B. International Residue Limits

There are currently no U.S. or international Codex tolerances established for pyridalyl.

C. Revisions to Petitioned-For Tolerances

Based on its review of submitted crop field trial data, EPA determined that the proposed tolerances for *Brassica* head and stem, subgroup 5A; and for fruiting vegetables, group 8 should be reduced to 3.5 and 1.0 ppm, respectively. The Agency determined also that the data were not sufficient to support the proposed tolerance for Brassica leafy greens, subgroup 5B; although a mustard green tolerance at 30 ppm was supported by the data.

V. Conclusion

Therefore, tolerances are established for residues of pyridalyl *per se*, in or on vegetables, leafy, except *Brassica*, group 4 at 20 ppm; *Brassica*, head and stem, subgroup 5A at 3.5 ppm; vegetables, fruiting, group 8 at 1.0 ppm; mustard greens at 30 ppm; and turnip greens at 30 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 23, 2008.

Debra Edwards,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.640 is added to read as follows:

180.640 Pyridalyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of pyridalyl, pyridine,2-[3-[2,6-dichloro-4-[(3,3-dichloro-2-propenyl)oxy]phenoxy]propoxy]-5-(trifluoromethyl, in or on the following raw agricultural commodities:)

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	3.5
Mustard greens	30
Turnip greens	30
Vegetable, fruiting, group 8	1.0
Vegetables, leafy, except *Brassica*, group 4	20

(b) *Section 18 emergency exemption*. [Reserved]

(c) *Tolerances with regional registration*. [Reserved]

(d) *Indirect or inadvertent residues*. [Reserved]

[FR Doc. E8–9823Filed 5–6–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0398; FRL–8362–2]

Spirodiclofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of spirodiclofen in or on hop, dried cones. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 7, 2008. Objections and requests for hearings must be received on or before July 7, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also

Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0398. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

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

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

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

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0398 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before July 7, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0398, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL–8134–9), 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 7E7204) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.608 be amended by establishing tolerances for residues of the insecticide/miticide spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate, in or on hop, dried cones at 30 parts per million (ppm). That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of spirodiclofen on hop, dried cones at 30 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Spirodiclofen has a low acute toxicity via oral, dermal or 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. The most sensitive target organ of spirodiclofen is the adrenal gland. Adrenal effects (e.g., increased adrenal weights, increased incidence and severity of small cytoplasmic vacuolation in the cortex of adrenal glands) were observed in rats, dogs and mice with the dog being the most sensitive species.

There was no evidence of neurotoxicity in the acute neurotoxicity study in rats. In the subchronic neurotoxicity study in rats, functional-observational-battery (FOB) effects and decreased motor and locomotor activities were observed in females at the high dose only. The effects were considered to be due to the large decrease in body weight in these animals. In one of two developmental neurotoxicity (DNT) studies in rats, a decrease in retention (memory) was observed in the postnatal day (PND) 60 females only. These effects were not seen in a repeated DNT study conducted using the same doses and experimental conditions.

There was no evidence (qualitative or quantitative) of increased susceptibility in the rabbit developmental toxicity study or the rat reproduction toxicity study following *in utero* or postnatal exposure to spirodiclofen. However, evidence of 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 milligrams/kilogram/day (mg/kg/day)) which did not cause any maternal toxicity. The results of the two DNT studies for spirodiclofen also suggest increased susceptibility. In the first study, memory and brain morphometric differences were observed at doses that did not result in maternal toxicity. While these effects were not seen in the second DNT study, body weight changes were seen at non-maternally toxic doses.

EPA has classified spirodiclofen as ''likely to be carcinogenic to humans'' by the oral route of exposure, based on evidence of testes Leydig cell adenomas in male rats, uterine adenomas and/or adenocarcinoma in female rats, and liver tumors in mice. 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 the document *Spirodiclofen. Petition No. 7E7204. Human Health Risk Assessment for Use on Hops* at pages 45–48 in docket ID number EPA–HQ–OPP–2007–0398.

B. Toxicological Endpoints

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

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for spirodiclofen used for human risk assessment can be found at *http://www.regulations.gov* in the document *Spirodiclofen. Petition No. 7E7204. Human Health Risk Assessment for Use on Hops* at page 34 in docket ID number EPA–HQ–OPP–2007–0398.

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 CSFII. As to residue levels in food, EPA assumed that all food commodities contain residues at the average field trial level. EPA also assumed average field trial residues for feed commodities in calculating anticipated livestock dietary burdens and anticipated residues in meat and milk. Residue estimates were further refined using available experimentally-derived processing factors as well as projected percent crop treated (PPCT) information for several crops.

iii. *Cancer*. EPA has classified spirodiclofen as ''likely to be carcinogenic to humans'' by the oral route of exposure and determined that quantification of human cancer risk

using a linear low-dose extrapolation approach is appropriate. Cancer risk was assessed using the same exposure assumptions as discussed in Unit III.C.1.ii. above.

