



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0587; FRL-9987-34]

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. Interregional Research Project No. 4 (IR-4) 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-2017-0587, 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. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp>.

C. How Can I File an Objection or Hearing Request?

Under FFDC 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-2017-0587 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-2017-0587, 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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>

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 January 26, 2018 (83 FR 3658) (FRL-9971-46), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a

pesticide petition (PP 7E8613) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition 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 Arugula at 30.0 parts per million (ppm); Avocado at 1.5 ppm; Berry, low growing, subgroup 13-07G, except Cranberry and Blueberry, lowbush at 3.0 ppm; Bushberry, subgroup 13-07B at 7.0 ppm; Caneberry, subgroup 13-07A at 7.0 ppm; Celtuce at 30.0 ppm; Cottonseed, subgroup 20C at 0.70 ppm; Florence fennel at 30.0 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; Garden cress at 30.0 ppm; Leaf petiole vegetable, subgroup 22B at 30.0 ppm; Leafy greens, subgroup 4-16A at 30.0 ppm; Onion, bulb, subgroup 3-07A at 0.09 ppm; Onion, green, subgroup 3-07B at 10.0 ppm; Upland cress at 30.0 ppm; Vegetable, fruiting, group 8-10 at 1.0 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm.

The petitioner also requested that the following established tolerances be removed upon establishment of the petitioned-for tolerances: Cotton, undelinted seed at 0.70 ppm; Grape at 2.0 ppm; Potato at 0.01 ppm; and Vegetable, leafy, except Brassica, group 4 at 30.0 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>. Although a comment was submitted to the docket for the notice of filing, the issue raised is outside the scope of this rulemaking.

Based upon review of the data supporting the petition, EPA is establishing the petitioned-for tolerances with some variations consistent with its authority in FFDCA section 408(d)(4)(A). The reasons for these variations 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 FFDC section 408(b)(2)(D), and the factors specified in FFDC 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 findings across species and studies were effects on bodyweight and bodyweight 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.

Further detail of the toxicological profile for tolfenpyrad is discussed in Unit III.A. of the final rule published in the **Federal Register** of June 22, 2018 (83 FR 29017) (FRL-9976-21).

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 for Section 3 New Use Requests and Crop Group Tolerance Conversions*” on page 31 in docket ID number EPA-HQ-OPP-2017-0587.

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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

A summary of the toxicological endpoints for tolfenpyrad used for human risk assessment is discussed in Unit III B. of the final rule published in the **Federal Register** of June 22, 2018 (83 FR 29020) (FRL-9976-21).

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 the Dietary Exposure Evaluation Model DEEM-FCID™ (Ver. 3.16). This model uses food consumption data from the 2003-2008 United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues for all foods and assumed 100%

crop treated (PCT) for all current and proposed crops. The assessment was refined with the application of empirical processing factors where available. Where empirical processing factors were not available or were not translated, default processing factors were used. Additional refinements include a factor to account for the reduction in residues when wrapper leaves are removed (head lettuce, radicchio, cabbage, Chinese Napa cabbage, and Brussels sprouts). Empirical processing factors were available for processed commodities of apple, orange, cottonseed, grape, plum, potato and tomato, and were translated to other processed commodities where appropriate. Where empirical processing factors were not available or were not translated, default processing factors were used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the DEEM-FCID™ (Ver. 3.16). This model uses food consumption data from the 2003-2008 USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed 100% PCT and average residue levels from crop field trials as well as the refinements described above for the acute assessment.

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 residue and percent crop treated (PCT) information.* 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 FFDCAs 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 FFDCAs 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 FFDCAs section 408(b)(2)(E) and authorized under FFDCAs 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 <https://www.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. 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 value of 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. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 <https://www.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 there is evidence of 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 pre- 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) was observed 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. While there was evidence of qualitative susceptibility in one study, the Agency's concern for the susceptibility is low because it was not observed in other studies with tolfenpyrad; offspring effects consistently occurred at or above the dose associated with significant maternal toxicity; there was a clear NOAEL/LOAEL; and endpoints and doses selected for risk assessment are protective of the susceptibility.

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 percent crop treated assumptions (100%). The chronic dietary assessment incorporates some refinement in that average residue values were used. For both the acute and chronic dietary exposure, actual exposures to tolfenpyrad will likely be lower than the estimated exposures. Furthermore, conservative, upper-bound assumptions were used to estimate exposure through drinking water, such that these exposures have not been underestimated. No residential exposures are expected. 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 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 63% 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 97% 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 intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposures to food and water (considered to be background exposure levels). 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 method with tandem mass spectrometry detection (LC/MS/MS) is 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 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; 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for tolfenpyrad on potato at 0.01 ppm. Due to crop group conversions, the established potato tolerance will be covered by Vegetable, tuberous and corm, subgroup 1C. Therefore, the Codex MRL for potato is harmonized with the U.S. tolerance for Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm.

