

Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This action only delays the effective date of the December 5, 2008 rule and does not impose any additional enforceable duty.

#### *E. Executive Order 13132: Federalism*

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the states, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action will not impose direct compliance costs on state or local governments, and will not preempt state law. Thus, Executive Order 13132 does not apply to this action.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175 (59 FR 22951, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action presents a disproportionate risk to children.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113; section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable VCS. This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or

environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment.

#### *K. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary, or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore. EPA will submit a report containing this rule and other required information to the United States Senate, the United States 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).

Dated: March 26, 2009.

**Lisa P. Jackson,**  
Administrator.

[FR Doc. E9–7301 Filed 3–31–09; 8:45 am]

**BILLING CODE 6560–50–P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA–HQ–OPP–2008–0362; FRL–8405–2]**

### **Quinoxifen; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of quinoxifen in or on artichoke, globe; fruit, stone, group 12; squash, winter; pumpkin; and gourd, edible. This regulation also deletes the established cherry, sweet;

and cherry, tart tolerances, as they will be superseded by inclusion in the stone fruit crop group. This regulation additionally deletes the time-limited tolerances for pumpkin; winter squash; and melon subgroup 9A, as the tolerances expired on December 31, 2007. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 1, 2009. Objections and requests for hearings must be received on or before June 1, 2009, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0362. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**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; e-mail address: [nollen.laura@epa.gov](mailto: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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. How Can I Access Electronic Copies of this Document?*

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

###### *C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, 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-2008-0362 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 1, 2009.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0362, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### **II. Petition for Tolerance**

In the **Federal Register** of June 4, 2008 (73 FR 31862) (FRL-8365-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7325) by Interregional Research Project Number 4 (IR-4), 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.588 be amended by establishing tolerances for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on artichoke, globe at 1.4 parts per million (ppm); fruit, stone, group 12 at 0.70 ppm; squash, winter at 0.20 ppm; pumpkin at 0.20 ppm; and gourd, edible at 0.20 ppm. IR-4 additionally proposed to remove the established tolerances for the residues of quinoxyfen in or on the food commodities cherry, sweet; and cherry, tart at 0.30 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

##### **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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for residues of quinoxifen on artichoke, globe at 1.4 ppm; fruit, stone, group 12 at 0.70 ppm; squash, winter at 0.20 ppm; pumpkin at 0.20 ppm; and gourd, edible at 0.20 ppm. EPA’s assessment of exposures and risks associated with establishing tolerances 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 existing quinoxifen data indicate that it possesses low acute toxicity via the oral, dermal and inhalation routes. It is a mild eye irritant and dermal sensitizer, but it is not a dermal irritant.

The primary target organs affected by quinoxifen are the liver and kidney. Subchronic effects in rats and mice included increased liver weights, hepatocellular hypertrophy and individual cell hepatocellular necrosis, and chronic effects in the dog included increased liver weights, increased alkaline phosphatase levels and increased incidences of slight microscopic hepatic lesions. Kidney effects were noted only in the rat combined chronic/carcinogenicity study, resulting in an increased severity of chronic progressive glomerulonephropathy in males. Rabbits were much more susceptible to the effects of quinoxifen than any other species. Systemic effects observed in the rabbit developmental study included inanition, loss of body weight, perineal soiling, blood in the cage pan associated with urine, and abortions.

Long-term dietary administration of quinoxifen did not result in an overall treatment-related increase in incidence of tumor formation in rats or mice. As a result, EPA classified quinoxifen as “not likely to be carcinogenic to humans.” Quinoxifen did not show evidence of mutagenicity in *in vitro* or *in vivo* studies. No evidence of neurotoxicity or neuropathology was seen in any of the submitted studies, including the acute and subchronic neurotoxicity studies.

The toxicology data for quinoxifen provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. No maternal or developmental toxicity was observed in the rat developmental toxicity study. The rabbit developmental toxicity study included maternal toxic effects (inanition, decreased body weight and weight gain, decreased fecal output, perineal soiling, blood in the cage pan associated with urine, and abortions) at the same dose as developmental effects (increased abortions). In the 2-generation reproduction study conducted with rats, increased quantitative susceptibility of offspring (minimally reduced pup weights) was noted in the absence of maternal toxicity at the high dose. There was no evidence of immunotoxicity in the database.

