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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0679; FRL-9951-80]

Spirotetramat; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of spirotetramat in or on asparagus. Bayer CropScience LP 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-2015-0679, 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-2015-0679 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-2015-0679, 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 May 19, 2016 (81 FR 31581) (FRL-9946-02), 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 5E8376) by Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.641 be amended by establishing tolerances for residues of the insecticide spirotetramat in or on asparagus at 0.10 parts per million (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*. A comment was received on the notice of filing. EPA's response to this comment is discussed 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 target organs of toxicity following subchronic and chronic oral exposures to spirotetramat were different in rats and dogs. The thyroid and thymus glands were the target organs identified in subchronic and chronic toxicity studies in dogs while the testes were the target organs identified in rats. The dog was the most sensitive species, and in both rats and dogs, males were more sensitive than females. The thyroid effects in the dog consisted of lower circulating levels of thyroid hormones (T3 and/or T4) along with a reduction in follicle size, a possible indication of reduced amount of colloid. The effects in the dog thymus were described microscopically as involution, which also resulted in decreased organ weight.

In rats, reported testicular effects consisted of abnormal spermatozoa and hypospermia in the epididymis, decreased testicular weights, and testicular degenerative vacuolation. An investigative subchronic study where rats were dosed with a primary enol metabolite of spirotetramat reproduced the same testicular effects as the parent chemical,

suggesting that this metabolite is, at minimum, a primary contributor to the observed male reproductive toxicity. Consistent with this notion, orally administered spirotetramat was demonstrated in rats to be extensively metabolized, and males were noted to achieve much higher systemic exposures than their female counterparts, which helps explain the higher sensitivity of males. Other effects reported in a rat chronic toxicity study were associated with kidney effects consisting of decreased organ weight and tubular dilatation.

In one- and two-generation rat reproductive toxicity studies, male reproductive toxicity (abnormal sperm cells and reproductive performance) similar to that reported in subchronic toxicity studies with adult rats was reported in the first generation (F_1) males at relatively high dose levels. In all cases, a well-defined no-observed adverse-effect level (NOAEL) was established.

There was evidence of increased qualitative susceptibility in the rat developmental study with reduced fetal weight and increased incidences of malformations and skeletal deviations observed at the limit dose, while maternal effects at this dose consisted of only body weight decrements. There was no evidence of increased quantitative or qualitative susceptibility to offspring following pre- or postnatal exposure to spirotetramat in the rabbit developmental or two-generation reproduction studies.

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. The rat subchronic neurotoxicity (SCN) 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. There is no evidence of carcinogenicity in chronic

toxicity/carcinogenicity studies performed in rats and mice and spirotetramat was also negative for mutagenicity and clastogenicity in guideline 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 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 "*Spirotetramat. Human Health Risk Assessment for the Petition for a Tolerance for Residues in/on Asparagus Without a U.S. Registration"* at page 19 in docket ID number EPA-HQ-OPP-2015-0679.

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 shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Spirotetramat 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 (General population including infants and children)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day	**Acute neurotoxicity (rat)** LOAEL = 200 mg/kg based on clinical signs and decreased motor activity in males
Chronic dietary (All populations)	NOAEL = 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	**Chronic toxicity (dog)** LOAEL = 20 mg/kg/day based on thymus involution in males
Cancer (Oral, dermal, inhalation)	Classification: "not likely to be carcinogenic to humans" based on lack of evidence of carcinogenicity in rats and mice.		

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).

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 food consumption information from the United States Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA **a**ssumed tolerance-level residues for all foods, Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors where provided, and 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA (2003-2008). As to residue levels in food, EPA assumed average field trial residues for some commodities, tolerance-level residues for the remaining commodities, and 100 PCT.

