EPA-APPROVED FLORIDA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	**Federal Register**, notice	Explanation
* *	*	*	* *	* *
110(a)(1) and (2) Infrastructure Requirements for the 2008 8-Hour Ozone NAAQS.	10/3/2017	4/11/2019	[Insert **Federal Register** citation] ..	Addressing prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0673; FRL–9990–02]

Fenazaquin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective April 11, 2019. Objections and requests for hearings must be received on or before June 10, 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–2017–0673, 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–2017–0673 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 June 10, 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–2017–0673, 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 March 6, 2018 (83 FR 9471) (FRL–9973–27), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8618) by Gowan Company, LLC, P.O. Box 556, Yuma, AZ 85364. The petition requested that 40 CFR 180.632 be amended by establishing tolerances for residues of the miticide/insecticide fenazaquin, 4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy] quinazoline, in or on alfalfa, forage at 4.0 parts per million (ppm); alfalfa, hay at 15 ppm; avocado at 0.15 ppm; bushberry, subgroup 13–07B at 0.8 ppm; caneberry, subgroup 13–07A at 0.7 ppm;

fruit, citrus, group 10–10 at 0.4 ppm; fruit, low growing berry, subgroup 13–07G at 2.0 ppm; corn, field, grain at 0.09 ppm; corn, field, forage at 7.0 ppm; corn, field, stover at 40 ppm; corn, field, aspirated grain fractions at 3.0 ppm; corn, field, refined oil at 0.2 ppm; corn, sweet, forage at 9.0 ppm; corn, sweet, grain at 0.03 ppm; cotton, gin byproducts at 15.0 ppm; cotton, undelinted seed at 0.4 ppm; fruit, pome, group 11–10 at 0.4 ppm; fruit, small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.7 ppm; fruit, stone, group 12–12 at 1.5 ppm; grape, raisins at 0.8 ppm; mint at 10.0 ppm; vegetable, cucurbit, group 9 at 0.3 ppm; vegetable, fruiting, group 8–10 at 0.3 ppm; vegetable, legume, edible podded, subgroup 6A at 0.4 ppm; vegetables, legumes, dried shelled pea and bean (except soybean) subgroup 6C at 0.3 ppm; vegetables, legumes, succulent shelled pea and bean subgroup 6B at 0.02 ppm; beef, fat at 0.05 ppm; pork, fat at 0.05 ppm; sheep, fat at 0.05 ppm; milk at 0.01 ppm; liver at 0.02 p.m.; and kidney at 0.01 ppm. That document referenced a summary of the petition prepared by Gowan Company, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* EPA received one favorable comment in response to the Notice of Filing from the Northwest Horticultural Council in support of establishing tolerances for fruit, pome, group 11–10 and fruit, stone, group 12–12.

Based upon review of the data supporting the petition, EPA has modified the commodity definitions and the tolerance levels for many of the proposed uses. Additionally, EPA is increasing the current tolerance level for citrus, oil and is not establishing tolerances on alfalfa, cotton, corn, and livestock commodities. The reasons for the changes and modifications are further 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 fenazaquin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenazaquin 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 most consistently observed effects of fenazaquin exposure across species, sexes, and treatment durations were decreases in body weight, food consumption, and food efficiency. The effects on body weight and food consumption were consistent with the commonly observed effects for compounds that disrupt mitochondrial respiration. Other effects noted were mild dehydration and certain clinical signs seen at relatively high dose levels in the acute activity, sluggish arousal, unusual posture, abnormal gait, and altered response to auditory stimuli were seen in the absence of any neuropathological changes and were not considered to be related to neurotoxicity. In a 90-day study in hamsters, treated animals had an increased incidence of testicular hypospermatogenesis and reduced testicular and prostate weight; however, these findings were not replicated in the hamster carcinogenicity study which suggest the effects were transient or reversible.

