Subpart SS—Texas

■ 2. In § 52.2270, the second table in paragraph (e) entitled ''EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Texas SIP'' is amended by revising the entry for ''Approval of the Speed Limits Local Initiative Measure in the DFW nine county area.''

The revision reads as follows:

§ 52.2270 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Comments
* *	* *	*	* *	*
Approval of the Speed Limits Local Initiative Measure in the DFW nine county area. Affected counties are Dallas, Tarrant, Collin, Denton, Parker, Johnson, Ellis, Kaufman, Rockwall.	Dallas-Fort Worth	9/16/2010	1/9/2014 [Insert *FR* page number where document begins].	Recategorized as a Transportation Control Measure.
* *	* *	*	* *	*

[FR Doc. 2014–00047 Filed 1–8–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0909; FRL–9904–70]

Tolfenpyrad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tolfenpyrad in or on multiple commodities which are identified and discussed later in this document. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 9, 2014. Objections and requests for hearings must be received on or before March 10, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0909, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–0001; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0909 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 March 10, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0909, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any

information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 02, 2012 (77 FR 25954) (FRL–9346–1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7791) by Nichino America, Inc., 4550 New Linden Hill Rd., Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the insecticide tolfenpyrad (4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolyloxy) benzyl] pyrazole-5-carboxamide, in or on head lettuce at 5 ppm; leaf lettuce at 30 ppm; leaf petioles, subgroup 4B at 12.5 ppm; spinach at 24 ppm; *Brassica,* head and stem, subgroup 5A at 3.6 ppm; *Brassica,* leafy, subgroup 5B at 44 ppm; vegetable, fruiting group 8 at 0.6 ppm; potatoes at 0.04 ppm; nut, tree group 14 (including pistachio) at 0.04 ppm; almond, hulls at 5.0 ppm; fruit, pome, group 11 at 0.6 ppm; apple, wet pomace at 5.0 ppm; vegetable, cucurbit, group 9 at 0.8 ppm; fruit, stone, group 12 at 3.0 ppm; pomegranates at 3.0 ppm; persimmons at 3.0 ppm; citrus, group 10 at 1.0 ppm; citrus, pulp, dried at 2.0 ppm; citrus, oil at 16.0 ppm; grapes at 2.0 ppm; raisins at 5 ppm; cotton, undelinted seed at 0.6 ppm; cotton, gin byproducts at 9.0 ppm; tea at 20 ppm; milk at 0.03 ppm; cattle, fat, at 0.01 ppm; goat, fat at 0.01 ppm; horse, fat at 0.01 ppm; sheep, fat at 0.01 ppm; cattle, kidney at 0.3 ppm; goat, kidney at 0.3 ppm; horse, kidney at 0.3 ppm; sheep, kidney at 0.3 ppm; cattle, liver at 0.7 ppm; goat, liver at 0.7 ppm; horse, liver at 0.7 ppm; sheep, liver at 0.7 ppm; cattle, meat at 0.02 ppm; goat, meat at 0.02 ppm; horse, meat at 0.02 ppm, and sheep, meat at 0.02 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., 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 nearly all of the proposed tolerances. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tolfenpyrad including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tolfenpyrad 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. Tolfenpyrad is a broad-spectrum pyrazole insecticide that is proposed for use to control thrips, aphids and scales through the egg, larval, nymph, and adult stages. The toxicity database for tolfenpyrad is complete. Tolfenpyrad is acutely toxic by oral route, but has low acute inhalation and dermal toxicity. It is also not irritating to the eye and skin and is not a skin sensitizer.

Toxicological testing indicates that tolfenpyrad is not neurotoxic or immunotoxic and it is classified as ''not likely to be carcinogenic to humans.'' However, the most consistent finding across species and studies was effects on body weight and body weight gain. Decreases in body weight and/or body weight gain were observed in adults of all species (rat, mice, rabbit, and dog) in the majority of the subchronic oral and dermal toxicity studies, and all chronic toxicity studies.

The rat is the species most sensitive to body weight changes, with effects observed at much lower doses than in other species. In rats, significant decreases in body weight and body weight gain were observed in subchronic oral and acute and subchronic neurotoxicity studies. Decreases in body weight and body weight gain were also seen in chronic rat studies but at lower doses than observed in the other rat studies. Although seen at lower doses, the body weight decrements noted in the chronic study were not as pronounced as seen after subchronic exposure or in the neurotoxicity studies. Decreases in body weight and body weight gain were also observed in reproduction, developmental toxicity, and developmental immunotoxicity studies at doses comparable to the chronic study. Body weight changes observed in other species were similar in magnitude to those in rats, but were observed at higher doses. Significant decreases in body weight and body weight gain were seen in both mice and dogs after subchronic exposure; these effects were also noted in rabbits in a developmental toxicity study. Chronic exposure resulted in body weight and body weight gain decreases in mice and dogs at lower doses. The severity of body weight changes increased with dose in mice while body weight effects in dogs were seen only at the highest dose tested.

