Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 14, 2005.

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 180.460 paragraph (a) is revised to read as follows:

§ 180.460 Benoxacor; tolerances for residues.

(a) *General.* Tolerances are established for residues of the inert ingredient (safener) benoxacor (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1, 4-benzoxazine) at 0.01 parts per million (ppm) when used in pesticide formulations containing metolachlor or S-metolachlor in or on raw agricultural commodities for which tolerances have been established for metolachlor or S-metolachlor.

* * * * *

[FR Doc. 05–8119 Filed 4–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0046; FRL–7705–1]

Spiromesifen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for: Primary crops 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; rotational crops for the inadvertent or indirect combined 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), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents; and livestock commodities 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 metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties, calculated as the parent compound equivalents. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 27, 2005. Objections and requests for hearings must be received on or before June 27, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0046. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Thomas Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at*http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 28, 2004 (69 FR 45047) (FRL–7366–2), 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 3F6537) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing a tolerance for the combined residues of the insecticide/miticide:

1. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester [subsequently referred to as (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 strawberry at 2.0 parts per million (ppm); vegetable, tuberous and corm, crop subgroup 1C, at 0.01 ppm (subsequently revised to 0.02 ppm); vegetable, leafy greens (except Brassica), crop subgroup 4A at 10 ppm (subsequently revised to vegetable, leafy greens, subgroup 4A at 12 ppm); vegetable, Brassica, head and stem, crop subgroup 5A, at 2.0 ppm; vegetable, Brassica, leafy, crop subgroup 5B at 12 ppm; vegetable, fruiting, crop group 8, at 0.30 ppm; tomato, paste at 0.60 ppm; vegetable, cucurbit, crop group 9, at 0.10 ppm; corn, field, grain, at 0.01 ppm (subsequently revised to 0.02 ppm); corn, field, forage, at 3.0 ppm; corn, field, stover, at 5.0 ppm; cotton (subsequently defined as cotton, undelinted seed) at 0.50 ppm; and cotton, gin byproducts, at 15 ppm.

2. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester [subsequently referred to as (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one)] in or on the rotational crop commodities alfalfa, forage, at 1.5 ppm; alfalfa, hay, at 3.0 ppm; wheat, grain, at 0.01 ppm (subsequently revised to 0.03 ppm); wheat, forage, at 0.20 ppm; wheat, hay, at 0.15 ppm; wheat, straw, at 0.25 ppm; wheat, bran, at 0.05 ppm (subsequently combined with wheat, shorts and defined together as ''wheat milled byproducts'' with no tolerance required); wheat, shorts, at 0.03 ppm (subsequently combined with wheat, bran and defined together as ''wheat milled byproducts'' with no tolerance required); barley, grain, at 0.02 ppm (subsequently revised to 0.03 ppm); barley, hay, at 0.25 ppm; barley, straw, at 0.25 ppm (subsequently revised to 0.15 ppm); beet, sugar, tops, at 0.20 ppm; beet, sugar, roots, at 0.02 ppm (subsequently revised to 0.03 ppm); and beet, sugar, molasses, at 0.05 ppm (tolerance subsequently not required).

3. Spiromesifen; butanoic acid, 3,3-dimethyl-, 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl ester [subsequently referred to as 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate), and its metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties)] in or on the raw agricultural commodities cattle, fat, at 0.05 ppm; cattle, meat byproducts, at 0.05 ppm; milk at 0.01 ppm (tolerance subsequently not required); and milk, fat, at 0.03 ppm (subsequently revised to 0.10 ppm).

Following the review of all data, tolerances are also required for the following commodities: Goat, fat at 0.05 ppm; goat meat byproducts at 0.05 ppm; sheep, fat at 0.05 ppm; sheep, meat byproducts at 0.05 ppm; horse, fat at 0.05 ppm; and horse, meat byproducts at 0.05 ppm.

