

environmental effects of their programs, policies and activities on minority populations and low-income populations in the United States.

EPA has determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. We believe there will be no negative environmental or economic impacts resulting from today's action compared to the February 26, 2007 rule this action modifies.

*K. 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 the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This final rule will be effective on May 12, 2008.

**Statutory Provisions and Legal Authority**

The statutory authority for the fuels controls in today's final rule can be found in sections 202 and 211(c) of the Clean Air Act (CAA), as amended. Support for any procedural and enforcement-related aspects of the fuel controls in today's rule, including recordkeeping requirements, comes from sections 114(a) and 301(a) of the CAA.

**List of Subjects in 40 CFR Part 80**

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Fuel additives, Gasoline, Imports, Labeling, Motor vehicle fuel, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

Dated: March 6, 2008  
**Stephen L. Johnson,**  
*Administrator.*

■ For the reasons set forth in the preamble, 40 CFR part 80 is amended as set forth below:

**PART 80—REGULATION OF FUELS AND FUEL ADDITIVES**

■ 1. The authority citation for part 80 continues to read as follows:

**Authority:** 42 U.S.C. 7414, 7542, 7545 and 7601(a).

■ 2. Section 80.1275 is amended as follows:

- a. By adding paragraph (d)(1)(v).
- b. By redesignating paragraph (d)(2) as paragraph (d)(3).
- c. By adding paragraph (d)(2).

**§ 80.1275 How are early benzene credits generated?**

\* \* \* \* \*

(d) \* \* \*  
 (1) \* \* \*

(v) Providing for benzene alkylation.  
 (2)(i) A refiner may petition EPA to approve, for purposes of paragraph (d)(1) of this section, the use of operational changes and/or improvements in benzene control technology that are not listed in paragraph (d)(1) of this section to reduce gasoline benzene levels at a refinery.

(ii) The petition specified in paragraph (d)(2)(i) of this section must be sent to: U.S. EPA, NVFEL-ASD, Attn: MSAT2 Early Credit Benzene Reduction Technology, 2000 Traverwood Dr., Ann Arbor, MI 48105.

(iii) The petition specified in paragraph (d)(2)(i) of this section must show how the benzene control technology improvement or operational change results in a net reduction in the refinery's average gasoline benzene level, exclusive of benzene reductions due simply to blending practices.

(iv) The petition specified in paragraph (d)(2)(i) of this section must be submitted to EPA prior to the start of the first averaging period in which the refinery plans to generate early credits.

(v) The refiner must provide additional information as requested by EPA.

(3) Has not included gasoline blendstock streams transferred to, from, or between refineries, except as noted in paragraph (d)(1)(iv) of this section.

\* \* \* \* \*

[FR Doc. E8-4917 Filed 3-11-08; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0331; FRL-8351-7]

**Spiromesifen; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of spiromesifen and its enol metabolite in or on bean, dry; bean, succulent; bean, edible podded; and cowpea, forage. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 12, 2008. Objections and requests for hearings must be received on or before May 12, 2008, 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-2007-0331. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

#### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2007-0331 in the subject line on the first page of your submission. All requests must be in writing, and must be

mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before May 12, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0331 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’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

#### **II. Petition for Tolerance**

In the **Federal Register** of May 9, 2007 (72 FR 26375) (FRL-8128-1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7195) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.607 be amended by establishing tolerances for combined residues of the insecticide spiromesifen, (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), in or on bean, edible, podded at 1.4 ppm; bean, succulent at 0.10 ppm; bean, dry at 0.02 ppm; cowpea, forage at 35 ppm; cattle, fat at 0.20 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.30 ppm; goat, fat at 0.20 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.30 ppm; hog, fat at 0.20 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.30 ppm; horse, fat at 0.20 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.30 ppm; sheep, fat at 0.20 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at

0.30 ppm; and milk at 0.01 ppm. This notice referenced a summary of the petition prepared by Bayer Crop Science, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised tolerance expressions for bean, edible, podded; cowpea, forage; milk, whole; milk, fat; in meat of cattle, goats, horses, and sheep; in meat, byproducts, of cattle, goats, horses, and sheep; and in fat of cattle, goats, horses, and sheep. A tolerance for cowpea, hay was also included. The reason for these changes is explained in Unit IV.C.

