TABLE 4 OF APPENDIX A—PROCEDURES FOR ESTIMATING S_o

If the estimated LOD (LOD_1, expected approximate LOD concentration level) is no more than twice the calculated LOD, use Procedure I as follows. Estimate the LOD (LOD_1) and prepare a test standard at this level. The test standard could consist of a dilution of the analyte described in Section 5.0.	If the estimated LOD (LOD_1, expected approximate LOD concentration level) is greater than twice the calculated LOD, use Procedure II as follows. Prepare two additional standards (LOD_2 and LOD_3) at concentration levels lower than the standard used in Procedure I (LOD_1).
Using the normal sampling and analytical procedures for the method, sample and analyze this standard at least 7 times in the laboratory.	Sample and analyze each of these standards (LOD_2 and LOD_3) at least 7 times.
Calculate the standard deviation, S_1, of the measured values	Calculate the standard deviation (S_2 and S_3) for each concentration level.
Calculate the LOD_0 (referred to as the calculated LOD) as 3 times S_1, where $S_0 = S_1$.	Plot the standard deviations of the three test standards (S_1, S_2 and S_3) as a function of concentration.
	Draw a best-fit straight line through the data points and extrapolate to zero concentration. The standard deviation at zero concentration is S_o.
	Calculate the LOD_0 (referred to as the calculated LOD) as 3 times S_o.

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[FR Doc. 2011–12058 Filed 5–17–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0263; FRL–8865–8]

Spirotetramat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spirotetramat, including its metabolites and degradates, in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 18, 2011. Objections and requests for hearings must be received on or before July 18, 2011, 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–2009–0263. All documents in the docket are listed in the docket index available at *http://www.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 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.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods & Guidelines."

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–2009–0263 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 July 18, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0263, 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 Facility'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. Summary of Petitioned-for Tolerance

In the **Federal Register** of June 10, 2009 (74 FR 27538) (FRL–8417–7), 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 9F7537) by Bayer CropScience LLC, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested 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 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 pistachio at 0.25 parts per million (ppm); cotton, undelinted seed at 0.4 ppm; acerola, atemoya, avocado, birida, black sapote, canistel, cherimoya, custard apple, feijoa, guava, ilama, jaboticaba, longan, mamey sapote, mango, passionfruit, persimmon, pulasan, rambutan, sapodilla, soursop, Spanish lime, star apple, starfruit, sugar apple, wax jambu, and white sapote at 1.5 ppm; vegetables, legume, group 06 (except soybean) at 4 ppm; plum, prune, dried at 4.5 ppm; vegetables, foliage of legume, except soybean, subgroup 07A at 5 ppm; cotton, gin byproducts at 7 ppm; soybean at 4 ppm; soybean, forage at 9 ppm; soybean, aspirated grain fractions at 10 ppm; lychee at 12 ppm; and soybean, hay at 16 ppm and okra at 2.5 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing. A correction notice was published in the **Federal Register** on July 23, 2009 (74 FR 36487) (FRL–8425–2), and August 21, 2009 (74 FR 42302) (FRL–8427–1), to add papaya at 1.5 ppm. There were no comments received in response to the correction notice.

In the **Federal Register** of October 26, 2009 (74 FR 54999) (FRL–8794–2) (docket number EPA–HQ–OPP–2009–0735), EPA also published a notice pursuant to section 3(c)(4) of the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA) as amended, announcing receipt of an application from Bayer CropScience to register new uses for Spirotetramat Technical and three end use products (EPA Registration Numbers 264–1049, 264–1050, 264–1051, 264–1065), on cotton; soybeans; vegetable, legume, crop group 6; acerola; atemoya; avocado; birida; black sapote; canistel; cherimoya; custard apple; feijoa; guava; Ilama; jaboticaba; longan; mamey sapota; mango; papaya; passionfruit; persimmon; pulasan; rambutan; sapodilla; soursop; Spanish lime; star apple; starfruit; sugar apple; wax jambu; white sapote; lychee; okra; pistachio; and dried prune. The Agency provided 30 days for the public to comment on this notice, and a comment dated November 25, 2009 was received from the Natural Resources Defense Council (NRDC), expressing concerns about both human health and environmental effects of spirotetramat. The heading of those comments referenced the **Federal Register** citation of October 26, 2009 (FRL–8794–2) for the Notice of Receipt (NOR) under FIFRA, but the docket number for this Notice of Filing (NOF) under the FFDCA (EPA–HQ–OPP–2009–0263). Although that comment was timely submitted for purposes of the NOR, it was not timely submitted for purposes of the present NOF. Nevertheless, the Agency has responded to the human health portion of the comments, which is relevant to the present NOF. The NRDC comment and the Agency's response to the human health portion of the comment can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2009–0263.

