



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0107; FRL-9391-6]

RIN 2070-ZA16

Spirotetramat; Proposed Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish tolerances for residues of

spirotetramat in or on persimmon and sweet corn, kernel plus cob with husks removed;

and to revise established tolerances in or on feijoa, papaya, and Spanish lime under the

Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before [*insert date 30 days after publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (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 Confidential Business Information (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.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete

version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. This Proposal

EPA, on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to establish a tolerance for residues of the insecticide spirotetramat, in or on corn, sweet, kernel plus cob with husks removed at 1.5 parts per million (ppm). Additionally, EPA has noted several errors published in 40 CFR 180.641 that the Agency is also proposing to correct. Established tolerances for residues of spirotetramat in or on feijoa, papaya, and Spanish lime in 40 CFR 180.641(a)(1) are incorrectly listed and the previously recommended tolerance for residues in or on persimmon is missing. The tolerances are proposed to be corrected as follows: Feijoa from 0.30 ppm to 2.5 ppm; papaya from 2.5 ppm to 0.40 ppm; Spanish lime from 0.60 ppm to 13 ppm; and persimmon at 2.5 ppm.

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....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of FFDCa section 408 and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

Consistent with 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, consistent with FFDCa section 408(b)(2), for tolerances for residues of spirotetramat in or on corn, sweet, kernel plus cob with husks removed; feijoa; papaya; Spanish lime; and persimmon. As discussed below, EPA is relying upon the findings in the preamble to the May 15, 2013 rule establishing tolerances for spirotetramat (78 FR 28507) (FRL-9382-8) and supporting risk assessments to establish and revise these tolerances.

On May 15, 2013, EPA published a final rule establishing tolerances for residues of the insecticide spirotetramat, (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl-ethyl carbonate) and its metabolites in or on taro leaves; watercress; pomegranate; banana; bulb vegetable group 3-07; low growing berry, except strawberry, subgroup 13-07H; bushberry subgroup 13-07B; globe artichoke; pome fruit group 11-10; fruiting vegetable group 8-10; citrus fruit group 10-10; pineapple; coffee, green bean; and instant coffee, based on EPA's conclusion that aggregate exposure to spirotetramat is safe for the general population, including infants and children. In addition to the tolerances listed above, EPA also considered the following uses in the risk assessments that supported the May 15, 2013 final rule: persimmon and sweet corn,

kernel plus cob with husks removed; and revised tolerances in or on feijoa, papaya, and Spanish lime.

Since the publication of the May 15, 2013 final rule, the toxicity profile of spirotetramat has not changed, and the risk assessments that supported the establishment of those spirotetramat tolerances published in the May 15, 2013 **Federal Register** remain valid. Those risk assessments also recommended the proposed new uses and revised tolerances listed above. Therefore, EPA is relying on those risk assessments in order to propose the new and revised tolerances. For a detailed discussion of the aggregate risk assessments and determination of safety for the proposed tolerances, please refer to the May 15, 2013 **Federal Register** document and its supporting documents, available at <http://www.regulations.gov>. EPA relies upon those supporting risk assessments and the findings made in the **Federal Register** document in support of this proposed rule.

IV. Background for This Proposal

On February 4, 2011, President Barack Obama and the Prime Minister of Canada, Stephen Harper, announced the creation of the United States-Canada Regulatory Cooperation Council (RCC) in order to increase regulatory transparency and coordination between the two countries. One of the areas of focus of the RCC is in agricultural production, in particular, the further alignment of crop protection product approvals and establishment of U.S. tolerances and Canadian maximum residue limits (MRLs) for major and minor uses of pesticides in both countries.

One action item identified through the activities of the RCC was the initiation of a pilot project for the joint review of residue data for spirotetramat in the United States and Canada, whereby both countries would work together to further align practices and

tolerances/MRLs resulting from the joint review of domestic and import tolerances/MRLs in both countries.

