VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 26, 2008

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.568 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.568 Flumioxazin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Corn, field, forage	0.02
Corn, field, grain	0.02
Corn, field, stover	0.02
* * *	* *

* * * * *

[FR Doc. E8–15316 Filed 7–8–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0475; FRL–8367–1]

Spirotetramat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of spirotetramat and its metabolites BYI 08330-enol, BYI 08330-ketohydroxy, BYI08330-enol-, and BYI 08330-mono-hydroxy, calculated as spirotetramat equivalents, in or on vegetable, tuberous and corm, subgroup 1C; potato, flakes; onion, bulb, subgroup 3A-07; vegetable, leafy, except brassica, group 4; brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; vegetable, fruiting, group 8; vegetable, cucurbit, group 9; fruit, citrus, group 10; citrus, oil; fruit, pome, group 11; fruit, stone, group 12; nut, tree, group 14; almond, hulls; small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F; grape; raisin; strawberry; hop, dried cones; and for the combined residues of spirotetramat and its metabolite BYI 08330-enol, calculated as spirotetramat equivalents, in or on milk; and meat, fat, and meat byproducts of cattle, goat; sheep, and horse. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 2008, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0475. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address: *kumar.rita@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0475 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 8, 2008.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0475, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of July 15, 2007 (FR 40877) (FRL–8137–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7119) by Bayer CropScience LLC, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 . The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide spirotetramat, (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate, and its metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro4.5dec-3-en-2-one, calculated as spirotetramat equivalents, in or on the raw agricultural commodities vegetable, tuberous and corm, subgroup 1C at 1.0 parts per million (ppm); potato, granules/flakes at 2.5 ppm; onions, dry bulb, subgroup 3A at 0.3 ppm; vegetables, leafy, except brassica, group 4 at 5.0 ppm brassica, head and stem, subgroup 5A at 3.0 ppm; brassica, leafy greens, subgroup 5B at 16.0 ppm; vegetables, fruiting, group 8 at 1.0 ppm; tomato, dried pomace at 2.5 ppm; vegetable, cucurbit, group 9 at 0.2 ppm; fruit, citrus, group 10 at 0.5 ppm; citrus, oil at 4.0 ppm; fruit, pome, group 11 at 0.5 ppm; fruit, stone, group 12 at 2.0 ppm; nut, tree, group 14 at 0.5 ppm; almond, hulls at 9.0 ppm; grape at 1.0 ppm; grape, raisin at 2.5 ppm; hop at 10.0 ppm; strawberry at 0.5 ppm; cattle, goat, hog, sheep and horse, meat at 0.01 ppm; cattle, goat, hog, sheep and horse, fat at 0.01 ppm; cattle, goat, hog, sheep and horse, liver at 0.01 ppm; cattle, goat, hog, sheep and horse, meat byproducts, except liver at 0.02 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised tolerance expression for vegetable, tuberous and corm, subgroup 1C; potato, granules/flakes; vegetables, leafy, except brassica, group 4; brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; vegetables, fruiting, group 8; tomato, dried pomace; vegetable, cucurbit, group 9; fruit, citrus, group 10; citrus, oil; fruit, pome, group 11; fruit, stone, group 12; nut, tree, group 14; small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F; grape; raisin; strawberry; cattle, goat, hog, sheep and horse, meat; cattle, goat, hog, sheep and horse, fat; cattle, goat, hog, sheep and horse, liver; cattle, goat, hog, sheep and horse, meat byproducts, except liver. A tolerance for milk was also included. The reasons 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for combined residues of spirotetramat. EPA's assessment of exposures and risks associated with establishing tolerances 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 acute, short-term, and long-term toxicity of spirotetramat is well understood. Spirotetramat technical demonstrated moderate to low acute toxicity via the oral, dermal, and inhalation routes. Spirotetramat is non-irritating to the skin, although it is an irritant to the eyes and exhibits a skin-sensitization potential in animals and humans. The thyroid and thymus glands were target organs in oral subchronic toxicity studies in the dog; whereas, the testes-epididymides were the target organs following subchronic oral treatment of rats. Long-term toxicity studies reflected the short-term toxicological profile of spirotetramat with the thymus and thyroid as target organs following one-year oral exposure of dogs. Chronic exposure of rats to spirotetramat also reflected the subchronic pattern of testicular toxicity. No evidence of tumor formation was found following long-term studies of rodents, and spirotetramat was also negative for mutagenicity and clastogenicity in several standard in vivo and in vitro assays.

