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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0107; FRL-9382-8]

Spirotetramat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spirotetramat in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes several permanent and time-limited tolerances, because they are superseded by new tolerances established by this document. Interregional Research Project Number 4 (IR-4) requested these tolerances 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-2012-0107, 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), EPA West 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *nollen.laura@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-2012-0107 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-2012-0107, 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 April 4, 2012 (77 FR 20334) (FRL-9340-4), 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 1E7958) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.641 be amended by establishing tolerances for residues of the insecticide spirotetramat, cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate, and its metabolites, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as spirotetramat equivalents, in or on taro, leaves at 9 parts per million (ppm); watercress at 1.5 ppm; pomegranate at

0.5 ppm; banana at 4 ppm; vegetable, bulb, group 3-07 at 0.6 ppm; berry, low growing, except strawberry, subgroup 13-07H at 0.3 ppm; bushberry, subgroup 13-07B at 3 ppm; artichoke, globe at 2 ppm; vegetable, fruiting, group 8-10 at 2.5 ppm; fruit, pome, group 11-10 at 0.7 ppm; fruit, citrus, group 10-10 at 0.6 ppm; pineapple at 0.3 ppm; pineapple, process residue at 0.36 ppm; coffee, green beans at 0.2 ppm; and coffee, roast beans at 0.32 ppm. The petition additionally requested to remove the established spirotetramat tolerances in 40 CFR 180.641 for onion, bulb, subgroup 3A-07 at 0.30 ppm; fruit, citrus, group 10 at 0.60 ppm; fruit, pome, group 11 at 0.70 ppm; okra at 2.5 ppm; and vegetable, fruiting, group 8 at 2.5 ppm, because they would be superseded by new tolerances.

That document referenced a summary of the petition prepared on behalf of IR-4 by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance levels for several proposed commodities. The Agency has also determined that the proposed tolerances on pineapple, process residue, and coffee, roast beans, are not necessary and a tolerance on coffee, instant, should be established. The reasons for these changes are 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...."

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 spirotetramat including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spirotetramat 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 thyroid and thymus glands were target organs in oral subchronic toxicity studies in dogs, the most sensitive species tested. The thyroid effects in dogs consisted of lower circulating levels of thyroid hormones along with a reduction in follicle size, a possible indication of reduced amount of colloid. Thymus effects in dogs were described

microscopically as involution, which also resulted in decreased organ weight. In rats, the testes were the target organs following subchronic and chronic oral treatments. The effects on the rat testes consisted of abnormal spermatozoa and hypospermia in the epididymis, decreased testicular weights, and testicular degenerative vacuolation.

The 2-generation rat reproductive toxicity study showed evidence of male reproductive toxicity similar to chronic and subchronic studies with adult rats. However, development of the sexual organs in the offspring (balano-preputial separation, vaginal opening) was unaffected. In an investigative study designed to explore the time of onset of testicular toxicity in rats, decreased epididymal sperm counts were noted after 10 days of exposure. Similar effects were observed after repeated dosing with the enol metabolite of spirotetramat. In the rat developmental toxicity study, offspring toxicity (reduced fetal weight and increased incidences of malformations and skeletal deviations) was observed at the same dose level (limit dose) as maternal toxicity (decreased maternal body weight and food consumption). In the developmental toxicity study in the rabbit, late abortions and other signs of systemic toxicity were observed only in the presence of impaired maternal food and water consumption and body weight loss.

The only evidence of neurotoxicity in the rat acute neurotoxicity study was based on decreased motor and locomotor activity, which occurred only at relatively high dose levels. EPA's preliminary review of a recently submitted rat subchronic neurotoxicity study does not indicate a concern for neurotoxicity, even at relatively high dose levels. The results of an immunotoxicity study in rats do not indicate any functional deficits in immune function. No evidence of tumor formation was found following long-term

carcinogenicity studies in mice and rats, and spirotetramat was also negative for mutagenicity and clastogenicity in several standard *in vivo* and *in vitro* assays.

