determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in the preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not cause an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this temporary rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation because it modifies an existing bridge operation regulation.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. Effective 9 a.m. until 10 a.m. on October 28, 2003, § 117.301 is temporarily suspended and a new § 117.302 is added to read as follows:

§ 117.302 Massalina Bayou.

The draw of the Tarpon Dock bascule span bridge, Massalina Bayou, mile 0.0, shall open on signal; except that from 9 a.m. until 10 a.m. on October 18, 2003, the draw need not open for the passage of vessels. The draw will open at any time for a vessel in distress.

Dated: September 9, 2003.

R.F. Duncan,

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

[FR Doc. 03–24015 Filed 9–16–03; 3:57 pm]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0278; FRL–7326–4]

Cyprodinil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil in or on brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; carrot; herb, subgroup 19A, dried; herb, subgroup 19A, fresh; longan; lychee; pulasan; rambutan; spanish lime; and turnip, greens. 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 September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0278, must be received on or before November 18, 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 VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you an are agricultural producer, food manufacturer, and pesticide manufacturer Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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–2003–0278. 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 April 21, 2003 (68 FR 19528) (FRL–7301–6), 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 2E6447, 2E6461, 2E6485, 3E6529, and 3E6530) by IR-4, 681 US Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta Crop Protection Incorporated, the registrant.

The petitions requested that 40 CFR 180.532 be amended by establishing tolerances for residues of the fungicide, cyprodinil, CGA 219417; 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on the following commodities: brassica, head and stem, subgroup 5A at 2.0 parts per million (ppm); and brassica, leafy greens, subgroup 5B at 10.0 ppm (PP 2E6485); carrot at 0.5 (PP 2E6461); herb subgroup 19A at 10.0 ppm (3E6529); longan; lychee; pulasan; rambutan; and spanish lime at 2.0 ppm (PP 2E6447); and turnip, greens at 10.0 ppm (PP 2E6485).

Petition numbers 2E6485, 2E6461 and 3E6529 were subsequently amended to propose tolerances for brassica, head and stem, subgroup 5A at 1.0 ppm; and brassica, leafy greens, subgroup 5B at 10.0 ppm (PP 2E6485); carrot at 0.75 ppm (PP 2E6461); herb, subgroup 19A, dried at 15.0 ppm, and herb, subgroup 19A, fresh at 3.0 ppm (3E6529); longan; lychee; pulasan; rambutan; and spanish lime at 2.0 ppm (PP 2E6447); and turnip, greens at 10.0 ppm (PP 2E6485). There were no comments received on these petitions.

