12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: January 16, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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), 346(a) and 374.

2. Section 180.1150 of subpart D is revised to read as follows:

§ 180.1150 6-Benzyladenine; exemption from the requirement of a tolerance.

(a) The plant growth regulator 6-benzyladenine is exempt from the requirement of a tolerance when used as a fruit-thinning agent at an application rate not to exceed 30 grams of active ingredient per acre in or on apples.

(b) 6-Benzyladenine is temporarily exempt from the requirement of a tolerance in or on apples at ≤182 grams of active ingredient per acre per season, and in or on pistachio at ≤60 grams of active ingredient per acre per season when used in accordance with the Experimental Use Permit 73049–EUP–2. The temporary exemption from a tolerance will expire on January 31, 2005.

[FR Doc. 03–2431 Filed 2–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0344; FRL–7289–7]

Cyprodinil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil in or on the bushberry subgroup, caneberry subgroup, juneberry, lingonberry, pistachio, salal and watercress. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) , as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective February 5, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0344, must be received on or before April 7, 2003.

ADDRESSES: Written objections and hearing requests may besubmitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@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:

- 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 provides 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0344. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 1, 2002 (67 FR 21671)(FRL–6833–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6359, 2E6365, 2E6377 and 2E6393) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions 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 caneberry subgroup at 10.0 parts per million (ppm) (2E6393), watercress at 20 ppm (2E6365), pistachio at 0.07 ppm (2E6377) and the bushberry subgroup, lingonberry, juneberry, and salal, at 3.0 ppm (2E6359). IR-4 subsequently revised the petition to propose the following tolerances for cyprodinil residues in or on the caneberry subgroup at 10.0 parts per million (ppm), watercress at 20 ppm, pistachio at 0.10 ppm and the bushberry subgroup, lingonberry, juneberry, and salal, at 3.0 ppm.

Section 408(b)(2)(A)(i) of the 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 the 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 the 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of cyprodinil on the caneberry subgroup at 10.0 parts per million (ppm), watercress at 20 ppm, pistachio at 0.10 ppm and the bushberry subgroup, lingonberry, juneberry, and salal, at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cyprodinil are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effectlevel (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity mouse	NOAEL = 73.3/103 (male/female (m/f)) milligram/kilogram/day (mg/kg/day) LOAEL = 257/349 (m/f) mg/kg/day based on histopathological changes in the liver (m/f)
870.3100	90–Day oral toxicity rat	NOAEL = 3.14 (mg/kg/day) LOAEL = 19 mg/kg/day based on increasedtubular kidney lesions in males
870.3150	90–Day oral-toxicity - dog	NOAEL = 210/232 (m/f) mg/kg/day LOAEL = 560/581 mg/kg/day based on lowerbody-weight gains and decreased food consumption inboth sexes
870.3200	Carcinogenicity - mice	NOAEL = 16.1 mg/kg/day LOAEL = 212.4 mg/kg/day based on a dose-related increase in the incidence of focal and multifocal hyperplasia of the exocrine pancreas in males No evidence of carcinogenicity
870.3700	Prenatal developmental - rat	Maternal NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based on lower body-weight/body-weight gain and reduced food consumption Developmental NOAEL = 200 mg/kg/day LOAEL = 1,000 mg/kg/day based on lowermean fetal weights and increased incidence of delayedossification
870.3700	Prenatal developmental - rabbit	Maternal NOAEL = 150 mg/kg/day LOAEL = 400 mg/kg/day based on decreasedbody-weight gain Developmental NOAEL = 150 mg/kg/day LOAEL = 400 mg/kg/day based on slight increase of litters showing extra (13th) ribs
870.3800	Reproduction and fertility effects - rat	Parental/Systemic NOAEL = 81 mg/kg/day LOAEL = 326 mg/kg/day based on lowerbody-weights in the F_0 females during the pre-matingperiod. Reproductive/Developmental NOAEL = 81mg/kg/day LOAEL = 326 mg/kg/day based on decreasedpup weights (F_1 and F_2)
870.4100	Chronic toxicity dogs	NOAEL = 65.63/67.99 (m/f) mg/kg/day LOAEL = 449.25/446.3 (m/f) mg/kg/day based on lower body-weight gains and decreased food consumption and food efficiency
870.4300	Chronic toxicity/Carcinogenicity(feeding) - rat	NOAEL = 2.7 mg/kg/day LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatis) in males No evidence of carcinogenicity
870.5265 and 870.5100	Gene Mutation	In a reverse gene mutation assay with*Salmonella typhimurium/Escherichia coli*, cyprodinil was negative up to concentrations (≥1,250 μg/plate +/-S9) that produced reproducible cytotoxicity for the majority of strains. Compound insolubility was reported at ≥313 μg/plate.
870.5300	Gene Mutation	In a Chinese hamster V79 cell HGPRT forward gene mutation assay, cyprodinil was negative up to cytotoxic concentrations (≥96.0 μg/mL with S9) (≥24 μg/mL without S9).
870.5375	Cytogenetics/*In vitro* Chromosomal Aberration	In an *in vitro* assay for chromosome aberrations in Chinese hamster ovary (CHO) cells, cyprodinil gave negative results up tocytotoxic concentrations (≥50 μg/mL without S9, 18– or 42–hour cell harvest or ≥25 μg/mL with S9, 18–hour cell harvest) or to the highest subcytotoxic concentration (50 μg/mL with S9, 42–hour cell harvest).

