5. *Aggregate cancer risk for U.S. population.* For spiroxamine, there were no observed evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spiroxamine was determined to be non-mutagenic in bacteria, negative in an *in vivo* mammalian cytogenetics assay and did not cause unscheduled DNA synthesis in mammalian cells *in vitro.* Therefore, spiroxamine 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 spiroxamine residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography/mass spectrometry (GC/MS) Bayer AG Method No. 00407) 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

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 U.N. 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.

There are no currently established Codex, Canadian, or Mexican maximum residue limits for spiroxamine on artichoke, asparagus and fruiting vegetables (crop group 8).

C. Revisions to Petitioned-for Tolerances

EPA is revising the tolerance expression to spiroxamine to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerances cover residues of the spiroxamine, including its metabolites and degradates, but that compliance with the specified tolerance levels is to be determined by measuring only the sum of spiroxamine and its metabolites containing the N-ethyl-N-propyl-1,2-dihyroxy-3-amino propane moiety, calculated as the stoichiometric equivalent of spiroxamine, in or on the commodity. In addition, although it was not noted in the company petition, a request for import tolerances (only) was petitioned of the Agency for the uses in this final rule.

V. Conclusion

Therefore, tolerances are established for residues of spiroxamine, including its metabolites and degradates in or on artichoke, globe, import at 0.7 ppm; asparagus, import at 0.05 ppm and vegetables, fruiting (crop group 8), import at 1.2 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) (Pub. L. 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: November 17, 2010.

G. Jeffrey Herndon,

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 180.602 is amended by revising paragraph (a) introductory text and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.602 Spiroxamine; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide spiroxamine, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the following table is to be determined by measuring only spiroxamine, [(8-(1,1-dimethylethyl)-N-ethyl-N-propyl-1,4-dioxaspiro[4,5]decane-2-methanamine) in or on the commodities.

Commodity	Parts per million
Artichoke, globe, import [1]	0.7
Asparagus [1]	0.05
* * * * *	
Vegetable, fruiting , crop group 8 [1]	1.2

[1] No U.S. registration as of December 1, 2010.

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[FR Doc. 2010–30114 Filed 11–30–10; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 100507218–0325–02]

RIN 0648–AY91

International Fisheries; South Pacific Tuna Fisheries; Procedures To Request Licenses and a System To Allocate Licenses

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: Pursuant to its authority under the South Pacific Tuna Act of 1988 (SPTA), NMFS issues regulations to modify the procedures that U.S. purse seine vessels use to request fishing licenses to fish in areas managed under the SPTA. This rule also establishes a system for allocating licenses in the event more applications are received than there are licenses available. Such an allocation system is needed because the number of applications is approaching the number of available licenses, and may exceed that number. The license allocation system includes objective criteria to be used by NMFS in prioritizing among license applicants. The license application procedures are modified in accordance with the allocation system, and are designed to provide license holders and prospective license applicants with a clear and certain regulatory process. The regulations for vessels licensed under the SPTA are also modified to require that the vessel monitoring system units (VMS units), also known as mobile transmitting units, installed and carried on the vessels are a type that is NMFS-approved.

DATES: This final rule is effective January 3, 2011.

ADDRESSES: Copies of supporting documents that were prepared for this final rule, including the regulatory impact review (RIR), as well as the proposed rule, are available via the Federal e-Rulemaking portal, at *http://www.regulations.gov.* Those documents are also available from the Regional Administrator, NMFS, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814–4700.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to NMFS, Pacific Islands Regional Office (see contact information above), and by e-mail to *OIRA_Submission@omb.eop.gov* or fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Tom Graham, NMFS, Pacific Islands Regional Office, 808–944–2219.

SUPPLEMENTARY INFORMATION:

Electronic Access

This final rule is also accessible at *http://www.gpoaccess.gov/fr.*

Background

On June 28, 2010, NMFS published a proposed rule in the **Federal Register** (75 FR 36619) that would modify the regulations at 50 CFR part 300, subpart D. Those regulations are issued under the authority of the South Pacific Tuna Act of 1988 (SPTA) (16 U.S.C. 973–973r), which was enacted to implement the Treaty on Fisheries between the Governments of Certain Pacific Island States and the Government of the United States of America and its annexes, schedules, and implementing agreements, as amended ("the Treaty"). The SPTA authorizes the Secretary of Commerce (Secretary), with the concurrence of the Secretary of State and after consultation with the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to issue regulations as may be necessary to carry out the purposes and objectives of the Treaty and the SPTA. The authority to issue regulations has been delegated to NMFS.

The Treaty governs the conduct of U.S. fishing vessel operations in the Treaty Area, as defined at 50 CFR 300.31, and which encompasses approximately 10 million square miles (26 million square kilometers) of the western and central Pacific Ocean (WCPO). The Treaty allows U.S. purse seine vessels access to a large portion of the WCPO by authorizing, and regulating through a licensing system, U.S. purse seine vessels operations within all or part of the exclusive economic zones (EEZs) of the 16 Pacific Island Parties (PIPs) to the Treaty. Licenses to operate in the Licensing Area under the Treaty are issued by the Pacific Islands Forum Fisheries Agency (FFA), based in Honiara, Solomon Islands, which acts as the Treaty Administrator on behalf of the PIPs. Licenses are issued on an annual basis, with the licensing period starting June 15th of each year. U.S. purse seine vessels licensed under the Treaty are used to target skipjack tuna and yellowfin tuna.

Currently, the Treaty allows for a maximum of 45 licenses to U.S. purse seine fishing vessels to fish in the Licensing Area of the Treaty. Of the 45 licenses, 5 are reserved for U.S. vessels engaged in "joint venture" arrangements designed to maximize the benefits generated for the PIPs. The Licensing Area comprises the entire Treaty Area, with the exception of areas subject to the jurisdiction of the United States and areas closed to fishing under the Treaty. It thus includes all or part of the EEZs of the following countries: Australia, Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, and Vanuatu.