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 and PCT 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 Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spirotetramat in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spirotetramat. 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 Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of spirotetramat and its metabolites for acute exposures are estimated to be 395 parts per billion (ppb) for surface water and 7.99 ppb for ground water, and for chronic exposures are estimated to be 395 ppb for surface water and 5.36 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both 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 currently registered for the following uses that could result in residential exposures: golf courses and residential citrus trees. The golf course use could result in potential post-application dermal exposure; however, there is no dermal hazard and therefore, quantification of dermal risk is not necessary. For the residential citrus tree use, because the product is sold in bulk packaging for agricultural uses and the label requires that handlers wear specific clothing (e.g., long-sleeve shirt/long pants) and the use of personal-

protective equipment (e.g., gloves), based on current Agency policy, EPA has made the assumption that this product is not meant for homeowner use, and therefore, there is no need to conduct a quantitative residential handler assessment.

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

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

to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of quantitative susceptibility of offspring following pre- or postnatal exposure. There is evidence of qualitative susceptibility in the rat developmental study, such that reduced fetal weight and increased incidences of malformations and skeletal deviations were observed at the limit dose, while maternal effects at this dose consisted of only body weight decrements. Concern is low since effects were only seen at the limit dose, effects were seen in the presence of maternal toxicity, and selected endpoints are protective of the observed effects.

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.

ii. Although there is evidence of neurotoxicity in the acute neurotoxicity study, concern is low since the effects are well-characterized with clearly established NOAEL/LOAEL values, the selected endpoints are protective of the observed neurotoxic effect, there are no neurotoxic effects seen in the subchronic neurotoxicity study, and the existing toxicological database indicates that spirotetramat is not a neurotoxic chemical.

iii. There was no evidence of quantitative susceptibility of offspring following pre- or postnatal exposure. There is evidence of qualitative susceptibility in the rat developmental study; however, there is no residual uncertainty concerning these effects due to the clear NOAEL/LOAELs in the study for these effects. Moreover, concern for these effects is low since effects were only seen at the limit dose, effects were seen in the presence of maternal toxicity, and selected endpoints are protective of the observed effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food and drinking water exposure assessment utilizes tolerance-level residues and 100 PCT information for all commodities. The chronic dietary food and drinking water exposure assessment utilizes average field trial residues for some commodities, tolerance-level residues for the remaining commodities, and 100 PCT. The chronic assessment is somewhat refined; however, since it is based on reliable data, it will not underestimate exposure and risk. The drinking water assessments provide conservative, health-protective, high-end estimates of water concentrations that will not likely be exceeded. These assessments of exposure are not likely to underestimate the resulting estimates of risk from exposure to 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 77% of the cPAD for children 1-2 years old, the population group receiving the

greatest exposure. There are no residential uses for spirotetramat resulting in long-term exposure that require a quantitative risk assessment.

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). A short- and intermediate-term inhalation adverse effect was identified; however, spirotetramat is not registered for any use patterns that would result in either short- or intermediate-term inhalation residential exposure. In a dermal toxicity study, no evidence of dermal hazard was found; therefore, dermal risk was not included in the aggregate assessment. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or 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 short-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 (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 not established a MRL for spirotetramat in or on asparagus.

C. Response to Comments

EPA received one comment to the Notice of Filing noting general concerns about the potential effects on the cornea, thymus and thyroid, and testicular histopathy and stating, in part, that EPA should deny any approval of use of this chemical on any food products. The Agency understands the commenter’s concerns and recognizes that some individuals believe

that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (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. EPA has assessed the effects of this chemical on human health and determined that aggregate exposure to it will be safe. 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.

V. Conclusion

Therefore, tolerances are established for residues of spirotetramat, including its metabolites and degradates, in or on asparagus at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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). 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: October 14, 2016.

Michael Goodis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.641:

a. Add alphabetically the commodity "Asparagus" to the table in paragraph (a)(1); and

b. Revise the footnote at the end of the table in paragraph (a)(1).

The additions and revisions read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

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

Commodity	Parts per million
****	***
Asparagus[1]	0.10
****	***

[1] There are no U.S. registrations for these commodities.

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[FR Doc. 2016-25638 Filed: 10/24/2016 8:45 am; Publication Date: 10/25/2016]