



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2016-0384; FRL-9970-05]**

**Quinclorac; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of quinclorac in or on the bushberry subgroup 13-07B, the caneberry subgroup 13-07A, and asparagus. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0384, 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](mailto: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](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-2016-0384 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0384, 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 November 30, 2016 (81 FR 86312) (FRL-9954-06), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8488) by IR-4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid in or on asparagus at 0.06 parts per million (ppm); the bushberry subgroup 13-07B, except lowbush blueberry at 0.6 ppm; and the caneberry subgroup 13-07A at 0.06 ppm. That document referenced a summary of the petition prepared by Albaugh, 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 review of the data supporting the petition, EPA has modified the levels at which the tolerances are being established. The reason for these changes is explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDC section 408(b)(2)(A)(i) of FFDC 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 FFDC 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 FFDC 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 quinclorac including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with quinclorac 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.

Subchronic toxicity of quinclorac includes decreased body weight gains, increased water intake, increased liver enzymes (SGOT, SGPT) and focal chronic interstitial nephritis (rats). Chronic toxic effects of quinclorac include body weight decrement, increase in kidney and liver weights, and hydropic degeneration of the kidneys (dogs). At high doses, chronic toxicity also includes increased incidences of pancreatic acinar cell hyperplasia and adenomas (rats). Neurotoxic effects were not observed in any of the acute, subchronic, and chronic studies with quinclorac.

There was no increased qualitative or quantitative fetal or offspring susceptibility in the prenatal developmental or postnatal reproduction studies. Developmental toxicity in the rabbit consisted of increased resorptions, post-implantation loss, decreased number of live fetuses, and reduced fetal body weight. These effects occurred at much higher doses than the maternal

effects of decreased food consumption and increased water consumption and decreased body weight gain. In the rat, no developmental toxicity was observed at the highest dose tested (438 mg/kg/day). In the 2-generation reproduction study, parental toxicity and offspring toxicity occurred at the same dose. Parental toxicity consisted of reduced body weight in both sexes during pre-mating and lactation periods. Offspring toxicity consisted of decreased pup weight, developmental delays and possible marginal effect on pup viability. No reproductive toxicity occurred at the highest dose tested (480 mg/kg/day).

There are no mutagenicity concerns. Quinclorac is not mutagenic in bacterial assays and does not cause unscheduled DNA damage in primary rat hepatocytes. There is also no evidence of a genotoxic response in whole animal test systems (*in vivo* mouse bone marrow micronucleus assay). Quinclorac was negative in a mammalian cell *in vitro* cytogenetic chromosomal aberration assay in Chinese hamster ovary cells (CHO). Quinclorac was classified by the Agency as a group D carcinogen - not classifiable as to human carcinogenicity. Quantification of cancer risk is not required because the chronic RfD will adequately account for all chronic effects, including carcinogenicity, that may result from exposure to quinclorac.

Specific information on the studies received and the nature of the adverse effects caused by quinclorac 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 the document titled "*Quinclorac: Human Health Risk Assessment for New Proposed Use on Bushberry Subgroup 13-07B, Caneberry Subgroup 13-07A, and Asparagus*" on pages 41-46 in docket ID number EPA-HQ-OPP-2016-0384.

#### *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 quinclorac used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 29, 2013 (78 FR 71523) (FRL-9902-15).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to quinclorac, EPA considered exposure under the petitioned-for tolerances as well as all existing quinclorac tolerances in 40 CFR 180.463. EPA assessed dietary exposures from quinclorac 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.

For the general population including infants and children, no such effects were identified in the toxicological studies for quinclorac; therefore, a quantitative acute dietary exposure assessment for these population groups is unnecessary.

However, for females 13 to 49 years of age, such effects were identified for quinclorac. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 2003-2008 USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT.

iii. *Cancer.* Based on the current cancer classification of quinclorac, quantification of cancer risk is not required and the chronic RfD will adequately account for all chronic effects, including carcinogenicity, that may result from exposure to quinclorac.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for quinclorac. 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 quinclorac in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of quinclorac. 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 Tier 1 Rice Model and the Pesticide Water Calculator-Ground Water exposure model, the estimated drinking water concentrations (EDWCs) of quinclorac for acute exposures are estimated to be 511 parts per billion (ppb) for surface water and 817 ppb for ground water and for chronic exposures are estimated to be 481 ppb for surface water and 543 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 817 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 543 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).

Quinclorac is currently registered for the following uses that could result in residential exposures: turf grass and ornamentals. EPA assessed residential exposure using the following assumptions: short-term residential handler inhalation exposure is expected from the existing uses. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios: loading/applying granules for belly grinder; loading/applying granules for push type rotary spreader; loading/applying granules for a spoon; loading/applying granules for a cup and shaker can; applying granules by hand; mixing/loading/applying liquid and dry flowable formulations via manually-pressurized handwand, a hose-end sprayer, a backpack, and a sprinkler can; and mixing/loading/applying ready-to-use formulation via a trigger sprayer, and a hose-end sprayer.

Post-application short-term dermal and incidental oral exposure is expected from quinclorac treated turf in residential settings (i.e., lawns). Dermal exposures were not quantified due to a lack of a dermal toxicological endpoint. Incidental oral exposure risk estimates were calculated for hand-to-mouth, object-to-mouth, and soil ingestion exposures for 1 to <2-year old children playing in the treated turf. Even though there is a granular product, an assessment for episodic granular ingestion was not done since there is no applicable endpoint (i.e., no acute dietary point of departure for children).

