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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0505; FRL-9982-21]

Spiromesifen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of spiromesifen in or on coffee. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0505, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please

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

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0505 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0505, by one of the following methods:

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

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

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8584) 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 tolerances for residues of spiromesifen; 2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, and its enol metabolite (4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one calculated as the stoichiometric equivalent of spiromesifen in or on the raw agricultural commodities: Coffee bean, green at 0.20 parts per million (ppm); coffee, instant at 0.20 ppm; and coffee bean, roasted at 0.20 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the commodities for which tolerances are being established. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spiromesifen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spiromesifen follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of

the sensitivities of major identifiable subgroups of consumers, including infants and children.

Following oral administration of spiromesifen, the target organs included the thyroid gland for rats and dogs (increased thyroid-stimulating hormone (TSH), increased thyroxine binding capacity, decreased triiodothyronine (T_3) and thyroxine (T_4) levels, colloidal alteration, and thyroid follicular cell hypertrophy), the liver for rats and dogs (increased alkaline phosphatase, alanine transaminase (ALT), and decreased cholesterol and triglycerides), the spleen for rats (atrophy, decreased spleen cell count, and increased macrophages), and the adrenal gland for mice (discoloration, decrease in fine vesiculation, and the presence of cytoplasmic eosinophilia in zona fasciculata cells). For rats, additional effects included reduced body weights and clinical signs (piloerection, reduced motility, spastic gait, and increased reactivity when touched).

There were no adverse effects in rats following dermal exposure up to the limit dose (1,000 milligrams/kilograms/day (mg/kg/day)). Decreased spleen weights were also observed for rats in a 5-day inhalation toxicity study, along with gross pathological findings in the lung (dark red areas or foci) and clinical signs (e.g., tremors, clonic-tonic convulsions, reduced activity, bradypnea, etc.).

While the clinical signs observed in rats following oral and inhalation exposures could indicate neurotoxicity, there was no evidence of neurotoxicity in the rest of the toxicological database, including the acute neurotoxicity study up to the limit dose (2,000 milligrams/kilograms (mg/kg)) and the subchronic neurotoxicity study; however, the doses tested in the subchronic neurotoxicity study were lower than the doses causing

clinical signs in the 90-day dietary study in rats. There was no evidence of immunotoxicity in an antibody plaque-cell forming assay.

There was no evidence of increased pre- or post-natal susceptibility. In the developmental toxicity studies in rats and rabbits, maternal effects were observed in the absence of fetal effects. In the rat two-generation reproductive toxicity study, the reported parental effects, consisting of decreased spleen weights (relative and absolute) and a decreasing number of ovarian follicles, occurred at a dose level that also caused pup body weight decrements during lactation.

Spiromesifen is classified as "Not likely to be Carcinogenic to Humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies. There was no concern for mutagenicity or genotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by spiromesifen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in the document titled, "*Spiromesifen. Human Health Risk Assessment in Support of Proposed Tolerance for Residues of in/on Imported Coffee*" in docket ID number EPA-HQ-OPP-2017-0505.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a

careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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

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

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	NOAEL= 2.2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.022 mg/kg/day cPAD = 0.022 mg/kg/day	<u>Two-Generation Reproduction Study - Rats</u> Parental LOAEL = 8.8 mg/kg bw/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.

Oral short-term (1 to 30 days) and intermediate-term (1-6 months)	NOAEL= 2.2 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	<u>Two-Generation Reproduction Study - Rats</u> Parental LOAEL = 8.8 mg/kg bw/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.
Inhalation short-term (1 to 30 days) and intermediate-term (1-6 months)	Inhalation study NOAEC= 0.0794 mg/L/day UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	<u>5-Day Inhalation Toxicity Study - Rats</u> LOAEC = 0.5143 mg/L/day based on clinical signs (tremors, clonic-tonic convulsions, reduced activity, bradypnea, labored breathing, vocalization, avoidance reaction, giddiness, piloerection, limp, emaciation, cyanosis, squatted posture, apathy and salivation), gross pathology (dark red areas or foci in the lungs and bloated stomachs and pale livers), and decreased spleen weights.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies.		

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

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 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2003-2008). As to residue levels in food, the chronic (food and water) analysis assumed 100 percent crop treated (PCT) and tolerance-level residues or tolerance-level residues adjusted to account for the residue of concern.