The body weight changes observed in the database were most often seen in the presence of decreased food consumption and in some studies, additional toxicity including liver/kidney effects and clinical signs. Increased liver and kidney weights, liver and kidney hypertrophy, hyaline droplets in the kidney, and color change in the kidney were seen after subchronic exposure in rats. Chronic exposure resulted in similar effects along with color changes in the liver and liver histopathology at slightly lower doses than in the subchronic studies. Other effects noted in rats were effects on the

harderian gland and lymph nodes. In dogs, both liver and kidney histopathology, along with testicular atrophy and clinical signs (emaciation, decreased movement, and staggering gait) were seen in short-term studies. Long-term exposure resulted in histopathology in the liver only, along with increased liver enzymes. No treatment-related effects were noted in the liver or kidney in mice. However, rough coats, hunched posture, ataxia, and hypoactivity were seen in subchronic studies. Missing ears and ear lesions (scabs, sores, ulceration, and inflammation) were seen in a chronic toxicity study. The ear lesions observed were likely self inflicted since the mice in the study were individually caged. No explanation was given to why the lesions occurred and the toxicological significance of this finding is unclear.

Moribundity and/or mortality were noted in at least one study in all species at ≥ 3 milligrams/kilogram/day (mg/kg/day). Moribundity and mortality were noted in two dams in a rat reproduction study, and mortality was noted in one dam in a rabbit developmental toxicity study. Mortality was also observed in two animals in an inhalation toxicity study (range-finding only). In mice and dogs, mortality was observed in both subchronic and chronic toxicity studies. In all cases, effects were observed in the presence of body weight changes and the points of departure (POD) are protective of the observed mortality.

There is no evidence of increased quantitative or qualitative susceptibility in the guideline rat and rabbit developmental studies, or the rat reproduction study. Although several adverse effects were noted in young animals in these studies, the effects were observed in the presence of significant maternal toxicity (significant body weight changes and/or moribundity/mortality). In a non-guideline rat developmental immunotoxicity (DIT) study, a potential increase in qualitative susceptibility was seen. In the study, decreased survival, body weight, body weight gain, increased blackish abdominal cavity, and dark green abnormal intestinal contents were observed in offspring animals at 3 mg/kg/day. At the same dose, decreased body weight (up to 10%), body weight gain (up to 36%) and food consumption were seen in maternal animals. There was no evidence of immunotoxicity observed in the study.

No evidence of neurotoxicity was observed in acute and subchronic neurotoxicity studies for tolfenpyrad. Although hunched posture, ataxia, and hypoactivity were seen in mice in a 28-day toxicity study, these effects were not seen in a 90-day study or after chronic exposure. In dogs, decreased spontaneous movement, and staggering gait were observed after 13 weeks. In rats, decreased motor activity and prone position (lying face down) prior to death were noted in a reproduction study. Overall, the effects noted in the database were agonal effects mainly seen at high doses, not associated with neuropathology, and not noted in long-term studies. The effects observed are consistent with the mode of action for tolfenpyrad (mitochondrial inhibitor) and are not considered evidence of neurotoxicity.

No evidence of carcinogenicity was observed in cancer studies with mice and rats. Therefore, in accordance with EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005), tolfenpyrad is classified as ''not likely to be carcinogenic to humans.'' Specific information on the studies received and the nature of the adverse effects caused by tolfenpyrad 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 ''Tolfenpyrad. Human Health Risk Assessment'' in docket ID number EPA–HQ–OPP–2012–0909.

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 tolfenpyrad used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOLFENPYRAD FOR USE IN DIETARY HUMAN HEALTH RISK ASSESSMENTS

Exposure/scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Acute Dietary (General Population, including Infants and Children).	NOAEL = 10 mg/kg/day.	UF_A = 10 × ..... UF_H = 10 × FQPA SF = 1×	Acute RfD = 0.1 mg/kg/day. aPAD = 0.1 mg/kg/day	LOAEL = 20 mg/kg/day from an acute neurotoxicity study in rats, based on decreased body weight, body weight gain and food consumption
Chronic Dietary (All Populations).	NOAEL = 0.6 mg/kg/day.	UF_A = 10 × ..... UF_H = 10 × FQPA SF = 1×	Chronic RfD = 0.006 mg/kg/day. cPAD = 0.006 mg/kg/day	LOAEL = 1.5 mg/kg/day from a combined chronic/carcinogenicity in rats, based on decreased body weight, body weight gain, and food consumption of females, gross changes in the Harderian glands of males, and histopathological changes in the liver, kidney, and mesenteric lymph nodes of females and the kidney of males

