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: April 20, 2010.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.474 is amended by revising the introductory text of paragraphs (a)(1), (a)(2), and (c) and alphabetically add the commodity "vegetable, fruiting, group 8" to the table in paragraph (a)(1) to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol), in or on the commodity.

Commodity	Parts per million
* *	* * *
Vegetable, fruiting, group 8	1.3
* *	* * *

(2) Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) and its diol metabolite (1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol), calculated as the stoichiometric equivalent of tebuconzole, in or on the commodity.

* * * * *

(c) *Tolerances with Regional Registrations.* Tolerances are established for residues of the fungicide tebuconazole, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only tebuconazole, alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol, in or on the commodity.

* * * * *

[FR Doc. 2010–10406 Filed 5–4–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0139; FRL–8820–4]

Spirodiclofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spirodiclofen per se (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate) 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 5, 2010. Objections and requests for hearings must be received on or before July 6, 2010, 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–2009–0139. 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 cite at *http://www.gpoaccess.gov/ecfr.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2009–0139 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 6, 2010. 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 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–2009–0139, 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. Petition for Tolerance

In the **Federal Register** of June 10, 2009 (74 FR 27538) (FRL–8915–5), 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 8F7500) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, N.C. 27709. The petition requested that 40 CFR 180.608 be amended by establishing tolerances for residues of the insecticide spirodiclofen,(3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate), in or on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple at 1.3 parts per million (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.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances to 1.0 ppm; and changed the tolerance expression to spirodiclofen per se (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate). 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 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 spirodiclofen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spirodiclofen 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.

Spirodiclofen has a low acute toxicity via the oral, dermal, and inhalation routes. It is not an eye or dermal irritant. However, it is a potential skin sensitizer. Following oral administration, spirodiclofen is rapidly absorbed, metabolized, and excreted via urine and feces. A rat whole body autoradiography study showed no accumulation in any specific organs or tissues following oral administration. Evidence of developmental toxicity was not observed in the rabbit developmental toxicity study. The rat

developmental toxicity study resulted in an increased incidence of slight dilatation of the renal pelvis 1,000 milligrams/kilograms/day (mg/kg/day); highest dose tested (HDT) at a dose which did not cause maternal toxicity. In the 2-generation reproductive toxicity study, developmental effects were observed in F1 males (i.e., delayed sexual maturation, decreased testicular spermatid and epididymal sperm counts (oligospermia); and atrophy of the testes, epididymides, prostate, and seminal vesicles) and F1 females (i.e., increased severity of ovarian luteal cell vacuolation/degeneration) but at a higher dose (1,750 ppm) than the systemic effects seen for parents and offspring (350 ppm). Spirodiclofen did not show any evidence of neurotoxicity in the acute and subchronic neurotoxicity studies. In a developmental neurotoxicity study (DNT), a decrease in retention was observed in the memory phase of the water maze for postnatal day (PND) 60 females at all doses. In this DNT study, the morphometric measurements were not performed at the low- and mid-doses; therefore, the registrant conducted a new study using identical experimental conditions as the previous study. The results of the new study demonstrated no treatment related maternal or offspring toxicity at the HDT. Therefore, it can be concluded that spirodiclofen is unlikely to be a neurotoxic or developmentally neurotoxic compound.

Spirodiclofen has been shown to have adverse effects on several organs of the endocrine system at relatively low doses. Testicular effects were observed in dogs, rats, and mice, manifested as Leydig cell vacuolation in dogs, hypertrophy in dogs and mice, and hyperplasia progressing to adenomas in rats, following chronic exposure. In female rats, increased incidence of uterine nodules and uterine adenocarcinoma were observed at terminal sacrifice in the chronic toxicity study. Cytoplasmic vacuolation in the adrenal cortex, accompanied by increased adrenal weight, was consistently observed in rats, dogs, and mice of both sexes.

Chronic toxicity and carcinogenicity studies showed increased incidence of uterine adenocarcinoma in female rats, Leydig cell adenoma in male rats, and liver tumors in mice. EPA classified spirodiclofen as "likely to be carcinogenic to humans" by the oral route based on evidence of testes Leydig cell adenomas in male rats, uterine adenomas and/or adenocarcinoma in female rats, and liver tumors in mice. Mutagenicity studies conducted with the technical spirodiclofen formulation and its major metabolites did not demonstrate any mutagenic potential. EPA has determined that quantification of human cancer risk using a linear low-dose extrapolation approach is appropriate.