Based upon review of the data supporting the petition, EPA has revised the tolerance expression; and also revised the proposed tolerances on most of the commodities. In addition, EPA will be establishing import only tolerances for cotton, undelinted seed, and cotton gin byproduct at this time. 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 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 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 1-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 a 2-generation reproductive toxicity study. However, development of the sexual organs of offspring (balano-preputial separation, vaginal opening) was unaffected. In an investigative study designed to explore the time of onset of testicular toxicity in rats, decreased epididymal sperm counts were noted after 10 days of exposure. Similar effects were observed after repeated dosing with the enol metabolite of spirotetramat. 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 in/on Cotton, Legume Vegetables including Soybean (Crop Groups 6 and 7a), and Tropical Fruit"; Appendix A pp 39–47 in docket ID number EPA–HQ–OPP–2009–0263.

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 (LOC) 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 the NOAEL and the LOAEL of concern are identified. 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) (a = acute or c = chronic) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPIROTETRAMAT FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary ..... (General population including infants and children).	NOAEL = 100 milligrams/kilogram/day (mg/kg/day). UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day ..... aPAD = 1.0 mg/kg/day	Acute neurotoxicity (rat; gavage) LOAEL = 200 mg/kg/day based on clinical signs male and female (M&F) and decreased motor activity (M).
Chronic dietary ..... (All populations)	NOAEL= 5 mg/kg/day ..... UF_A = 10x ..... UF_H = 10x ..... FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day ..... cPAD = 0.05 mg/kg/day	Chronic toxicity (dog; dietary) LOAEL = 20 mg/kg/day based on thymus involution.
Cancer (Oral, dermal, inhalation) ..	Classification: "Not Likely to be Carcinogenic to Humans" based on lack of evidence of carcinogenicity in two oral rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor.

C. Exposure Assessment

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

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

Such effects were identified for spirotetramat. In estimating acute dietary exposure, EPA used food consumption information from the U.S. 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 Dietary Exposure Evaluation Model (DEEM™) (ver. 7.81) default processing factors were used for processed commodities. Drinking water was incorporated directly in the dietary assessment using the acute concentrations for surface water generated by the First Index Reservoir 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 PCT. Drinking water was incorporated directly in the dietary assessment using the chronic concentrations for surface water generated by the FIRST model.

iii. *Cancer.* No evidence of carcinogenicity was seen in the cancer studies performed with spirotetramat on rats and mice, and EPA has classified spirotetramat as "not likely" to be a human carcinogen by any relevant route of exposure. Therefore, an exposure assessment to evaluate cancer risk was not conducted.

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. Tolerance-level residues and 100 PCT were assumed for all food commodities. The chronic dietary assessment assumed average field-trial residues and 100 PCT.

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

Based on the FIRST, and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of spirotetramat 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.

For chronic exposures, 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.