Specific information on the studies received and the nature of the adverse effects caused by quinoxifen 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 “Quinoxifen. Human Health Risk Assessment for the Proposed Food Use of Quinoxifen on Stone Fruits Crop Group 12 (excluding Cherry), Artichoke, Winter Squash, (Pumpkin and Edible Gourds),” at pages 45–48 in docket ID number EPA–HQ–OPP–2008–0362.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory

animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 quinoxifen used for human risk assessment can be found at <http://www.regulations.gov> in document “Quinoxifen. Human Health Risk Assessment for the Proposed Food Use of Quinoxifen on Stone Fruits Crop Group 12 (excluding Cherry), Artichoke, Winter Squash, (Pumpkin and Edible Gourds),” at pages 25–26 in docket ID number EPA–HQ–OPP–2008–0362.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to quinoxifen, EPA considered exposure under the petitioned-for tolerances as well as all existing quinoxifen tolerances in 40 CFR 180.588. EPA assessed dietary exposures from quinoxifen 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.

No such effects were identified in the toxicological studies for quinoxifen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998

Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, Dietary Exposure Evaluation Model (DEEM) default processing factors, and assumed 100 percent crop treated (PCT) for all proposed commodities.

iii. *Cancer.* Based upon lack of evidence of carcinogenicity in rats and mice by all routes of exposure, EPA has classified quinoxifen as "not likely to be carcinogenic to humans;" therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for quinoxifen. 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 quinoxifen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of quinoxifen. 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 First Index Reservoir Screening Tool (FIRST) model for surface water, and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of quinoxifen for surface water are estimated to be 9.9 parts per billion (ppb) for acute exposures, and 0.66 ppb for chronic exposures. For ground water, the estimated drinking water concentration is 0.0034 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.66 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).

Quinoxifen is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a

tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found quinoxifen to share a common mechanism of toxicity with any other substances, and quinoxifen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that quinoxifen 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://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 data for quinoxifen provides no indication of increased susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies up to the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day). In the multi-generation rat reproduction study, offspring effects were noted at the high dose of 100 mg/kg/day tested (minimally reduced F<sub>1a</sub> pup weights) in the absence of maternal toxicity at the same level; thereby showing quantitative evidence of increased susceptibility in rat offspring. However, concern is low since:

i. The effects in pups are well-characterized with a clear NOAEL of 20 mg/kg/day.

ii. The pup effects are minimal at the LOAEL and only noted in the first generation offspring.

iii. The doses and endpoints selected for regulatory purposes would address

the concerns of the pup effects noted in the rat reproduction study.

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 quinoxifen is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The available data for quinoxifen do not show potential for immunotoxic effects. Therefore, EPA does not believe that conducting the immunotoxicity study will result in a NOAEL lower than the NOAEL of 20 mg/kg/day already set for quinoxifen. Consequently, an additional database uncertainty factor does not need to be applied.

ii. There is no indication that quinoxifen is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is quantitative evidence of increased susceptibility of offspring (minimally reduced pup weights) in the absence of maternal effects in the rat multi-generation reproduction study, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment. Therefore, there are no residual concerns regarding developmental effects in the young.

iv. There are no residual uncertainties identified in the exposure databases. Dietary food exposure assessments were performed based on 100% crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to quinoxifen in drinking water. These assessments will not underestimate the exposure and risks posed by quinoxifen.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by

all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No acute dietary endpoint was identified for any segment of the United States (U.S.) population. Therefore, quinoxifen is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to quinoxifen from food and water will utilize 2% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for quinoxifen to consider.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Quinoxifen is not registered for any use patterns that would result in residential exposure. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to quinoxifen through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, quinoxifen was classified as "not likely to be carcinogenic to humans." Therefore, quinoxifen is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to quinoxifen residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with mass-selective detection (GC-MSD)) 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; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no Mexican maximum residue limits (MRLs) established for residues of quinoxifen in crops associated with this review. Codex MRLs exist for quinoxifen on cherry, sweet and tart at 0.4 ppm; and Canadian MRLs exist for cherry, sweet and tart at 0.3 ppm. However, the proposed tolerance for fruit, stone, group 12 (0.70 ppm), of which cherry is a part, cannot be harmonized with the Codex or Canadian MRLs on these commodities because field trial data supporting the stone fruit group tolerance shows residue levels that are higher than 0.4 ppm.