That notice included a summary of the petition prepared by Bayer CropScience, the registrant. A comment was received from a private citizen who challenged the value of using animal testing for evaluating pesticide toxicity and questioned the data gaps related to the tolerance proposal process. This commenter's objections have been addressed in prior rulemaking documents. See (69 FR 63083, 63096) (October 29, 2004).

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for the combined residues of spiromesifen on the crops and animal commodities listed above.

EPA's assessment of exposures and risks associated with establishing the 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. The nature of the toxic effects caused by spiromesifen are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3050	28–Day oral toxicity (mouse)	NOAEL was not established LOAEL (M/F) = 202.6/269.6 mg/kg/day based on decreased body weight gain
870.3050	28–Day oral toxicity (mouse)	NOAEL was not established LOAEL (M/F) = 444.3 mg/kg/day based on decreased body weight gain and increase in alkaline phosphatase
870.3100	28–Day oral toxicity (rat)	NOAEL = 53.4 mg/kg/day LOAEL = 536.3 mg/kg/day based on clinical signs (piloerection, reduced motility, spastic gait, discolored feces and increased reactivity when touched), decrease in body weight gain, and food consumption, hematology (thromboplastin time increase), clinical chemistry (increased aspartateaminotransferase and alanine aminotransferase), liver enzyme (increased aldrin expoxidase and epoxide hydrolase), increased spleen and lymph node cell proliferation, organ-weights (increase brain, heartand kidneys, decrease in weights in the ovaries, spleen and thymus), gross pathology (thin appearance, discolored adrenal glands and white mucous in the duodenum and jejunum), and microscopic findings (vacuolation of the superficial mucosal cells in the jejunum and duodenum, increased follicular cell hypertrophy in the thyroid, indistinct corticomedullary junction in the thymus and cytoplasmic changes in the adrenal glands)
870.3150	90–Day oral toxicity (nonrodent)	NOAEL = 9.2 mg/kg/day LOAEL = 71 mg/kg/day (HDT) based on clinical chemistry(increased ALP) and liver histopathology
870.3150	90–Day oral toxicity (nonrodent)	NOAEL was not established LOAEL = 98.4 mg/kg/day (HDT) based on increase in alkalinephosphatase and liver histopathology (cytoplasmic changes)
870.3150	90–Day oral toxicity (rat)	NOAEL (M/F) = 31.7/7.7 mg/kg/day. LOAEL (F) = 36.6 mg/kg/day based on thyroid effects (increased thyroid stimulating hormone, thyroxine binding capacity and thyroid follicular cell hypertrophy), kidney effects (mineralization), and liver effect (increased ALP) LOAEL (M) = 204.0 mg/kg/day based on thyroid effect (colloidal alteration, follicular cell hypertrophy, decreased T_3 and T_4 and increased TBC and TSH), kidney effects (Hyalin droplets), and liver effects (increase in ALP and ALAT)
870.3200	21/28–Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day (HDT) LOAEL was not established
870.3465	5–Day inhalation toxicity (rat)	NOAEL = 20.7 mg/kg/day LOAEL = 134.2 mg/kg/day based onthe clinical signs (tremors, clonic-tonic convulsions, reduced activity,bradypnea, labored breathing,vocalization, avoidance reaction,giddiness, piloerection, limp,emaciation, cyanosis, squattedposture, apathy, and salivation), andgross pathology (dark red areas orfoci in the lungs, bloated stomachsand pale liver)
870.3465	30–Day inhalation toxicity (rat)	NOAEL >21.1 mg/kg/day LOAEL was not established
870.3700	Prenatal developmental (rat)	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 70 mg/kg/daybased on decreased body weight gainand reduced food consumption. Developmental NOAEL ≥ 500mg/kg/day (HDT) Developmental LOAEL > 500 mg/kg day
870.3700	Prenatal developmental (nonrodent)	Maternal NOAEL = 5 mg/kg/day Maternal LOAEL = 35 mg/kg/day based on body weight loss and reduced food consumption Developmental NOAEL ≥ 250 mg/kg/day Developmental LOAEL > 250 mg/kg/day