For acute dietary risk assessment, the water concentration value of 0.212 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 1.37×10^{-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 Web site 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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of 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 except for an immunotoxicity study and a subchronic neurotoxicity study which are required due to recent amendments to the data requirements in 40 CFR part 158. Despite the absence of these studies, EPA has reliable data showing an additional safety factor is not necessary to protect infants and children. Although the toxicology database for spirotetramat shows effects in the thymus gland, an organ of the immune system, this finding does not raise uncertainty given the lack of an immunotoxicity study. The endpoint selected for risk assessment was based on accelerated thymus involution and decreased thyroid hormone levels in the dog. Thymus involution has been demonstrated to occur in animals when the thyroid is induced to decrease hormone levels, so it is reasonable to conclude that the thymus involution in these dogs was secondary to the thyroid effects, rather than a direct effect on the immune system. The dose at which these effects were observed was chosen as a point of departure because there was some consistency of dose and effect seen across the subchronic and chronic toxicity studies. However, the effects occurred in relatively few animals and thus selection of this endpoint is considered a very protective point of departure; it is at least tenfold lower than any other potential point of departure. With respect to immunotoxicity, no immunotoxic effects were seen in rats or mice, the species in which immunotoxicity studies are conducted. Thus, the Agency does not believe that conducting a functional immunotoxicity study in any rodent species will result in a lower POD than that currently used for overall risk assessment. For this reason and because the current POD is considered extremely protective, a UFDB is not

needed to account for the lack of this study. Data regarding neurotoxicity is discussed in Unit III. D.3.ii.

ii. EPA has concluded that spirotetramat is not a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Although a subchronic neurotoxicity study is now required as part of the revisions to 40 CFR part 158, the existing toxicological database indicates that spirotetramat is not a neurotoxic chemical in mammals. The only clinical signs at any dose in the acute neurotoxicity study were staining of the fur or perianal region with urine and decreased motor activity. The urine staining that was identified is not considered a neurotoxic effect and was likely due to a colored metabolite that was excreted into the urine or feces or to a change in the pH of the urine due to an excreted metabolite. The decreased motor activity observed is not considered evidence of neurotoxicity because there were no effects on movement or gait and there were no confirmatory findings of neurological pathology. Thus, both of these effects are considered signs of general toxicity (malaise). Further, the effects seen in the acute neurotoxicity study are not corroborated by any other study in the database. Although brain dilation was found in one dog in the 1-year dog study, EPA concluded that this effect was most likely not caused by administration of spirotetramat given evidence showing this to be a congenital anomaly in the test species, and because there is no other evidence of brain pathology in the database. Finally, the conclusion that spirotetramat is not a neurotoxic chemical is supported by the fact that the acute, subchronic and developmental neurotoxcity studies available for structurally-related compounds (spirodiclofen and spiromesifen) do not show evidence of neurotoxicity in adults or young.

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

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 or average field-trial residues. The submitted residue data for tropical fruit is not appropriate for the proposed use pattern as the trials were conducted at 2X use rate. The Agency is thus requesting that the petitioner conduct bridging studies with lychee and guava (one trial each with four samples per treatment regimen) in order to determine the relationship between residues resulting from the labeled use pattern and that used in the submitted field trials. Based on this relationship, the submitted residue data will be adjusted and the appropriate tolerances determined. As the recommended tolerances are based on exaggerated-rate field trial data, it is likely that any future adjustment of these tolerances will be to a lower level. This risk assessment is thus likely to over-estimate the dietary risk from spirotetramat residues in/on tropical fruit. Use of tolerance levels based on exaggerated application rates in a risk assessment will tend to overstate exposure even more than the overestimate usually supplied by use of the assumption of 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.

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 population adjusted dose (aPAD) and chronic population adjusted dose (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 11% 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 93% 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 short-term residential exposure. Therefore, the short-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.

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.* 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. Spirotetramat has been classified as "not likely" to be a human carcinogen by any relevant route of exposure and 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

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; e-mail 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. Canadian MRLs have been established and are harmonized with the United States.

C. Response to Comments

There were no timely comments received in response to the notice of filing. However, as described in Unit II, the NRDC did submit comments well after the close of the comment period on the notice of filing that pertain, in part, to the risk determinations made in this rulemaking. Both the comment and the Agency's response to the human health portion of the comment can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2009–0263.