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5395	Cytogenetics/*In vivo* bone marrow micronucleus	In an *in vivo* bone marrow micronucleus assay, cyprodinil was negative when administered orally (gavage) at 5,000 mg/kg(HDT) to both sexes of Tif:MAGF mice. No signs of overt toxicity or clear evidence of cytotoxicity for the target organ were noted at any dose or sacrifice time.
870.5550	Unscheduled DNA Synthesis	In an Unscheduled DNA Synthesis(UDS) assay in primary rat hepatocytes, cyprodinil was negative up to a cytotoxic concentration (80μg/mL).
870.7485	Metabolism and pharmacokinetics	Single oral doses (0.5 or 100 mg/kg bw) of phenyl or pyrimidyl-radiolabelled cyprodinil (purity ≥98%) were administered toTif:RAIf(SPF) rats, with one low-dose group receiving unlabelled cyprodinil (purity ≥99%) for 2 weeks prior to treatment with radiolabelled compound. Absorption was very rapid (tcmax= 0.3 hours) with rapid clearance (tcmax/2=1.2 hours). A minimum of 75% of the administered dose was absorbed. Excretion was rapid and almost complete, with urine as the principle route of excretion (48–68%), and >90%of the administered dose detected in the urine and feces within 48 hours. Excretion, distribution and metabolite profiles were essentially independent of dose level, pretreatment, and type of label, although there were some quantitative differences sex-dependent qualitative differences in two urinary metabolite fractions.
870.7485	Metabolism and pharmacokinetics	Excreta (Group D1 and D2) and bile (Group G1) from radiolabelled cyprodinil-treated Tif:RAIf(SPF) rats were used to characterize, isolateand identify cyprodinil metabolites. Eleven metabolites were isolated from urine, feces and bile, and the metabolic pathways in the rat were proposed. All urinary and biliary metabolites (with the exception of 7U) were conjugated with glucuronic acid or sulfonated, and excreted. Cyprodinil was almostcompletely metabolized by hydroxylation of the phenyl ring (position 4) or pyrimidine ring (position 5), followed by conjugation. An alternative pathwayinvolved oxidation of the phenyl ring followed by glucuronic acid conjugation. A quantitative sex difference was observed with respect to sulfonation ofthe major metabolite that formed 6U. The monosulfate metabolite (1U) was predominant in females, whereas equal amounts of mono- and disulfate (6U) conjugates were noted in males. Most of the significant metabolites in feces were exocons of biliary metabolites (2U, 3U, 1G). These were assumed to be deconjugated in the intestines, partially reabsorbed into the generalcirculation, conjugated again, and eliminated renally. The major metabolic pathways of cyprodinil were not significantly influenced by the dose, treatment regimen, or sex of the animal.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the

LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyprodinil used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYPRODINIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50years of age	Developmental NOAEL = 150 mg/kg/day UF = 100 Acute RfD = 1.5 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 1.5 mg/kg/day	Developmental Toxicity - rabbit Developmental LOAEL = 400 mg/kg/day based on slight increase of litters showing extra ribs (13th).
Chronic Dietary all populations	NOAEL= 2.7 UF = 100 Chronic RfD = 0.03 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.03 mg/kg/day	2–Year Chronic Toxicity/Carcinogenicity-rat LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatis) in males.
Cancer (oral, dermal, inhalation)	Classification: ''not likely to be carcinogenic tohumans''		

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique tothe FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.352) for the residues of cyprodinil, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from cyprodinil in food as follows:

i. *Acute exposure.* Acute dietary 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA insert 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: 100% crop treated (PCT) and tolerance-level residues for cyprodinil on all treated crops. This assessment was a Tier I analysis. However, the only acute endpoint identified was for the population subgroup females 13–50 years old based on a slight increase of litters showing extra ribs (13th). No effects that could be attributed to a single exposure were observed (no end point was chosen) for any other population subgroup, including the general U.S. population; therefore, an acute dietary assessment for the general U.S. population or other subgroups was not conducted.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% crop treated (PCT) and tolerance-level residues for cyprodinil on all treated crops. This assessment was a Tier I analysis.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cyprodinil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of cyprodinil.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent of reference dose or percent of population adjusted dose. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cyprodinil they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of cyprodinil for acute exposures are estimated to be 32 parts per billion (ppb) for surface water and 0.04 ppb for ground water. The EECs for chronic exposures are estimated to be 6 ppb for surface water and 0.04 ppb for ground 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 use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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 does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyprodinil has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses following*in utero* exposure in the developmental studies with cyprodinil. There is no evidence of increased susceptibility of young rats in the reproduction study with cyprodinil.

