BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0394; FRL-9359-7]

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 which are identified and discussed later in this document, associated with Pesticide Petition (PP) 1E7854, and establishes a tolerance in or on leaf petioles subgroup 4B, associated with PP 1E7869. Interregional Research Project Number 4 (IR-4) and Syngenta Crop Protection requested the tolerances associated with PP 1E7854 and 1E7869, respectively, 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-2011-0394, is available either electronically through *http://www.regulations.gov* or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7390; email address: *Nollen.Laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0394 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0394, by one of the following methods:

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

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

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 20, 2011 (76 FR 43231) (FRL-8880-1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of PP 1E7854 by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. 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 onion, bulb, subgroup 3-07A at 0.6 parts per million (ppm); onion, green, subgroup 3-07B at 4.0 ppm; caneberry subgroup 13-07A at 10.0 ppm; bushberry subgroup 13-07B at 3.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; berry, low growing, subgroup 13-07G, except cranberry at 5.0 ppm; dragon fruit at 2.0 ppm; fruit, pome, group 11-10 at 1.7 ppm; vegetable, fruiting, group 8-10 at 1.3 ppm; and leafy greens subgroup 4A at 40 ppm.

Upon approval of the aforementioned tolerances, the petition additionally requested amendment of 40 CFR 180.532 by removing the established tolerances for the residues of cyprodinil in or on onion, bulb at 0.60 ppm; onion, green at 4.0 ppm; caneberry subgroup 13A at 10 ppm; bushberry subgroup 13B at 3.0 ppm; Juneberry at 3.0 ppm; lingonberry at 3.0 ppm; salal at 3.0 ppm; grape at 2.0 ppm; strawberry at 5.0 ppm; fruit, pome at 1.7 ppm; tomatillo at 0.45 ppm; tomato at 0.45 ppm; and leafy greens

subgroup 4A, except spinach at 30 ppm. The published notice of the petition referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to this notice of filing.

In the **Federal Register** of April 4, 2012 (77 FR 20334) (FRL-9340-4), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of PP 1E7869 by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27409. The petition requested that 40 CFR 180.532 be amended by establishing tolerances for residues of the fungicide cyprodinil in or on leafy petioles subgroup 4B at 30 parts per million. That notice referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received to this notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the proposed tolerance levels for several commodities. 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.

Cyprodinil has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Cyprodinil is mildly irritating to the eyes and negligibly irritating to the skin. It is a dermal sensitizer. The major target organs of cyprodinil are the liver in both rats and mice and the kidney in rats. Liver effects observed consistently in subchronic and chronic studies in rats and mice included increased liver weights and increases in serum clinical chemistry parameters associated with adverse effects on liver function,

hepatocyte hypertrophy, and hepatocellular necrosis. Adverse kidney effects included tubular lesions and inflammation following subchronic exposure of male rats. The hematopoietic system also appeared to be a target of cyprodinil, causing mild anemia following subchronic exposure to cyprodinil in rats. Chronic effects in dogs were limited to decreased body weight gain, decreased food consumption and decreased food efficiency.

Fetal toxicity reported in developmental toxicity studies in the rat included significantly lower fetal weights and an increased incidence of delayed ossification in the rat and showed a slight increase in litters showing extra ribs in the rabbit. In a rat 2-generation reproduction study, significantly lower pup weights were observed in F_1 and F_2 offspring. However, each of these fetal and neonatal effects occurred at the same dose levels at which maternal toxicity (decreased body weight gain) was observed, and the effects were considered to be secondary to maternal toxicity.

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, 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. The subchronic neurotoxicity study in rats, showed no treatment-related effects related to neurotoxicity. An immunotoxicity study in mice resulted in no apparent suppression of the humoral component of the immune system. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies.

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: Expansions of Existing Crop Group/Representative Commodity Uses to Numerous Crop Subgroups, Adding Use on Leafy Petiole Subgroup 4B, and Adding Use on the Remaining Crops in Fruiting Vegetables Group 8-10." pp 34-38 in docket ID number EPA-HQ-OPP-2011-0394."

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 (LOC) 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 (U/SF) 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 shown in Table 1 of this unit.