C. Revisions to Petitioned-For Tolerances

The petitioner requested tolerances for residues of tolfenpyrad and cited the International Union of Pure and Applied Chemistry (IUPAC) name for the chemical. The residue definition for tolfenpyrad tolerances currently established under 40 CFR §180.675 complies with the Agency's *Guidance on Tolerance Expressions*, except that the IUPAC chemical name is listed rather than the Chemical Abstracts Service (CAS) chemical name. The Agency's practice is to use the CAS name; therefore, the tolerance expression is being revised. This change also results in harmonization of the chemical name expression with that used by the Pest Management Regulatory Agency (PMRA).

EPA reviewed the current residue data and tolerance conversion proposals and is establishing some the proposed tolerance levels for residues of tolfenpyrad in accordance with the Agency's rounding practice. In addition, using the highest overall average residue level from the greenhouse tomato decline trial (at a post-harvest interval (PHI) of 5 days instead of a PHI of 1 day), the Agency is establishing a tolerance for Vegetable, fruiting, group 8-10 at 1.5 ppm instead of 1.0 ppm.

While the petitioner requested individual tolerances for arugula, garden cress, and upland cress, individual tolerances are not necessary since these commodities are included in *Brassica*, leafy greens, subgroup 4-16B.

Finally, the Agency is establishing a tolerance for the requested commodity Florence fennel as a tolerance for Fennel, Florence, fresh leaves and stalk to conform to the Agency's preferred vocabulary for this commodity.

V. Conclusion

Therefore, tolerances are established for residues of tolfenpyrad, (4-chloro-3-ethyl-1-methyl-*N*-[[4-(4-methylphenoxy)phenyl]methyl]-1*H*-pyrazole-5-carboxamide), including its metabolites and degradates, in or on Avocado at 1.5 ppm; Berry, low growing, subgroup 13-07G, except cranberry and lowbush blueberry at 3.0 ppm; Bushberry subgroup 13-07B at 7.0 ppm; Caneberry subgroup 13-07A at 7.0 ppm; Celtuce at 30 ppm; Cottonseed subgroup 20C at 0.70 ppm; Fennel, Florence, fresh leaves and stalk at 30 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; Leaf petiole vegetable subgroup 22B at 30 ppm; Leafy greens subgroup 4-16A at 30 ppm; Onion, bulb, subgroup 3-07A at 0.09 ppm; Onion, green, subgroup 3-07B at 10 ppm; Vegetable, fruiting, group 8-10 at 1.5 ppm; and Vegetable, tuberous and corm, subgroup 1C at 0.01 ppm. In addition, EPA is removing the following tolerances from paragraph (a) as they are superseded by the new tolerances being established in this rulemaking Cotton, undelinted seed at 0.70 ppm; Grape at 2.0 ppm; Potato at 0.01 ppm; and Vegetable, leafy except *Brassica*, group 4 at 30.0 ppm. EPA is also removing the time-limited tolerance for onion, dry bulb at 0.09 ppm in §180.675(b) as it is no longer needed with the establishment of a new permanent tolerance for onion, bulb subgroup 3-07A in paragraph (a)(1).

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) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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: December 10, 2018,

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40CFR 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 introductory text of paragraph (a)(1);

b. In the table to paragraph (a)(1):

i. Add alphabetically the entries “Avocado”; “Berry, low growing, subgroup 13-07G, except cranberry and lowbush blueberry”; “Bushberry, subgroup 13-07B”; “Caneberry, subgroup 13-07A”; “Celtuce”; “Cottonseed, subgroup 20C”; “Fennel, Florence, fresh leaves and stalk”; “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F”; “Leaf petiole vegetable subgroup 22B”; “Leafy greens, subgroup 4-16A”; “Onion, bulb, subgroup 3-07A”; “Onion, green, subgroup 3-07B”; and “Vegetable, tuberous and corm, subgroup 1C”;

ii. Revise the entry for “Vegetable, fruiting, group 8-10”;

iii. Remove the entries “Cotton, undelinted seed”; “Grape”; “Potato”; and “Vegetable, leafy except *Brassica*, group 4”;

c. Revise the introductory text of paragraph (a)(2);

d. Revise paragraph (b).

The additions and revisions 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-(4-methylphenoxy)phenyl]methyl]-1*H*-pyrazole-5-carboxamide) in or on the commodity.

Commodity	Parts per million
* * *	* * * *
Avocado	1.5
Berry, low growing, subgroup 13-07G, except cranberry and lowbush blueberry	3.0
* * *	* * * *
Bushberry, subgroup 13-07B	7.0
Caneberry, subgroup 13-07A	7.0
Celtuce	30
* * *	* * * *
Cottonseed, subgroup 20C	0.70
Fennel, Florence, fresh leaves and stalk	30
* * *	* * * *
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
* * *	* * * *
Leaf petiole vegetable subgroup 22B	30
Leafy greens, subgroup 4-16A	30
* * *	* * * *
Onion, bulb, subgroup 3-07A	0.09
Onion, green, subgroup 3-07B	10

* * * * *	
Vegetable, fruiting, group 8-10	1.5
Vegetable, tuberous and corm, subgroup 1C	0.01

(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-(4-methylphenoxy)phenyl]methyl]-1*H*-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.

* * * * *

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

* * * * *

[FR Doc. 2018-27605 Filed: 12/20/2018 8:45 am; Publication Date: 12/21/2018]