3. *Conclusion*. With the exception of missing 21/28–day dermal- toxicity and 28–day inhalation-toxicity studies in rats, there is a complete toxicity data base for cyprodinil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Since there are no residential uses for cyprodinil the only exposure route to infants and children is the oral route, for which the toxicity and exposure data base is complete. Therefore dermal and inhalation-toxicity studies, are not needed to assess risk to infants and children and EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X.

The FQPA 10X safety factor is removed because:

- i. There are currently no registered or proposed residential(non-occupational) uses of cyprodinil.
- ii. There was no evidence (qualitative or quantitative) of increased susceptibility in the developmental rat or rabbit study following *in utero* exposure or in the two-generation reproduction study following pre- or post-natal exposure.
- iii. There was also no evidence of a neurodevelopmental effect in the rat or rabbit developmental toxicity studies or in the rat two-generation reproductive-toxicity study.
- iv. There are no data deficiencies for pre- and/or post-natal exposure and hence there are no residual uncertainties.
- v. Food and drinking water exposure assessments will notunderestimate the potential exposure for all populations, including infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in

drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cyprodinil will occupy <1% of the aPAD for the subpopulation females 13–50 years old, the only population for whom an effect attributable to an acute exposure could be observed. In addition, there is potential for acute dietary exposure to cyprodinil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYPRODINIL

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	1.5	<1.0	32	0.04	44,000

2. *Chronic risk*.Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyprodinil from food will utilize 7.4% of the cPAD for the U.S. population, 24% of the cPAD for all infants (< 1 year old) and 22% of the cPAD for children 1–6 years old. There are no residential uses for cyprodinil that result in chronic residential exposure to cyprodinil. Based the use pattern, chronic residential exposure to residues of cyprodinil is not expected. In addition, there is potential for chronic dietary exposure to cyprodinil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYPRODINIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.03	7.4	6	0.04	970
All Infants (< 1 year old)	0.03	24	6	0.04	230
Children 1–6 years old	0.03	22	6	0.04	230
Children 7–12 years old	0.03	9.1	6	0.04	270
Females 13–50years old	0.03	5.3	6	0.04	1,000

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyprodinil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Cyprodinil has been classified as ''not likely to be carcinogenic in humans'' based on the results of a carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats. 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, and to infants and children from aggregate exposure to cyprodinil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The results of Multiresidue Method testing of cyprodinil and its metabolite CGA–232449 have been forwarded to the Food and Drug Administration (FDA). Cyprodinil was tested according to the FDA Multiresidue protocols (Protocols C, D, and E), and acceptable recoveries were obtained for cyprodinil fortified in apples at 0.50 ppm using Protocol D. The petitioner is proposing the Method AG–631A as a tolerance enforcement method for residues of cyprodinil in/on the subject crops. This method, entitled ''Analytical Method for the Determination of Residues of CGA–219417 in Crops by High Performance Liquid Chromatography With Column Switching,'' is a reissue of Methods AG–631 and REM 141.01. The method includes confirmatory procedures using gas chromatography/nitrogen/phosphorus detector (GC/NPD). The method has successfully undergone radiovalidation using ^{14}C-labeled tomato samples and independent laboratory validation. In addition, the method has been the subject of acceptable Agency petition method validations on stone fruits and almond nutmeat and hulls.

B. International Residue Limits

There are no Mexican, Canadian or Codex maximum residue limits established for cyprodinil in/on caneberries, bushberries, pistachios and watercress, and thus no compatibility issues to be reconciled.

C. Conditions

The Agency is requiring as conditions for registration the following:An acceptable 21/28–day dermal-toxicity study in rats (GLN 870.3200). A 28–day inhalation-toxicity study in rats (GLN 870.3465)

V. Conclusion

Therefore, the tolerance is established for residues of cyprodinil on the caneberry subgroup at 10.0 ppm, watercress at 20 ppm, pistachio at 0.10 ppm and the bushberry subgroup, lingonberry, juneberry, and salal, at 3.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number –OPP–2002–0344 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 on or before April 7, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2002–0344, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since

tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: January 24, 2003.

Peter Caulkins,

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), 346(a) and 371.

2. Section 180.532 is amended by adding alphabetically the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.532 Cyprodinil; tolerances forresidues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Bushberry subgroup 13B	3.0
Caneberry subgroup 13A	10
* * *	* *
Juneberry	3.0
Lingonberry	3.0
Pistachio	0.10
* * *	* *
Salal	3.0
Watercress	20

* * * * *

[FR Doc. 03–2771 Filed 2–4–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0355; FRL–7285–9]

Thiophanate Methyl; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of thiophanate methyl and its metabolite (methyl 2-benzimidazoyl carbamate (MBC)) in or on mushrooms. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on mushroom spawn. This regulation establishes a maximum permissible level for residues of thiophanate methyl in this food commodity. The tolerance will expire and is revoked on December 31, 2004.

DATES: This regulation is effective February 5, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0355, must be received on or before April 7, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: conrath.andrea@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:

- Crop producers (NAICS 111)
- Animal producers (NAICS 112)
- Food manufacturing (NAICS 311)