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TOLFENPYRAD FOR USE IN DIETARY HUMAN HEALTH RISK ASSESSMENTS—Continued

Exposure/scenario	Point of departure	Uncertainty/FQPA safety factors	RfD, PAD, level of concern for risk assessment	Study and toxicological effects
Cancer	Classification: ''Not likely to be Carcinogenic to Humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tolfenpyrad, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from tolfenpyrad in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for tolfenpyrad. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues.

ii. *Chronic exposure.* The chronic assessment is significantly refined. Inputs to the chronic assessment include average residue levels from crop field trials; use of projected PCT estimates for foods that were shown to have a high contribution to the overall dietary exposure (as discussed in Unit III.C.1.iv.) and assumptions of 100 PCT for the rest of the commodities; liberal translation of juice processing factors; and reduction of residues from removal of head lettuce and cabbage wrapper leaves.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that there was no evidence of carcinogenicity in cancer studies with mice and rats. Therefore, a cancer exposure assessment was not conducted.

iv. *Anticipated residue and 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.

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 estimated the PCT for new uses as follows: 40% for oranges; 65% for table grapes; and 50% for spinach.

EPA estimates PCT for new uses for tolfenpyrad based on the PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that site over the three most recent years of available data. 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 a new insecticide). The PCTs included in the analysis may be for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year. Typically, EPA uses 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.

The estimated PCT for new uses, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PCT 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 5 years of actual use. The predominant factors that bear on whether the estimated PCT for new uses could be exceeded are (1) the extent of pest pressure on the crops in question; (2) the pest spectrum of the new pesticide in comparison with the market leaders as well as whether the market leaders are well-established for this use; and (3) resistance concerns with the market leaders.

All information currently available has been considered for tolfenpyrad, and it is the opinion of the Agency that it is unlikely that actual PCT for tolfenpyrad will exceed the estimated PCT for new uses during the next 5 years.

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 novaluron 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 tolfenpyrad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tolfenpyrad. 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 tolfenpyrad for acute exposures are 26.9 parts per billion (ppb) in surface water and 11 ppb for ground water; for chronic exposures, 12.2 ppb in surface water and 11 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration of value 26.9 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 12.2 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).

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

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA 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.* Although there seems to be increased qualitative susceptibility in the young in the developmental immunotoxicity study (DIT) in rats, there is low concern and there are no residual uncertainties regarding increased quantitative or qualitative prenatal and/or postnatal susceptibility for tolfenpyrad. When the DIT study is considered along with the reproduction study, the offspring toxicity in the DIT study was observed at the same dose as comparable maternal toxicity (moribundity/mortality) in the reproduction study. Therefore, EPA does not consider the isolated incident in the DIT a true indicator of qualitative susceptibility. Additionally, the effects observed in the DIT study are well-characterized, a clear NOAEL was identified, and the endpoints chosen for risk assessment are protective of potential offspring effects.

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

i. The toxicity database for tolfenpyrad is complete.

ii. There is no indication that tolfenpyrad is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is some evidence that tolfenpyrad may result in increased susceptibility, the concern for developmental or reproductive effects is low for the reasons contained in Unit III.D.2., and thus, a 10X FQPA safety factor is not necessary to protect infants and children.

iv. There are no residual uncertainties with regard to the exposure assessment. The acute dietary exposure assessment is based on high-end health protective residue levels (that account for parent and metabolites of concern), processing factors, and PCT assumptions (100%). The chronic dietary assessment incorporates significant refinement in that average residue values were used and projected PCT estimates were used for a few crops, the estimates are below the level of concern for all population subgroups because conservative assumptions, including the highly unlikely scenario that 100% of the planted acreage would be treated. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water, such that these exposures have not been underestimated. There are no residential exposure scenarios at this time.

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. For the acute assessment, the dietary risk for the U.S. population is estimated to be 62% of the aPAD. Children 3–5 years old are the highest-exposed population subgroup, with an estimated exposure at the 95th percentile of 0.076 mg/kg/day, which corresponds to 76% of the aPAD. Typically EPA has concerns when estimated exposures exceed 100% of the acute or chronic population-adjusted dose (aPAD or cPAD). Acute dietary risk estimates are below EPA's level of concern for all population subgroups.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tolfenpyrad from food and water will utilize 69% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of topramezone is not expected.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, tolfenpyrad is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for tolfenpyrad.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, tolfenpyrad is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tolfenpyrad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available in Pesticide Analytical Manual II (PAM II) for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). Additionally, Method M–073 and M–936–95–2 have been validated by the Agency and submitted for inclusion in PAM II as enforcement methods. These five methods are adequate for enforcement of the tolerances on plants and livestock. Method M–073 and M–936–95–2 may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for tolfenpyrad.