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.

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 used projected percent crop treated (PPCT) information for the new crop (hops) as well as several currently registered crops (apples, grapes, oranges and peaches). Since spirodiclofen has only been registered on these crops since 2005, PCT estimates based on actual usage data were not deemed sufficient indicators of potential usage on currently registered crops. The Agency used PPCT information as follows: Hops 92%; apples 15%; grapes 7%; oranges (except temple) 14%; peaches 10%.

EPA estimates PPCT for spirodiclofen use by assuming that the PCT during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the dominant or market leader pesticide (i.e. the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide types (i.e., the dominant insecticide on the use site is selected for comparison with the new insecticide/miticide). Since spirodiclofen is a miticide, EPA identified miticides that are the market leaders to project PCT. Petroleum distillate and petroleum oil were excluded as market leaders and the next miticide market leader was chosen. The PCTs included in the average may be for the same pesticide or for different pesticides, since the same or different pesticides may dominate for each year selected. Typically, EPA uses U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data, because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

These estimated PPCTs, based on the average PCT of the market leaders, are appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the PPCT could be exceeded are whether the new pesticide use or new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide(s). All relevant information currently available regarding the predominant factors has been considered for the use of spirodiclofen on hops; oranges, except temple; grapes, all; peaches; and apples; and it is unlikely that these spirodiclofen uses will exceed the estimated PPCTs during the next 5 years, because the target pest range of the market leaders is generally broader than spirodiclofen's, often including both insect and mite pests. Furthermore, the Agency has received no Section 18 emergency exemption requests for spirodiclofen and there are no readily discernible resistance issues with target pest mites, which might indicate an increased need for spirodiclofen on these crops.

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 Pesticide Root Zone Model/Exposure Analysis Modeling System (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 parts per billion (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 prenatal and postnatal toxicity database for spirodiclofen includes prenatal developmental toxicity studies in rats and rabbits, a 2–generation reproduction toxicity study in rats and two developmental neurotoxicity (DNT) studies in rats. There was no evidence (qualitative or quantitative) of increased susceptibility in the rabbit developmental toxicity study or the rat reproduction toxicity study following *in utero* or postnatal exposure to spirodiclofen. However, evidence of quantitative susceptibility was observed in the 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) which did not cause any maternal toxicity. The results of the two available DNT studies for spirodiclofen also suggest increased susceptibility. In the first study, memory and brain morphometric differences were observed at doses that did not result in maternal toxicity. While these effects were not seen in the second DNT study, body weight changes were seen at non-maternally toxic doses.

The degree of concern is low for the quantitative susceptibility seen in the prenatal developmental and DNT studies in the rat for the following reasons:

The renal pelvic dilation seen in the rat developmental toxicity study was slight and observed only at the limit dose without statistical significance or dose response. Renal pelvic dilation was considered to be a developmental delay and not a severe developmental effect. The low background incidence of renal pelvic dilations seen in this study may be idiosyncratic to this strain (Wistar) of rats, since they are commonly seen at higher incidences in other strains (Sprague-Dawley or Fisher). In addition, doses selected for risk assessment of spirodiclofen are much lower than the dose that caused these developmental delays.

The degree of concern for the increased susceptibility seen in the second DNT study is also low, because there is a well established NOAEL, the toxicity is marginal (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.

In the first DNT study, no significant differences were noted between treated and control groups in reproductive parameters (litter size, sex ratio, number of deaths, live birth, viability and lactation), and no treatment-related clinical signs were observed at any dose in either sex. No treatment-related differences in functional observational battery (FOB), motor activity or locomotor activity were observed during the pre-weaning and post-weaning periods; and no treatment-related differences in the passive avoidance tests were observed at any dose. The trials to criterion for the memory phase of the water maze test showed a treatment-related effect at all doses for postnatal day (PND) 60 females. The memory effects occurred only in adults and were not seen in younger animals; therefore, these effects do not raise a concern for susceptibility.

On postmortem examination, differences in certain morphometric measurements (caudate putamen, parietal cortex, hippocampal gyrus and dentate gyrus) were observed at the high dose, the only dose for which morphometric measurements were made. The magnitude of these effects was minute but statistically significant. The lack of measurements at the mid- and low doses precluded establishment of a clear NOAEL or a determination as to the toxicological significance of these minor changes at the high dose. Therefore, EPA requested similar morphometric analyses at the mid- and low doses in both sexes. Since inappropriate preservation of brain tissues from the first study precluded additional morphometric analyses, the registrant elected to conduct a second DNT study using the same doses and experimental conditions. The morphometric differences observed in the first DNT study were not seen in the second study. EPA has no concern for the increased susceptibility seen in the first DNT study because:

- The magnitude of the morphometric changes was minor.
- They occurred at the high dose; the doses selected for risk assessment are significantly lower than the dose at which these effects were seen.
- No other neurotoxic effects were observed in young pups in the first DNT study.
- The results were not reproduced in the second study conducted using identical doses and experimental conditions. The results of the second study suggest that the findings in the first study are spurious and not toxicologically significant.