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

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for spiromesifen. Tolerance level residues or tolerance-level residues adjusted to account for the residue of concern and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spiromesifen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spiromesifen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Provisional Cranberry model and Pesticide Water Calculator – Groundwater (PWC-GW) model, the estimated drinking water concentrations (EDWCs) of spiromesifen for chronic exposures are estimated to be 188 parts per billion (ppb) for surface water and 116 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 188 ppb was used to assess the contribution to drinking water.

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

Spiromesifen is currently registered for the following uses that could result in residential exposures: Ornamentals. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposure to residential handlers is expected. A dermal assessment (handler and post-application) was not conducted since no hazard was identified via the dermal route. Post-application inhalation exposures were not assessed due to the low vapor pressure and the expected dilution in outdoor

sites. Post-application incidental oral exposure is considered unlikely since the use is restricted to ornamental plants (turf treatment is not permitted). Therefore, only short-term inhalation exposure to handlers was assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

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

EPA has not found spiromesifen to share a common mechanism of toxicity with any other substances, and spiromesifen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spiromesifen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides***.**

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased pre- or post-natal susceptibility. In the developmental toxicity studies in rats and rabbits, maternal effects were observed in the absence of fetal effects. In the rat two-generation reproductive toxicity study, the reported parental effects, consisting of decreased spleen weights (relative and absolute) and a decreasing number of ovarian follicles, occurred at a dose level that also caused pup body weight decrements during lactation.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for spiromesifen is complete.

ii. There is no indication that spiromesifen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (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 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spiromesifen in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spiromesifen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

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

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spiromesifen from food

and water will utilize 68% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spiromesifen is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Spiromesifen is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to spiromesifen.

Because the level of concern (LOC) for inhalation (LOC for MOEs <30) and oral (LOC for MOEs <100) exposure differ, the aggregate assessment was calculated using the aggregate risk index (ARI) approach. The ARI was devised as a way to aggregate MOEs that have dissimilar uncertainty factors. The ARI is an extension of the MOE concept and as with the MOE, risk increases as the ARI decreases. An ARI that is greater than or equal to 1 is not of concern.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate ARI of 1.87. Because EPA's level of concern for spiromesifen is an ARI of 1 or below, this ARI is not of concern.

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

An intermediate-term adverse effect was identified; however, spiromesifen is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for spiromesifen**.**

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

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

Codex has a MRL for residues of only spiromesifen in/on coffee beans of 0.05 ppm. Since the residue expression for the U.S. and Codex tolerances differ and since the maximum combined residues of spiromesifen and BSN 2060-enol in/on coffee green bean from the field trials was greater than 0.1 ppm, harmonization with the Codex expression/value is not possible. Note that BSN 2060-enol is included in the tolerance expression due to the demonstrated degradation of parent to BSN 2060-enol during storage.

C. Response to Comments

Three comments were submitted to the docket for this action. Two comments, one about “China’s ongoing economic war against the United States” and another about air and water pollution in China relative to that of the United States, are not relevant to

this action. The third comment stated in part that "the people drinking coffee should not have this toxic chemical as part of its drink."

The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops; however, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework nor have they provided any specific information or allegation that would support a finding that these tolerances are unsafe.

D. Revisions to Petitioned-For Tolerances

The green coffee bean tolerance being established is identical to that proposed by the petitioner. EPA has determined that separate tolerances for the processed commodities of roasted coffee bean and instant coffee are unnecessary because the processing data indicates that combined residues of spiromesifen and BSN 2060-enol do not concentrate in roasted or instant coffee.

V. Conclusion

Therefore, a tolerance is established for residues of spiromesifen, including its metabolites and degradates, in or on coffee, green bean at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled

"Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or

between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 28, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.607, add alphabetically the commodity "coffee, green bean" and footnote 1 to the table in paragraph (a)(1) to read as follows:

§ 180.607 Spiromesifen; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
*******	
Coffee, green bean[1]	0.20
*******	

[1] This use has not been registered in the United States as of August 28, 2018.

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[FR Doc. 2018-19760 Filed: 9/10/2018 8:45 am; Publication Date: 9/11/2018]