Specific information on the studies received and the nature of the adverse effects caused by spirodiclofen 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 "Human Health Risk Assessment Associated with the Section 3 Registration Application for Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple," p.10 in docket ID number EPA–HQ–OPP–2009–0139.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for spirodiclofen used for human risk assessment can be found at *http://www.regulations.gov* in document "Human Health Risk Assessment Associated with the Section 3 Registration Application for Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple," p. 12 in docket ID number EPA–HQ–OPP–2009–0139.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to spirodiclofen, EPA considered exposure under the petitioned-for tolerances as well as all existing spirodiclofen tolerances in 40 CFR 180.608. EPA assessed dietary exposures from spirodiclofen 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.

No such effects were identified in the toxicological studies for spirodiclofen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Survey of Food Intake (CSFII). As to residue levels in food, EPA assumed the following:

a. Average field trial residues;

b. Experimentally determined processing factors for apple and grape processed commodities and for citrus oil, peeled citrus, and citrus peel (DEEM (ver 7.81) defaults assumed for the remaining processed commodities); and

c. Maximum reasonably balanced livestock diets.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has classified spirodiclofen as "Likely to be Carcinogenic to Humans" and used a linear approach to quantify cancer risk. Exposure for evaluating cancer risk was assessed using the same estimates as discussed in Unit III.C.1.ii.

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. Average field trial residues were assumed for chronic and cancer analysis.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition A: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition B: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition C: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Hop (92%), pome fruit (15%), stone fruit (10%), grape (7%), and citrus (14%).

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition A, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions B and C, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which spirodiclofen may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for spirodiclofen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spirodiclofen. 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 PRZM/EXAMS and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of spirodiclofen for chronic exposures for non-cancer assessments are estimated to be 4.99 ppb for surface water and 0.44 ppb for ground water. The EDWCs of spirodiclofen for chronic exposures for cancer assessments are estimated to be 1.67 ppb for surface water and 0.44 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value 4.99 ppb was used to assess the contribution to drinking water.

For cancer dietary risk assessment, the water concentration of value 1.67 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).

Spirodiclofen 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 spirodiclofen to share a common mechanism of toxicity with any other substances, and spirodiclofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spirodiclofen 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*. The spirodiclofen toxicity database is adequate to evaluate the potential increased susceptibility of infants and children. In 2004, the Agency determined that there is no evidence (qualitative or quantitative) of increased

susceptibility in the rabbit developmental toxicity study or in the rat reproduction toxicity study following *in utero* and/or pre-/post-natal exposure of spirodiclofen. However, evidence for quantitative susceptibility was observed in a rat developmental toxicity study where an increased incidence of slight dilatation of the renal pelvis was observed at a dose (1,000 mg/kg/day; the limit dose) which did not cause any maternal toxicity. Two rat developmental neurotoxicity (DNT) studies were submitted to EPA following the assessment in 2004. The first study demonstrated increased susceptibility in the offspring based on the observed decreased retention in the memory phase of the water maze for postnatal day 60 females at all doses (LOAEL 6.5 mg/kg/day) and changes in brain morphometric parameters at the HDT (135.9 mg/kg/day; caudate putamen, parietal cortex, hippocampal gyrus, and dentate gyrus); there was no maternal toxicity at doses up to and including 135.9 mg/kg/day HDT. EPA requested information concerning the brain morphometric parameters in the low and mid doses with the petitioner indicating that the brain tissues were not appropriately preserved and analysis was therefore not possible. As a result, a second rat DNT study was submitted which also indicated increased susceptibility in offspring based on decreased pre-weaning body weight and body weight gain in males and females and decreased post-weaning body weights in males (LOAEL = 119.2 mg/kg/day; NOAEL = 28.6 mg/kg/day). Neurotoxicity was not observed in offspring in the second DNT study, and there was no maternal toxicity observed at doses up to and including 119.2 mg/kg/day.

