failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective August 6, 2001 unless EPA receives adverse written comments by July 23, 2001.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 21, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Ozone, Nitrogen oxides, Transportation conformity.

Dated: June 14, 2001.

David A. Ullrich,

Acting Regional Administrator, Region 5.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart KK—Ohio

2. Section 52.1885 is amended by adding paragraph (a)(15) to read as follows:

§ 52.1885 Control strategy: ozone.

(a) * * *

(15) Approval—On May 31, 2001, Ohio submitted a revision to the ozone maintenance plan for the Cleveland/Akron/Lorain area. The revision consists of allocating a portion of the Cleveland/Akron/Lorain area's NO_X safety margin to the transportation conformity mobile source emissions budget. The mobile source emissions budgets for transportation conformity purposes for the Cleveland/Akron/Lorain area are now: 92.7 tons per day of volatile organic compound emissions for the year 2006 and 104.4 tons per day of oxides of nitrogen emissions for the year 2006. This approval only changes the VOC transportation conformity emission budget for Cleveland/Akron/Lorain.

* * * * *

[FR Doc. 01–15749 Filed 6–21–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301120; FRL–6778–7]

RIN 2070–AB78

Cyprodinil; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of cyprodinil in or on strawberry, dry bulb onion, and green onion. IR-4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire on December 31, 2003.

DATES: This regulation is effective June 22, 2001. Objections and requests for hearings, identified by docket control number OPP–301120, must be received by EPA on or before August 21, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301120 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301120. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 21, 2000 (65 FR 38535) (FRL–6558–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) 8E5012 for tolerances by, IR-4, North Brunswick, New Jersey 08902–3390. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.532 be amended by establishing tolerances for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on strawberry at 5.0 parts per million (ppm) and the bulb vegetable crop group at 5 ppm. The petition was subsequently amended by IR-4 to propose time-limited tolerances for residues of cyprodinil in or on strawberry at 5.0 ppm, dry bulb onion at 0.60 ppm, and green onion at 4.0 ppm. These tolerances will expire on December 31, 2003.

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) 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) 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 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), 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), for tolerances for residues of cyprodinil on strawberry at 5.0 ppm, dry bulb onion at 0.6 ppm and green onion at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. 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
	28–Day oral toxicity (gavage) (rat)	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on based on increased liver weights and abnormalities in liver morphology
870.3150	90–Day oral toxicity (dog)	NOAEL = 210 mg/kg/day (males) and 232 mg/kg/day (females) LOAEL = 560 mg/kg/day (males) and 581 mg/kg/day (females) based on lower body weight gains and decreased food consumption in both sexes
870.3200	28–Day dermal toxicity (rat)	NOAEL = 5 mg/kg/day (females) and 125 mg/kg/day (males)

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

Guideline No.	Study Type	Results
		LOAEL = 25 mg/kg/day for females and 1,000 mg/kg/day for males based on alterations in clinical signs (piloerection)
870.3100	90–Day oral toxicity (rat)	NOAEL = 3.14 mg/kg/day LOAEL = 19 mg/kg/day based on increased chronic tubular kidney lesions in males
870.3100	90–Day oral toxicity (mouse)	NOAEL = 73.3/103 mg/kg/day, males/females LOAEL = 257/349 mg/kg/day, males/females based on histopathological changes in the liver
870.3700a	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 lower mean fetal weights and an increased incidence of delayed ossification
870.3700b	Prenatal developmental (rabbit)	Maternal NOAEL = 150 mg/kg/day LOAEL = 400 mg/kg/day based on decreased body weight gain Developmental NOAEL = 150 mg/kg/day LOAEL = 400 mg/kg/day based on a 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 based on lower body weights in F_0 females during the pre-mating period Reproductive NOAEL = 81 mg/kg/day LOAEL = 326 mg/kg/day based on decreased pup weights (F_1 and F_2.
870.4300	Chronic toxicity/carcinogenicity (rat)	NOAEL = 2.7 mg/kg/day LOAEL = 35.6 mg/kg/day based on degenerative liver lesions (spongiosis hepatis) in males. There was no evidence of carcinogenicity in rat fed diets containing 0, 0.177, 2.7, 35.6 or 73.6 mg/kg/day (males); 0, 0.204, 3.22, 41.2 or 87.1 mg/kg/day (females) for 24-months. There was an increase in mammary fibroadenomas from controls to high dose, which was considered to be non-treatment related.
870.4100b	Chronic toxicity (dog)	NOAEL = 65.63 mg/kg/day (males) and 67.99 mg/kg/day (females) LOAEL = 446.37 mg/kg/day (females) and 449.25 mg/kg/day (males) based on lower body weight gains and decreased food consumption and food efficacy.
870.4200	Carcinogenicity in mice	NOAEL = 16.1 mg/kg/day (males). LOAEL = 212.4 mg/kg/day based on a dose-related increase in the incidence of focal and mutltifocal hyperplasia of the exocrine pancreas in males. There was no evidence of carcinogenicity.
870.5100	Gene mutation/bacteria	Negative in bacterial cells (*S. typhimurium* and (*E. coli*) and mammalian cells (V79/HGPRT assay)
870.5300	Gene mutation/Mammalian cell	Negative with and without activation
870.5375	Chromosome aberration (Chinese hamster ovary)	Negative; up to 25 micrograms/milliter (μg/ml) (-S9); up to 50 μg/ml (+S9)
870.5550	*In vitro* unscheduled DNA synthesis assay - primary rat hepatocytes	Negative; 0.74 to 80 μg/ml; cytotoxicity was seen at concentrations of 80 μg/ml

