

III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because this action merely corrects erroneous crop group names and an erroneous tolerance level that were due to an inadvertent error. Both the correct crop group names and tolerance level received prominent notice in the published notice of the petition and in EPA's preamble to the final rule. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

IV. Do any of the statutory and Executive Order reviews apply to this action?

No. For a detailed discussion concerning the statutory and executive order reviews, refer to Unit VI. of the October 3, 2007 final rule.

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 12, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is corrected 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 Section 180.628, the table to paragraph (a) is amended as follows:

■ i. Remove the entries for Cotton, undelinted seed; Lunaria, seed;

Rapeseed subgroup 20B; Sunflower subgroup 20C; Vegetable, foliage of legume, group 7, forage; and Vegetable, foliage of legume, group 7, hay.

■ ii. Add alphabetically entries for Rapeseed subgroup 20A; Sunflower subgroup 20B; and Vegetable, foliage of legume, group 7.

The added entries read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
Rapeseed subgroup 20A	2.0
Sunflower subgroup 20B	2.0
Vegetable, foliage of legume, group 7	90

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0010; FRL-9372-4]

Quinclorac; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of quinclorac in or on berry, low growing, except strawberry, subgroup 13-07 H and rhubarb. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 21, 2012. Objections and requests for hearings must be received on or before February 19, 2013, 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-2012-0010, 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), EPA West 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: nollen.laura@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://ecfr.gpoaccess.gov/cgi/t/text/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-2012-0010 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 February 19, 2013. 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-2012-0010, 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 Confidential Business Information (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.htm>.

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 4, 2012 (77 FR 20334) (FRL-9340-4), 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 1E7957) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.463 be amended by establishing tolerances for residues of the herbicide quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on berry, low growing, except strawberry, subgroup 13-07H at 1.1 parts per million (ppm) and rhubarb at 0.4 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by BASF Corporation, 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 revised the tolerance levels for the proposed commodities. 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 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 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.

Quinclorac has a low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not a skin irritant, but is a mild eye irritant and tested positive for dermal sensitization. Following subchronic exposures to quinclorac, signs of toxicity included decreased body weight gains, increased water intake, increased

liver enzymes, and focal chronic interstitial nephritis (rats). Chronic toxic effects included body weight decrement, increase in kidney and liver weights, and hydropic degeneration of the kidneys (dogs). At high doses, chronic toxicity also included increased incidences of pancreatic acinar cell hyperplasia and adenomas in rats. There was no evidence of neurotoxicity in any acute, subchronic and chronic studies for 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 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 up to the highest dose tested (HDT). In the 2-generation rat 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, and offspring toxicity consisted of decreased pup weight, developmental delays, and possible marginal effect on pup viability. No reproductive toxicity occurred up to the HDT in this study.

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) and was negative in a mammalian cell *in vitro* cytogenetic chromosomal aberration assay in Chinese hamster ovary cells. Quinclorac produced an equivocal increase in the incidence of one type of benign tumor (pancreatic acinar cell adenomas) in only one sex of one species of animals (male Wistar rats). There was no evidence of carcinogenicity in mice or female rats. Based on this limited evidence on cancer, a quantification of cancer risk is not warranted 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>.

www.regulations.gov in document, "Quinlorac: First Risk Assessment In Support of Registration Review and for New Proposed Use on Rhubarb and Berry, low growing, except Strawberry, Subgroup 13-07H," pp. 62-65 in docket ID number EPA-HQ-OPP-2012-0010.

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 quinlorac used for human risk assessment is shown in following Table.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 200 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day. aPAD = 2.0 mg/kg/day	Developmental toxicity study in rabbits. LOAEL = 600 mg/kg/day based on increased early resorptions and postimplantation loss, decreased live fetuses, decreased fetal body weight.
Acute dietary (General population including infants and children).	Not applicable. An endpoint for acute dietary exposure to the general population was not selected because there was no available endpoint attributable to a single exposure that was appropriate for this scenario (effects observed in the available studies are presumed to require more than one exposure).		
Chronic dietary (All populations)	NOAEL= 37.5 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.38 mg/kg/day. cPAD = 0.38 mg/kg/day	Carcinogenicity study in mice. LOAEL = 150 mg/kg/day based on decreased body weight.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 70 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity study in rabbits. LOAEL = 200 mg/kg/day based on decreased maternal body weight gain and food consumption, and increased water consumption.
Incidental oral short-term (1 to 30 days).	NOAEL= 70 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity study in rabbits. LOAEL = 200 mg/kg/day based on decreased maternal body weight gain and food consumption, and increased water consumption.
Cancer (Oral, dermal, inhalation)	The chronic RfD will adequately account for all chronic effects, including carcinogenicity, that may result from exposure to quinlorac.		

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_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 quinlorac, EPA considered exposure under the petitioned-for tolerances as well as all existing quinlorac tolerances in 40 CFR 180.463. EPA assessed dietary exposures from quinlorac 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. EPA identified such an effect (increased early resorptions and post-implantation loss, decreased live fetuses, and decreased fetal body weight in developmental toxicity study in

rabbits) for the population subgroup females 13 to 49 years old; however, no such effect was identified for the general population, including infants and children.