EPA determined that the degree of concern is low for the quantitative susceptibility seen in the developmental toxicity study in rats. The increased incidence of slight renal pelvic dilation was observed at the limit-dose only without statistical significance and dose response. Renal pelvic dilation was considered to be a developmental delay and not a severe effect for developmental toxicity. The low background incidences in this study may be idiosyncratic to the strain of rats tested (Wistar), since renal pelvis dilations are commonly seen at higher incidences in other strains (Sprague-Dawley or Fisher) of rats. In addition, doses selected for risk assessment of spirodiclofen are much lower than the dose that caused these developmental delays. The two DNT studies suggest increased susceptibility of offspring due to exposure to spirodiclofen. However, there is no concern for the increased susceptibility seen in the first DNT study because the results were not reproduced in the second DNT study conducted using the identical doses and experimental conditions. The concern for increased susceptibility in the second DNT study is low because there is a well established NOAEL, marginal toxicity (slight changes in body weights), and all developmental/functional parameters were comparable to controls. In addition, doses selected for risk assessment of spirodiclofen are much lower than the dose that caused these marginal changes in the body weights of offspring in the second DNT study. There was no evidence of increased susceptibility in the developmental toxicity study in rabbits or the 2-generation reproduction study in rats.

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 spirodiclofen is complete except for an immunotoxicity study which is required as a part of new data requirements in the 40 CFR part 158. However, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. The toxicology database for spirodiclofen does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not target the immune system. Therefore, a database uncertainty factor (UFDB) is not needed to account for the lack of this study.

ii. Based on the results of acute, subchronic and developmental neurotoxicity studies in rats (see Units III.A. and III.D.2.), EPA has concluded that there is no indication that spirodiclofen is a neurotoxic chemical.

iii. There is no evidence (qualitative or quantitative) of increased susceptibility in the rabbit developmental toxicity study or in the rat reproduction toxicity study following *in utero* and/or pre-/post-natal exposure of spirodiclofen. However, evidence for quantitative susceptibility was observed in a rat developmental toxicity study and the second DNT study. See Unit III.D.2. for a detailed discussion of why EPA determined that the degree of concern is low for the quantitative susceptibility seen in this studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using reliable PCT information and anticipated residue values calculated from residue field trial results. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to spirodiclofen in drinking water. Residential exposures are not expected. These assessments will not underestimate the exposure and risks posed by spirodiclofen.

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*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, spirodiclofen is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spirodiclofen from food and water will utilize 3.3% of the cPAD for all infants < 1 year old the population group receiving the greatest exposure. There are no residential uses for spirodiclofen.

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

Spirodiclofen is not registered for any uses that would result in residential exposure. Therefore the short-term/intermediate-term aggregate risk is the sum of the risk from exposure to spirodiclofen through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions described in Unit III.C.1.iii. for cancer, EPA has concluded that exposure to spirodiclofen to cancer from

food and water will result in a life-time cancer risk of 3 x 10^{-6}. EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3 x 10^{-7} and 3 x 10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above in this Unit, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3 x 10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. For the reasons explained below in this Unit, EPA concludes that there are significant conservatisms in the spirodiclofen exposure assessment. First, residue values are based on average field trial levels and not monitoring data. Monitoring data tends to be significantly lower than field trial data and the spirodiclofen monitoring data confirms this (all less than the limit of detection (LOD); LOD = 0.001-0.05 ppm; 2.5-23x lower than the residue used in the cancer assessment). Second, based on a critical commodity analysis conducted in DEEM-FCID, the major contributors to the cancer risk were hops (40% of the total exposure), water (19% of the total exposure), and orange juice (16% of the total exposure) and conservative residue estimates were used for these three commodities as follows:

i. *Hops.* Dietary exposure from hops is the result of beer consumption. DEEM-FCID assumes that 100% of the residue in hops are transferred to beer during the brewing process (no residue remain in/on the spent hops). Since spirodiclofen has low water solubility, this is a conservative assumption;

ii. *Drinking water.* The water residue estimate assumed 87% of the basin is cropped with 100% of the crops treated. Spirodiclofen is proposed/registered for application to orchard crops (pome fruit, citrus fruit, stone fruit, tree nuts, grape, and tropical fruits) which are unlikely to occupy 87% of a water basin. In addition, it is unlikely that spirodiclofen will capture the entire market within a water basin.

iii. *Orange juice.* Pending the submission of a new orange processing study, default grapefruit (2.1x), lemon (2.0x), lime (2.0x), orange (1.8x), and tangerine (2.3x) juice processing factors were assumed. In all likelihood this exaggerates exposure estimates given that grape and apple processing studies with spirodiclofen resulted in a reduction in residues in juice.

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 spirodiclofen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a liquid chromatography (LC)/mass spectrometry (MS)/(MS) method) 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, Canadian, or Mexican maximum residue limits (MRLs) in/on these crops.