The worst-case residential exposure scenario used in the adult aggregate assessment reflects inhalation exposure from residential handlers mixing/loading/applying water-dispersible granule/dry flowable formulations with a manually-pressurized handwand and/or backpack equipment.

The worst-case residential exposure scenario used in the children 1<2 years old aggregate assessment reflects hand-to-mouth exposures from post-application exposure to treated turf.

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 FFDCFA 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 quinclorac to share a common mechanism of toxicity with any other substances, and quinclorac does not appear to produce a toxic metabolite produced by other

substances. For the purposes of this tolerance action, therefore, EPA has assumed that quinclorac 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.* The toxicology database for quinclorac consists of developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. There is no indication of increased qualitative or quantitative susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

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 quinclorac is complete.

ii. There is no indication that quinclorac 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 quinclorac 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 quinclorac in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by quinclorac.

#### *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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. For the general population including infants and children, no adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, quinclorac is not expected to pose an acute risk to these population groups. However, an adverse effect was identified for

females 13 to 49 years of age, and therefore an acute aggregate risk assessment was performed for this population group.

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to quinclorac will occupy 2.4% of the aPAD for females 13 to 49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to quinclorac from food and water will utilize 9.4% of the cPAD for all infants <1 year 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 quinclorac 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).

Quinclorac 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 quinclorac.

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 2,100 for adults and 1,500 for children 1<2 years old. Because EPA's level of concern for quinclorac is a MOE of 100 or below, these MOEs are not of concern.

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).

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, quinclorac is not registered for any use patterns that would result in intermediate-term residential exposure; therefore, an intermediate-term aggregate risk assessment was not performed nor required. In addition, since the short- and intermediate-term PODs are the same, the estimates for short-term duration are protective of intermediate-term duration.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk. As there is no chronic risk of concern, EPA does not expect any cancer risk to the U.S. population from aggregate exposure to quinclorac.

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 quinclorac residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate analytical methods (gas chromatography/electron capture detector (GC/ECD)) are available for enforcing quinclorac tolerances on plant and livestock commodities. The methods have undergone successful agency method validation trials and have been submitted to the Food and Drug Administration (FDA) for publication in the Pesticide Analytical Manual (PAM) II as the tolerance enforcement methods. The Limit of Quantitation (LOQ) of both methods is 0.05 ppm for all matrices.

Other adequate LC/MS/MS based analytical methods, BASF Method D9708/02 (for quinclorac) and BASF Method D9806/02 (for quinclorac methyl ester), are available for data

collection and tolerance enforcement of residues of quinclorac and its methyl ester metabolite in/on plant commodities. The validated LOQ for both methods is 0.05 ppm. Both methods monitor two ion transitions. The Agency concurred with BASF's proposal to designate BASF Method D9708/02 and BASF Method D9806/02 as the new tolerance enforcement methods for quinclorac and quinclorac methyl ester, respectively. These LC/MS/MS enforcement analytical methods without the methylation step are preferable to the previous GC/ECD method.

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 any MRLs for quinclorac on any of the crops covered by this document.

#### *C. Revisions to Petitioned-For Tolerances*

Using the amended residue data in the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures, the Agency is establishing the tolerance of 0.08 ppm for combined residues of quinclorac and its methyl ester metabolite, in/on the bushberry subgroup 13-07B, the caneberry subgroup 13-07A, and asparagus. The tolerance of 0.08 ppm in/on the caneberry subgroup 13-07A and asparagus is higher than the petitioned-for tolerance (0.06 ppm) because the quinclorac residue values from the submitted field trial data did not include the residue values of methyl ester metabolite. However, the tolerance in/on the bushberry subgroup 13-07B is much lower than the petitioned-for tolerance (0.6 ppm). In blueberry trials, the petitioner included the single lowbush blueberry trial (ME03) in the tolerance calculation for bushberry subgroup 13-07B. Trial ME03 gives a quinclorac residue value (HAFT: 0.374 ppm) that is approximately sixteen times greater than the residue value (HAFT: 0.024 ppm) in/on blueberries from the six highbush blueberry trials. The difference in residue value is largely attributed to application patterns. The single lowbush blueberry sample (ME03) was subjected to two applications — one broadcast to the ground, the other broadcast to the foliage, whereas samples of highbush blueberry (subgroup 13-07B) were conducted with banded soil application twice. After excluding ME03 the tolerance value of blueberry from the OECD calculator (0.08 ppm) is significantly lower than the proposed tolerance (0.6 ppm).

Lastly, the Agency is modifying the proposed commodity definition of “Bushberry Subgroup 13-07B, except lowbush blueberry” to “Bushberry Subgroup 13-07B” because the lowbush blueberry tolerance is covered by the established tolerance at 1.5 ppm in/on berry, low growing, except strawberry, subgroup 13-07H.

## **V. Conclusion**

Therefore, tolerances are established for residues of quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on asparagus at 0.08 ppm; the bushberry, subgroup 13-07B at 0.08 ppm; and the caneberry subgroup 13-07A at 0.08 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); 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 15, 2017.

Michael L. 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 § 180.463, add alphabetically the commodities “Asparagus”; “Bushberry, subgroup 13-07B”; and “Caneberry subgroup 13-07A” to the table in paragraph (a)(1) to read as follows:

**§ 180.463 Quinclorac; tolerances for residues.**

(a)(1) \* \* \*

Commodity	Parts per million
Asparagus	0.08
* * *	* * *
Bushberry, subgroup 13-07B	0.08
Caneberry subgroup 13-07A	0.08
* * *	* * *

\* \* \* \* \*