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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0156; FRL-9976-21]

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 [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2017-0156, 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), West William Jefferson Clinton 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: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; 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*.

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-2017-0156 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2017-0156, 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.html*. 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 June 8, 2017 (82 FR 26641) (FRL-9961-14), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7F8544 and PP 7F8543) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808-2951. The petitions requested that 40 CFR 180.675 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 *Brassica* head and stem vegetable group (crop group 5-16) at 5.0 parts per million (ppm) (PP 7F8544); *Brassica* leafy greens subgroup (4-16B) at 40 ppm (PP 7F8544); Vegetables, cucurbit, group 9 at 0.7 ppm (PP 7F8544); Vegetables, fruiting, group 8-10 at 0.7 ppm (PP 7F8544); Fruit, pome, group 11-10 at 0.7 ppm (PP 7F8544); and Apple, wet pomace at 2.5 ppm (PP 7F8544). The petitions also requested that established tolerances be amended for residues of tolfenpyrad in or on Fruit, citrus, group 10-10 at 0.9 ppm (PP 7F8544; PP 7F8543); Citrus, dried pulp at 3.0 ppm (PP 7F8544; PP 7F8543); and Citrus, oil at 28.0 ppm (PP 7F8544; PP 7F8543). 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 notices of filing. Consistent with the authority in section 408(d)(4)(A)(i), EPA is establishing tolerances that vary from what the petitioner sought. The reasons for these changes are explained in Unit IV.C.

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.

A variety of toxic effects were noted in the toxicology database for tolfenpyrad. However, the most consistent finding across species and studies was decreased body weight and/or body weight gain, which 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. 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 for longer duration studies.

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 changes in 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 histopathological changes in the liver, 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.

Moribundity and/or mortality were noted in at least one study in all tested species at ≥ 3 milligrams/kilogram/day (mg/kg/day). Moribundity and mortality were noted in two dams in

a rat reproduction study. Mortality was also noted in one dam in a rabbit developmental toxicity study, as well as in two rats from an inhalation toxicity study (range-finding only). In mice and dogs, mortality was observed in both subchronic and chronic toxicity studies. In all cases, these effects were observed only after repeat-dose exposures, and the current points of departure (PODs) for the relevant exposure durations 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, 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. This is consistent with the other developmental toxicity studies in the database, in which offspring toxicity is observed at the same dose as significant maternal toxicity. 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 – Aggregate Human Health Risk Assessment of Proposed New Uses on Multiple Commodities" at pages 11-15 in docket ID number EPA-HQ-OPP-2017-0156.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

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 Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL = 10 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Acute Neurotoxicity Study in rats LOAEL = 20 mg/kg/day based on decreased bodyweight, bodyweight gain and food consumption.
Chronic dietary (All populations)	NOAEL= 0.6 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.006 mg/kg/day cPAD = 0.006 mg/kg/day	Combined Chronic/Carcinogenicity Study in rats LOAEL = 1.5 mg/kg/day based on decreased bodyweight, bodyweight 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.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference

dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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 as well as all existing tolfenpyrad tolerances in 40 CFR 180.675. 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 2003-2008 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumes 100 percent crop treatment (PCT) and tolerance-level residues with minor refinements including a factor to account for the reduction in residues when wrapper leaves are removed from head lettuce and cabbage, as well as empirical processing factors for tomato juice, paste, and puree, cottonseed oil, citrus juice, and grape juice (which was translated broadly to other juices for which empirical data were not available).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumes 100 PCT and average residue levels from crop field trials as well as minor refinements listed above for acute exposure. Although partially refined, the chronic exposure estimates still retain a high level of conservatism due to the source and scope of the refinements, and are likely to overestimate the actual chronic dietary risk.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that tolfenpyrad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residues and percent crop treated.* Although EPA did not use any percent crop treated estimates for this action, the Agency relied on average residue 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.

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

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 estimated to be 26.9 parts per billion (ppb) for surface water and 11.0 ppb for ground water, for

chronic exposures for non-cancer assessments are estimated to be 12.2 ppb for surface water and 11.0 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 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 website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

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 evidence is noted for 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 identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues for the acute dietary exposure and average residue levels from crop field trials for the chronic dietary exposure. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tolfenpyrad in drinking water. These assessments will not underestimate the exposure and risks posed by tolfenpyrad.

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 margin of exposure (MOE) exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tolfenpyrad will occupy 54% of the aPAD for children 1-2 years of age, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tolfenpyrad from food and water will

utilize 68% of the cPAD for children 1-2 years of age, the population group receiving the greatest exposure. There are no residential uses for tolfenpyrad.