Although Canada's Pest Management Regulatory Agency (PMRA) had received a petition for the use of spirotetramat on sweet corn in Canada, EPA did not. So, as part of the RCC pilot project to work together and align tolerances/MRLs, EPA is proposing a tolerance without U.S. registration for residues of spirotetramat and its metabolites and degradates in or on corn, sweet, kernel plus cob with husks removed based on the evaluation of the sweet corn residue data. As noted above, EPA has also considered the sweet corn use in its risk assessments, and has made a determination of safety finding for the use. Additional information regarding the RCC pilot project may be found at the following website: <http://www.epa.gov/oppfead1/international/naftatwg/us-canada-rcc.html>.

In addition to the proposed use of spirotetramat in or on sweet corn, EPA has identified several errors contained in 40 CFR 180.641. EPA is also proposing to correct these errors. Established tolerances for residues of spirotetramat in or on feijoa, papaya, and Spanish lime in 40 CFR 180.641(a)(1) are incorrectly listed and the previously recommended tolerance for residues in or on persimmon is missing. The tolerances are proposed to be corrected as follows: Feijoa from 0.30 ppm to 2.5 ppm; papaya from 2.5 ppm to 0.40 ppm; Spanish lime from 0.60 ppm to 13 ppm; and persimmon at 2.5 ppm.

In the last risk assessment relied upon for the May 15, 2013 rule, EPA took a conservative approach by utilizing tolerance values of 2.5 ppm for feijoa (which is higher than the established tolerance), papaya (which is the value of the established tolerance),

and persimmon and 13 ppm for Spanish lime (which is higher than the established tolerance).

Based on the risk assessments and information described above, 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. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the May 15, 2013 **Federal Register** action, as well as the proposed new and revised spirotetramat tolerances can be found at

<http://www.regulations.gov> in the document entitled: "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." Further information regarding correcting the errors for spirotetramat in 40 CFR 180.641 may be found in the document:

"Spirotetramat: Acute and Chronic Dietary (Food and Drinking Water) Exposure and Risk Assessment to Support the Section 3 Registration Request For Use of Spirotetramat 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.” Both documents may be found in docket ID number EPA-HQ-OPP-2012-0107.

V. 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 papaya at 0.4 mg/kg. While the EPA originally assessed for a tolerance in or on papaya at 0.35 ppm, the Agency is proposing to revise the tolerance to 0.40 ppm in order to harmonize with Codex. There is no risk concern with proposing a tolerance in or on papaya at 0.40 ppm because EPA assessed the dietary estimates using the conservative assumption of 2.5 ppm in the risk assessments supporting the use. Therefore, the dietary estimate is expected to slightly decrease upon the establishment of the revised papaya tolerance.

VI. Conclusion

Tolerances are proposed for residues of spirotetramat in corn, sweet, kernel plus cob with husks removed at 1.5 ppm, and persimmon at 2.5 ppm. Amended tolerances are also proposed in or on feijoa from 0.30 ppm to 2.5 ppm; papaya from 2.5 ppm to 0.40 ppm; and Spanish lime from 0.60 ppm to 13 ppm.

VII. Statutory and Executive Order Reviews

This proposed rule proposes to establish tolerances under FFDCA section 408(d). 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or impose any enforceable duty or contain any unfunded mandate as described under Title II of the

Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *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); or OMB review or any Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published on May 4, 1981 (46 FR 24950) and on December 17, 1997 (62 FR 66020), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Any comments about the Agency’s determination should be submitted to the EPA along with comments on the proposal, and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This

proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: July 2, 2013.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be 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, in the table in paragraph (a), alphabetically add the commodities “Corn, sweet, kernel plus cob with husks removed” and “Persimmon” and revise the entries for “Feijoa”, “Papaya” and “Spanish lime,” and footnote 1 to read as follows:

§180.641 Spirotetramat; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	* * *
Corn, sweet, kernel plus cob with husks removed ¹	1.5
* * * *	* * *
Feijoa	2.5
* * * *	* * *
Papaya	0.40
* * * *	* * *
Persimmon	2.5
* * * *	* * *
Spanish lime	13
* * * *	* * *

¹There are no U.S. registrations as of [date of effective date of final rule] for use on corn, sweet, kernel plus cob with husks removed.

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