#### **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....” These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for combined residues of spiromesifen on bean, dry at 0.02 ppm; bean, succulent at 0.10 ppm; bean, edible podded at 0.80 ppm; cowpea, forage at 30 ppm; cowpea, hay at 86 ppm; cattle, fat at 0.10 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.15 ppm; goat, fat at 0.10 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.15 ppm; horse, fat at 0.10 ppm; horse, meat at 0.02 ppm; horse, meat

byproducts at 0.15 ppm; sheep, fat at 0.10 ppm; sheep, meat at 0.02 ppm; sheep, meat byproducts at 0.15 ppm; milk at 0.01 ppm; and milk, fat at 0.20 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

#### A. Toxicological Profile

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

Spiromesifen shows low acute toxicity via the oral, dermal and inhalation routes of exposure. It was neither an eye nor dermal irritant, but showed moderate potential as a contact sensitizer in a Magnusson and Kligman maximization assay. Acute dietary-exposure limits for all populations, including infants and children, were not necessary because an endpoint of concern attributable to a single exposure (dose) was not identified from the oral toxicity studies. In addition, there are no developmental concerns based on rat and/or rabbit developmental toxicity studies. The rat two-generation reproduction study was selected for chronic dietary, as well as long-term dermal- and inhalation-exposure risk assessments.

In the 2-generation reproduction study in rat the following effects were noted at the lowest observed adverse effect level (LOAEL): Significantly decreased spleen weight (absolute and relative in parental females and F1 males) and significantly decreased growing ovarian follicles in females. Spiromesifen shows no significant developmental or reproductive effects, is not likely to be carcinogenic based on bioassays in rat and mouse, and lacks in vivo and in vitro mutagenic effects. Spiromesifen is not a neurotoxic chemical based on results of acute and subchronic neurotoxicity studies.

Specific information on the studies received and the nature of the adverse effects caused by spiromesifen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the document entitled "Spiromesifen: Human Health Risk Assessment for a Section 3 Registration on Beans;" pages 44-52 at [www.regulations.gov](http://www.regulations.gov). The referenced document is available in docket EPA-HQ-OPP-2007-0331.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for spiromesifen used for human risk assessment can be found at <http://www.regulations.gov> in the document entitled "Spiromesifen: Human Health Risk Assessment for a Section 3 Registration on Beans;" pages 18-19; docket ID number EPA-HQ-OPP-2007-0331.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spiromesifen, EPA considered exposure under the petitioned-for tolerances as well as all existing spiromesifen tolerances in (40 CFR 180.607). EPA assessed dietary exposures from spiromesifen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for spiromesifen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996, and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues for all commodities with existing and proposed tolerances except for the leafy-green and leafy-*Brassica* vegetable subgroups (4A and 5B). An additional metabolite, BSN 2060-4-hydroxymethyl, was observed in the metabolism studies of lettuce only. Since this metabolite's toxicity is expected to be comparable to the parent compound, it was included in the risk assessment for leafy crops (subgroups 4A and 5B), but not in the tolerance expression. To account for this additional toxicity exposure, the recommended tolerance level was multiplied by a correction factor of 1.3x. For all commodities, 100%CT as well as DEEM™ Version 7.81 default processing factors were used.

iii. *Cancer.* Spiromesifen has been classified as "not likely to be carcinogenic to humans." Therefore, a cancer dietary risk assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for spiromesifen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of spiromesifen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Parent spiromesifen is not likely to persist in the environment as it readily undergoes both biotic and abiotic degradation; however, its primary degradate BSN2060 is expected to persist. While parent spiromesifen strongly sorbs to sediment and is not likely to be mobile, its enol degradate does not sorb to sediment and is expected to leach into groundwater. Spiromesifen has limited solubility in water and in some cases has been

reported to have a practical solubility limit of 40 to 50 µg/L. The pesticide degrades primarily through aerobic soil metabolism and hydrolysis; however, in clear shallow water it will readily undergo photolysis. Field studies indicate that spiromesifen readily dissipates with dissipation half lives ranging from 2 to 10 days. The compound is not likely to bioconcentrate appreciably given its relatively rapid degradation and depuration.