C. Revisions to Petitioned-For Tolerances

Nearly all of the commodity definitions for the petitioned-for tolerances are inconsistent with the current Agency definitions and must be revised. For head lettuce, spinach, and celery subgroup 4B leaf petioles, EPA has concluded that a group tolerance of 30 ppm for vegetable, leafy, except Brassica, group 4 is appropriate. For all remaining crops (except prune, grape, milk, and cattle, goat, horse, and sheep fat), EPA revised the tolerance values based on residue data and the use of the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures.

The submitted data for processed commodities are adequate and sufficient for the assessing and establishing tolerances associated with the proposed registration. EPA cannot determine the cause of the differences in the proposed tolerances for citrus dried pulp and oil, and raisin.

EPA is establishing tolerances for meat and meat byproducts that differ from the requested livestock tolerances due to differences between the dietary burden calculation generated by the petitioner and that generated by the Agency.

Finally, as EPA explained in its latest crop group rulemaking (77 FR 50617, August 22, 2012) (FRL–9354–3), EPA will attempt to conform petitions seeking tolerances for crop groups to the newer established crop groups, rather than establish new tolerances under the pre-existing crop groups, as part of its effort to eventually convert tolerances for any pre-existing crop group to tolerances with coverage under the revised crop group. Therefore, although the petitioner requested tolerances for crop groups 8 (fruiting vegetables), 10 (citrus fruit), 11 (pome fruit), 12 (stone fruit), and 14 (tree nuts), EPA evaluated and is establishing tolerances for crop groups 8–10 (fruiting vegetables), 10–10 (citrus fruit), 11–10 (pome fruit), 12–12 (stone fruit), and 14–12 (tree nuts).

V. Conclusion

Therefore, tolerances are established for residues of tolfenpyrad, (4-chloro-3-ethyl-1–methyl-*N*-[4-(*p*-tolyloxy) benzyl] pyrazole-5-carboxamide in or on almond, hulls at 6.0 ppm; citrus, dried pulp at 8.0 ppm; citrus, oil at 70 ppm; cotton, undelinted seed at 0.70 ppm; cotton, gin byproducts at 15 ppm; fruit, citrus, group 10–10 at 1.5 ppm; fruit, stone, group 12–12 at 2.0 ppm; grape at 2.0 ppm; grape, raisin at 6.0 ppm; nut, tree, group 14–12 at 0.05 ppm; persimmon at 2.0 ppm; plum, prune at 3.0 ppm; pomegranate at 2.0 ppm; potato at 0.01 ppm; tea at 30 ppm; vegetable, leafy, except Brassica, group 4 at 30 ppm; milk at 0.03. ppm; cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.35 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.35 ppm; horse, fat at 0.01 ppm; horse,

meat at 0.01 ppm; horse, meat by products at 0.35 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.35 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this 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) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 23, 2013.

Steven Bradbury,

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. Add § 180.675 to subpart C to read as follows:

§ 180.675 Tolfenpyrad; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide tolfenpyrad, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only tolfenpyrad, 4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl]pyrazole-5-carboxamide.

Commodity	Parts per million
Almond hulls	6.0
Citrus, dried pulp	8.0
Citrus, oil	70.0
Cotton, gin byproducts	15.0
Cotton, undelinted seed	0.70
Fruit, stone, group 12–12	2.0
Fruits, citrus, group 10–10	1.5
Grape	2.0
Grape, raisin	6.0
Nuts, tree, group 14–12	0.05
Persimmon	2.0
Plum, prune	3.0
Pomegranate	2.0
Potato	0.01
Tea	30.0
Vegetable, leafy, except Brassica, group 4	30.0

(2) Tolerances are established for residues of the insecticide tolfenpyrad, 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 the sum of tolfenpyrad, 4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl]pyrazole-5-carboxamide, and its metabolite 4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylamino-methyl]phenoxy]-benzoic acid, calculated as the

stoichiometric equivalent of tolfenpyrad.

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.35
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.35
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.35
Milk	0.03
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.35

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

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

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

[FR Doc. 2014–00163 Filed 1–8–14; 8:45 am]

BILLING CODE 6560–50–P