

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: April 10, 2015.

Robert McNally,

Director, Biopesticides and Pollution Prevention 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 § 180.1330 to subpart D to read as follows:

§ 180.1330 1-Octanol; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of 1-octanol in or on root and tuber vegetables when applied as a plant growth regulator in accordance with label directions and good agricultural practices.

[FR Doc. 2015-10364 Filed 5-5-15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0075; FRL-9925-97]

Fenazaquin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenazaquin in or on almonds and cherries. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 6, 2015. Objections and requests for hearings must be received on or before July 6, 2015, 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-2006-0075, 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: Susan Lewis, 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: RDFFRNotices@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-2006-0075 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 July 6, 2015. 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-2006-0075, 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 April 20, 2011 (76 FR 22067) (FRL-8869-7), 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 1F7825) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR 180.632 be amended by establishing tolerances for residues of the insecticide fenazaquin, 4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline, in or on fruit, pome group at 0.35 parts per million (ppm); cucurbit group at 0.25 ppm; almond, hulls at 4.5 ppm; apple, wet pomace at 0.6 ppm; berry fruit group at 0.6 ppm;

vegetable, fruiting group at 0.25 ppm; grape at 0.9 ppm; hop at 2.0 ppm; mint at 6.0 ppm; stone fruit group at 1.5 ppm; strawberry at 1.5 ppm; tree nut group at 0.02 ppm; alfalfa, forage at 4.5 ppm; alfalfa, hay at 8.0 ppm; avocado at 0.15 ppm; citrus fruit group at 0.3 ppm; citrus, oil at 2.5 ppm; cotton, seed (undelinted) at 0.5 ppm; cotton, gin byproducts at 12.0 ppm; bean, shelled dry subgroup at 0.2 ppm; bean, edible podded subgroup at 0.3 ppm; beans and pea, succulent subgroup at 0.02 ppm; corn, field, grain at 0.15 ppm; corn, field, forage at 9.0 ppm; corn, field, stover at 30 ppm; corn, field, aspirated grain fractions at 9.0 ppm; corn, field, refined oil at 0.6 ppm; corn, sweet at 0.04 ppm; and corn, sweet, forage at 9.0 ppm. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon EPA review of the data supporting the petition, Gowan Company, the registrant, revised their petition by limiting their request for tolerances to almond and cherry. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on

aggregate exposure for 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, genders, and treatment durations were decreases in body weight, food consumption, and food efficiency. Other effects noted were mild dehydration and certain clinical signs seen at relatively high dose levels in the acute neurotoxicity study. These clinical signs, which included increased foot splay, decreased motor 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; 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."

The database for fenazaquin shows no evidence of 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)).

Fenazaquin has high acute oral toxicity, low acute toxicity by dermal and inhalation routes of exposure, is not a skin irritant, is minimally irritating to the eye, and is considered to be a dermal sensitizer.

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 for Proposed New Uses on Almonds and Cherries* on page 30 in docket ID number EPA-HQ-OPP-2006-0075.

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 fenazaquin used for

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENAZAQUIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children and females 13–50 years of age).	NOAEL = 15 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.15 mg/kg/day. aPAD = 0.15 mg/kg/day	[Immunotoxicity—Rat]. LOAEL = 30 mg/kg/day based on clinical signs (general ataxia/hypoactivity) observed in 1 animal on Day 02 and 3 animals on Day 03 of dosing.
Chronic dietary (All populations)	NOAEL = 5 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day. cPAD = 0.05 mg/kg/day	Co-Critical: Subchronic Toxicity—Dog. LOAEL = 15 mg/kg/day based on decreased body weight and food consumption/efficiency. Chronic Toxicity—Dog. LOAEL = 12 mg/kg/day based on decreased body weight and food consumption/efficiency.
Incidental oral short-term (1 to 30 days).	NOAEL = 5 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Co-Critical: Subchronic and Chronic Toxicity—Dog. Same as Chronic Dietary.
Inhalation short-term (1 to 30 days) and Intermediate Term (1 to 6 months).	Inhalation (or oral) study NOAEL = 5 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Co-Critical: Subchronic and Chronic Toxicity—Dog. Same as Chronic Dietary.
Cancer (Oral, dermal, inhalation).	Classification: “Not likely to be Carcinogenic to Humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. 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 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 food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANS/WWEIA). As to residue levels in food, EPA included

tolerance level residues for all registered and proposed crops and 100 percent crop treated (PCT). Default processing factors were used for all processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA included tolerance level residues for all registered and proposed crops and 100 PCT. Default processing factors were used for all processed commodities.