The reproductive and developmental toxicity potential of spirotetramat was tested in rats and rabbits. In addition to

testicular histopathology observed following subchronic and chronic exposure of rats to spirotetramat, male reproductive toxicity was recorded in the two-generation reproductive toxicity study. However, development of the sexual organs of offspring (balanopreputial separation, vaginal opening) was unaffected. In an investigative study designed to explore the time of onset of testicular toxicity in rats, decreased epididymal sperm counts were noted after 10 days of exposure. Therefore, repeated dosing with spirotetramat is necessary to produce male reproductive toxicity in rats. Similar effects were observed after repeated dosing with the enol metabolite of spirotetramat. Developmental toxicity was not observed with spirotetramat in the absence of maternal toxicity in either the rat or rabbit.

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 Proposed Uses on Citrus (Crop Group 10); Cucurbit Vegetables (Crop Group 9); Fruiting Vegetables (Crop Group 8); Grape (Crop Subgroup 13F); Hops; Leafy Brassica Vegetables (Crop Group 5); Leafy Non-Brassica Vegetables (Crop Group 4); Pome Fruit (Crop Group 11); Potato and Other Tuberous and Corm Vegetables (Crop Subgroup 1C); Stone Fruit (Crop Group 12); Tree Nuts (Crop Group 14); Onions; Strawberries; Livestock Commodities*; and *Greenhouses/Nurseries*, pages 38–58 in docket ID number EPA–HQ–OPP–2007–0475.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in document *Spirotetramat Human-Health Risk Assessment for Proposed Uses on Citrus (Crop Group 10); Cucurbit Vegetables (Crop Group 9); Fruiting Vegetables (Crop Group 8); Grape (Crop Subgroup 13F); Hops; Leafy Brassica Vegetables (Crop Group 5); Leafy Non-Brassica Vegetables (Crop Group 4); Pome Fruit (Crop Group 11); Potato and Other Tuberous and Corm Vegetables (Crop Subgroup 1C); Stone Fruit (Crop Group 12); Tree Nuts (Crop Group 14); Onions; Strawberries; Livestock Commodities*; and *Greenhouses/Nurseries*, page 21 in docket ID number EPA–HQ–OPP–2007–0475.

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. 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 one-day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), and tolerance-level residues for all foods. Empirical and DEEM™ (ver. 7.81) default processing factors were used for processed commodities. Drinking water was incorporated directly in the dietary assessment using the acute concentration for surface water generated by the First Index Resevoir Screening Tool (FIRST) model.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA conducted a conservative chronic dietary assessment assuming average field-trial residues, empirical and DEEM™ (ver. 7.81) default processing factors, and 100% CT. Drinking water was incorporated directly into the dietary assessment using the chronic concentration for surface water generated by the FIRST model.

iii. *Cancer*. Spirotetramat was classified as ''not likely to be carcinogenic to humans.'' Therefore, a quantitative cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spirotetramat and its metabolites in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spirotetramat. 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 FIRST and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spirotetramat and its metabolites:

i. For acute exposures are estimated to be 0.212 parts per billion (ppb) for surface water and 3.96×10^{-4} ppb for ground water;

ii. For chronic exposures for non-cancer assessments are estimated to be 1.37×10^{-3} ppb for surface water and 3.96×10^{-4} ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. a. For acute dietary risk assessment, the water concentration value of 0.212 ppb was used to assess the contribution to drinking water. b. For chronic dietary

risk assessment, the water concentration of value 1.37x10-^{3} ppb was used to assess the contribution to drinking water.

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

Spirotetramat is not registered for any specific use patterns that would result in residential exposure.

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

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

D. Safety Factor for Infants and Children

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

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

i. The toxicity database for spirotetramat is complete.

ii. There is no indication that spirotetramat is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Clinical signs of toxicity and decreased motor activity were observed in adult rats following a single dose of spirotetramat in the acute neurotoxicity study in the rat; however, these effects only attained statistical significance at high doses and were not observed at the limit dose in the acute oral toxicity study in the rat. There is no concern for neurotoxicity with spirotetramat in the developing animal based on the fact that brain dilation in the one-year dog study is most likely a congenital anomaly that was not observed in any other study in the spirotetramat database, and the fact that the structurally related compounds spirodiclofen and spiromesifen are not neurotoxic in adults or young.

iii. There is no evidence that spirotetramat results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

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

v. There are no registered or proposed uses of spirotetramat which could result in residential exposure.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

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 10% 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.

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

Spirotetramat is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to spirotetramat through food and water and will not be greater than the chronic aggregate risk.

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

Spirotetramat is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to spirotetramat through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*.Spirotetramat has been classified as ''Not Likely to be Carcinogenic to Humans.'' Spirotetramat is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that

no harm will result to the general population, or to infants and children from aggregate exposure to spirotetramat residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

If the method is not published in the Pesticide Analytical Manual, but has been approved by EPA, use the following:

Adequate enforcement methodology liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no CODEX or Mexican maximum residue limits (MRLs) for spirotetramat. Canadian MRLs have been established and are harmonized with the US.

C. Response to Comments

There were no comments received in response to the notice of filing.