In brief, NRDC challenged EPA's determination to remove the children's safety factor on two grounds. First, NRDC questioned whether EPA had accurately determined, based on several developmental studies, that the young did not demonstrate any quantitative sensitivity compared to adults. NRDC did not assert that the studies showed quantitative sensitivity but suggested that, given the wide dose spacing in the studies, if the studies had used a tighter dose spacing, they might have shown that maternal and fetal effects did not occur at the same dose. While NRDC makes an interesting theoretical point, the fact of the matter is that the best data available showed no sensitivity in the young and, more importantly, these data identify a clear NOAEL for the effects seen in the young. Thus, EPA has a reliable basis for choosing a safe dose that is protective of the safety of infants and children. A finding on the sensitivity of the young is not determinative by itself on the safety of the pesticide or on the applicability of the children's safety factor; rather, the fundamental question is whether there are reliable data on safety. Moreover, the impact of use of the wide dose spacing here compared to a narrower spacing of doses is likely to provide a larger margin of safety for infants and children. A tighter dose spacing may provide greater precision with regard to the level at which effects occur and do not occur in the maternal compared to the juvenile animals; however, to the extent these revised dose levels provide more precise information on the NOAEL, that NOAEL could only be higher (and potentially significantly higher given the wide dose spacing). Thus, the wide dose spacing may very well provide a lower POD (by overstating the NOAEL), and thus a more conservative basis, for assessing risk.

Second, NRDC argued that EPA did not adequately take into account the severity of the effects relating to the young seen in the spirotetramat database. NRDC cites malformations and skeletal defects in the rat developmental study, thyroid effects in the chronic dog study, neurotoxicity (staining of the fur with urine) in a rat study, and the potential that spirotetramat "may impair the synthesis of lipids that are necessary for the formation of cell membranes—including those of brain cells—and for hormone synthesis." EPA adequately considered each of these effects. As to the malformations and skeletal defects, EPA notes that while these effects are serious they occurred at a dose level 10,000 to 20,000 times higher than the safe dose level chosen by EPA. With regard to the thyroid effects, EPA believes that it took a very conservative approach to even treating the observed decrease in thyroid levels as an adverse effect given the absence of any corroborating signs of thyroid toxicity in the relevant studies. Notably, these studies show no decreases in thyroid weight, no thyroid histopathology, no compensatory increases in thyroid stimulating hormone (TSH), no effect on UDP-glucuronosyltransferase activity, and no clinical signs of toxicity or changes in body weight that might result from decreased thyroid output. In any event, there was a clear NOAEL for these minimal thyroid effects and EPA reduced this NOAEL by a 100X SF in deriving a safe dose for spirotetramat. Next, EPA disputes NRDC's claim that spirotetramat has neurotoxic effects. The staining of the fur seen in one study is not a neurotoxic effect but likely the result of the use of a colored metabolite in the study that was excreted in the urine. No other effects in the database could be corroborated as neurotoxic. Finally, NRDC's speculation that spirotetramat may interfere with the synthesis of lipids necessary to cell growth is not supported by the spirotetramat mammalian toxicity database. While spirotetramat does interfere with lipid biosynthesis in insects, the mammalian database shows no effects on plasma lipid parameters such as plasma triglycerides and plasma cholesterol which would be indicative of disruption of lipid biosynthesis in mammals.

D. Revisions to Petitioned-for Tolerances

Based on residue data submitted with this petition, several petitioned-for tolerances were revised. Additionally, as a result of the potential for increased dietary exposure to livestock, it was considered necessary to establish a tolerance for eggs and for meat byproducts of hog and poultry, and revise the tolerances on meat byproducts of cattle, goat, horse, and sheep. The proposed tolerance on dried prunes was not required as residues in the processed commodity are not expected to exceed the tolerance established for the raw agricultural commodity. A crop group tolerance on tropical fruits was not established because this is not a recognized crop group. Instead, tolerances on several individual tropical fruit commodities were established. Tolerances on sugar apple, atemoya, custard apple, cherimoya, ilama, soursop, and birida were not established, because field trial residue data were not submitted. 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 in/on Cotton, Legume Vegetables including Soybean (Crop Groups 6 and 7a), and Tropical Fruits" at page 47 in docket ID number EPA–HQ–OPP–2009–0263.

