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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0180; FRL-9943-85]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil in or on Nut, Tree, Crop Group 14-12; except almond and pistachio. Syngenta Crop Protection, LLC 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-2015-0180, 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-2015-0180 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-2015-0180, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 22, 2015 (80 FR 22466) (FRL-9925-79), 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 4F8333) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.532 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, in or on Nut, Tree, Crop Group 14-12; except almond and pistachio at 0.04 parts per million (ppm). That document referenced a summary of the petition prepared by Syngenta Crop Group, LLC, 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.

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 male and female rats and mice in both sub-chronic and chronic studies and typically included increased liver weights along with 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, adverse effects were seen as chronic tubular lesions and chronic kidney inflammation following sub-chronic exposure of male rats. Chronically, cyprodinil caused increased kidney weights and progressive nephropathy in male rats. Chronic

effects in dogs were limited to decreased body-weight gain, decreased food consumption and decreased food efficiency; liver toxicity was not seen in the dog. The hematopoietic system also appeared to be a target of cyprodinil as mild anemia was seen in rats exposed sub-chronically (reductions in hematocrit and hemoglobin and microcytosis). Although increases in thyroid weight and/or hypertrophy of thyroid follicular cells were observed at higher doses in the rat 28-day oral-toxicity studies and in the 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 mean absolute, relative (to body weight), and adjusted liver weights for the 5000 ppm group. There were no treatment-related effects on absolute, adjusted, or relative spleen or thymus weights; no effects on specific activity or total activity of splenic Immunoglobulin M antibody-forming cells to the T cell-dependent red blood cell antigens. No dermal or systemic toxicity was seen following repeated dermal application at the highest dose in a 21-day dermal toxicity study in rabbits.

An acute neurotoxicity study indicated systemic toxicity with signs of induced hunched posture, piloerection, and reduced responsiveness to sensory stimuli and reduced motor activity. Females were slightly more affected than males per daily clinical observations, which disappeared by day 3 to 4. A dose-related reduction in body temperature was seen in all treated animals, thus hypothermia is considered a compound-related effect in the highest dose tested and was found to be statistically significant, whereas the lower dosed animals was not or only marginally significant and was fully reversible in all groups. Clinical signs, hypothermia, and changes in motor activity were found to all be reversible by day 8 and 15 investigations. There were no histopathological findings to support evidence of damage to the central nervous system, eyes, optic nerves, or skeletal muscles. A sub-chronic neurotoxicity study showed no treatment related effects on mortality, clinical signs, or gross or histological neuropathology. Functional observational battery 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 (13^{th}) in the rabbit, was reported in developmental toxicity studies. In a rat two-generation reproduction study, significantly lower pup weights for F_1 and F_2 offspring were observed. However, each of these fetal/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.

Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to the carcinogenic potential, cyprodinil was classified as "not likely to be carcinogenic to humans."

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 the document, "Human Health Risk Assessment for the Petition Proposing a New Tolerance for the Use of cyprodinil in/on Nut, Tree, Crop Group 14-12; except almond and pistachio" in docket ID number EPA-HQ-OPP-2015-0180.

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 the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk

assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for 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. 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). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA utilized the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID, Version 3.16 default processing factors and tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used food consumption information from the USDA NHANES/WWEIA dietary survey conducted from 2003 to 2008. As to residue levels in food, EPA utilized residue data from field trials to obtain average residues and assumed 100 PCT. Empirically derived processing factors were used in these assessments when available; all other processing factors used the DEEM-FCID Version 7.81 default processing factors.

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 was not conducted.

iv. *Anticipated residue information*. Section 408(b)(2)(E) of FFDCA 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 FFDCA 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA 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 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS), Screening Concentration in Ground Water (SCI-GROW) models and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (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. For acute dietary risk assessment, the water concentration value of 34.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 24.7 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).

Cyprodinil is currently registered for the following uses that could result in residential exposures: Ornamental plants. EPA assessed residential exposure using the following assumptions: only short-term inhalation exposures to adult residential handlers from application to ornamental plants. Though there may be short-term dermal exposures to handlers, this was not assessed since no dermal endpoint was identified. Post-application exposures to adults and children are not expected. Intermediate or chronic exposures are not expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of 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 engendered 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either

retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. 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/variations were considered to be a transient developmental delay that occurs secondary to the maternal toxicity noted in the high-dose group. In the rabbit study, the only treatment related developmental effect was indication of an increased incidence of a 13^{th} rib at maternally toxic doses. Signs of fetal effects in the reproductive toxicity study included significantly lower F_1 and F_2 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 F_1 generation only. 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 routes of exposure and retained at 10X for inhalation exposure scenarios for all population groups. That decision is based on the following findings:

i. The toxicity database for cyprodinil is complete, except for a 90-day inhalation toxicity study required to reduce uncertainty associated with the use of an oral POD for assessing risk via the inhalation route. In the absence of a route-specific inhalation study, a 10x FQPA SF factor for residential scenarios will be retained for risk assessments involving inhalation exposure.

ii. As indicated by an acute neurotoxicity study in mice, 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, 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 3 to 4. In a sub-chronic neurotoxicity study in rats, there were no treatment related effects on mortality, clinical signs, or gross or histological neuropathology. No clinical signs suggestive of neurobehavioral alterations or evidence of neuropathological effects were observed in the

available oral-toxicity studies. Based on this evidence, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. In the prenatal developmental rat and rabbit studies and in the 2-generation reproduction rat study, toxicity to the fetuses/offspring, when observed, occurred at the same doses at which effects were observed in maternal/parental animals. All of these fetal effects were considered to be secondary to maternal toxicity. 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 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary assessment was conservative and based on 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, post-application exposure to children as well as incidental oral exposure to 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 population adjusted dose (aPAD) and chronic population adjusted dose (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 estimated short-term food, water and residential exposures. For adults, oral dietary and inhalation estimates were combined using the total aggregate risk index (ARI) methodology since the levels of concern (LOC) for oral and dietary exposure (LOC=100) and inhalation (LOC 1,000) are different. The short-term ARI for adults is 70 which is greater than 1 and is therefore, 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 HPLC/UV methods (AG-631 and AG-631B) are available for enforcing tolerances of cyprodinil on plant commodities.

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 an MRL for cyprodinil in/on tree nut commodities other than pistachio and almond.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, in or on Nut, Tree Crop Group 14-12; except almond and pistachio at 0.04 ppm.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 7, 2016.

Daniel J. Rosenblatt,

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, add alphabetically the commodity "Nut, tree, group 14-12; except almond and pistachio" to the table in paragraph (a), to read as follows:

§ 180.532 Cyprodinil; tolerances for residues

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

Commodity	Parts per million
*******	
Nut, tree, group 14-12; except almond and pistachio	0.04
*******	

* * * * *

[FR Doc. 2016-09028 Filed: 4/18/2016 8:45 am; Publication Date: 4/19/2016]