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 100 PCT 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 fenazaquin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenazaquin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier II Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) for surface water, the estimated drinking water concentrations (EDWCs) of fenazaquin for acute and chronic exposures were estimated to be 5.74 parts per billion (ppb) and 2.09 ppb,

respectively, and were entered directly into the dietary exposure model. The groundwater EDWC from the screening concentration in ground water (SCI-GROW) model was estimated to be 0.704 ppb. The modeled estimates were corrected for the default percent cropped area of 0.87. The drinking water assessment was conducted using the total toxic residue (TTR) approach. The residues considered in the assessment include fenazaquin (parent), Metabolite 1, and Metabolite 29.

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 uses. EPA assessed residential exposure using the following assumptions: EPA assessed potential exposures for residential handlers using several application methods including handwand and backpack sprayers to treat ornamental plants. MOEs were calculated for the inhalation route of exposure only since no systemic toxicity associated with dermal exposure to fenazaquin was observed. Adult post-applications exposures were not quantitatively assessed since no dermal hazard was identified for fenazaquin and inhalation exposures are typically negligible in outdoor settings. Furthermore, the inhalation exposure assessment performed for residential handlers is representative of worst case inhalation exposures and is considered protective for post-application inhalation scenarios. Since there is no residential incidental oral exposure expected for children 1<2 years old on ornamental plants, a post-application exposure assessment was not conducted and the aggregate assessment for children will only include exposure from food and water.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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 sensitivity/susceptibility in the developing or young animal. Clear NOAELs and LOAELs are available for all the parental and offspring effects. Therefore, there are no residual prenatal or postnatal concerns.

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 considered complete and sufficient for assessing susceptibility to infants and children.
- ii. There is no indication that fenazaquin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that fenazaquin results in increased susceptibility in *in utero* rats or rabbits

in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenazaquin in drinking water. EPA also made conservative assumptions in the non-dietary residential exposures estimates including maximum application rates and standard values for unit exposures, amount handled. 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 10% 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 10% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fenazaquin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenazaquin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fenazaquin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 5,200 for adults. Because EPA's level of concern for fenazaquin is a MOE of 100 or below, the MOE is not of concern. Since there is no residential exposure expected for children, there is no potential that a short-term aggregate risk for children could be higher than the dietary (food and drinking water) risk.

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, fenazaquin is not registered for any use patterns that would result in intermediate-term residential exposure.

Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fenazaquin.

5. *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.

6. *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 enforcement methodology (high performance liquid chromatography and tandem mass spectrometry (HPLC-MS/MS)) is available 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 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 a MRL for fenazaquin.

C. Revisions to Petitioned-For Tolerances

EPA's review of the data supporting the petition, showed that there was not sufficient data to support some of the tolerances originally proposed by the registrant. Gowan Company, the registrant, revised their petition by limiting their request for tolerances to almond and cherry, which are supported by the available data. The Organization of Economic Cooperation and Development (OECD) tolerance derivation procedures indicates the need for the following changes in the proposed tolerances: Cherries from 1.5 ppm to 2.0 ppm and almond hull from 0.6 ppm to 4.0 ppm. The Agency is also revising the tolerance expression to clarify that (1) as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of fenazaquin not specifically mentioned and (2) compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of fenazaquin, 4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline, in or on almond at 0.02 ppm, almond hulls at 4.0 ppm, and cherry at 2.0 ppm.

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). 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: April 27, 2015.

Susan Lewis,

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, the section heading and paragraph (a) are revised to read as follows:

§ 180.632 Fenazaquin; Tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide fenazaquin, 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 fenazaquin, or 4-[2-[4-(1,1-dimethylethyl)phenyl]ethoxy]quinazoline.

Commodity	Parts per million
Almond	0.02
Almond, hulls	4.0
Apple	0.2
Cherry	2.0
Citrus Oil	10
Fruit, Citrus, Group 10 except Grape fruit	0.5
Pear	0.2

* * * * *

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-6107-IFC]

RIN 0938-AS60

Medicare Program; Changes to the Requirements for Part D Prescribers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises requirements related to beneficiary access to covered Part D drugs. Under these revised requirements, pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions, written by prescribers other than physicians and eligible professionals who are permitted by state or other applicable law to prescribe medications, will not be rejected at the point of sale or denied by the plan if all other requirements are met. In addition, a plan sponsor will not reject a claim or deny a beneficiary request for reimbursement for a drug when prescribed by a prescriber who does not meet the applicable enrollment or opt-out requirement without first providing provisional coverage of the drug and individualized written notice to the beneficiary. This interim final rule with comment period also revises certain terminology to be consistent with existing policy and to improve clarity.

DATES:

Effective date: These regulations are effective on June 1, 2015.

Applicability date: The provisions at § 423.120(c)(6) are applicable January 1, 2016.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 6, 2015.

ADDRESSES: In commenting, please refer to file code CMS-6107-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following

address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6107-IFC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6107-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786-1302 for enrollment issues.

Lisa Thorpe, (410) 786-3048, for provisional coverage, notice, and all other issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in