Specific information on the studies received and the nature of the adverse effects caused by spirotetramat as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document: "Spirotetramat. Human-Health Risk Assessment for the Proposed Uses in/on Taro, Leaves; Watercress; Pomegranate; Banana; Vegetable, Bulb, Group 3-07; Low growing Berry Subgroup 13-07H, Except Strawberry and Lowbush Blueberry; Bushberry Subgroup 13-07B; Artichoke, Globe; Vegetable, Fruiting, Group 8-10; Fruit, Pome, Group 11-10; Fruit, Citrus, Group 10-10; Pineapple; and Coffee; and Tolerances without U.S. Registration in/on Corn, Sweet, Kernel Plus Cob with Husks Removed as Part of the U.S.-Canada Regulatory Cooperation Council (RCC) Pilot Project" at pp. 38-43 in docket ID number EPA-HQ-OPP-2012-0107.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for spirotetramat used for human risk assessment is discussed in Unit III. B. Toxicological Points of Departure/Levels of Concern of the final rule published in the **Federal Register** issue of May 18, 2011 (76 FR 28675) (FRL-8865-8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spirotetramat, EPA considered exposure under the petitioned-for tolerances as well as all existing spirotetramat tolerances in 40 CFR 180.641. EPA assessed dietary exposures from spirotetramat in food as follows:

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

In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16,

which uses food consumption data from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all commodities. DEEM version 7.81 default processing factors were used for processed commodities, where provided.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used 100 PCT, average field trial residues for some commodities, and tolerance-level residues for the remaining commodities. Empirical processing factors were used for apple, grape, orange, pineapple, and tomato juices; applesauce; and dried apple and tomato. DEEM version 7.81 default processing factors were used for other processed commodities, where provided.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that spirotetramat 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 information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section

408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The residues of concern in drinking water for risk assessment purposes are spirotetramat and the metabolites spirotetramat-enol and spirotetramat-ketohydroxy. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spirotetramat and its metabolites in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spirotetramat and its metabolites. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Tier 1 Rice Model and Screening Concentration in Ground Water (SCI-GROW) model, the estimated drinking water concentrations (EDWCs) of spirotetramat and its metabolites for surface water are estimated to be 395 parts per billion (ppb) for acute and chronic exposures. For ground water, the EDWCs are estimated to be 1.24×10^{-3} ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute and chronic dietary risk assessments, the water concentration value of 395 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). Spirotetramat is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found spirotetramat to share a common mechanism of toxicity with any other substances, and spirotetramat does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spirotetramat does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children(start)

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 (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased qualitative or quantitative susceptibility of rats or rabbits to prenatal or postnatal exposure

to spirotetramat. In the rat developmental toxicity study, offspring toxicity was observed at the same dose as maternal toxicity, at the limit dose. In the developmental toxicity study in the rabbit, only maternal toxicity was observed. In both reproductive toxicity studies, offspring toxicity (decreased body weight) was observed at the same dose as parental toxicity. Therefore, no evidence of increased susceptibility of offspring was found across four relevant toxicity studies with spirotetramat.

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 spirotetramat is complete. Immunotoxicity and subchronic neurotoxicity studies were reported as data gaps for spirotetramat in the last published final rule, published in the **Federal Register** issue of May 18, 2011. Since that final rule, an immunotoxicity study in rats has been submitted and reviewed by the Agency. Although the toxicology database for spirotetramat shows effects in the thymus gland in dog studies, the results of the rat immunotoxicity study do not indicate any functional deficits in the immune function. Thymus involution has been demonstrated to occur when hypothyroidism is induced in animals, so it is reasonable to conclude that the thymus involution in dogs was secondary to thyroid effects, rather than a direct effect on the immune system.

The Agency has also recently received the subchronic neurotoxicity study in rats. Though a complete review of the study is pending, a preliminary review of the recently submitted subchronic rat neurotoxicity study does not indicate a concern for neurotoxicity, even at relatively high dose levels, which is consistent with the Agency's

conclusions regarding the potential neurotoxicity of spirotetramat in the May 18, 2011 final rule, and consistent with what the Agency expects for structurally related compounds. In the available acute neurotoxicity study, the only evidence of neurotoxicity was based on decreased motor and locomotor activity, which occurred only at relatively high dose levels (200 milligrams/kilogram body weight (mg/kg bw)). The observed decreased motor activity was not considered evidence of direct neurotoxicity because there were no effects on movement or gait and there were no confirmatory findings of neurological pathology observed at relatively high doses. Moreover, the existing toxicological database indicates that spirotetramat is not a neurotoxic chemical in mammals. Finally, the acute, subchronic, and developmental neurotoxicity studies available for structurally related compounds (spirodiclofen and spiromesifen) do not show evidence of neurotoxicity in adults or the young.

ii. There is no evidence that spirotetramat 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.

iii. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level or average field trial residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spirotetramat in drinking water. These assessments will not underestimate the exposure and risks posed by spirotetramat.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to spirotetramat will occupy 16% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spirotetramat from food and water will utilize 76% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for spirotetramat.