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

Guideline No.	Study Type	Results
870.5395	*In vivo* mouse micronucleus assay - bone marrow	Negative; single dose (gavage) 1,250 or 5,000 mg/kg
870.7485	Metabolism and pharmacokinetics	In a metabolism study in rats, single oral doses (0.5 or 100 mg/kg bw) of phenyl or pyrimidyl-radiolabelled cyprodinil were administered, with one low-dose group receiving unlabeled cyprodinil for 2 weeks prior to treatment with radiolabelled compound. Excretion was rapid and almost complete, with urine as the principle route of excretion. Tissue residues declined rapidly, with the highest concentrations (≥ 1.8 ppm) found in kidneys, liver, lungs, spleen, thyroid, whole blood, and carcass. Unchanged parent compound was detected in feces extract only. Excretion, distribution and metabolite profiles were essentially independent of dose level, pretreatment, and type of label, although there were some sex- dependent qualitative differences in two urinary metabolite fractions. Eleven metabolites were isolated from urine, feces and bile, and the metabolic pathways in the rat were proposed. All urinary and biliary metabolites (with one exception) 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. The monosulfate metabolite was predominant in females, whereas equal amounts of mono- and disulfate conjugates were noted in males. Most of the significant metabolites in feces were exocons of biliary metabolites. 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.

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 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 Safety Factor.

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 1×10^{-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 CYPRODONIL 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 (all populations)	Not applicable	Not applicable	There were no effects that could be attributed to a single exposure (dose) in oral toxicity studies including the developmental toxicity studies in rats and rabbits.

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations)	NOAEL= 2.7 mg/kg/day UF = 100 Chronic RfD = 0.03 mg/kg/day	FQPA SF = 1 cPAD = 0.03 ÷ 1 0.03 mg/kg/day	Combined/chronic toxicity - rat LOAEL = 35.6 mg/kg/day based on increased incidence of spongiosis hepatis in the liver
Short-term dermal (1–7 days)	Dermal study NOAEL= 25.0 mg/kg/day	LOC for MOE = 100 (includes the FQPA SF)	21–day dermal study - rat LOAEL = 125 mg/kg/day based on hunched posture
Intermediate- term dermal (1 week – several months)	Dermal study NOAEL= 25.0 mg/kg/day	LOC for MOE = 100 (includes the FQPA SF)	21–day dermal study - rat LOAEL = 125 mg/kg/day based on hunched posture
Long-term dermal (several months - lifetime)	Not applicable	Not applicable	Based on the current use pattern, there is no potential for long-term dermal exposure.
Inhalation (any time period)	Not applicable	Not applicable	The current use pattern, the low exposure potential and the low toxicity (Toxicity Category III) do not indicate a significant potential for exposure via this route.
Cancer (oral, dermal, inhalation)	''Not likely'' to be a human carcinogen	Not applicable	There is no evidence of carcinogenic potential, therefore, cancer risk assessment is not required.

* The reference to the FQPA Safety Factor refers to any additional safety factor 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(a)) for the residues of cyprodinil, in or on food commodities as follows: almond nutmeats at 0.02 ppm, almond hulls at 0.05 ppm, pome fruit at 0.1 ppm, apple, wet pomace at 0.15 ppm, grapes at 2.0 ppm, raisins at 3.0 ppm and stone fruit at 2.0 ppm. Time-limited tolerances in association with section 18 of FIFRA (emergency exemptions) have been established under 180.532(b) for caneberries at 10 ppm and strawberries at 5.0 ppm. 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 1 day or single exposure. The Agency did not conduct an acute dietary risk assessment since no toxicological endpoint of concern was identified during the review of the available data.

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: A conservative analysis was performed using published and proposed tolerance level residues and 100% crop treated information for all commodities.

iii. *Cancer*. Cyprodinil is classified as ''not likely'' to be a human carcinogen by all routes of exposure based on lack of evidence of carcinogenicity in mice and rats, therefore, a cancer risk assessment was not performed.