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3800	Reproduction and fertility effects (rat)	Parental/Systemic NOAEL (M/F) = 2.2/3.8 mg/kg/day Parental/Systemic LOAEL (M/F) = 8.8/13.2 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 Reproductive NOAEL (M/F) = 37/64 mg/kg/day (HDT) Reproductive LOAEL = Not established Offspring NOAEL = 2.2 mg/kg/day Offspring LOAEL = 8.8 mg/kg/day based on pup body weight decrements during lactation
870.4100	Chronic toxicity (rat)	NOAEL (M/F) = 15.9/19.3 mg/kg/day LOAEL (M/F) = 42.4/51.7 mg/kg/day based on increase in T3 hormone in males, gross pathology (enlarged liver in males, dilated uterus and discolored adrenal gland in females) and histopathology (adrenal cytoplasmic eosinophilia, metritise, thyroid colloidal alteration in female and thyroid follicular cell hypertrophy in both males and females)
870.4100	Chronic toxicity (non-rodent)	NOAEL (M/F) = 11.5/10.8 mg/kg/day LOAEL (M/F) = 109/117 mg/kg/day based on increase in alkaline phosphatase and liver histopathology (cytoplasmic changes, inclusions and vacuoles)
870.4200	Carcinogenicity (rat)	NOAEL (M/F) = 14.8/19.5 mg/kg/day LOAEL (M/F) = 40.0/53.5 mg/kg/day based on clinical signs (palpable masses, vaginal bleeding and pallor), gross necropsy (discolored area in the lungs, nodules/dilation of uterus) and hispathology (osseus metaplasia and granulomatous inflammation of the lungs in the males, liver necrosis; endometritis/metritis, endometrial hyperplasia of the cervix uteria and colloidal alteration of the thyroid gland in females) and increased TSH in females. No evidence of carcinogenicity
870.4200	Carcinogenicity (mouse)	NOAEL (M/F) = 3.3/3.8 mg/kg/day LOAEL (M/F) = 22/30 mg/kg/day based on gross (enlarged adrenal gland in males) and microscopic changes (cytoplamic eosinophilia, ceroid deposits, and diffuse fatty changes of the adrenal cortex and pancreatic amyloidosis in both sexes) No evidence of carcinogenicity
870.5100	Gene mutation--*In Vitro* bacteria	Negative
870.5300	Cytogenetics *In Vitro* Mammalian Gene Mutation	Negative
870.5375	Cytogenetics--*In Vitro* Mammalian	Negative
870.5395	Cytogenetics *In Vivo* Mammalian Micronucleus (mouse)	Negative
870.6200	Acute neurotoxicity screening battery	NOAEL = 2,000 mg/kg/day LOAEL = Not established
870.6200	Subchronic neurotoxicity screening battery	NOAEL (M/F) = 31.8/38.3 mg/kg/day. LOAEL (M/F) = 122.7/149.3 mg/kg/day based on decreased body weight gain and food consumption.
870.7485	Metabolism and pharmacokinetics (rat)	Spiromesifen exhibits moderate absorption (approximately 43%), relatively rapid excretion primarily via the urine and feces. Approximately 39% of the administered dose was excreted in the urine and 55 to 57% in the feces with 88 to 90% of the dose being eliminated within the first 24 hours. Maximum concentration in the blood achieved within 1 to 6 hours post- dose depending upon the dose. Concentrations of residual radioactivity in the tissues were quite low at 72 hours post-dose. The test material was initially metabolized to the keto-enol by loss of the dimethylbutyric acid moiety. Both the phenyl and cyclopentyl rings were hydoxylated and the methyl groups on the phenyl ring were ultimately oxidized to a carboxylic acid. These metabolites were largely recovered in the bile and urine. The predominate moiety recovered in the feces was the unmetabolized test material.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7600	Dermal penetration (non-rodent)	Intravenous injection resulted in excretion of the radiolabel mainly via urine: Urine (54.32%), feces (13.08%), and cage debris/rinse (26.57%). Excretion was rapid in that 70% of the dose was excreted within 24 hours. Dermal application of spiromesifen resulted in limited absorption after 8–hour exposure (3.3%), which a large portion was recovered from urine and cage debris/rinse showing that it is poorly absorbed through the skin layers.
870.7800	4–Week immunotoxicity (rat)	NOAEL (M/F) = 52.8/45.7 mg/kg/day LOAEL (M/F) = 291.6/288.6 mg/kg/day based on mortality, clinical signs and decreased body weights, body weight gains and food consumption.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for spiromesifen used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPIROMESIFEN FOR USE IN HUMAN RISK ASSESSMENT

1Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effect
Acute dietary (females 13-49 years of age)	Not applicable	None	An endpoint of concern attributable to a single dose was not identified. An aRfD was not established.
Acute dietary (general population)			

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SPIROMESIFEN FOR USE IN HUMAN RISK ASSESSMENT—Continued

1Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effect
Chronic dietary (all populations)	NOAEL= 2.2 mg/kg/day UF = 100X Chronic RfD = 0.022 mg/kg/day	Special FQPA SF = 1X	2–generation reproduction study in rats. The parental systemic LOAEL: 13.2 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.
Cancer (oral, dermal, inhalation)	Classification: ''Not likely to be carcinogenic to humans.''		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. No tolerances have previously been established for spiromesifen. Risk assessments were conducted by EPA to assess dietary exposures from spiromesifen in food as follows:

i. *Acute exposure*. Acute dietary 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. Acute dietary exposure limits for all populations, including infants and children, were not performed because an endpoint of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) and the Lifeline™ model version 2.0, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. Percent crop treated and anticipated residues were not used.

An unrefined, Tier 1 chronic dietary exposure assessment was conducted using the following:

a. Recommended tolerances for all plant and livestock except the leafy-green and leafy-Brassica vegetable subgroups;

b. EPA calculated residues of concern (parent and metabolites) for the leafy-green and leafy-Brassica vegetable subgroups;

c. 100% crop treated (CT) information for all proposed uses; and

d. Default processing factors for all commodities.

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

1.3 = Metabolites in Risk Assessment (ppm)/Metabolites in Tolerance Expression (ppm).

The dietary-exposure assessment was conducted for the general U.S. population and various population subgroups. This assessment concludes that the chronic dietary exposure estimates are below EPA's level of concern (<100% cPAD) for the general U.S. population (27% cPAD and 29% cPAD, based on the Lifeline™ and DEEM-FCID™ analyses, respectively) and all population subgroups. Both Lifeline™ and DEEM-FCID™ estimate that children 3 to 5 years old are the most highly-exposed subpopulation with risks of 30% cPAD and 37% cPAD, respectively.

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

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for spiromesifen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of spiromesifen.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of

comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to spiromesifen they are further discussed in the aggregate risk sections in Unit E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of spiromesifen for acute exposures are estimated to be 7.1 parts per billion (ppb) for surface water and 0.005 ppb for ground water. The EECs for chronic exposures are estimated to be 0.70 ppb for surface water and 0.005 ppb for ground water.

EECs of spiromesifen and its metabolites for acute exposures are estimated to be 26 ppb for surface water and 28 ppb for ground water. The EECs for chronic exposures are estimated to be 11 ppb for surface water and 28 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).

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

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spiromesifen and any other substances and spiromesifen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that spiromesifen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to spiromesifen. In a rat developmental toxicity study, no developmental toxicity was observed at doses up to 500 mg/kg/day (the highest dose tested) in the presence of maternal toxicity. The rat maternal LOAEL was determined to be 70 mg/kg/day based on decreased body-weight gain and reduced food consumption. In the rabbit developmental toxicity study, there was no developmental toxicity observed at doses up to 250 mg/kg/day (the highest dose tested), but the maternal LOAEL was determined to be 35 mg/kg/day based on body weight loss and reduced food consumption. There is no qualitative and/or quantitative evidence of increased susceptibility to spiromesifen following pre/postnatal exposure in a 2–generation reproduction study in rats.

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

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

- There is a complete toxicity data base for spiromesifen.
- 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 maternal toxicity.
- There are no neurotoxicity concerns based on acute and subchronic neurotoxicity studies.
- The dietary food exposure assessment uses proposed tolerance levels or higher residues and assumed 100% crop-treated (CT) information for all commodities. By using these screening-level assessments, chronic exposures and risks will not be underestimated. The ''higher residues'' are those that were calculated using a modifying factor to account for the lack of spiromesifen-4-hydroxymethyl residue data.
- The dietary drinking water assessment (Tier 2 estimates) uses values generated by model and associated modeling parameters which are designed to provide conservative, health protective, and high-end estimates of water concentrations.
- Residential exposure is not expected--spiromesifen will be registered for agricultural and greenhouse/ornamental uses only.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average

food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Spiromesifen is not expected to pose an acute risk because an endpoint of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure and the EECs from DEEM-FCID™ as these were slightly higher, and thus are more conservative, than the Lifeline™ estimates, EPA has concluded that exposure to spiromesifen from food will utilize 29% of the cPAD for the U.S. population, 15% of the cPAD for all infants less than 1 year old, and 37% of the cPAD for children 3-5 years old. There are no residential uses for spiromesifen that result in chronic residential exposure to spiromesifen. There is no concern regarding spiromesifen in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPIROMESIFEN + METABOLITES

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)[1]	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.022	29	11	28	545
All Infants (<1 year old)	0.022	15	11	28	187
Children (1-2 years old)	0.022	35	11	28	142
Children (3-5 years old)	0.002	37	11	28	138
Children (6-12 years old)	0.022	30	11	28	155
Youth (13-19 years old)	0.022	25	11	28	492
Adults (20-49 years old)	0.022	29	11	28	544
Adults (50 + years old)	0.022	29	11	28	470
Females (13-49 years old)	0.022	30	11	28	539

[1]Based on exposure estimates from DEEM-FCID

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

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

5. *Aggregate cancer risk for U.S. population*. Spiromesifen is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

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

V. Conclusion

Therefore, the tolerance is established for:

1. Primary crops 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 strawberries at 2.0 parts per million (ppm); vegetable, tuberous and corm, subgroup 1C at 0.02 ppm; vegetable, leafy greens, subgroup 4A at 12 ppm; vegetable, Brassica, head and stem, subgroup 5A at 2.0 ppm; vegetable, Brassica, leafy greens, subgroup 5B at 12 ppm; vegetable, fruiting, group 8 at 0.30 ppm; tomato, paste at 0.60 ppm; vegetable, cucurbit, group 9 at 0.10 ppm; corn, field, grain at 0.02 ppm; corn, field, forage at 3.0 ppm; corn, field, stover at 5.0 ppm; cotton,

undelinted seed at 0.50 ppm; and cotton, gin byproducts at 15 ppm.

2. Rotational crops for the inadvertent or indirect combined 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), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in or on alfalfa, forage at 1.5 ppm; alfalfa, hay at 3.0 ppm; wheat, grain at 0.03 ppm; wheat, forage at 0.20 ppm; wheat, hay at 0.15 ppm; wheat, straw at 0.25 ppm; barley, grain at 0.03 ppm; barley, hay at 0.25 ppm; barley, straw at 0.15 ppm; beet, sugar, tops at 0.20 ppm; and beet, sugar, roots at 0.03 ppm.

3. Livestock commodities 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 metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties, calculated as the parent compound equivalents in or on cattle, fat at 0.05 ppm; cattle, meat byproducts at 0.05 ppm; milk, fat at 0.10 ppm; goat, fat at 0.05 ppm; goat, meat byproducts at 0.05 ppm; sheep, fat at 0.05 ppm; sheep, meat byproducts at 0.05 ppm; horse, fat at 0.05 ppm; and horse, meat byproducts at 0.05 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0046 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 27, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0046, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require

Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 14, 2005.