D. Revisions to Petitioned-For Tolerances

Based on residue chemistry data submitted with this petition, several petitioned-for tolerances were revised, and it was considered necessary to establish a tolerance for milk. A chart listing the petitioned-for tolerances and EPA recommended tolerances can be found at *http://www.regulations.gov* in document *Spirotetramat Human Health Risk* Assessment for Proposed Uses on Citrus (Crop Group 10); Cucurbit Vegetables (Crop Group 9); Fruiting Vegetables (Crop Group 8); Grape (Crop Subgroup 13F); Hops; Leafy Brassica Vegetables (Crop Group 5); Leafy Non-Brassica Vegetables (Crop Group 4); Pome Fruit (Crop Group 11); Potato and Other Tuberous and Corm Vegetables (Crop Subgroup 1C); Stone Fruit (Crop Group 12); Tree Nuts (Crop Group 14); Onions; Strawberries; Livestock Commodities; and *Greenhouses/ Nurseries* page 65 in docket ID number EPA–HQ–OPP–2007–0475.

V. Conclusion

Therefore, tolerances are established for combined residues of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate]) and its metabolites BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), BYI 08330-ketohydroxy (cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro 4.5 decane-2,4-dione), BYI08330-enol-Glc (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro 4.5 dec-3-en-4-yl beta-D-glucopyranoside), and BYI 08330-mono-hydroxy (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 decan-2-one), calculated as spirotetramat equivalents, in or on the following commodities: Fruit, citrus, group 10 at 0.60 ppm; citrus, oil at 6.0 ppm; vegetable, leafy, except brassica, group 4 at 9.0 ppm; fruit, pome, group 11 at 0.70 ppm; fruit, stone, group 12 at 4.5 ppm; small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F at 1.3 ppm; grape, raisin at 3.0 ppm; strawberry at 0.40 ppm; onion, bulb, subgroup 3A-07 at 0.30 ppm; vegetable, fruiting, group 8 at 2.5 ppm; vegetable, cucurbit, group 9 at 0.30 ppm; brassica, head and stem, subgroup 5A at 2.5 ppm; brassica, leafy greens, subgroup 5B at 8.0 ppm; vegetable, tuberous and corm, subgroup 1C at 0.60 ppm; potato, flakes at 1.6 ppm; nut, tree, group 14 at 0.25 ppm; almond, hulls at 9.0 ppm; hop, dried cones at 10 ppm. Tolerances are also established for the combined residues of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro 4.5 dec-3-en-4-yl-ethyl carbonate) and its metabolite BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), calculated as spirotetramat equivalents, in/on the following livestock commodities: Milk at 0.01 ppm; cattle, meat at 0.02 ppm; cattle, fat at 0.02 ppm; cattle, meat byproducts at 0.02 ppm; goat, meat at 0.02 ppm; goat, fat at 0.02 ppm; goat, meat byproducts at 0.02 ppm; sheep, meat at 0.02 ppm; sheep, fat at 0.02 ppm; sheep, meat byproducts at 0.02 ppm; horse, meat at 0.02 ppm; horse, fat at 0.02 ppm; horse, meat byproducts at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 24, 2008.

Debra Edwards,

Director, 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. Section 180.641 is added to read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolites BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), BYI 08330-ketohydroxy (cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro 4.5 decane-2,4-dione), BYI08330-enol-Glc (cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro 4.5 dec-3-en-4-yl beta-D-glucopyranoside), and BYI 08330-monohydroxy (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 decan-2-one), calculated as spirotetramat equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	9.0
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy, subgroup 5B	8.0
Citrus, oil	6.0
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.70
Fruit, stone, group 12	4.5
Grape, raisin	3.0
Hop, dried cones	10.0
Nut, tree, group 14	0.25
Onion, bulb, subgroup 3A-07	0.3
Potato, flakes	1.6
Small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13-07F	1.3
Strawberry	0.40
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8	2.5
Vegetable, leafy, except Brassica, group 4	9.0
Vegetable, tuberous and corm, subgroup 1C	0.60

(2) Tolerances are also established for the combined residues of spirotetramat (cis-3-(2,5-dimethlyphenyl)-8-methoxy-2-oxo-1-azaspiro [4.5] dec-3-en-4-yl-ethyl carbonate) and its metabolite BYI 08330-enol (cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro 4.5 dec-3-en-2-one), calculated as spirotetramat equivalents, in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.02
Milk	0.01
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.02

(b) Section 18 emergency exemptions. [Reserved]

(c) Tolerances with regional registrations. [Resereved]

(d) Indirect or inadvertant residues. [Reserved]

[FR Doc. E8–15521 Filed 7–8–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0893; FRL–8370–9]

Sethoxydim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, in or on various oilseed commodities. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 2008, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0893. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

• Crop production (NAICS code 111).