Fenazaquin did not cause any developmental or reproductive toxicity at the doses tested in rats and rabbits. In the rat study, developmental toxicity was not observed in the presence of maternal toxicity (*i.e.* decreases in body weight gain, food consumption, and food efficiency). In the rabbit study, no developmental or maternal toxicity was seen. In the reproduction study, systemic toxicity manifested in parental animals as excessive salivation and decreased body weight and food intake; and in offspring as decreased body weight gain; and there was no observed reproductive toxicity. Therefore, there is no developmental toxicity or reproductive susceptibility with respect to fetal and developing young animals with *in utero* and postnatal exposures.

Carcinogenicity was evaluated in the hamster instead of the mouse because the hamster was found to be more sensitive to the effects of fenazaquin than mice due to slower elimination kinetics for hamster. In a three-month feeding study in the mouse, it was found that 6–22x higher dose levels were required to elicit a comparable effect in mice than in the hamster. The results of the rat and hamster carcinogenicity studies demonstrated no increase in treatment-related tumor incidence. Therefore, fenazaquin was classified as ''*not likely to be carcinogenic to humans.*''

Fenazaquin did not cause mutagenicity, genotoxicity, neurotoxicity, or immunotoxicity. Fenazaquin did not demonstrate any systemic toxicity in a 21-day dermal toxicity study in rabbits up to the limit dose (1,000 milligram/kilogram/day (mg/kg/day)).

Specific information on the studies received and the nature of the adverse effects caused by fenazaquin 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 ''Fenazaquin: Human Health Risk Assessment in Support of Proposed Uses on Avocado, Bushberry Subgroup 13–07B, Caneberry Subgroup 13–07A, Citrus Fruit Group 10–10, Cucurbit Vegetables Group 9, Fruiting Vegetables Group 8–10, Edible-Podded Legume Vegetable Subgroup 6A, Succulent Pea And Bean Subgroup 6B, Dried Shelled Pea And Bean (Except Soybean) Subgroup 6C, Low Growing Berry Subgroup 13–07G, Mint, Pome Fruit Group 11–10, Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit 13–07F, and Stone Fruit Group 12–12'' in pages 11–17 in docket ID number EPA–HQ–OPP–2017–0673.

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 fenazaquin used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of May 6, 2015 (80 FR 25953) (FRL–9925–97).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenazaquin, EPA considered exposure under the petitioned-for tolerances as well as all existing fenazaquin tolerances in 40 CFR 180.632. EPA assessed dietary exposures from fenazaquin 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 fenazaquin. 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, DEEM default processing factors for tomato (paste and juice), dried apple, dried pear, dried apricot, cherry juice, plum/prune juice, and dried coconut, and 100 percent crop treated (PCT) for all proposed and registered uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM–FCID Version 3.16. This software uses USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues, DEEM default processing factors for tomato (paste and juice), dried apple, dried pear, dried apricot, cherry juice, plum/prune juice, and dried coconut, and 100 percent crop treated (PCT) for all proposed and registered uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenazaquin 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.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fenazaquin. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* In drinking water, the residues of concern are fenazaquin (parent) and two metabolites: Metabolite M29 or 2-(4-{2-[(2-hydroxyquinazolin-4-yl)oxy]ethyl}phenyl)-2-methylpropanoic acid and its tautomer 2-methyl-2-(4-{2-[(2-oxo-1,2-dihydroquinazolin-4-yl)oxy]ethyl}phenyl)propanoic acid; and Metabolite 1 or 4-[2-(4-tert-butyl-phenyl)-ethoxy]-quinazolin-2-ol and its tautomer 4-[2-(4-tert-butylphenyl)ethoxy]quinazolin-2(1H)-one..

Although a screening level drinking water assessment (DWA) was conducted, EPA used the solubility limit of fenazaquin at 20 °C, 102 parts per billion (ppb), in place of EDWCs from the modeling that are well below the solubility limit of fenazaquin, for the proposed new uses and rate increases in the human health risk assessment. This concentration is not representative of anticipated exposures in drinking water, but is used as an upper bound limit to represent the potential exposure to fenazaquin and the two additional residues of concern.

