Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	* * *	*	*	* *
Regional Haze Five-Year Progress Report.	Statewide	8/09/2017	11/26/2018, [Insert **Federal Register** citation].	

[FR Doc. 2018–25556 Filed 11–23–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0971; FRL–9977–14]

Pyrifluquinazon; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyrifluquinazon in or on multiple commodities that 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 November 26, 2018. Objections and requests for hearings must be received on or before January 25, 2019, 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–2011–0971, 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, Director, 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–2011–0971 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 January 25, 2019. 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–2011–0971, 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 Tolerances

In the **Federal Register** of December 9, 2016 (81 FR 89036) (FRL–9953–69) and September 15, 2017 (82 FR 43352) (FRL–9965–43), 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 6F8502 and PP 7E8578, respectively) by Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide pyrifluquinazon, (1-acetyl-3,4-dihydro-3-[(3-pyridinylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-2(1*H*)-quinazolinone), as follows: PP 6F8502 requested tolerances for residues in or on Almond, hulls at 0.4 parts per million (ppm); *Brassica* head and stem vegetables (crop group 5–16) at 0.4 ppm; Cattle, fat at 0.01 ppm; Cattle, meat at 0.01 ppm; Cattle, meat byproducts at 0.01 ppm; Citrus fruits (crop group 10–10) at 0.5 ppm; Citrus, oil at 14 ppm; Cotton, gin byproducts at 4.0 ppm; Cotton, undelinted seed at 0.2 ppm; Cucurbit vegetables (crop group 9)

at 0.06 ppm; Fruiting vegetables, tomato subgroup 8–10A at 0.20 ppm; Fruiting vegetables, pepper/eggplant subgroup 8–10B at 0.15 ppm; Goat, fat at 0.01 ppm; Goat, meat at 0.01 ppm; Goat, meat byproducts at 0.01 ppm; Horse, fat at 0.01 ppm; Horse, meat at 0.01 ppm; Horse, meat byproducts at 0.01 ppm; Leafy vegetables (crop group 4–16) at 5 ppm; Leaf petiole vegetables (crop subgroup 22B) at 1.5 ppm; Milk at 0.01 ppm; Pome fruits (crop group 11–10) at 0.04 ppm; Sheep, fat at 0.01 ppm; Sheep, meat at 0.01 ppm; Sheep, meat byproducts at 0.01 ppm; Small fruit vine climbing subgroup (crop subgroup 13–07F) except fuzzy kiwifruit at 0.6 ppm; Stone fruits, cherry subgroup 12–12A at 0.2 ppm; Stone fruits, peach subgroup 12–12B at 0.03 ppm; Stone fruits, plum subgroup 12–12C at 0.015 ppm; Tree nuts (crop group 14–12) at 0.01 ppm; and Tuberous and corm vegetables (crop subgroup 1C) at 0.01 ppm and PP 7E8578 requested a tolerance for residues in or on imported tea at 20 ppm. Those documents referenced summaries of the petitions prepared by Nichino America, Inc., the registrant, which are available in the docket, *http://www.regulations.gov*. Comments were received in response to the first notice of filing, and EPA's response can be found in Unit IV.C.

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.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 pyrifluquinazon including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrifluquinazon 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.

The effects observed following dietary exposure to pyrifluquinazon, primarily targeted the liver, thyroid, kidney, hematopoietic system, and the male and female reproductive organs. Nasal toxicity was observed following chronic oral exposures to rats, mice, and dogs, but was not observed following inhalation exposure to rats. Inhalation exposure for 28 days in rats resulted in portal-of-entry effects in the form of terminal airway inflammation in the lungs of males at an equivalent oral dose that was higher than those causing nasal effects in dogs (the most sensitive species for nasal toxicity). Systemic effects following inhalation exposure to pyrifluquinazon consisted of clinical signs including palpebral closure, splayed gait, hunched posture, ataxia, piloerection, lethargy, and ocular effects. No adverse effects were seen in rats following dermal exposure. Pyrifluquinazon showed no signs of immunotoxicity.