#### V. Conclusion

Therefore, tolerances are established for residues of quinoxifen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on artichoke, globe at 1.4 ppm; fruit, stone, group 12 at 0.70 ppm; squash, winter at 0.20 ppm; pumpkin at 0.20 ppm; and gourd, edible at 0.20 ppm. This regulation also deletes the established tolerances in or on cherry, sweet; and cherry, tart, as they are superseded by inclusion in fruit, stone, group 12. This regulation additionally deletes the time-limited tolerances for pumpkin; winter squash; and melon subgroup 9A, as the tolerances expired on December 31, 2007.

#### VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the

**Federal Register.** This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: March 19, 2009.

**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. Section 180.588 is amended in paragraph (a), by removing the commodities "Cherry, sweet" and "Cherry, tart"; and by alphabetically adding the following commodities to the table; and in paragraph (b), by removing all of the commodities and reserving the paragraph designation and heading to read as follows:

**§ 180.588 Quinoxifen; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Artichoke, globe .....	1.4
Fruit, stone, group 12 .....	0.70
* * *	
Gourd, edible .....	0.20
* * *	
Pumpkin .....	0.20
Squash, winter .....	0.20
* * *	

(b) Section 18 emergency exemptions. [Reserved]

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0097; FRL-8407-2]

**Captan, 2,4-D, Dodine, DCPA, Endothall, Fomesafen, Propyzamide, Ethofumesate, Permethrin, Dimethipin, and Fenarimol; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** EPA issued a final rule in the **Federal Register** of September 12, 2007, revoking, revising, and establishing certain tolerances. This document is being issued to correct a terminology omission associated with DCPA and onions.

**DATES:** This final rule is effective April 1, 2009.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0097. All documents in the docket are listed in the docket index available in <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Jane Smith, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0048; e-mail address: [smith.jane-scott@epa.gov](mailto:smith.jane-scott@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document

electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>.

**II. What Does this Technical Amendment Do?**

EPA issued a notice of proposed rulemaking in the **Federal Register** of June 6, 2007 (72 FR 31221) (FRL-8122-7), that proposed to revoke, revise, and establish certain tolerances for captan, 2,4-D, dodine, DCPA, endothall, fomesafen, propyzamide, ethofumesate, permethrin, dimethipin, and fenarimol. On page 31228, third column, first full paragraph, the Agency stated the following:

... EPA is proposing to revise commodity terminology and tolerances to conform to current Agency practice in 40 CFR 180.185(a) for the combined residues of the herbicide DCPA and its metabolites MTP and TCP (calculated as DCPA) in or on melon, honey dew to muskmelon; and onion to onion, bulb ...

The June 6, 2007 **Federal Register** publication was intended only to update commodity terminology, and not to revoke or revise the scope of existing tolerances. The existing tolerance for "onion" covered both "onion, bulb" and "onion, green" as defined under current commodity terminology. The reference to "onion, green" was inadvertently omitted from both the June 6, 2007 proposed rule and the final rule published on September 12, 2007 (72 FR 52013) (FRL-8142-2). Use on both "onion, bulb" and "onion, green" continues to be permitted according to labels of currently registered DCPA products, and the required safety findings for the residues permitted under the tolerance were made taking into account both types of onions. Therefore, 40 CFR 180.185(a) is amended by establishing a tolerance for DCPA in/on onion, green at 1.0 ppm to effectuate EPA's original intention in the proposed and final rules changing terminology only.

**III. Why is this Technical Amendment Issued as a Final Rule?**

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(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 today's technical amendment final without prior proposal and opportunity for comment, because this action merely corrects a drafting error in the rulemaking that was