The solubility limit of fenazaquin at 20 °C, 102 ppb, was directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 102 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 102 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).

Fenazaquin is currently registered for the following uses that could result in residential exposures: Ornamental plants. There is a potential for exposure associated with handling (*i.e.,* mixing, loading and applying), as well as post-application exposure from the use of fenazaquin on ornamental plants. However, for residential exposure associated with handlers, all registered fenazaquin product labels with residential use sites (*e.g.,* ornamental plants) require that handlers wear specific clothing (*e.g.,* long-sleeve shirt/long pants/chemical resistant gloves) and/or use personal protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not for homeowner use, and has not conducted a quantitative residential handler assessment. With respect to the potential residential post-application exposure from the use of fenazaquin on ornamental plants, since there is (1) no adverse systemic hazard via the dermal route of exposure; (2) inhalation exposures are typically negligible in outdoor settings; and (3) there is no incidental oral exposure expected from fenazaquin use on ornamental plants, a residential post-application assessment is unnecessary. Furthermore, since the extent to which young children engage in activities associated with these areas or utilize these areas for prolonged periods of play is low, significant non-dietary ingestion exposure is not expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.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 fenazaquin to share a common mechanism of toxicity with any other substances, and fenazaquin does not

appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenazaquin 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 Food Quality Protection Act Safety Factor (FQPA 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.* Susceptibility/sensitivity in the developing animals was evaluated in developmental toxicity studies in rats and rabbits as well as a reproduction and fertility study in rats. The data showed no evidence of increased sensitivity/susceptibility in the developing or young animal. Clear NOAELs and LOAELs are available for all the parental and 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 fenazaquin is complete.

ii. There is no indication that fenazaquin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional Uncertainty Factors (UFs) to account for neurotoxicity.

iii. There is no concern for susceptibility in infants and young children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were based on 100% CT and tolerance level residues for both the acute and chronic dietary exposure. EPA made conservative (protective) assumptions when using the solubility limit of fenazaquin to account for exposure to fenazaquin in drinking water. These assessments will not underestimate the exposure and risks posed by fenazaquin.

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 fenazaquin will occupy 31% of the aPAD for children 1–2 years old, 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 fenazaquin from food and water will utilize 37% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for fenazaquin which contribute to the aggregate exposure.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there is no toxicological hazard via the dermal route of exposure for fenazaquin, short-term and intermediate-term aggregate exposure consists solely of chronic exposure to food and water, which is below the Agency's level of concern.

4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenazaquin 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 fenazaquin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available for enforcing fenazaquin tolerances on plant commodities. The high-performance liquid chromatography (HPLC) method with tandem mass spectrometry detection (HPLC/MS–MS) method is the same as that used for data collection and has been shown to be acceptable over a range of commodities. The method has undergone successful independent laboratory confirmation and radio validation. The ion transitions monitored for fenazaquin are m/z 307.0 → 161.2 for (quantitation) and m/z 307.0 → 147.2 (confirmation). The LOQ of the method was determined to be 0.01 ppm for fenazaquin. 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 FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for fenazaquin.

C. Revisions to Petitioned-for Tolerances

Based upon review of the data supporting the petition, EPA is establishing tolerances for the following commodities requested using the Agency's preferred commodity terminology: Instead of establishing a tolerance for grape, raisins as requested, the Agency is establishing a tolerance for grape, raisin; revising fruit, low