James Jones,

Director, 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 added to read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

(a) *General.* (1) Tolerances are established 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 the following primary crop commodities:

Commodity	Parts per million
Corn, field, forage	0.02
Corn, field, grain	3.0
Corn, field, stover	5.0
Cotton, gin byproducts	15
Cotton, undelinted seed	0.50
Strawberry	2.0
Tomato, paste	0.60
Vegetable, brassica, head and stem, subgroup 5A	2.0
Vegetable, brassica, leafy greens, subgroup 5B	12
Vegetable, cucurbit, group 9	0.10
Vegetable, fruiting, group 8	0.30
Vegetable, leafy greens, subgroup 4A	12
Vegetable, tuberous and corm, subgroup 1C	0.02

(2) Tolerances are established for the inadvertent or indirect combined 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), and its metabolites containing the 4-hydroxymethyl moiety (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one), calculated as the parent compound equivalents in the following rotational crop commodities:

Commodity	Parts per million
Alfalfa, forage	1.5
Alfalfa, hay	3.0
Barley, grain	0.03
Barley, hay	0.25
Barley, straw	0.15
Beet, sugar, roots	0.20
Beet, sugar, tops	0.03
Wheat, forage	0.03
Wheat, grain	0.20
Wheat, hay	0.15
Wheat, straw	0.25

(3) Tolerances are established 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 metabolites containing the enol (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and 4-hydroxymethyl (4-hydroxy-3-[4-(hydroxymethyl)-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one) moieties, calculated as the parent compound equivalents in the following livestock commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, meat byproducts	0.05
Goat, fat	0.05
Goat, meat byproducts	0.05
Horse, fat	0.05
Horse, meat byproducts	0.05
Milk, fat	0.10
Sheep, fat	0.05

Commodity	Parts per million
Sheep, meat byproducts	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 05–8120 Filed 4–26–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0142; FRL–7710–9]

Trifluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of trifluralin in spearmint and peppermint oil under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The FQPA substantially rewrote section 408 of FFDCA. As a result, the revisions made it necessary, once again, to establish tolerances for mint oils that had previously been deemed unnecessary.

DATES: This regulation is effective April 27, 2005. Objections and requests for hearings must be received on or before June 27, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0142. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–8195; e-mail address: *pates.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

II. Background

In the **Federal Register** of November 24, 2004 (69 FR 68287) (FRL–7686–4), EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), announced a proposal to establish a permanent tolerance for residues of the herbicide trifluralin in spearmint and peppermint oil at 2.0 parts per million (ppm). The proposal included a summary of the exposure assessment prepared by the Agency. The Agency received three submissions for comment; two from private citizens and one from Dow AgroSciences, the registrant.

III. Response to Comments

Comments received from the registrant address the following areas: evidence of errors and inconsistencies/miscalculations, belief that potential risks are significantly overstated, belief that unrealistic assumptions have been made, and the position that relevant information has been omitted and not incorporated into the Agency's decision(s). Additionally, the registrant has asked for clarification on labeling requirements. However, in general, the registrant does agree with the assessments that have been conducted for the human health and residue chemistry risk studies available for trifluralin. Furthermore, the registrant does not state any objections to the establishment of a permanent tolerance for residues of the herbicide trifluralin in peppermint and spearmint oil at 2.0 ppm.

One of the private citizen's comments raised objections to any establishment of a tolerance for trifluralin. The citizen's comments and EPA's response to those comments follow:

1. *Comment.* Both 28–day dermal and developmental toxicity tests on rabbits as well as a 1–year oral capsule study on dogs have no validity and are abusive to the test animals.

EPA response. This commenter's objections to animal testing have been addressed in prior rulemaking documents. See 69 FR 63083, 63096 (October 29, 2004).

2. *Comment.* 1994 surveys of food intake are out of date.

EPA response. Consumption survey data is used in part to determine acute and chronic exposure. In assessing exposure to trifluralin, EPA relied on food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). These surveys are generally updated every 10 years or so.