3. *Short- and Intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, spirotetramat is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risks are assessed based on short- and intermediate-term residential exposures plus chronic dietary exposure. Because there are no short- or intermediate-term residential exposures 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 short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for spirotetramat**.**

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

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 spirotetramat residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, a high-performance liquid chromatography with tandem mass spectrometry (HPLC-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.

The Codex has established a MRL for spirotetramat in or on pome fruit at 0.7 ppm, which is harmonized with the pome fruit group 11-10 tolerance in the United States. However, Codex has established other MRLs for which the United States cannot harmonize tolerances: A Codex MRLs on fruiting vegetables except chili pepper at 1 ppm, chili pepper at 2 ppm, and dried chili pepper at 15 ppm are not harmonized with the U.S. tolerance on fruiting vegetable group 8-10 at 2.5 ppm; and a Codex MRL for citrus at 0.5 ppm is not harmonized with a U.S. tolerance on citrus 0.60 ppm. These MRLs are different than the tolerances established for spirotetramat in the United States because the residue definition in the United States includes additional metabolites not included in the Codex residue definition. Because of the differences in the residue definition, the residue field trial information in the United States results in different calculated tolerances than those established by Codex; therefore, the United States cannot harmonize with Codex.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA is revising the proposed tolerances in or on watercress from 1.5 ppm to 2.0 ppm; vegetable, bulb, group 3-07 from 0.6 ppm to 0.80 ppm; and artichoke, globe from 2 ppm to 1.5 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the

Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures. Additionally, the Agency determined that the proposed tolerances in or on pineapple, process residue, and coffee, roast beans, are not necessary because the calculated tolerance values for these processed commodities are less than the recommended tolerances in or on pineapple and coffee, green bean. Finally, based on the available processing data, EPA determined that a tolerance should be established in or on coffee, instant at 0.50 ppm.

V. Conclusion

Therefore, tolerances are established for residues of spirotetramat, cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate, and its metabolites, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, in or on taro, leaves at 9.0 ppm; watercress at 2.0 ppm; pomegranate at 0.50 ppm; banana at 4.0 ppm; vegetable, bulb, group 3-07 at 0.80 ppm; berry, low growing, except strawberry, subgroup 13-07H at 0.30 ppm; bushberry subgroup 13-07B at 3.0 ppm; artichoke, globe at 1.5 ppm; fruit, pome, group 11-10 at 0.70 ppm; vegetable, fruiting, group 8-10 at 2.5 ppm; fruit, citrus, group 10-10 at 0.60 ppm; pineapple at 0.30 ppm; coffee, green bean at 0.20 ppm; and coffee, instant at 0.50 ppm. This regulation additionally removes established tolerances of spirotetramat in or on onion, bulb, subgroup 3A-07 at 0.30 ppm; fruit, citrus, group 10 at 0.60 ppm; fruit, pome, group 11 at 0.70 ppm; okra at 2.5 ppm; and vegetable, fruiting, group 8 at 2.5 ppm.

Finally, this final rule removes the time-limited tolerances in or on onion, dry bulb at 0.3 ppm and watercress at 1.5 ppm because they are superseded by new permanent tolerances.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under 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 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 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 of 1995 (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: May 1, 2013.

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. In § 180.641:

i. Remove from the table in paragraph (a)(1) the commodities "Fruit, citrus, group 10," "Fruit, pome, group 11," "Okra," "Onion, bulb, subgroup 3A-07[1]," and "Vegetable, fruiting, group 8."

ii. Add alphabetically to the table in paragraph (a)(1) the following commodities.

iii. Revise paragraphs (b) and (c).

The amendments read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Artichoke, globe	1.5
* * *	* *
Berry, low growing, except strawberry, subgroup 13-07H	0.30
* * *	* *
Bushberry subgroup 13-07B	3.0
* * *	* *
Coffee, green bean	0.20
Coffee, instant	0.50
* * *	* *
Fruit, citrus, group 10-10	0.60
Fruit, pome, group 11-10	0.70
* * *	* *
Pineapple	0.30
* * *	* *
Pomegranate	0.50

* * *	* *
Taro, leaves	9.0
Vegetable, bulb, group 3-07	0.80
* * *	* *
Vegetable, fruiting, group 8-10	2.5
* * *	* *
Watercress	2.0
* * *	* *

* * * * *

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

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the insecticide spirotetramat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate) and its metabolites cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl beta-D-glucopyranoside, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, calculated as the stoichiometric equivalent of spirotetramat, in or on the following commodities.

Commodity	Parts per million
Banana	4.0

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