growing berry, subgroup 13–07G to berry, low growing, subgroup 13–07G; revising the requested mint to peppermint, fresh leaves and spearmint, fresh leaves; revising the requested vegetables, legumes, succulent shelled pea and bean subgroup 6B to pea and bean, succulent shelled, subgroup 6B; revising vegetables, legumes, dried shelled pea and bean (except soybean) subgroup 6C to pea and bean, dried shelled, except soybean, subgroup 6C. In addition, based on supporting data, the Agency is establishing tolerance levels higher than requested for fruit, stone, group 12–12 at 2 ppm and for fruit, pome, group 11–10 at 0.6 ppm. In addition, because the current residue data supporting fruit, citrus, group 10–10 indicates that residues concentrate in citrus, oil, EPA is establishing a tolerance for fruit, citrus, group 10–10, oil consistent with the requirements in 40 CFR 180.40(f)(1). This tolerance supersedes the existing tolerance for citrus, oil, so EPA is removing that tolerance. The Agency is also establishing tolerances and revising current tolerance levels consistent the Organization for Economic Cooperation and Development (OECD) maximum residue limits calculator. Finally, due to a lack of supporting data, EPA is not establishing any tolerances for alfalfa, forage; alfalfa, hay; corn, field, forage; corn, field, aspirated grain fractions; corn, field, grain; corn, field, refined oil; corn, field, stover; corn, sweet, forage; corn, sweet, grain; cotton, gin byproducts; cotton, undelinted seed; beef, fat; pork, fat; sheep, fat; liver; kidney; and milk.

D. International Trade Considerations

In this rule, EPA is revising the commodity definition of and reducing the existing tolerance for citrus commodities as follows: Fruit, citrus, group 10 except grapefruit will become fruit, citrus, group 10–10 and the tolerance will be revised from 0.5 ppm to 0.4 ppm. The Agency is reducing this tolerance based on review of available data. This reduction in tolerance level 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 fenazaquin up to the existing tolerance level will be permitted; after the expiration date, residues will need to be compliant with the reduced tolerance level.

V. Conclusion

Therefore, tolerances are established for residues of fenazaquin, 4-[2-[4-(1,1-dimethylethyl)phenyl] ethoxy]quinazoline, in or on avocado at 0.15 ppm; berry, low growing, subgroup 13–07G at 2 ppm; bushberry, subgroup 13–07B at 0.8 ppm; caneberry, subgroup 13–07A at 0.7 ppm; fruit, citrus, group 10–10, oil at 20 ppm; fruit, citrus, group 10–10 at 0.4 ppm; fruit, pome, group 11–10 at 0.6 ppm; fruit, small fruit vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.7 ppm; fruit, stone, group 12–12 at 2 ppm; grape, raisin at 0.8 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.3 ppm; pea and bean, succulent shelled, subgroup 6B at 0.03 ppm; peppermint, fresh leaves at 10 ppm; spearmint, fresh leaves at 10 ppm; vegetable, cucurbit, group 9 at 0.3 ppm; vegetable, fruiting, group 8–10 at 0.3 ppm; and vegetable, legume, edible podded, subgroup 6A at 0.4 ppm. In addition, EPA is removing the following tolerances: (1) Individual tolerances for apple, pear, and cherry because they are superseded by the new tolerances for pome fruit group 11–10 and stone fruit group 12–12; (2) the group tolerance for fruit, citrus, group 10, except grapefruit because it is superseded by a new group tolerance for fruit, citrus, group 10–10; and (3) the tolerance for citrus, oil because it is superseded by the new group tolerance for fruit, citrus, group 10–10, oil. The Agency is setting a 6-month expiration date on the current group tolerance for fruit, citrus, group 10, except grapefruit to provide a reasonable interval for exporting countries to adjust to the lower fruit, citrus, group 10–10 tolerance.

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: March 28, 2019.

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 § 180.632, revise the table in paragraph (a) to read as follows:

§ 180.632 Fenazaquin; Tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	4
Avocado	0.15
Berry, low growing, subgroup 13–07G	2
Bushberry, subgroup 13–07B	0.8
Caneberry, subgroup 13–07A	0.7
Fruit, Citrus, Group 10 except Grapefruit[2]	0.5
Fruit, citrus, group 10–10	0.4
Fruit, citrus, group 10–10, oil	20
Fruit, pome, group 11–10	0.6
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.7
Fruit, stone, group 12–12	2
Grape, raisin	0.8
Hop, dried cones	30
Nuts, Tree, Group 14–12	0.02
Pea and bean, dried shelled, except soybean, subgroup 6C	0.3
Pea and bean, succulent shelled, subgroup 6B	0.03
Peppermint, fresh leaves	10
Pineapple[1]	0.2
Spearmint, fresh leaves	10
Tea, dried[1]	9
Vegetable, cucurbit, group 9	0.3
Vegetable, fruiting, group 8–10	0.3
Vegetable, legume, edible podded, subgroup 6A	0.4

[1] There are no U.S. registrations as of May 25, 2017 for use on pineapple and tea.