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 tolerances for residues of cyprodinil, CGA 219417; 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine on brassica, head and stem, subgroup 5A at 1.0 ppm; brassica, leafy greens, subgroup 5B at 10.0 ppm; carrot at 0.75; herb, subgroup 19A, dried at 15.0 ppm; herb, subgroup 19A, fresh at 3.0 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 2.0 ppm; and turnip, greens at 10.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 the following Table 1 as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (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 mg/kg/day, M/F LOAEL = 257/349 mg/kg/day, M/F, based on histopathological changes in the liver
870.3100	90–Day oral toxicity (rat)	NOAEL =3.14 mg/kg/day LOAEL = 19 mg/kg/day based on increased tubular kidney lesions in males
Non-guideline	28–Day Feeding/ Range Finding(rat)	NOAEL = 64.8/62.2 mg/kg/day, M/F LOAEL = 316/299 mg/kg/day, M/F, based on lower body-weight gains, microcytosis, increase cholesterol and phospholipid levels, and hepatocyte hypertrophy
Non-guideline	28–Day Gavage/ Range Finding(rat)	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on increased liver weights and abnormalities in liver morphology
870.3150	90–Day oral toxicity (dog)	NOAEL =210/232 mg/kg/day, M/F LOAEL = 560/581 mg/kg/day, M/F, based on lower body-weight gains and decreased food consumption in both sexes
870.3200	21/28–Day dermal-toxicity(rat)	NOAEL = 25/125 mg/kg/day, F/M LOAEL = 125/1000 mg/kg/day, F/M, based on clinical signs (hunched posture and/or piloerection).
870.3200	Carcinogenicity - (mouse)	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 Maternal LOAEL = 1,000 mg/kg/day based on lower body-weight/body-weight gain and reduced food consumption Developmental NOAEL = 200 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on lower mean fetal weights and increased incidence of delayed ossification
870.3700	Prenatal developmental (rabbit)	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 400 mg/kg/day based on decreased body-weight gain Developmental NOAEL = 150 mg/kg/day Developmental LOAEL = 400 mg/kg/day based on slight increase of litters showing extra (13th) ribs
870.3800	Reproduction and fertility effects(rat)	Maternal/Systemic NOAEL = 81 mg/kg/day Maternal/Systemic LOAEL = 326 mg/kg/day based on decreased body weight gain in the F0 females during the pre-mating period. Reproductive/Developmental NOAEL = 81 mg/kg/day Reproductive/Developmental LOAEL = 326 mg/kg/day based on decreased pup weights (F1 and F2)
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
870.4100	Chronic toxicity (dog)	NOAEL = 65.63/67.99 mg/kg/day, M/F LOAEL = 449.25/446.3, M/F, mg/kg/day based on lower body-weight gains and decreased food consumption and food efficiency
870.5100	Gene Mutation - Bacteria	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.
870.5100 CGA 249287	Metabolite Gene Mutation - Bacteria	In repeat gene mutation assays in bacteria, CGA 249287 was negative for induction of reverse mutation in the bacterial cultures assayed under the conditions of the experiments.

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

Guideline No.	Study Type	Results
870.5300	*In vitro* mammalian cell	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 to cytotoxic 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 sub-cytotoxic concentration (50 μg/mL with S9, 42–hour cell harvest).
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	UDS	In an UDS assay in primary rat hepatocytes, cyprodinil was negative up to a cytotoxic concentration (80 μg/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 to Tif: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 with rapid clearance. 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 and bile from radiolabelled cyprodinil-treated Tif:RAIf(SPF) rats were used to characterize, isolate and 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 almost completely metabolized by hydroxylation of the phenyl ring (position 4) or pyrimidine ring (position 5), followed by conjugation. An alternative pathway involved oxidation of the phenyl ring followed by glucuronic acid conjugation. A quantitative sex difference was observed with respect to sulfonation of the 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 general circulation, 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.
870.7600	Dermal Absorption (rat)	In a dermal absorption study with cyprodinil formulated as SWITCH 62.5 WG in the rat, the maximum systemic absorption was 21.71% (at 24 hours). An additional 12% of the applied dose (that is potentially available for absorption) remained on the treated skin at 24 hours.

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 factors (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 as1×10^{-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 the following Table 2:

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

Exposure Scenerio	Dose used in Risk Assessment UF	FQPA SF and Endpoint for Risk Assessment	Study, Toxicological Endpoint
Acute Dietary females 13–50 years of age	Developmental NOAEL = 150 mg/kg/day UF = 100 Acute RfD = 1.5 mg/kg/day	Special FQPA SF* = 1X aPAD = acute RfD ÷ Special 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	Special FQPA SF = 1X cPAD = chronic RfD ÷ Special 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.
Incidental Oral Short-Term (1–30 days)(Residential)	oral NOAEL= 62 mg/kg/day	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	28–Day Feeding/Range-finding - rat LOAEL = 299 mg/kg/day based on decreased body-weight gain, increased cholesterol and phospholipid levels, microcytosis, and hepatocyte hypertrophy.
Incidental Oral Intermediate-Term (1– 6 months)(Residential)	oral NOAEL= 2.7 mg/kg/day	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	2–Year Chronic Toxicity/ Carcinogenicity -rat LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatis) in males.
Dermal Short-Term (1–30 days)(Residential)	oral NOAEL= 62 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	28–Day Feeding/Range-finding - rat LOAEL = 299 mg/kg/day based on decreased body-weight gain, increased cholesterol and phospholipid levels, microcytosis, and hepatocyte hypertrophy.
Dermal Intermediate-Term(1–6 months) and Long-Term (26 months)(Residential)	oral NOAEL= 2.7 mg/kg/day(dermal absorption rate = 30%)	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	2–Year Chronic Toxicity/ Carcinogenicity - Rat LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatis) in males.
Inhalation Short-Term(1–30 days) (Residential)	oral NOAEL = 62 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	28–Day Feeding/Range-finding - rat LOAEL = 299 mg/kg/day based on decreased body-weight gain, increased cholesterol and phospholipid levels, microcytosis, and hepatocyte hypertrophy.
Inhalation Intermediate-Term(1–6 months) and Long-Term (26 months) (Residential)	oral NOAEL = 2.7 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the Special FQPA SF of 1X)	2–Year Chronic Toxicity/ Carcinogenicity in Rats 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 to humans''		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.532) for the residues of cyprodinil, in or on a variety of raw agricultural commodities: almond, hulls; almond nutmeats; apple, wet pomace; fruit, pome; fruit, stone; grape; and raisins. Time-limited tolerances are established (40 CFR 180.532 (a)(2)) for onion, dry bulb; onion, green; and strawberry (each set to expire December 31, 2003). A time-limited tolerance (40 CFR 180.532 (b)) on caneberries is also set to expire December 31, 2003. Risk assessments were conducted by EPA to assess dietary exposures from cyprodinil in food as follows:

i. *Acute exposure*. In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID®) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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: An unrefined, Tier 1 acute dietary exposure assessment (using tolerance-level residues, DEEM (version 7.76) default processing factors and assuming 100% CT for all proposed commodities) was conducted for the females 13– 49 years old population subgroup.

ii. *Chronic exposure*. In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID®) which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions was made for the chronic exposure assessment: An unrefined, Tier 1 chronic dietary exposure assessment (using tolerance-level residues, DEEM default processing factors, and assuming 100% CT for all proposed commodities) was conducted for the general U.S. population and various population subgroups.

iii. *Cancer*. A quantitative cancer aggregate-risk assessment was not performed because cyprodinil is not carcinogenic.

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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and 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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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 %RfD or %PAD. 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 in Unit III.E.

Environmental fate data suggest that as cyprodinil dissipates from the environment, it forms the transformation product CGA 249287 and other metabolites under natural conditions. CGA 249287 was observed at <11% of the applied parent in aerobic soil metabolism studies. It was also one of the transformation products observed at <14% in the terrestrial field dissipation studies.

EPA concluded that CGA 249287 is a potential concern in drinking water. Therefore, EEC's of CGA 249287 (along with the parent) were also simulated. The maximum application rate and relevant environmental fate parameters for cyprodinil and its metabolite CGA 249287 were used in the two screening models PRZM/EXAMS and SCI-GROW for EEC's in surface water and groundwater, respectively. The outputs of the two screening models represent estimates of the concentrations that might be found in surface water and groundwater due to the use of cyprodinil on cabbage and strawberry.

TABLE 3.—SUMMARY OF EPA'S EEC'S IN SURFACE WATER AND GROUNDWATER TABLE

Chemical	Surface Water (μg/L)		Groundwater (μg/L)
	Acute	Non-Cancer Chronic	
Florida Cabbage			
Cyprodinil	23.9	6.63	0.04
CGA 249287	5.29	1.42	0.12
Total	29.2	8.1	0.16

TABLE 3.—SUMMARY OF EPA'S EEC'S IN SURFACE WATER AND GROUNDWATER TABLE—Continued

Chemical	Surface Water (μg/L)		Groundwater (μg/L)
	Acute	Non-Cancer Chronic	
Florida Strawberry			
Cyprodinil	26.67	5.32	0.04
CGA 249287	6.20	1.04	0.12
Total	32.9	6.4	0.16

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. There are no registered or proposed uses of cyprodinil which result in potential residential exposures.

