Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction because it involves the establishment of a safety zone.

A final environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under ADDRESSES.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:


2. Add § 165.T09–0043 to read as follows:

§ 165.T09–0043 Safety Zone; Antique Boat Show, Niagara River, Grand Island, NY.

(a) Location. The safety zone will encompass all waters of the Niagara River, Grand Island, NY starting at position 42°59′59″ N, 078°56′22″ W, East to 42°59′54″ N, 078°56′14″ W, South to 42°57′54″ N, 078°56′04″ W, West to 42°05′74″ N, 078°56′22″ W. (NAD 83).

(b) Effective and Enforcement Period. This regulation is effective and will be enforced on September 8, 2012 from 9:30 a.m. until 4:30 p.m.

(c) Regulations.

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf. The on-scene representative of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.


S.M. Wischmann,
Captain, U. S. Coast Guard, Captain of the Port Buffalo.

Supplementary 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?


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 October 16, 2012. 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.
- http://www.epa.gov/dockets. 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 10.0 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 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 availability of PP 1E7869 by Syngenta Crop Protection, Inc., 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 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.” Under FFDCA 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
observed in F
dsignificantly lower pup weights were
2-generation reproduction study,
showing extra ribs in the rabbit. In a rat
showed a slight increase in litters
weights and an increased incidence of
and mice 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 F1 and F2 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
(NOAEI) 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

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>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary All populations) ...</td>
<td>NOAEL = 200 mg/kg/day. UF = 10x UFf = 10x FOPA SF = 1x</td>
<td>Acute RID = 2.0 mg/kg/day. aPAD = 2.0 mg/kg/day</td>
<td>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).</td>
</tr>
<tr>
<td>Chronic dietary (All populations)</td>
<td>NOAEL = 2.7 mg/kg/day. UF = 10x UFf = 10x FOPA SF = 1x</td>
<td>Chronic RID = 0.027 mg/kg/day. cFPA = 0.027 mg/kg/day</td>
<td>2-Year Chronic Toxicity/Carcinogenicity—rat LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatitis) in males.</td>
</tr>
</tbody>
</table>
TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYPRODINIL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation short-term (1 to 30 days).</td>
<td>Inhalation (or oral) study NOAEL = 62 mg/kg/day (inhalation absorption rate = 100%). UF&lt;sub&gt;α&lt;/sub&gt; = 10x UF&lt;sub&gt;H&lt;/sub&gt; = 10x FQPA SF = 10x</td>
<td>LOC for MOE = 1,000.</td>
<td>28-Day Feeding/Range-Finding—Rat LOAEL = 299 mg/kg/day based on decreased body-weight gain, increased cholesterol and phospholipid levels, microcysis, and hepatocyte hypertrophy.</td>
</tr>
<tr>
<td>Cancer (Oral, dermal, inhalation).</td>
<td>Not likely to be carcinogenic to humans.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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). RID = reference dose. UF = uncertainty factor. UF<sub>α</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = 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.

2. 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<sup>TM</sup> (ver. 7.81)) default processing factors.

3. 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<sup>TM</sup> (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.

4. 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](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 (SCIGROW) models, the estimated drinking water concentration (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 value of 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, termiteicides, 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 tract6a05.pdf](http://www.epa.gov/pesticides/trac/science tract6a05.pdf).

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA...
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 underestimate 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 UF's to account for neurotoxicity.

iii. In the prenat al developmental toxicity studies in rats and rabbits and the 2-gener ation 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/vari ations 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.

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/vari ations 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.

b. Toxicity to F1 and F2 offspring. 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.

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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 underestimate 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 UF’s to account for neurotoxicity.

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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.

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 Maps Rd., Ft. Meade, MD 20755–5350; telephonenumber: (410) 305–2005; email address: residumethods@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 raspberry 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 on fruit, pome, group 11–10 at 1.7 ppm. 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 3.0 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 citrus, oil, subgroup 3–07A at 0.6 ppm; cranberry subgroup 13–07A at 10 ppm; bushberry subgroup 13–07B at 3.0 ppm; grape, raisin at 5.0 ppm; strawberry at 5.0 ppm; tomato at 0.45 ppm; and pomegranate at 0.3 ppm.

D. Revisions to Petitioned-For Tolerances
Based on the data supporting the petitions, EPA has revised the 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 3.0 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; and pomegranate at 0.3 ppm.

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.
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 62249, 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) (Pub. L. 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 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.


Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

§ 180.532 Cyprodinil; tolerances for residues.

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

(1) 7.0

Appendix A to Part 180—[Reserved]

1 Import only.

[FR Doc. 2012–20235 Filed 8–16–12; 8:45 am]