○ Also, changed the note to paragraph (b): To replace ''Material Safety Data Sheets'' with ''Safety Data Sheets (SDS);'' and

• § 68.67 Process hazard analysis—revised to require that the PHA must now address the findings from all incident investigations required under § 68.81, as well as any other potential failure scenarios.

The only major rule provision that would be affected by this rule (because its March 14, 2018 compliance date is before the delayed effective date of this rule) is the emergency response coordination provision, which has an estimated annualized cost of $16 M.[22] [23] Therefore, based on the costs of the provisions that would be affected by this action, EPA has concluded that this action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 68

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 9, 2017.

E. Scott Pruitt,

Administrator.

[FR Doc. 2017–12340 Filed 6–13–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0255; FRL–9961–95]

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. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR–4) and Bayer CropScience, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 14, 2017. Objections and requests for hearings must be received on or before August 14, 2017, 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–2016–0255, 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; telephone number: (703) 305–7090; email address: *jackson.sidney@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–2016–0255 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 August 14, 2017. 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–2016–0255, 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 Wednesday, June 22, 2016 (81 FR 40594) (FRL–9947–32) and Monday, August 29, 2016 (81 FR 59165) (FRL–9950–22), EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3),

[22] See EPA, Regulatory Impact Analysis, Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7), December 16, 2016, pp 71, Docket ID No. EPA–HQ–OEM–2015–0725.

[23] The new compliance date for the emergency response coordination provision will be February 19, 2019, unless we propose and finalize a revised compliance date in conjunction with future revisions to the Risk Management Program Amendments.

announcing the filing of pesticide petitions (PPs) by IR–4 (PP 6E8467); and Bayer CropScience (PP 6F8461). These petitions request that 40 CFR 180.641 be amended by 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 *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 several commodities as follows:

Pesticide petition 6E8467 submitted by IR–4 Project Headquarters, 500 College Road East, Suite 201 W., Princeton, NJ 08540 requests tolerances for carrot, roots at 0.15 parts per million (ppm); fruit, stone, group 12–12 at 4.5 ppm; and nut, tree, group 14–12 at 0.25 ppm.

Pesticide petition 6F8461 submitted by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 requests tolerances on sugar beet, molasses at 0.20 ppm and sugar beet, root at 0.15 ppm.

Summaries of the petitions prepared by the registrant, Bayer CropScience, are available in the docket, *http://www.regulations.gov* under document ID EPA–HQ–OPP–2016–0255. One comment was received in response to the notices of filings. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the tolerance levels for several proposed commodities and corrected several commodity listings. The reason for these changes are 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 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. In all dog studies, thymus effects were observed (reduced size, atrophy). In the one-year study, this was described microscopically as involution.

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 post-natal 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. Spirotetramat has been classified as ''not likely to be carcinogenic to humans'' based on lack of evidence for carcinogenicity in rodent studies. Spirotetramat was also negative for mutagenicity and clastogenicity in *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 Tolerance Petition for Residues in/on Sugar Beet and Carrot and Crop Group Conversions for

Tree Nut Group 14–12 and Fruit, Stone, Group 12–12.'' at pages 25–30 in docket ID number EPA–HQ–OPP–2016–0255.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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** of Tuesday, October 25, 2016 (81 FR 73342) (FRL–89951–80).

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 data from the U.S. Department of Agriculture's (USDA's) 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 tolerance-level residues, 100 percent crop treated (PCT) information for all commodities and Dietary Exposure Evaluation Model (DEEM) 7.81 default processing factors where available.

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.

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 percent crop treated (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.

The Agency did not use percent crop treated estimates.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

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 and degradates of concern for acute exposures are estimated to be 395 parts per billion (ppb) for surface water and 7.99 ppb for ground water.