C. Response to Comments

There were no comments received in response to the notice of filing of the pesticide petition 8F7500.

D. Revisions to Petitioned-For Tolerances

EPA has revised the proposed tolerance levels and tolerance expression of spirodiclofen in/on the following commodities: Avocado from 1.3 ppm to 1.0 ppm; black sapote from 1.3 ppm to 1.0 ppm; canistel from 1.3 ppm to 1.0 ppm; mamey sapote from 1.3 ppm to 1.0 ppm; mango from 1.3 ppm to 1.0 ppm; papaya from 1.3 ppm to 1.0 ppm; sapodilla from 1.3 ppm to 1.0 ppm; and star apple from 1.3 ppm to 1.0 ppm. Based on review of the residue chemistry data submitted in support of this petition, EPA concluded that 1.0 ppm tolerance for residues of spirodiclofen per se in/on these crops is appropriate.

V. Conclusion

Therefore, tolerances are established for residues of spirodiclofen per se, (3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate), in or on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple at 1.0 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, 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 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: April 20, 2010.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In § 180.608, alphabetically add the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.608 Spirodiclofen; tolerances for residues.

(a) General. (1) * * *

Commodity	Parts per million
* * * * *	
Avocado	1.0
Black sapote	1.0
Canistel	1.0
* * * * *	
Mamey sapote	1.0
Mango	1.0
* * * * *	
Papaya	1.0
* * * * *	
Sapodilla	1.0
Star apple	1.0

* * * * *

[FR Doc. 2010–10129 Filed 5–4–10; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 300–3, 301–10, 301–51, 301–52, 301–70, 301–75, Appendix C to Chapter 301, 302–6, and 302–9

[FTR Amendment 2010–02; FTR Case 2010–302; Docket Number 2010–0010, sequence 1]

RIN 3090–AJ02

Federal Travel Regulation (FTR); Transportation in Conjunction With Official Travel and Relocation

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Travel Regulation (FTR), by adding new terms and definitions for "Official travel" and "Transit system"; clarifies reimbursement for transportation at an official station while en route to and/or from an authorized temporary duty (TDY) location; clarifies reimbursement for transportation expenses within the surrounding area of a TDY location and provisions for payment under the FTR; and clarifies when the Government contractor-issued travel charge card must be used while on official travel. Clarification of this rule is addressed in the supplementary information below.

DATES: *Effective date:* This final rule is effective June 4, 2010. *Applicability date:* This final rule is applicable to travel performed on and after June 4, 2010.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat (MVCB), Room 4041, GS Building, Washington, DC 20405, (202) 501–4755, for information pertaining to status or publication schedules. For clarification of content, contact Rick Miller, Office of Governmentwide Policy, at (202) 501–3822 or e-mail at *rodney.miller@gsa.gov.* Please cite FTR Amendment 2010–02, FTR case 2010–302.

SUPPLEMENTARY INFORMATION:

A. Background

Title 5, United States Code § 5707 (5 U.S.C. 5707), authorizes the Administrator of General Services to prescribe necessary regulations to implement laws regarding Federal employees who are traveling while in the performance of official business away from their official stations. Similarly, 5 U.S.C. 5738 mandates that the Administrator of General Services prescribe regulations relating to official relocation. The overall implementing authority is the Federal Travel Regulation (FTR), codified in Title 41 Code of Federal Regulations, Chapters 300–304 (41 CFR chapters 300–304). Expenses incurred at an employee's official station not in conjunction with TDY and/or relocation do not fall under the authority of the FTR. Therefore, this final rule adds terms and definitions for "Official travel" and "Transit system" and also removes references to "local travel," "local transit system," "local transportation," "local transportation system," "local telephone calls," and "local metropolitan transportation fares," for reimbursement that is not in conjunction with TDY and/or relocation. Federal employees should adhere to their agency's policies for reimbursement of expenses incurred for transportation within the vicinity of their official stations when expenses do not pertain to TDY or relocation. This final rule clarifies that the Government contractor-issued travel charge card will only be used for the purposes of official travel-related expenses and not for personal use while on an official travel authorization.

B. Executive Order 12866

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This final rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the revisions are not considered substantive. This final rule is also exempt from the Regulatory Flexibility Act per 5 U.S.C. 553(a)(2) because it applies to agency management.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the FTR do not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*