Dated: August 18, 2008.

Fred M. Rosa, Jr.,

Rear Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. E8–19894 Filed 8–26–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1069; FRL–8377–8]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on tomato; tomatillo; tomato, paste; avocado; sapote, black; canistel; sapote, mamey; mango; papaya; sapodilla; star apple; parsley, leaves; parsley, dried leaves; vegetable, leaves of root and tuber, group 2; vegetable, root, except sugarbeet, subgroup 1B; lemon; lime; citrus, dried pulp; citrus, oil; kiwifruit; onion, bulb; onion, green; strawberries; vegetable, cucurbit, group 9; and meat byproducts of cattle, goats, horses and sheep. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 27, 2008. Objections and requests for hearings must be received on or before October 27, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1069. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–1069 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 27, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–1069, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of January 23, 2008 (73 FR 3964) (FRL–8345–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E7235) by Interregional, Research Project Number 4 (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 the food commodities tomato at 0.40 parts per million (ppm); tomatillo at 0.40 ppm; tomato, paste at 1.0 ppm; avocado at 1.2 ppm; sapote, black at 1.2 ppm; canistel at 1.2 ppm; sapote, mamey at 1.2 ppm; mango at 1.2 ppm; papaya at 1.2 ppm; sapodilla at 1.2 ppm; star apple at 1.2 ppm; herbs subgroup19A, fresh at 25 ppm; herbs subgroup 19A, dried at 170 ppm; vegetable, root and tuber, group, leaves at 9.0 ppm; vegetable, root, except sugarbeet subgroup at 0.60 ppm; lemon at 0.6 ppm; lime at 0.6 ppm; kiwifruit at 1.8 ppm; onion, dry bulb at 0.50 ppm; onion, green at 1.2 ppm; strawberry at 7.0 ppm; and cucurbits at 0.40 ppm. That notice referenced a summary of the petition prepared by IR-4, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is revising some of the items as proposed in this Unit. The reason for these changes is 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine on tomato; tomatillo; tomato, paste; avocado; sapote, black; canistel; sapote, mamey; mango; papaya; sapodilla; star apple; parsley, leaves; parsley, dried leaves; vegetable, leaves of root and tuber, group 2; vegetable, root, except sugarbeet, subgroup 1B; lemon; lime; citrus, dried pulp; citrus, oil; kiwifruit; onion, bulb; onion, green; strawberries; vegetable, cucurbit, group 9; and meat byproducts of cattle, goats, horses and sheep. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Cyprodinil has low acute toxicity via the oral, dermal, and inhalation routes. 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 were consistent among male and female rats and mice in both subchronic 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 manifested as chronic tubular lesions and chronic kidney inflamation following subchronic 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, causing mild anemia in rats exposed subchronically. There was no evidence of carcinogenic potential in either the rat chronic toxicity/carcinogenicity or mouse carcinogenicity studies and no concern for mutagenicity. There was no evidence of increased susceptibility in the developmental rat or rabbit study following *in utero* exposure or in the 2-generation reproduction study following prenatal or postnatal exposure. No clinical signs of toxicity suggestive of neurobehavioral alterations nor evidence of neuropathological effects were observed in the available oral-toxicity studies. There was also no evidence of a neurodevelopmental effect in the rat or rabbit developmental toxicity studies or in the rat 2-generation reproductive-toxicity study.

Specific information on the studies received and the nature of the adverse effects caused by cyprodinil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document *Cyprodinil Human Health Risk Assessment for the uses in/on tomato, avocado, herbs, root vegetables, leaves of root and tuber vegetables, lemon, lime, cucurbits, kiwifruit, green and dry bulb onions, and strawberries*, page 16 in docket ID number EPA–HQ–OPP–2007–1069.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which the LOAEL of concern are identified or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for cyprodinil used for human risk assessment can be found at *http://www.regulations.gov* in document *Cyprodinil Human Health Risk Assessment for the uses in/on tomato, avocado, herbs, root vegetables, leaves of root and tuber vegetables, lemon, lime, cucurbits, kiwifruit, green and dry bulb onions, and strawberries*, page 22 in docket ID number EPA–HQ–OPP–2007–1069.

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.

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 used tolerance-level residues, DEEM default processing factors and assumed 100 percent crop treated (PCT) for all existing and proposed commodities.

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 used tolerance level residues, DEEM default processing factors, and assumed 100 PCT for all existing and proposed commodities.

iii. *Cancer* An aggregate exposure assessment for the purpose of assessing cancer risk was not performed because cyprodinil has been classified as ''not likely to be carcinogenic to humans.''

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyprodinil. Tolerance level residues and 100 PCT were assumed for all existing and proposed food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for 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*.

For surface water the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) Tier 2 aquatic models were used, and for ground water, the Tier 1 aquatic model Screening Concentration in Ground Water (SCI–GROW) was utilized. For the assessment, maximum application rates and minimum intervals between applications were used. The Agency has concluded that the transformation product CGA–249287 of cyprodinil is of potential concern for drinking water sources. Therefore, estimated drinking water concentrations (EDWCs) of CGA–249287 were also simulated using the PRZM/EXAMS and SCI–GROW models. For surface water, this degradate was modeled individually, as opposed to the use of the total residue approach due to the fact that only one degradate was modeled and sufficient information was available for the modeling.

Based on the Tier 2 PRZM/EXAMS and the Tier 1 SCI–GROW models, the EDWCs of cyprodinil and its transformation product CGA–249287 for acute exposures are estimated to be 34.56 parts per billion (ppb) for surface water and 0.108 ppb for ground water. For chronic exposures for non-cancer assessments the concentrations are estimated to be 20.05 ppb for surface water and 0.108 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 34.56 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 20.05 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 not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found 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 (MOS) 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 MOS will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There are no concerns or residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyprodinil is complete.

ii. There is no indication that cyprodinil is a neurotoxic chemical and

there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. 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. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to cyprodinil in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyprodinil will occupy 4% of the aPAD for females 13–49 years old, the only population group of concern.

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 67% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for cyprodinil.

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

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).

Cyprodinil is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to cyprodinil through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, cyprodinil was classified as ''not likely to be carcinogenic to humans.'' Therefore, 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 enforcement methodology (high performance liquid chromatography with ultraviolet detector (HPLC/UV)) is available to enforce the tolerance expression on plant commodities. In addition, a high performance liquid chromatography with mass spectrometry (HPLC/MS) method (Method No. GRM010.01A) is available for determining residues of cyprodinil and its metabolite CGA–304075 (free+conjugated) in livestock commodities. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established or proposed Canadian or Mexican MRLs for cyprodinil on any of the plant commodities of interest in these petitions. There are Codex MRLs for tomato, bulb onion, cucurbit, and summer squash. Tomato has a proposed tolerance of 0.45 ppm and a Codex MRL of 0.5 ppm, therefore no change in the tolerance is necessary for harmonization purposes. The Codex MRLs for bulb onion at 0.3 ppm (vs 4.0 ppm for green onion and 0.60 ppm for dry bulb onion), cucurbit at 0.2 ppm (vs 0.70 ppm for cucurbit vegetables), and summer squash at 0.2 ppm (vs 1.0 ppm for head and stem Brassica, 5A) were established based on application levels from 0.21 to 0.26x the domestic rate. Harmonization of U.S. tolerances on these commodities is not possible at this time.

Codex MRLs have been established for livestock commodities, and these MRLs are set at the method LOQ. For both the Canadian and Codex MRLs, the regulated residues include cyprodinil per se. As the U.S. definition for cyprodinil residues in livestock commodities is different than those established for Canada and Codex, harmonization of U.S. tolerances on livestock commodities is not possible at this time.

C. Response to Comments

EPA received one comment to the Notice of Filing that had a general objection to ''this product being allowed on food.'' The comment contained no scientific data or other substantive evidence to rebut this conclusion or the Agency's finding that there is a reasonable certainty that no harm will result from aggregate exposure to cyprodinil from the establishment of these tolerances. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63096 (October 29, 2004) for the Agency's previous responses to these objections.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petitions, EPA determined that separate tolerances are needed for fresh parsley at 35 ppm; dried parsley at 170 ppm; citrus, dry pulp at 8.0 ppm; citrus, oil at 340 ppm; and meat byproducts of cattle, goats, horses and sheep at 0.02 ppm. EPA is establishing those tolerances in this action. In addition, EPA revised the tolerances for tomato from 0.40 ppm to 0.45 ppm; tomatillo from 0.40 ppm to 0.45 ppm; herb subgroup 19A fresh from 25 ppm to 3 ppm and re-naming herb subgroup 19A fresh, except parsley; herb subgroup 19A dried from 170 ppm to 15 ppm and re-naming herb subgroup 19A, dried, except parsley; leaves of root and tuber vegetables from 9.0 ppm to 10 ppm; root vegetables, except sugar