Pyrifluquinazon showed signs of increased pre- and postnatal quantitative susceptibility in rats. In the rat developmental toxicity study, maternal effects (decreased body weights, and mean gravid uterine weights) were seen at a higher dose than fetal effects (decreased anogenital distances (AGD) in males, increased incidences of skeletal variations, and increased incidences of supernumerary ribs). In the two-generation reproduction study in rats, systemic parental effects were consistent with the general systemic toxic effects in rats and occurred at doses higher than those eliciting offspring and reproductive effects. Offspring effects included decreased body weights and decreased AGD in the male pups, which is also considered a reproductive effect. In the rabbit developmental toxicity study, a decreased number of live fetuses per doe was observed, which is considered a maternal and developmental adverse effect since it is unknown whether the effect occurred from toxicity to maternal animals or the fetuses. In addition, effects were observed in reproductive organs (epididymides, testes, uterus).

Signs of neurotoxicity were observed in the acute neurotoxicity (ACN) study, and consisted of: Decreased motor activity, prostrate, ataxia, hyporeactivity, hunched posture, loss of the righting reflex, coldness to touch, lacrimation, bradyapnea, piloerection, and ptosis. Signs of neurotoxicity were also observed in the subchronic oral study and the inhalation study in rats at doses that caused portal-of-entry effects.

Exposure to pyrifluquinazon resulted in increased incidences of testicular interstitial cell tumors (Leydig tumors) in both male rats and mice. Based on its review of the available data, EPA has concluded that pyrifluquinazon is ''not likely to be carcinogenic to humans at levels that do not alter rodent hormone homeostasis.'' This conclusion is based on the following: (1) The Agency was only able to conclude that one type of Leydig cell tumor (in the male mice) is treatment-related because the type of rat tested has a high background rate for this tumor type; (2) the suggested mode of action is supported by the available data and indicates that the tumors are not likely to occur below doses that trigger androgen receptor degradation in sex-specific tissues leading to changes in circulating androgen related hormones; and (3) neither the parent molecule nor its metabolites showed evidence of genotoxicity or mutagenicity. For these reasons and because the level that triggers tumor development is higher than 70.1 mg/kg/day and the chronic reference dose is 0.06 mg/kg/day, EPA has determined that quantification of cancer risk using a non-linear approach (*i.e.,* chronic reference dose) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to pyrifluquinazon.

Specific information on the studies received and the nature of the adverse effects caused by pyrifluquinazon 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 ''Pyrifluquinazon: Human Health Risk Assessment for the Proposed Use on Tuberous and Corm Vegetables, Leafy

Vegetables (including greenhouse-grown lettuce), *Brassica* Head and Stem Vegetables, Fruiting Vegetables (including greenhouse-grown pepper and tomato), Cucurbit Vegetables (including greenhouse-grown cucumber), Citrus Fruits, Pome Fruits, Stone Fruits, Small Vine Climbing Fruit (excluding fuzzy kiwifruit), Tree Nuts, Leaf Petiole Vegetables, and Cotton, and for the Establishment of a Tolerance without a U.S. Registration for Residues in/on Imported Tea'' on pages 16–24 in docket ID number EPA–HQ–OPP–2011–0971.

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

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRIFLUQUINAZON 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 (Females 13–49 years of age).	NOAEL = 5 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.05 mg/kg/day. aPAD = 0.05 mg/kg/day	Developmental Toxicity Study (rat) LOAEL = 10 mg/kg/day based on decreased AGD in males, increased incidences of skeletal variations (total), and increased incidences of supernumerary ribs.
Acute dietary (General population including infants and children).	NOAEL = 100 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 1 mg/kg/day. aPAD = 1 mg/kg/day	Acute Neurotoxicity Screening Battery LOAEL = 300 mg/kg/day based on increased incidences of clinical signs and effects on functional observational parameters, dehydration, decreased motor activity, prostrate, ataxia, hyporeactivity, scant or no feces, hunched posture, lost righting reflex, decreased body temperatures, lacrimation, bradyapnea, piloerection, ptosis, and decreased grip strength), decreased body weights and body-weight gains, decreased food consumption, and decreased brain weights.
Chronic dietary (All populations)	NOAEL= 6.25 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.06 mg/kg/day. cPAD = 0.06 mg/kg/day	Carcinogenicity (mouse) LOAEL = 27.1/25.0 mg/kg/day (M/F) based on decreased mean body weight in males; and increased incidences of tactile hair loss in males, endometrial hyperplasia of the uterine horn in females, follicular cell hypertrophy of the thyroid in males, and subcapsular cell hyperplasia of the adrenal in males.
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be carcinogenic to humans at levels that do not alter rodent hormone homeostasis.''		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. 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_{DB} = to account for the absence of data or other data deficiency. 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 pyrifluquinazon, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pyrifluquinazon 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 pyrifluquinazon. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the 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 assumed tolerance level residues, default processing factors, and 100 percent crop treated (PCT) for all proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment

EPA used DEEM–FCID, Version 3.16 software with 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance level residues, default processing factors, and 100 PCT for all proposed and registered uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyrifluquinazon would not pose a cancer risk to humans at dose levels below the chronic reference dose. Therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyrifluquinazon. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for pyrifluquinazon in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrifluquinazon. 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 Pesticides in Water Calculator (PWC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of pyrifluquinazon for acute exposures are estimated to be 7.52 parts per billion (ppb) for surface water and 10.3 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 3.99 ppb for surface water and 9.02 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 10.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 9.02 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). Pyrifluquinazon 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 pyrifluquinazon to share a common mechanism of toxicity with any other substances, and pyrifluquinazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrifluquinazon 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.* Pyrifluquinazon showed signs of increased pre- and postnatal quantitative susceptibility in the developmental toxicity study and in the two-generation reproduction study in rats. In the rabbit developmental toxicity study, observed maternal and developmental effects were considered adverse since it is unknown whether the effects occurred from toxicity to maternal animals or the fetuses.

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 pyrifluquinazon is complete.

ii. Evidence of potential neurotoxicity was observed for pyrifluquinazon; however, the concern is low since there were no neuropathological changes in any tissue, clear NOAELs were established for the observed effects, and the endpoints selected are protective. No additional UFs were required to account for neurotoxicity.

iii. Although there is evidence of increased quantitative fetal susceptibility following in utero exposure to pyrifluquinazon in rats and quantitative postnatal susceptibility in the two-generation reproduction study, the concern for all observed effects is low because: (1) The effects are well characterized, (2) clear NOAELs were established, and (3) risk assessment endpoints used were from the developmental rat and 2-generation reproduction studies.

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. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyrifluquinazon in drinking water. These assessments will not underestimate the exposure and risks posed by pyrifluquinazon.

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 (food plus water) risk for the U.S. population utilizes 1.2% of the acute population-adjusted dose (aPAD) and 2.5% for children 1–2 years old, who had the highest exposure estimate. For females 13 to 49 years old, for which the Agency used a different endpoint, the acute risk utilized 23% of the aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded

that chronic risk from pyrifluquinazon in food and water will utilize 13% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. There are no residential uses for pyrifluquinazon.

3. *Short- and intermediate-term risk.* The Agency's assessment of short- and intermediate-term risk aggregates 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, pyrifluquinazon is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Because there is no 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-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 pyrifluquinazon.

4. *Aggregate cancer risk for U.S. population.* Based on the information referenced in Unit III.A., EPA has concluded that exposure to pyrifluquinazon is unlikely to cause cancer effects at doses that do not alter rodent hormone homeostasis. Because the chronic reference doses is protective of those alterations and the Agency's assessment concludes that aggregate exposure to pyrifluquinazon does not pose a chronic risk, EPA has determined that aggregate exposure to pyrifluquinazon is unlikely to pose a cancer risk to the U.S. population.

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 pyrifluquinazon residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, high-performance liquid chromatography with tandem mass-spectrometry detection (HPLC–MS/MS) is available to enforce the tolerance expression for crop commodities. For livestock commodities, the method used is a modified QuEChERS LC/MS/MS method. These methods 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. Section 408(b)(4) of the FFDCA specifically requires that EPA determine whether the Codex Alimentarius Commission (Codex) has established a maximum residue level (MRL) for the commodity and to explain the reasons for departing from the Codex level when establishing tolerances at a different level. 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 also take into account MRLs established by other countries when determining what tolerance levels to set domestically.

The Codex has not established a MRL for residues of pyrifluquinazon. EPA is establishing the tolerance for residues of pyrifluquinazon in or on tea to harmonize with Japan.

C. Response to Comments

EPA received two comments, only one of which was specific to the petition for pyrifluquinazon tolerances. The specific comment opposed ''allowing such high residues'' but did not provide any information relevant to the safety of the pesticide. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops; however, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Almost all the tolerances being established in this rule differ from the petitioner requested in minor ways. For crop subgroups ''vegetable, tuberous and corm, subgroup 1C,'' ''stone fruits, plum subgroup 12–12C,'' and crop group ''nut, tree, group 14–12,'' the appropriate tolerance level (0.02 ppm) is based on the sum of the LOQs for pyrifluquinazon and metabolite IV–01, rather than on the LOQ for one analyte (0.01 ppm), as requested. In addition, EPA determined that a tolerance is needed for residues in or on the processed commodity citrus dried pulp, so EPA is establishing that tolerance in accordance with 40 CFR 180.40(f)(1)(i)(A). Based on the dietary burden calculations and the residue profile in the cattle feeding study, EPA concluded that tolerances are not needed for pyrifluquinazon residues of concern in milk, livestock meat, fat, or meat byproducts as expected secondary residues are less than 1/10th the combined LOQs. However, a tolerance for livestock liver is needed at the LOQ (pyrifluquinazon, metabolite IV–01, and metabolite IV–203) corresponding to a tolerance of 0.04 ppm. The combined LOQs for pyrifluquinazon, metabolite IV–01, and metabolite IV–203 in parent equivalents corresponded to 0.035 ppm; therefore, a tolerance of 0.04 ppm is required for the liver of cattle, goat, horse, and sheep. For the remainder of tolerances being established, EPA used corrected commodity names, and adjusted tolerances levels based on available residue data, proportionality adjustments to the crop field trial data. and correcting for potential decline during frozen storage, which resulted in increased recommended tolerances. Finally, EPA notes that although the notice of filing indicated that the petition requested a tolerance for almond, hulls at 0.01 ppm, the petition itself requested a tolerance at 0.4 ppm. Nevertheless, based on available residue data, the Agency has determined that a tolerance of 0.60 ppm is necessary to cover residues from this use.

V. Conclusion

Therefore, tolerances are established for residues of pyrifluquinazon, (1-acetyl-3,4-dihydro-3-[(3-pyridinylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-2(1*H*)-quinazolinone), and its metabolites in or on Almond, hulls at 0.60 ppm; Cherry subgroup 12–12A at 0.30 ppm; Citrus, dried pulp at 2.0 ppm; Citrus, oil at 30 ppm; Cotton, gin byproducts at 6.0 ppm; Cotton, undelinted seed at 0.30 ppm; Fruit, citrus, group 10–10 at 0.70 ppm; Fruit, pome, group 11–10 at 0.07 ppm; Fruit small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.30 ppm; Leaf petiole vegetable, subgroup 22B at 1.5 ppm; Peach subgroup 12–12B at 0.04 ppm; Plum subgroup 12–12C at 0.02 ppm; Nut, tree, group 14–12 at 0.02 ppm; Tea, dried at 20 ppm; Vegetable,

brassica, head and stem, group 5–16 at 0.60 ppm; Vegetable, cucurbit, group 9 at 0.07 ppm; Vegetable, fruiting, group 8–10 at 0.30 ppm; Vegetable, leafy, group 4–16 at 5.0 ppm; Vegetable, tuberous and corm, subgroup 1C at 0.02 ppm; Cattle, liver at 0.04 ppm; Goat, liver at 0.04 ppm; Horse, liver at 0.04 ppm; and Sheep, liver at 0.04 ppm. For the plant commodities, compliance with the tolerance is determined by measuring residues of the parent compound and the IV–01 metabolite; for the livestock commodities, compliance is determined by measuring residues of the parent compound and the free and conjugated forms of IV–01 and IV–203 metabolites.