[2] This tolerance expires on October 11, 2019.

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[FR Doc. 2019–07173 Filed 4–10–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

RIN 0991–AC10

Privacy Act; Implementation

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or Department) is issuing this final rule to make effective the exemptions that HHS proposed for certain records covered in a new Privacy Act system of records, System No. 09–90–1701, HHS Insider Threat Program Records.

DATES: This final rule is effective April 11, 2019.

FOR FURTHER INFORMATION CONTACT: Michael W. Schmoyer, Assistant Deputy Secretary for National Security by email at *insiderthreat@hhs.gov* or telephone at (202) 690–5756, or by mail to the HHS Office of Security and Strategic Information (OSSI), 200 Independence Ave. SW, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 552a (Privacy Act or Act), the exemptions were described in a Notice of Proposed Rulemaking (NPRM) published for public notice and comment at 83 FR 42627 (Aug. 23, 2018). The new system of records is described in a System of Records Notice (SORN) which was published for public notice and comment the same day, at 83 FR 42667 (Aug 23, 2018). Only law enforcement investigatory material and classified intelligence information were proposed to be exempted, based on subsections (k)(1) and (k)(2) of the Act, from the requirements contained in subsections (c)(3), (d)(1)-(4), (e)(1), (e)(4)(G), (H), and (I), and (f) of the Act, which require the agency to provide an accounting of disclosures; provide notification, access, and amendment rights, rules, and procedures; maintain only relevant and necessary information; and identify categories of record sources. The NPRM also explained that if the HHS Insider Threat Program obtains law enforcement investigatory material from another Privacy Act system of records that has been exempted from Privacy Act requirements based on subsection (j)(2) of the Act, that material will be exempt in System No. 09–90–1701 to the same extent it is exempt in the source system, so it may be exempt from requirements in any of these subsections of the Act: (c)(3)–(4); (d)(1)–(4); (e)(1)–(3), (e)(4)(G)–(I), (e)(5), (e)(8), (e)(12); (f); (g); and (h).

The comment period for the SORN and NPRM was open through September 24, 2018. No comments were received on the NPRM and no comments were received on the SORN. No changes to the proposed exemptions or to the SORN were made following the public comment period.

The specific rationales that support the exemptions as to each affected Privacy Act provision, remain as stated in the NPRM; the exemptions from the particular subsections are necessary and appropriate, and justified for the following reasons:

• *5 U.S.C. 552a(c)(3) (the requirement to provide accountings of disclosures) and 5 U.S.C. 552a(d)(1)–(4) (requirements addressing notification, access, and amendment rights, collectively referred to herein as access requirements).* Providing individual record subjects with accountings of disclosures and with notification, access, and amendment rights with respect to Insider Threat Program records could reveal the existence of an investigation, investigative interest, investigative techniques, details about an investigation, security-sensitive information such as information about security measures and security vulnerabilities, information that must remain non-public to protect national security or personal privacy-identities of law enforcement personnel, or other sensitive or classified information. Revealing such information to record subjects would thwart or impede pending and future law enforcement investigations and efforts to protect national security, and would violate personal privacy. Revealing the information would enable record subjects or other persons to evade detection and apprehension by security and law enforcement personnel; destroy, conceal, or tamper with evidence or fabricate testimony; or harass, intimidate, harm, coerce, or retaliate against witnesses, complainants, investigators, security personnel, law enforcement personnel, or their family members, their employees, or other individuals. With