Table 1.—Summary of Toxicological Doses and Endpoints for Cyprodinil for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day aPAD = 2.0 mg/kg/day	Acute Neurotoxicity - Rat LOAEL = 600 mg/kg/day based on clinical signs of toxicity (hunched posture, piloerection, and reduced responsiveness to sensory stimuli, reduced motor activity and hypothermia)

Chronic dietary (All populations)	NOAEL= 2.7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.027 mg/kg/day cPAD = 0.027 mg/kg/day	2-Year Chronic Toxicity/ Carcinogenicity- rat LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatitis) in males.
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 62 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 10x	LOC for MOE = 1,000	28-Day Feeding/Range-Finding - Rat LOAEL = 299 mg/kg/day based on decreased body-weight gain, increased cholesterol and phospholipid levels, microcytosis, and hepatocyte hypertrophy.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic to humans.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

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

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) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, 100 percent crop treated (PCT) estimates, and Dietary Exposure Evaluation Model (DEEM™ (ver. 7.81)) default processing factors.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues for most commodities; average field trial residues for pome fruit, head lettuce, leaf lettuce, and grapes; and 100 PCT estimates. DEEM™ (ver. 7.81) default and empirical processing factors for tomato paste/puree (1x) and lemon/lime juice (1x) were 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 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 in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyprodinil. 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) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of cyprodinil for surface water are expected to be 34.79 parts per billion (ppb) for acute exposures and 24.65 ppb for chronic exposures. The EDWCs of cyprodinil for ground water are expected to be 0.0861 ppb for acute and chronic exposures.

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

of 34.79 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 24.65 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 landscapes. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposures to residential handlers are expected from application to ornamental landscapes. Dermal exposures were not assessed, since there is no dermal POD. Residential handler exposure scenarios are considered to be short-term only, due to the infrequent use patterns associated with homeowner products. Postapplication exposures are not expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found 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 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 cyprodinil toxicity database is adequate to evaluate potential increased susceptibility of infants and children, and includes developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. 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 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 inhalation data, EPA is relying on an oral study for estimating risk from inhalation exposures. EPA evaluation of use of oral studies to extrapolate an inhalation endpoint has shown that such extrapolation may understate risk. Accordingly, to address the uncertainty caused by extrapolating an inhalation endpoint from an oral study for cyprodinil, EPA has concluded that the 10X FQPA SF should be retained for risk assessments involving inhalation exposure.

ii. In the subchronic neurotoxicity study in rats, there was no indication that cyprodinil is a neurotoxic chemical. 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 3 to 4. Based on this evidence, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, toxicity to the fetuses and/or offspring, when observed, occurred at the same doses at which effects were observed in maternal/parental animals. Additionally, the skeletal anomalies/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 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. The chronic dietary food exposure assessment was partially refined, assuming average field trial residues and empirical processing factors for some commodities, and tolerance level residues and DEEM™ (ver. 7.81) default for the remaining commodities. 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 aPAD and cPAD. For linear cancer risks,

EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyprodinil will occupy 8.2 % of the aPAD for children 1-2 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 75 % of the cPAD for children 1-2 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 to adults, 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 9,000. 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 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 established MRLs for cyprodinil in or on several commodities that are not harmonized with the tolerances being established in the United States, as follows: Codex MRL on eggplant at 0.2 ppm, pepper at 0.5 ppm, and tomato at 0.5 ppm and U.S. tolerance on vegetable, fruiting, group 8-10 at 1.5 ppm; Codex MRL on onion, bulb at 0.3 ppm and U. S. tolerance on onion, bulb, subgroup 3-07A at 0.6 ppm; Codex MRL on black and red raspberry at 0.5 ppm and U.S. tolerance on caneberry subgroup 13-07A at 10 ppm; Codex MRL on head and leaf lettuce at 10 ppm and U. S. tolerance on leafy greens subgroup 4A at 50 ppm; and Codex MRLs on apple at 0.05 ppm and pear at 1 ppm and U. S. tolerance on fruit, pome, group 11-10 at 1.7 ppm. The United States

tolerance recommendations cannot be harmonized with the Codex MRLs established for cyprodinil because the residue data supporting the tolerance necessitate a higher value.

Additionally, Codex has an established MRL on grape at 3 ppm and dried grapes at 5 ppm. The EPA is establishing the tolerance for fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F (for which grape is the representative commodity) at 3 ppm and grape, raisin at 5 ppm in order to harmonize with the Codex MRLs. Codex has not established MRLs on the other commodities associated with these petitions.