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: November 9, 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. Add § 180.701 to subpart C to read as follows:

§ 180.701 Pyrifluquinazon; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide pyrifluquinazon, 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 the sum of pyrifluquinazon (1-acetyl-3,4-dihydro-3-[(3-pyridinylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-2(1*H*)-quinazolinone) and its metabolite IV–01 (3-[(pyridin-3-ylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1*H*-quinazolin-2-one), calculated as the stoichiometric equivalent of pyrifluquinazon.

Commodity	Parts per million
Almond, hulls	0.60
Cherry subgroup 12–12A	0.30
Citrus, dried pulp	2.0
Citrus, oil	30
Cotton, gin byproducts	6.0
Cotton, undelinted seed	0.30
Fruit, citrus, group 10–10	0.70
Fruit, pome, group 11–10	0.07
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.30
Leaf petiole vegetable, subgroup 22B	1.5
Peach subgroup 12–12B	0.04
Plum subgroup 12–12C	0.02
Nut, tree, group 14–12	0.02
Tea, dried[1]	20
Vegetable, *brassica,* head and stem, group 5–16	0.60
Vegetable, cucurbit, group 9	0.07
Vegetable, fruiting, group 8–10	0.30
Vegetable, leafy, group 4–16	5.0
Vegetable, tuberous and corm, subgroup 1C	0.02

[1] There are no U.S. registrations as of November 26, 2018 for use on tea.

(2) Tolerances are established for residues of the insecticide pyrifluquinazon, 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 the sum of pyrifluquinazon (1-acetyl-3,4-dihydro-3-[(3-pyridinylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-2(1*H*)-quinazolinone) and the free and conjugated forms of its metabolites IV–01 (3-[(pyridin-3-ylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1*H*-quinazolin-2-one) and IV–203 (6-[1,2,2,2-tetrafluoro-1-trifluoromethyl)ethyl]-1*H*-quinazolin-2,4-dione), calculated as the stoichiometric equivalent of pyrifluquinazon.

Commodity	Parts per million
Cattle, liver	0.04
Goat, liver	0.04
Horse, liver	0.04
Sheep, liver	0.04

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

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

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

[FR Doc. 2018–25690 Filed 11–23–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170828822–70999–04]

RIN 0648–XG633

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of Maryland is transferring a portion of its 2018 commercial summer flounder quota to the Commonwealth of Massachusetts. This quota adjustment is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial quotas for Maryland and Massachusetts.

DATES: Effective November 23, 2018, through December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Management Specialist, (978) 281–9180.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.110. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the initial 2018 allocations were published on December 22, 2017 (82 FR 60682), and corrected January 30, 2018 (83 FR 4165).

The final rule implementing Amendment 5 to the Summer Flounder Fishery Management Plan, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider the criteria in § 648.102(c)(2)(i)(A) through (C) in the evaluation of requests for quota transfers or combinations.

Maryland is transferring 3,169 lb (1,437 kg) of summer flounder commercial quota to Massachusetts through mutual agreement of the states. This transfer was requested to repay landings by a Maryland-permitted vessel that landed in Massachusetts under a safe harbor agreement. Based on the initial quotas published in the 2018 Summer Flounder, Scup, and Black Sea Bass Specifications and subsequent adjustments, the revised summer flounder quotas for calendar year 2018 are now: Maryland, 128,070 lb (58,092 kg); and Massachusetts, 413,361 lb (187,497 kg).

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 19, 2018.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–25566 Filed 11–23–18; 8:45 am]

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