EPA has also revised the tolerance expression in paragraphs (a)(1) and (a)(2) to clarify that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of spirotetramat not specifically mentioned; and that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

EPA has also added a footnote to currently established tolerances for onion, bulb, subgroup 3A–07 and strawberry to indicate that currently there are no U.S. registrations for these commodities. Use on these two commodities was assessed for import tolerances only.

EPA is establishing import only tolerances for cotton, undelinted seed, and cotton gin byproducts at this time, because the use on cotton under FIFRA, 7 U.S.C. 136 *et seq.,* has not been approved. The Agency has concerns with potential hazard of toxicity to bees, and use on cotton cannot be approved

until these concerns have been addressed.

V. Conclusion

Therefore, tolerances are established for residues of spirotetramat, including its metabolites and degradates, in or on the commodities listed in the regulatory text. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat and its metabolites calculated as the stoichiometric equivalent of spirotetramat, in or on the commodities.

In addition, the proposed uses and the submitted data also support permanent tolerances for residues of the insecticide spirotetramat, including its metabolites and degradates, in or on the commodities listed in the regulatory text. Compliance with the tolerance levels is to be determined by measuring only the sum of spirotetramat and its metabolite, calculated as the stoichiometric equivalent of spirotetramat, in or on the commodities.

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

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerances 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) (Pub. L. 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: May 2, 2011.

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 180.641 is amended by revising paragraph (a) to read as follows:

§ 180.641 Spirotetramat; tolerances for residues.

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

Commodity	Parts per million
Acerola	2.5
Almond, hulls	9.0
Aspirated grain fractions	10.0
Avocado	0.60
Black sapote	0.60
Brassica, head and stem, subgroup 5A	2.5
Brassica, leafy, subgroup 5B	8.0
Canistel	0.60
Citrus, oil	6.0
Cotton gin byproducts[1]	10.0
Cotton, undelinted seed[1]	0.30
Feijoa	0.30
Fruit, citrus, group 10	0.60
Fruit, pome, group 11	0.70
Fruit, stone, group 12	4.5
Grape, raisin	3.0
Guava	2.5
Hop, dried cones	10.0
Jaboticaba	2.5
Longan	13.0
Lychee	13.0
Mamey sapote	0.60
Mango	0.60
Nut, tree, group 14	0.25
Okra	2.5
Onion, bulb, subgroup 3A–07[1]	0.30
Papaya	2.5
Passionfruit	2.5
Pistachio	0.25
Potato, flakes	1.6
Pulasan	13.0
Rambutan	13.0
Sapodilla	0.60

Commodity	Parts per million
Small fruit vine climbing subgroup, except fuzzy kiwifruit, subgroup 13–07F	1.3
Soybean forage	8.0
Soybean hay	16.0
Soybean seed	5.0
Spanish lime	0.60
Star apple	0.60
Starfruit	2.5
Strawberry[1]	0.40
Vegetable, cucurbit, group 9	0.30
Vegetable, foliage of legume, except soybean, subgroup 07A	7.0
Vegetable, fruiting, group 8	2.5
Vegetable, legume, group 06, except soybean	2.5
Vegetable, leafy, except brassica, group 4	9.0
Vegetable, tuberous and corm, subgroup 1C	0.60
Wax jambu	2.5
White sapote	0.60

[1] Import tolerance only. There are no U.S. registrations for cotton, onion or strawberry.

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

Commodity	Parts per million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts	0.20
Eggs	0.02
Goat, fat	0.02
Goat, meat	0.02
Goat, meat byproducts	0.20
Hog, meat byproducts	0.02
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts	0.20
Milk	0.01
Poultry, meat byproducts	0.02
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts	0.20

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[FR Doc. 2011–11937 Filed 5–17–11; 8:45 am]

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