beet subgroup from 0.60 ppm to 0.75 ppm; cucurbits from 0.40 to 0.70 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on the food commodities tomato at 0.45 ppm; tomatillo at 0.45 ppm; tomato, paste at 1.0 ppm; avocado at 1.2 ppm; sapote, black at 1.2 ppm; canistel at 1.2 ppm; sapote, mamey at 1.2 ppm; mango at 1.2 ppm; papaya at 1.2 ppm; sapodilla at 1.2 ppm; star apple at 1.2 ppm; parsley, leaves at 35 ppm; parsley, dried leaves at 170 ppm; vegetable, leaves of root and tuber, group 2 at 10 ppm; vegetable, root, except sugarbeet, subgroup 1B at 0.75 ppm; lemon at 0.60 ppm; lime at 0.60 ppm; citrus, dried pulp at 8.0 ppm; citrus, oil at 340 ppm; kiwifruit at 1.8 ppm; onion, bulb at 0.60 ppm; onion, green at 4.0 ppm; strawberry at 5.0 ppm; vegetable, cucurbit, group 9 at 0.70 ppm; and meat byproducts of cattle, goats, horses and sheep at 0.02 ppm.

Also, the following entries in the table in paragraph (a)(1) are changed to read as follows: ''herb subgroup 19A, fresh'' is amended to ''herb subgroup 19A, fresh, except parsley''; ''herb subgroup 19A, dried'' is amended to ''herb subgroup 19 A, dried, except parsley''..

Further, the following entry is removed from the table in paragraph (a)(1): ''Carrot'' because of the establishment of the vegetable, root tolerance by this action.

And lastly, the following entries are removed from the table in paragraph (a)(2): ''Onion, bulb'' ''onion, green'', and ''strawberry'' because permanent tolerances are being established by this action.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 15, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.532 is amended as follows:

i. Paragraph (a)(2) is removed.

ii. Paragraph (a)(1) is redesignated as paragraph (a).

iii. Newly designated paragraph (a) is amended in the table by removing the commodity ''Carrot''; by revising the commodities ''Herb subgroup 19A, dried'' and ''Herb subgroup 19A, fresh'' to read ''Herb, subgroup 19A, dried, except parsley'' and ''Herb, subgroup 19A, fresh, except parsley'' respectively; and by alphabetically adding commodities.

The amendments read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Avocado	1.2
* * * * *	
Canistel	1.2
* * * * *	
Cattle, meat byproducts	0.02
Citrus, dried pulp	8.0
Citrus, oil	340
* * * * *	
Goat, meat byproducts	0.02
* * * * *	
Horse, meat byproducts	0.02
* * * * *	
Kiwifruit	1.8
* * * * *	
Lemon	0.60
Lime	0.60
* * * * *	
Mango	1.2
Onion, bulb	0.60
Onion, green	4.0
Papaya	1.2
Parsley, dried leaves	170
Parsley, leaves	35
* * * * *	
Sapodilla	1.2
Sapote, black	1.2
Sapote, mamey	1.2
Sheep, meat byproducts	0.02
* * * * *	
Star apple	1.2
Strawberry	5.0
Tomatillo	0.45
Tomato	0.45
Tomato, paste	1.0
* * * * *	
Vegetable, cucurbit, group 9	0.70
Vegetable, leaves of root and tuber, group 2	10
Vegetable, root, except sugarbeet, subgroup 1B	0.75
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[FR Doc. E8–19747 Filed 8–26–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1020; FRL–8378–5]

Bacillus subtilis GB03; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide *Bacillus subtilis* GB03 in or on all raw agricultural commodities when applied in accordance with good agricultural practices. Growth Products Ltd. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an amendment of the existing exemption from the requirement of a tolerance to cover use in or on all agricultural commodities and remove the regulatory text specifying ''when applied as a seed treatment.'' This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* GB03 in or on all raw agricultural commodities.

DATES: This regulation is effective August 27, 2008. Objections and requests for hearings must be received on or before October 27, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1020. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket identification (ID) number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.