4. *Cumulative effects from 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. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyprodinil and 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 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

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 are no concerns or residual uncertainties for pre- and/or postnatal exposure.

3. *Conclusion*. 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. EPA determined that the 10X Safety factor to protect infants and children should be reduced to 1X because:

i. The toxicological data base is complete for the assessment of toxicity and susceptibility following pre- and/or post-natal exposures. No clinical signs of neurotoxicity or neuropathology were observed in the data base, and the developmental neurotoxicity study was not required.

ii. 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.

iii. There are no residual concerns regarding pre- or post-natal toxicity or completeness of the toxicity or exposure data base.

iv. The dietary food exposure assessment is Tier 1, screening level, which is based on tolerance level residues and assumes 100% of all crops will be treated with cyprodinil. By using these screening level assessments, actual exposures/risks will not be underestimated.

v. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

vi. There are currently no registered residential uses of cyprodinil.

vii. These assessments will not underestimate the exposure/risks posed by current or proposed uses of cyprodinil.

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 Office of Water 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 2% of the aPAD for the females 13–49 years old. In addition, there is potential for acute dietary exposure to cyprodinil in drinking water. For the general U.S. population, no toxic effects of concern that could be attributed to a single exposure were observed in the oral-toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, an acute RfD was not established for this population subgroup and an acute dietary exposure assessment was not conducted for this population subgroup. 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 the following Table 4:

TABLE 4.—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 13–49 years old	1.5	2	32.9	0.16	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 25% of the cPAD for the U.S. population, 65% of the cPAD for (the most highly exposed population subgroup) children 1–2 years old, 32% of the cPAD for all infants <1 year old, and 21% of the cPAD for females 13–49 years old. Based on 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 the following Table 5:

TABLE 5.—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	25	8.1	0.16	790
Children (1–2 years old)	0.03	65	8.1	0.16	100
All Infants (<1 year old)	0.03	32	8.1	0.16	200
Females (13–49 years old)	0.03	21	8.1	0.16	710

3. *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.

4. *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. 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. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of cyprodinil in/on the proposed crops. Therefore, harmonization is not an issue.

V. Conclusion

Therefore, the tolerances are established for residues of cyprodinil, CGA 219417; 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on brassica, head and stem, subgroup 5A at 1.0 ppm; brassica, leafy greens, subgroup 5B at 10.0 ppm; carrot at 0.75 ppm; herb, subgroup 19A, dried at 15.0 ppm; herb, subgroup 19A, fresh at 3.0 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 2.0 ppm; and turnip, greens at 10.0 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–2003–0278 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 November 18, 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–2003–0278, 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. Congressional Review Act

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: September 10, 2003.

Debra Edwards,

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 commodities to the table in paragraph (a)(1) to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup 5A	1.0
Brassica, leafy greens, subgroup 5B	10.0
* * * * *	
Carrot	0.75
Herb, subgroup 19A, dried	15.0
Herb, subgroup 19A, fresh	3.0
* * * * *	
Longan	2.0
Lychee	2.0
* * * * *	
Pulasan	2.0
Rambutan	2.0
* * * * *	
Spanish lime	2.0
Turnip, greens	10.0
* * * * *	

* * * * *

[FR Doc. 03–23854 Filed 9–18–03; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0282; FRL–7324–6]

Butafenacil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of butafenacil (1,1-dimethyl-2-oxo-2-(2-propenyloxy)ethyl 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl] benzoate) in or on cotton and livestock commodities. Syngenta Crop Protection, Inc. requested this tolerance 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 September 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0282, must be received on or before November 18, 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 VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *Tompkins.Jim@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. 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–2003–0282. 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 February 26, 2003 (68 FR 8896) (FRL–7293–9), 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 a pesticide petition (PP 1F6309) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide butafenacil, the [2+2] cycloaddition dimer of butafenacil, and CGA-293731 in or on cotton, undelinted seed at 0.5 parts per million (ppm); and in or on cotton, gin byproducts at 13.0 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