3. *Short- and Intermediate-term risk*. Short- and intermediated-term aggregate exposures take into account short- and intermediate-term residential exposures 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 exposures. Short- and intermediate-term risks are assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there are no short- or intermediate-term residential exposures 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- and 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, utilizing high-performance liquid chromatography with tandem mass spectrometric detection (LC/MS/MS), are available for

enforcement of tolfenpyrad residue tolerances in/on plant commodities (Morse Laboratories Analytical Method #Meth-183, Revision #2). For livestock, a method described in PTRL West Study No. 1841W is available. The livestock method adequately determines residues of tolfenpyrad and its metabolites, PT-CA, OH-PT-CA, and PCA in milk, bovine meat, kidney, liver and fat. Residues are determined by LC/MS/MS analysis. These methods are adequate for enforcement and 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 any MRLs for tolfenpyrad in commodities in this action.

C. Revisions to Petitioned-For Tolerances

EPA's tolerance levels are expressed to provide sufficient precision for enforcement purposes, and this may include the addition of trailing zeros (such as 0.30 ppm rather than 0.3 ppm). This is done to avoid the situation where rounding of an observed violative residue to the

level of precision of the tolerance expression would result in a residue considered non-violative (such as 0.34 ppm being rounded to 0.3 ppm). EPA added additional zeros for fruiting vegetables group 8-10 and cucurbit vegetables group 9. EPA is establishing tolerances for residues in or on fruit, citrus, group 10-10 at 0.80 ppm instead of 0.9 ppm; citrus, oil at 30 ppm instead of 28.0 ppm; and citrus, dried pulp at 4.0 ppm instead of 3.0 ppm, based on the previously reviewed orange processing study, and the newly submitted lemon field trial residues as the input dataset for the Organization for Economic Cooperation and Development (OECD) MRL calculation procedure. In addition, the tolerances in fruits, pome, group 11-10 and apple wet pomace are based on the petitioner's revision of the proposed maximum annual use rate on pome fruits, from 0.42 lb ai per acre (lb ai/A) to 0.57 lb ai/A.

D. International Trade Considerations

In this rule, EPA is reducing the existing tolerances for citrus commodities as follows: fruit, citrus, group 10-10 from 1.5 ppm to 0.80 ppm; citrus, dried pulp from 8.0 ppm to 4.0 ppm; and citrus, oil from 70 ppm to 30 ppm. The Agency is reducing these tolerances because these reductions requested by the petitioner are supported by available data. This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA will notify the WTO of its tolerance revision. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force in order to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances remain in

effect for a period of six months after the effective date of this final rule, in order to address this requirement. Prior to the expiration date, residues of tolfenpyrad up to the existing tolerance levels will be permitted; after the expiration date, residues will need to comply with the reduced tolerance levels.

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 Vegetable, *Brassica*, head and stem, group 5-16 at 5.0 parts per million (ppm); *Brassica*, leafy greens, subgroup 4-16B at 40 ppm; Vegetable, cucurbit, group 9 at 0.70 ppm; Vegetable, fruiting, group 8-10 at 0.70 ppm; Fruit, pome, group 11-10 at 1.0 ppm; and Apple, wet pomace at 3.0 ppm. Furthermore, established tolerances are amended for residues of tolfenpyrad in or on Fruit, citrus, group 10-10 from 1.5 ppm to 0.80 ppm; Citrus, dried pulp from 8.0 ppm to 4.0 ppm; and Citrus, oil from 70 ppm to 30 ppm. Finally, the tolerances for "Vegetable, fruiting, group 8-10" at 0.70 ppm and "Watermelon" at 0.70 ppm in paragraph (b), which cover residues resulting from the section 18 emergency exemptions, are removed as it is superseded by the tolerances established for group 9 in this action.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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); Executive Order 13045, entitled "Protection of Children from

Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (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: June 8, 2018.

Michael Goodis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.675:

a. Revise the table in paragraph (a)(1); and

b. Remove the entries for "Vegetable, fruiting, group 8-10" and "Watermelon" in the table in paragraph (b).

The revision reads as follows:

§ 180.675 Tolfenpyrad; tolerance for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Almond hulls	6.0
Apple, wet pomace	3.0
Brassica, leafy greens, subgroup 4-16B	40
Citrus, dried pulp[1]	8.0
Citrus, dried pulp	4.0
Citrus, oil[1]	70.0
Citrus, oil	30
Cotton, gin byproducts	15.0
Cotton, undelinted seed	0.70
Fruit, citrus, group 10-10[1]	1.5
Fruit, citrus, group 10-10	0.80
Fruit, pome, group 11-10	1.0
Fruit, stone, group 12-12	2.0
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, *Brassica*, head and stem, group 5-16	5.0
Vegetable, cucurbit, group 9	0.70
Vegetable, fruiting, group 8-10	0.70
Vegetable, leafy, except *Brassica*, group 4	30.0

[1] This tolerance expires on December 24, 2018.

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