Spiromesifen and BSN 2060-enol are the predominant residues in drinking water. BSN 2060-enol may account for 75% of the total acute exposure and for over 90% for chronic exposure. Estimated drinking water concentrations (EDWCs) were generated for the total toxic residue which includes spiromesifen, the -enol and -carboxy metabolites, and unextracted material. The highest estimated surface water concentrations occurred with the NC sweet potato scenario.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentration (EEC) of spiromesifen for chronic exposure is estimated to be 11 parts per billion (ppb) for surface water. The EEC for chronic exposure is estimated to be 28 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 28 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Spiromesifen is 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 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 EPA's Web site 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 ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. 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 FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

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

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for spiromesifen is complete.

ii. There is no indication that spiromesifen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spiromesifen results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or

in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100%CT and tolerance-level residues or higher. Conservative ground and surface water modeling estimates were used. Residential exposure is not expected as spiromesifen will be registered for agricultural and greenhouse/ornamental uses only. These assessments will not underestimate the exposure and risks posed by spiromesifen.

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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* No such effects were identified in the toxicological studies for spiromesifen; therefore, acute exposure is not expected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spiromesifen from food and water will utilize 42% of the cPAD for the population group children 3-5 years old (the greatest exposure). There are no residential uses for spiromesifen that result in chronic residential exposure to spiromesifen.

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

Spiromesifen is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Aggregate cancer risk for U.S. population.* Spiromesifen has been classified as "not likely to be carcinogenic to humans." Spiromesifen is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spiromesifen residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology, high performance liquid chromatography/mass spectroscopy (HPLC/MS/MS)/ Method 00631/M001, is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: *residuemethods@epa.gov*.

*B. International Residue Limits*

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

*C. Explanation of Tolerance Revisions*

1. *Bean, edible podded and cowpea, forage.* The tolerances were revised based on analysis with the Agency's tolerance spreadsheet in accordance with the Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP.

2. *Cowpea, hay.* After reviewing the cowpea residue data, EPA determined an additional cowpea tolerance was necessary on cowpea hay.

3. *Livestock feed and milk.* Based on the dietary exposure levels and the residue data from an available ruminant feeding study, data indicate that a tolerance of 0.01 ppm is needed in milk, whole, 0.20 ppm in milk, fat, 0.02 ppm is needed for residues of spiromesifen in the meat of cattle, goats, horses, and sheep, 0.15 ppm in meat, byproducts, of cattle, goats, horses, and sheep, and 0.10 in the fat of cattle, goats, horses, and sheep. Based on the transfer coefficients for livestock tissues and the relatively low dietary burden for swine of 0.04 ppm for spiromesifen, tolerances in hogs are not needed.

**V. Conclusion**

Therefore, the tolerances are established for combined residues of spiromesifen, (2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate) and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one), in or on bean, dry at 0.02 ppm; bean, succulent at 0.10 ppm; bean, edible podded at 0.80 ppm; cowpea, forage at 30 ppm; cowpea, hay at 86 ppm; cattle, fat at 0.10 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts at 0.15 ppm; goat, fat at 0.10 ppm; goat, meat at 0.02 ppm; goat, meat byproducts at 0.15 ppm; horse, fat at 0.10 ppm; horse, meat at 0.02 ppm; horse, meat byproducts at 0.15 ppm; milk at 0.01

ppm; milk, fat at 0.20 ppm; sheep, fat at 0.10 ppm; sheep, meat at 0.02 ppm; and sheep, meat byproducts at 0.15 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) 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 6, 2000) do not apply

to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: March 4, 2008.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.607 is amended by alphabetically adding commodities to the table in paragraph (a)(1), and by revising the table in paragraph (a)(2) to read as follows:

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

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

Commodity	Parts per million
Bean, dry .....	0.02
Bean, edible podded .....	0.80
Bean, succulent .....	0.10
* * *	*
Cowpea, forage .....	30

Commodity	Parts per million
Cowpea, hay .....	86
* * *	*

(2) \* \* \*

Commodity	Parts per million
Cattle, fat .....	0.10
Cattle, meat .....	0.02
Cattle, meat byproducts .....	0.15
Goat, fat .....	0.10
Goat, meat .....	0.02
Goat, meat byproducts .....	0.15
Horse, fat .....	0.10
Horse, meat .....	0.02
Horse, meat byproducts .....	0.15
Milk .....	0.01
Milk, fat .....	0.20
Sheep, fat .....	0.10
Sheep, meat .....	0.02
Sheep, meat byproducts .....	0.15

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 271

[EPA-R08-RCRA-2006-0382; FRL-8541-5]

### Colorado: Final Authorization of State Hazardous Waste Management Program Revisions

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

**ACTION:** Immediate final rule.

**SUMMARY:** The Solid Waste Disposal Act, as amended, commonly referred to as the Resource Conservation and Recovery Act (RCRA), allows the Environmental Protection Agency (EPA) to authorize States to operate their hazardous waste management programs in lieu of the federal program. Colorado has applied to EPA for final authorization of the changes to its hazardous waste program under RCRA. EPA has determined that these changes satisfy all requirements needed to qualify for final authorization and is authorizing the State's changes through this immediate final action.

**DATES:** This final authorization will become effective on May 12, 2008, unless the EPA receives adverse written comment by April 11, 2008. If adverse comment is received, EPA will publish a timely withdrawal of the immediate final rule in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R08-RCRA-2006-0382, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>.

Follow the on-line instructions for submitting comments.

- **E-mail:** [daly.carl@epa.gov](mailto:daly.carl@epa.gov).

- **Fax:** (303) 312-6341.

- **Mail:** Send written comments to Carl Daly, Solid and Hazardous Waste Program, EPA Region 8, Mailcode 8P-HW, 1595 Wynkoop Street, Denver, Colorado 80202-1129.

- **Hand Delivery or Courier:** Deliver your comments to Carl Daly, Solid and Hazardous Waste Program, EPA Region 8, Mailcode 8P-HW, 1595 Wynkoop Street, Denver, Colorado 80202-1129.

Such deliveries are only accepted during the Regional Office's normal hours of operation. The public is advised to call in advance to verify the business hours. Special arrangements should be made for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA-R08-RCRA-2006-0382. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov>, or e-mail. The federal web site, <http://www.regulations.gov>, is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA

Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically through [www.regulations.gov](http://www.regulations.gov) or in hard copy at: EPA Region 8, from 9 a.m. to 4 p.m., 1595 Wynkoop Street, Denver, Colorado; contact: Carl Daly, phone number (303) 312-6416, or the Colorado Department of Public Health and Environment, from 9 a.m. to 4 p.m., 4300 Cherry Creek Drive South, Denver, Colorado 80222-1530; contact: Randy Perila, phone number (303) 692-3364. The public is advised to call in advance to verify the business hours.

**FOR FURTHER INFORMATION CONTACT:** Carl Daly, Solid and Hazardous Waste Program, EPA Region 8, 1595 Wynkoop Street, Denver, Colorado 80202, (303) 312-6416, [daly.carl@epa.gov](mailto:daly.carl@epa.gov).

#### SUPPLEMENTARY INFORMATION:

#### A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the federal program. As the federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when federal or state statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

#### B. What Decisions Have We Made in This Rule?

We conclude that Colorado's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Colorado final authorization to operate its hazardous waste program with the changes described in the authorization applications. Colorado has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders, except in Indian