In estimating acute dietary exposure for females 13–49, the population group identified as having an acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database

(DEEM–FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture’s National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), conducted from 2003–2008. As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all commodities. In addition, DEEM version 7.81 default processing factors were used when appropriate.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA’s 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues for all commodities. In addition, DEEM version 7.81 default processing factors were used when appropriate.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to quinclorac. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for quinclorac. Tolerance level residues and/or 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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier I Rice Model, Version 1.0, the estimated drinking water concentrations (EDWCs) of quinclorac for surface water are estimated to be 511 parts per billion (ppb) for acute and chronic exposures. Based on the Screening Concentration in Ground Water (SCI GROW) model, the EDWCs for ground water are estimated to be 29 ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessments, the water concentration value of 511 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 inhalation exposures for residential handlers from mixing, loading, and applying quinclorac to residential turf and short-term postapplication incidental oral exposures (hand-to-mouth activities) of children from contact with treated turf. Intermediate-term exposures resulting from adult handler and postapplication exposures were not assessed due to a lack of a dermal point of departure. Incidental oral scenarios for children are considered to be short-term only. 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 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 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 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 incidental oral exposures (hand-to-mouth activities) of toddlers to quinclorac. 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to quinclorac will occupy 1.6% of the aPAD for females 13–49, the population group for which a potential acute risk was identified.

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 8.9% of the cPAD for infants less than 1 year of age, 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 1,600 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). An intermediate-term adverse effect was identified; however, quinclorac 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 quinclorac.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects.

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

An adequate gas chromatography with electron capture detection (GC/ECD) method (BASF Method A8902), 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 quinclorac.

C. Revisions to Petitioned-for Tolerances

Based on analysis of the residue field trial data supporting the petition, EPA revised the proposed tolerances on berry, low growing, except strawberry, subgroup 13–07H from 1.1 ppm to 1.5 ppm and rhubarb from 0.4 ppm to 0.5 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Co-operation

and Development (OECD) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, in or on berry, low growing, except strawberry, subgroup 13–07H at 1.5 ppm; and rhubarb at 0.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 12, 2012.

Lois Rossi,

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 following commodities to the table in paragraph (a) to read as follows:

§ 180.463 Quinclorac; tolerances for residues.

(a) * * *

Commodity	Parts per million
Berry, low growing, except strawberry, subgroup 13-07H	1.5
Rhubarb	0.5

Commodity	Parts per million
* * * * *	* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2012-0740; FRL-9373-8]

RIN 2070-AB27

Significant New Use Rule on Certain Chemical Substances; Withdrawal of Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures. EPA received notices of intent to submit adverse comments on these rules. Therefore, the Agency is withdrawing these SNURs, as required under the expedited SNUR rulemaking process. EPA intends to publish in the near future proposed SNURs for these eight chemical substances under separate notice and comment procedures.

DATES: This final rule is effective January 2, 2013.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: Moss.Kenneth@epa.gov.
For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

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SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** of November 2, 2012 (77 FR 66149) (FRL-9366-7). If you have questions regarding

the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What rule is being withdrawn?

In the **Federal Register** of November 2, 2012 (77 FR 66149), EPA issued several direct final SNURs, including SNURs for the chemical substances that are the subject of this withdrawal. These direct final rules were issued pursuant to the procedures in 40 CFR part 721, subpart D. In accordance with § 721.160(c)(3)(ii), EPA is withdrawing the rule issued for eight chemical substances which were the subject of PMNs P-11-327, P-11-328, P-11-329, P-11-330, P-11-331, P-11-332, P-12-298, and P-12-299, because the Agency received notices of intent to submit adverse comments. EPA intends to publish a proposed SNUR for these chemical substances under separate notice and comment procedures.

For further information regarding EPA's expedited process for issuing SNURs, interested parties are directed to 40 CFR part 721, subpart D, and the **Federal Register** of July 27, 1989 (54 FR 31314). The record for the direct final SNURs for the chemical substances that are being withdrawn was established at EPA-HQ-OPPT-2012-0740. That record includes information considered by the Agency in developing these rules and the notices of intent to submit adverse comments.

III. How do I access the docket?

To access the electronic docket, please go to <http://www.regulations.gov> and follow the online instructions to access docket ID number EPA-HQ-OPPT-2012-0740. Additional information about the Docket Facility is provided under **ADDRESSES** in the **Federal Register** of November 2, 2012 (77 FR 66149). If you have questions, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

IV. Statutory and Executive Order Reviews

This final rule revokes or eliminates an existing regulatory requirements and does not contain any new or amended requirements. As such, the Agency has determined that this withdrawal will not have any adverse impacts, economic or otherwise. The statutory and executive order review requirements applicable to the direct final rules were discussed in the **Federal Register** of November 2, 2012 (77 FR 66149). Those review requirements do not apply to this action because it is a withdrawal