C. Response to Comments

One comment was received to the Notice of Filing for PP 1E7869, which requested additional information about the nature of the residue and the adverse effects noted from exposure to cyprodinil. Specific information on the nature of the residue, including physical and chemical characteristics, as well as the adverse effects caused by cyprodinil from the toxicity studies can be found in the supporting and related material at http://*www.regulations.gov* in docket ID number EPA-HQ-OPP-2011-0394.

D. Revisions to Petitioned-For Tolerances

Based on the data supporting the petitions, EPA has revised the proposed tolerance on vegetable, fruiting, group 8-10 from 1.3 ppm to 1.5 ppm; and leafy greens subgroup 4A from 40 ppm to 50 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures.

Additionally, the Agency revised the proposed tolerance in or on fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F from 2.0 ppm to 3.0 ppm in order to harmonize with the established Codex MRL on grape at 3 ppm. The Agency has also

revised the established tolerance in or on grape, raisin from 3.0 ppm to 5.0 ppm in order to align with the Codex MRL on dried grapes at 5 ppm.

EPA determined that the established tolerance on tomato, paste at 1.0 ppm should be removed, as it will be superseded by the tolerance in or on fruiting vegetable group 8-10 tolerance at 1.5 ppm.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, 4-cyclopropyl-6-methyl- *N* -phenyl-2-pyrimidinamine, in or on onion, bulb, subgroup 3-07A at 0.6 ppm; onion, green, subgroup 3-07B at 4.0 ppm; caneberry subgroup 13-07A at 10 ppm; bushberry subgroup 13-07B at 3.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 3.0 ppm; grape, raisin at 5.0 ppm; berry, low growing, subgroup 13-07G, except cranberry at 5.0 ppm; vegetable, fruiting, group 8-10 at 1.5 ppm; leafy greens subgroup 4A at 50 ppm; fruit, pome, group 11-10 at 1.7 ppm; dragon fruit at 2.0 ppm; and leaf petioles subgroup 4B at 30 ppm. Additionally, the established tolerance on citrus, oil is amended from 340 ppm to 60 ppm. Finally, this regulation removes tolerances of cyprodinil in or on onion, bulb at 0.60 ppm; onion, green at 4.0 ppm; caneberry subgroup 13A at 10 ppm; bushberry subgroup 13B at 3.0 ppm; grape at 2.0 ppm; strawberry at 5.0 ppm; tomato at 0.45 ppm; Juneberry at 3.0 ppm; lingonberry at 3.0 ppm; salal at 3.0 ppm; tomatillo at 0.45 ppm; fruit, pome at 1.7 ppm; leafy greens subgroup 4A, except spinach at 30 ppm; and tomato, paste at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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: August 10, 2012.

Daniel J. Rosenblatt,

Acting 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, the table in paragraph (a)(1) is revised to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Almond	0.02
Almond, hulls	8.0
Apple, wet pomace	4.6
Avocado	1.2
Bean, dry	0.6
Bean, succulent	0.6
Berry, low growing, subgroup 13-07G, except cranberry	5.0
Brassica, head and stem, subgroup 5A	1.0
Brassica, leafy greens, subgroup 5B	10.0
Bushberry subgroup 13-07B	3.0
Caneberry subgroup 13-07A	10

Canistel	1.2
Canola, seed[1]	0.03
Citrus, dried pulp	8.0
Citrus, oil	60
Dragon fruit	2.0
Fruit, pome, group 11-10	1.7
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	3.0
Fruit, stone, group 12	2.0
Grape, raisin	5.0
Herb subgroup 19A, dried, except parsley	15.0
Herb subgroup 19A, fresh, except parsley	3.0
Kiwifruit	1.8
Leaf petioles subgroup 4B	30
Leafy greens subgroup 4A	50
Lemon	0.60
Lime	0.60
Longan	2.0
Lychee	2.0
Mango	1.2
Onion, bulb, subgroup 3-07A	0.6

Onion, green, subgroup 3-07B	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
Pistachio	0.10
Pulasan	2.0
Rambutan	2.0
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Spanish lime	2.0
Star apple	1.2
Turnip, greens	10.0
Vegetable, cucurbit, group 9	0.70
Vegetable, fruiting, group 8-10	1.5
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugarbeet, subgroup 1B	0.75
Watercress	20

[1]Import only.

* * * * *

[FR Doc. 2012-20235 Filed 08/16/2012 at 8:45 am; Publication Date: 08/17/2012]