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 for chronic dietary exposures, the only exposures considered in this risk assessment, since an acute dietary endpoint has not been identified for spirodiclofen and there are no residential uses that would result in short-term or intermediate-term non-dietary exposures. The decision to reduce the FQPA SF to 1X for chronic dietary exposures is based on the following findings:

i. The toxicity database for spirodiclofen is complete.

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 spirodiclofen is unlikely to be a neurotoxic or developmentally

neurotoxic compound and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was no evidence (qualitative or quantitative) of increased susceptibility in the rabbit developmental toxicity study or the rat reproduction toxicity study following *in utero* or postnatal exposure to spirodiclofen. The degree of concern is low for the quantitative susceptibility seen in the prenatal developmental and DNT studies in the rat, and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of spirodiclofen.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were refined using reliable PPCT 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 3.2% of the cPAD for infants less than 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 exposures take into account short-term and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Spirodiclofen is not registered for any use patterns 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 from food and water will result in a lifetime cancer risk of 3×10^{-6} for the U.S. population.

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 3.16×10^{-7} and 3.16×10^{-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, cancer risk should generally not be assumed to exceed the benchmark LOC of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. Since the calculated cancer risk for spirodiclofen does not exceed this level, estimated cancer risk is considered to be negligible.

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

No maximum residue limits (MRLs) have been established by Canada, Mexico or Codex for spirodiclofen on hops.

V. Conclusion

Therefore, a tolerance is established for residues of spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutanoate, in or on hop, dried cones at 30 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of

power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this rule. In addition, This 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 24, 2008.

Donald R. Stubbs,

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 180.608 is amended by alphabetically adding the following commodity to the table in paragraph (a)(1) to read as follows:

§ 180.608 Spirodiclofen; tolerances for residues.

(a) * * *.

(1) * * *

Commodity	Parts per million
* * *	* *
Hop, dried cones	30
* * *	* *

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[FR Doc. E8–9826 Filed 5–6–08; 8:45 am]

BILLING CODE 6560–50–S

GENERAL SERVICES ADMINISTRATION

41 CFR Part 302–17

[FTR Amendment 2008–03; FTR Case 2008–302; Docket 2008–002, Sequence 1]

RIN 3090–AI48

Federal Travel Regulation; Relocation Income Tax (RIT) Allowance Tax Tables—2008 Update

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

ACTION: Final rule.

SUMMARY: This rule updates the Federal, State, and Puerto Rico tax tables for calculating the relocation income tax (RIT) allowance, to reflect changes in Federal, State, and Puerto Rico income tax brackets and rates. The Federal, State, and Puerto Rico tax tables contained in this rule are for use in calculating the 2008 RIT allowance for tax year 2007 to be paid to relocating Federal employees.

DATES: Effective Date: This final rule is effective on May 7, 2008.

Applicability date: January 1, 2008.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat (VIR), Room 4035, GSA Building, Washington, DC 20405, telephone (202)208–7312, for information pertaining to status or publication schedules. For clarification of content, contact Ed Davis, Office of Governmentwide Policy, Travel Management Policy (MTT), Washington, DC 20405, telephone (202) 501–4755. Please cite FTR Amendment 2008–03, FTR case 2008–302.

SUPPLEMENTARY INFORMATION:

A. Background

Section 5724b of Title 5, United States Code, provides for reimbursement of substantially all Federal, State, and local income taxes incurred by a transferred Federal employee on taxable moving expense reimbursements. Policies and procedures for the calculation and payment of the RIT allowance are contained in the Federal Travel Regulation (41 CFR part 302–17). GSA updates Federal, State, and Puerto Rico tax tables for calculating RIT allowance payments yearly to reflect changes in Federal, State, and Puerto Rico income tax brackets and rates.

This amendment also provides a tax table necessary to compute the RIT allowance for employees who received reimbursement for relocation expenses in previous years.

B. Executive Order 12866

This regulation is excepted from the definition of ''regulation'' or ''rule'' under Section 3(d)(3) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993 and, therefore, was not subject to review under Section 6(b) of that Executive Order.

C. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment as per the exemption specified in 5 U.S.C. 553(a)(2); therefore, the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does 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.

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Part 302–17

Government employees, Income taxes, Relocation allowances and entitlements, Transfers, Travel and transportation expenses.

Dated: May 1, 2008.

David L. Bibb,

Acting Administrator of General Services.

■ For the reasons set forth in the preamble, under 5 U.S.C. 5738, GSA amends 41 CFR Part 302–17 as set forth below:

PART 302–17—RELOCATION INCOME TAX (RIT) ALLOWANCE

■ 1. The authority citation for 41 CFR Part 302–17 is revised to read as follows: