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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0506; FRL-9930-04]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil in or on multiple commodities that are identified and discussed later in this document, and removes the established tolerance on fruit, stone, group 12. 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-2014-0506, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0506 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-2014-0506, 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 September 5, 2014 (79 FR 53009) (FRL-9914-98), 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 4E8293) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on acerola at 1.5 parts per million (ppm); artichoke, globe at 4.0 ppm; feijoa at 1.5 ppm; fruit, stone group 12–12 at 2.0 ppm; guava at 1.5 ppm; jaboticaba at 1.5 ppm; passionfruit at 1.5 ppm; pomegranate at 7.0 ppm; starfruit at 1.5 ppm; and wax jambu at 1.5 ppm. This petition additionally requested to remove the tolerance in 40 CFR 180.532 for residues of cyprodinil in or on fruit, stone, group 12 at 2.0 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, the registrant, which is available in the

docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance on pomegranate, and has revised the commodity definition for artichoke to artichoke, globe. The reasons for these changes are explained in Unit IV.D.

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 cyprodinil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyprodinil 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 major target organs of cyprodinil are the liver and the kidney. Liver effects were consistent among rats and mice in both subchronic and chronic studies and typically included increased liver weights and increases in serum clinical chemistry parameters, associated with adverse effects on liver function (*i.e.*, increased cholesterol and phospholipid levels). Microscopic lesions in rats and mice included hepatocyte hypertrophy and hepatocellular necrosis. In the kidneys, chronic tubular lesions and chronic kidney inflammation following subchronic exposure and increased kidney weights and progressive nephropathy following chronic exposures in male rats. Chronic effects in dogs were limited to decreased body-weight gain, decreased food consumption and decreased food efficiency. The hematopoietic system also appeared to be a target of cyprodinil, as mild anemia was seen following subchronic rat exposure (reductions in hematocrit and hemoglobin and microcytosis). Although increases in thyroid weight or hypertrophy of thyroid follicular cells were observed at higher doses in the 28-day and 90-day oral toxicity study in rats, treatment-related changes in thyroid weights or gross/microscopic observations were not observed in the chronic rat study or in other studies.

A 28-day dietary immunotoxicity study in mice resulted in no apparent suppression of the humoral component of the immune system. The only effect attributed to cyprodinil treatment was higher liver weights at the highest dose tested. There were no treatment-related effects on spleen or thymus weights; no effects on specific activity or total activity of splenic

immunoglobulin M (IgM) antibody-forming cells to the T cell-dependent antigen sheep red blood cells (sRBC).

An acute neurotoxicity study indicated systemic toxicity with signs of induced hunched posture, piloerection, and reduced responsiveness to sensory stimuli and reduced motor activity. Clinical signs, hypothermia, and changes in motor activity were found to be reversible by day 8 and 15 investigations. A subchronic neurotoxicity study showed no treatment related effects on mortality, clinical signs, or gross or histological neuropathology. Functional observational battery (FOB) and motor activity testing revealed no treatment related effects up to the highest dose tested.

There was no evidence of increased susceptibility in the developmental rat or rabbit study following *in utero* exposure or in the two-generation reproduction study following pre- and post-natal exposure. Fetal toxicity, manifested as significantly lower fetal weights and an increased incidence of delayed ossification in the rat and a slight increase in litters showing extra ribs in the rabbit, was reported in developmental toxicity studies. In a rat two-generation reproduction study, significantly lower pup weights for F₁ and F₂ offspring were observed. Each of these fetal or neonatal effects occurred at the same dose levels at which maternal toxicity (decreased body weight gain) was observed and were considered to be secondary to maternal toxicity.

Specific information on the studies received and the nature of the adverse effects caused by cyprodinil 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: *Cyprodinil. Human Health Risk Assessment for the Expansion of Existing Crop Group/Representative Commodity Uses to Stone Fruit Group 12-12,*

and Adding New Uses on the Artichoke, Guava, Pomegranate, Passionfruit, Feijoa, Jaboticaba, Wax Jambu, Starfruit, and Acerola and Amended Uses on Greenhouse Cucumbers and Small Tomatoes at pages 36-40 in docket ID number EPA-HQ-OPP-2014-0506.

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 cyprodinil used for human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of October 16, 2012 (77 FR 49732) (FRL-9359-7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyprodinil, EPA considered exposure under the petitioned-for tolerances as well as all existing cyprodinil tolerances in 40 CFR 180.532. EPA assessed dietary exposures from cyprodinil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for cyprodinil. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), from 2003 to 2008. As to residue levels in food, EPA utilized tolerance-level residues and 100 percent crop treated (PCT) for all commodities. The acute assessment also incorporated Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.18 default processing factors; and empirical processing factors for tomato paste/tomato puree and lemon/lime juice, where 1X empirical processing factors were used to modify the tolerance values.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA utilized average field trial residues for pome fruit, head lettuce, leaf lettuce, spinach, tomato, and grape and tolerance-level residues for the remaining commodities. The Agency also assumed 100 PCT. The chronic assessment also incorporated DEEM default processing factors except for tomato paste/tomato puree and lemon juice/lime juice, where a 1X empirical processing factor was used to modify the tolerance values.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that cyprodinil does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCFA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCFA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCFA section 408(b)(2)(E) and authorized under FFDCFA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The residues of concern in drinking water for risk assessment purposes are cyprodinil and the degradate CGA 249287. The estimated drinking water concentrations (EDWCs) for each of these was calculated using a molecular weight conversion and then combined for each modeled scenario. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyprodinil and CGA 249287 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyprodinil and CGA 249287. 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 Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS), Screening Concentration in Ground Water (SCI-GROW), and Pesticide Root Zone Model for Groundwater (PRZM-GW) models, the EDWCs of cyprodinil and CGA 249287 for

acute exposures are estimated to be 34.8 parts per billion (ppb) for surface water and 2.05 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 24.7 ppb for surface water and 1.80 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 34.8 ppb and 24.7 ppb were used to assess the contribution to drinking water for the acute and chronic dietary risk assessments, respectively.

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).

Cyprodinil is currently registered for the following uses that could result in residential exposures: Ornamental landscapes. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposures to adult residential handlers from the application of cyprodinil to ornamental landscapes. The residential handler exposure scenarios were considered to be short-term only, due to the infrequent use patterns associated with homeowner products. Dermal exposures were not assessed since there was no dermal endpoint identified for cyprodinil. Postapplication exposures to adults or children were not expected and were not assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

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 cyprodinil to share a common mechanism of toxicity with any other substances, and cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyprodinil 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.* In a rat developmental toxicity study, there were significantly lower mean fetal weights in the high dose group compared to controls as well as a significant increase in skeletal anomalies in the high dose group due to abnormal ossification. The skeletal anomalies or variations were considered to be a transient developmental delay that occurred secondary to the maternal toxicity noted in the high dose group. In the rabbit study,

the only treatment-related developmental effect was the indication of an increased incidence of a 13th rib at maternally toxic doses. Signs of fetal effects in the reproductive toxicity study included significantly lower F1 and F2 pup weights in the high dose group during lactation, which continued to be lower than controls post-weaning and after the pre-mating period in the F1 generation. Reproductive effects were seen only at doses that also caused parental toxicity.

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 for non-inhalation exposure scenarios. For inhalation exposure scenarios for all population groups, EPA is retaining a 10X FQPA SF. That decision is based on the following findings:

i. The toxicity database for cyprodinil is complete, except for a 90-day inhalation toxicity study. In the absence of a route-specific inhalation study, EPA is relying on the 28-day feeding/range-finding rat oral study to estimate risk from inhalation exposures. EPA has determined that the use of this study to extrapolate an inhalation endpoint may understate risk. Accordingly, to address this uncertainty, EPA has concluded that the 10X FQPA SF should be retained for risk assessments involving inhalation exposure.

ii. As to evidence of neurotoxicity, in an acute neurotoxicity study in rats clinical signs, hypothermia, and changes in motor activity were all found to be reversible and no longer seen at day 8 and 15 investigations. There were no treatment-related effects on mortality or gross or histological neuropathology. Reduced motor activity, induced hunched posture, piloerection and reduced responsiveness to sensory stimuli were observed and disappeared in all animals by day three to four. For the subchronic neurotoxicity study in rats, there was no indication that cyprodinil is a neurotoxic chemical. Based on this evidence, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. When toxicity was observed in the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, toxicity to the fetuses or offspring occurred at the same doses at which effects were observed in maternal/parental animals. Additionally, the skeletal anomalies or variations were considered to be a transient developmental delay that occurred secondary to the maternal toxicity noted in the high dose group. Therefore, there is no evidence that cyprodinil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary assessment was conservative and based upon 100 PCT and tolerance-level residues, as well as DEEM default and empirical processing factors. The chronic dietary assessment was partially refined with average field trial residues for some commodities and tolerance-level residues for the remaining commodities. DEEM default and empirical processing factors were also incorporated into the chronic dietary assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyprodinil in drinking water. Based on the discussion in Unit III.C.3, postapplication exposure of children as well as incidental oral exposure of toddlers is not expected. These assessments will not underestimate the exposure and risks posed by cyprodinil.

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 cyprodinil will occupy 8.6 % of the aPAD for children one to two years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyprodinil from food and water will utilize 85 % of the cPAD for children one to two years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of cyprodinil 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). Cyprodinil 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 cyprodinil.

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 an aggregate MOE of 7,900. Because EPA's level of concern for cyprodinil is a MOE of 1,000 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,

cyprodinil 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 cyprodinil.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyprodinil is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate high performance liquid chromatography, using ultra-violet detection (HPLC/UV) methods (Methods AG-631 and AG-631B) are available to enforce the tolerance expression of cyprodinil in/on plant commodities.

The methods 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 established MRLs for cyprodinil in or on stone fruit at 2.0 ppm. This MRL is the same as the tolerance established for cyprodinil in the United States for fruit, stone, group 12-12. The Codex has not established a MRL for cyprodinil in or on the other commodities associated with this action.

C. Response to Comments

Several comments were received in response to the notice of filing. All but one were concerned with potential environmental impacts, and were not specifically related to the cyprodinil action. EPA notes that these comments address potential environmental concerns; however, the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

One additional comment was received that did not specifically address the cyprodinil action, but that raised concerns about the toxicity of pesticides and requested that no tolerance

be established. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework. EPA has found that there is a reasonable certainty of no harm to humans after considering the toxicological studies and the exposure levels of humans to cyprodinil.

D. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA has determined that the proposed tolerance in or on pomegranate at 7.0 ppm should be established at 10 ppm. This tolerance level was determined by the Organization for Economic Cooperation and Development tolerance calculation procedures. Additionally, the Agency is establishing a tolerance in or on artichoke, globe, rather than the petitioned-for commodity artichoke in order to provide the correct commodity definition.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, in or on acerola at 1.5 ppm; artichoke, globe at 4.0 ppm; feijoa at 1.5 ppm; fruit, stone, group 12-12 at 2.0 ppm; guava at 1.5 ppm; jaboticaba at 1.5 ppm; passionfruit at 1.5 ppm; pomegranate at 10 ppm; starfruit at 1.5 ppm; and wax jambu at 1.5 ppm. Additionally, this action removes the tolerance established in or on fruit, stone, group 12

at 2.0 ppm as that crop group tolerance is superseded by the tolerance being established in this action for crop group 12-12.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the tolerances 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: August 13, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.532, remove the entry, “Fruit, stone, group 12” and alphabetically add the following commodities to the table in paragraph (a) to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

Commodity	Parts per million
Acerola	1.5
****	***
Artichoke, globe	4.0
****	***
Feijoa	1.5
****	***
Fruit, stone, group 12-12	2.0
****	***
Guava	1.5
****	***
Jaboticaba	1.5
****	***

Passionfruit	1.5
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Pomegranate	10
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Starfruit	1.5
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Wax jambu	1.5

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