Chronic exposures for non-cancer assessments 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 acute and chronic dietary risk assessment, 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: Citrus trees grown in residential areas and turf grass including sod farm and golf course turf only. There is the potential for post-application dermal exposure from both residential citrus tree and golf course uses. 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.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spirotetramat and 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 not assumed that spirotetramat has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at: *http://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 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 is no evidence of quantitative susceptibility of offspring following pre- or postnatal exposure to spirotetramat. There is evidence of qualitative susceptibility in the rat developmental study, where developmental effects, including reduced fetal weight and increased incidences of malformations and skeletal deviations, were observed in the presence of body weight decrements in maternal animals. However, concern is low since effects were only seen at the limit dose 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 spirotetramat was shown to elicit neurotoxic response in the acute neurotoxicity study; however, 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 is 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. There are no quantifiable potential exposure/risks from residential citrus tree and golf course uses. The drinking water assessments provide conservative, health-protective, high-end estimates of water concentrations that will not likely be exceeded. 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 77% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short- and Intermediate-term risks.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures 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 aggregate risks are assessed based on short- and intermediate-term residential exposures 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 risks 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.

C. Response to Comments

One comment was received from an anonymous source requesting that the Agency deny IR–4's petition for use of spirotetramat on all food items claiming it is a toxic chemical and its use would result in harm to humans.

The Agency's Response: The Agency recognizes that some individuals believe that certain pesticides are ''toxic chemicals'' that should not be permitted in our food; however, the commenter provided no information demonstrating toxicity of spirotetramat or that EPA could use to evaluate the safety of the pesticide. 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. When new or amended tolerances are requested for residues of a pesticide in food or feed, the Agency, as is required by Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), estimates the risk of the potential exposure to these residues. The Agency has concluded after this risk assessment, which includes the consideration of long-term animal studies with spirotetramat, that there is a reasonable certainty that no harm will result from aggregate human exposure to spirotetramat and that, accordingly, the use of spirotetramat on petitioned-for food commodities is ''safe.''

D. Revisions to Petitioned-For Tolerances

Based on available residue data, EPA is establishing tolerance level on sugar beet molasses at 0.30 ppm instead of 0.20 ppm, to cover anticipated residues. In addition, EPA corrected the commodity terminology for ''sugar beet root'' and ''sugar beet molasses'' to ''beet, sugar, roots'' and ''beet, sugar, molasses,'' respectively, in order to conform to terms used in the Agency's Food and Feed Commodity Vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of spirotetramat, (*cis*-3-(2,5-dimethylphenyl)-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 beet, sugar, molasses at 0.30 ppm; beet, sugar, roots at 0.15 ppm; carrot, roots at 0.15 ppm; fruit, stone, group 12–12 at 4.5 ppm; and nut, tree, group 14–12 at 0.25 ppm. In addition, EPA is revoking the existing tolerances for fruit, stone, group 12 and nut, tree, group 14 as they are superseded by the new tolerances for groups 12–12 and 14–12 established under this final rule.

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). 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: May 8, 2017.

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 § 180.641, in the table in paragraph (a)(1):
■ i. Add alphabetically the entries: ''Beet, sugar, molasses''; ''Beet, sugar, roots''; ''Carrot, roots''; ''Fruit, stone, group 12–12''; and ''Nut, tree, group 14–12''; and
■ ii. Remove entries for ''Fruit, stone, group 12'' and ''Nut, tree, group 14''.

The additions read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

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

Commodity	Parts per million
* * * * *	
Beet, sugar, molasses	0.30
Beet, sugar, roots	0.15
* * * * *	
Carrot, roots	0.15
* * * * *	
Fruit, stone, group 12–12	4.5
* * * * *	
Nut, tree, group 14–12	0.25
* * * * *	

* * * * *

[FR Doc. 2017–12348 Filed 6–13–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0263; FRL–9961–80]

Isofetamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on multiple commodities which are identified and discussed later in this document. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The regulation also removes the existing time-limited tolerances for residues on ''bushberry subgroup 13–07B'' and ''caneberry subgroup 13–07A'' because they are no longer needed as a result of this action.

DATES: This regulation is effective June 14, 2017. Objections and requests for hearings must be received on or before August 14, 2017, 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–2016–0263, 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 L. 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–2016–0263 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 August 14, 2017. 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–2016–0263, 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