2. *Dietary exposure from drinking water*. Cyprodinil has a low potential for significant movement into ground water under most conditions. There is a moderate risk of cyprodinil contaminating surface water as runoff and through erosion of soil particles to which cyprodinil is absorbed. However, if cyprodinil residues were to reach surface water and/or ground water, it may persist for a significant period of time.

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 ground water. 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 %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 below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of cyprodinil in surface water and ground water for acute exposures are estimated to be 52.9 parts per billion (ppb) for surface water and 0.033 ppb for ground water. The EECs for chronic exposures are estimated to be 51 ppb for surface water and 0.033 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).

Cyprodonil 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) 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. *Safety factor for infants and children*—i. *In general*. FFDCA section 408 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

2. *Conclusion*. EPA determined that the 10X safety factor to protect infants and children should be removed. The FQPA factor is removed because: The toxicology data base is complete for the assessment of the effects following *in utero* and/or postnatal exposure; there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; EPA determined that a developmental neurotoxicity study is not required; the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children; and there are no registered residential uses at the current time.

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 to calculate DWLOCs: 2L/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 ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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*. Acute aggregate risk is negligible since no acute toxicological endpoint of concern was identified.

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% of the cPAD for the U.S. population, 23% 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. 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 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYPRODINIL

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.03	7	51	0.033	974
Infant < 1 year old	0.03	23	51	0.033	230

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes 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.

4. *Aggregate cancer risk for U.S. population*. Cyprodinil is classified as ''not likely to be human carcinogen,'' therefore, EPA concludes that cyprodinil poses no greater than a negligible cancer risk.

5. *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

Ciby Geigy Method AG-631A is adequate for enforcement of tolerances for residues of cyprodinil in/on strawberry and dry bulb and green onions. Method AG-631A is a reissue of Method(s) AG-631/REM 141.01 which has successfully undergone an independent laboratory validation (ILV) as well as an Agency petition method validation (PMV) in conjunction with permanent tolerance petitions for use on stone fruits and almonds. The method includes a GC-NPD confirmatory method and has been radiovalidated using samples of ^{14}C cyprodinil-treated tomatoes. Once minor deficiencies cited in the PMVs have been resolved (the petitioner was required to submit a standard of cyprodinil and material safety data sheet (MSDS) to the EPA repository and to incorporate the necessary method revisions), the method will be forwarded to FDA for inclusion in PAM II.

The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian or Mexican maximum residue limits for strawberries, dry bulb onions or green onions.

C. Conditions

The residue field trials do not support permanent tolerances for cyprodinil residues in or on strawberry and onions. The residue field trials were conducted at exaggerated application rates (2.3 times the proposed use rates). Since EPA expects that residues from field trials preformed at the proposed use rates will be lower than those reported at the 2.3 times rate, conditional registration and time-limited tolerances may be established using the available data on strawberry and onions.

Based on the findings from a confined accumulation in rotational crops study, EPA has concluded that a field accumulation in rotational crop study should be conducted and residues of the cyprodinil metabolites (CGA-249287, CGA-263208, CGA-232449 and NOA-422054) should be monitored and reported to the Agency.

Based on structural similarities to genotoxic nucleotide analogs, there was concern that the pyrimidine metabolites (CGA-249287, NOA-422054) may be more toxic than the parent compound. However, EPA's review indicates similar results in an acute oral and mutagenicity studies with both the parent compound and the CGA-249287 metabolite. EPA concluded that the toxicity of the CGA-249287 and NOA-422054 metabolites is no greater than that of the parent, conditional on submission and review of confirmatory data of an acute oral toxicity study and bacterial reverse mutation assay for the NOA-422054 metabolite. Although the metabolites CGA-232449 and CGA-263208 were determined to be of potential toxicological concern, they are not expected to be more toxic than cyprodinil per se.

Upon receipt and evaluation of additional residue field trials for strawberries, dry bulb onions, and green onions; field accumulation in rotational crops study for the CGA-249287, NOA-422054, CGA-263208, and CGA-232449 metabolites; and formal submission and review of confirmatory data from an acute oral toxicity study and Ames assay for the CGA-249287 and NOA-422054 metabolites; the Agency will reassess these tolerances and, if appropriate, will establish permanent tolerances for strawberry, dry bulb onion and green onion. A rotational crop restriction will be imposed, which will limit the plant-back to crops which have established cyprodinil tolerances.

V. Conclusion

Therefore, these tolerances are established for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine, in or on strawberry at 5.0 ppm, dry bulb onion at 0.60 ppm, and green onion at 4.0 ppm. These tolerances will expire on December 31, 2003.

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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–301120 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 August 21, 2001.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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.

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.

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.2. Mail your copies, identified by docket control number OPP–301120, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 other 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

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: June 7, 2001.

James Jones,

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(a) is amended by designating the text following the paragraph heading as paragraph (a)(1) and adding paragraph (a)(2) to read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

(2) Time-limited tolerances are established for residues of the fungicide cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on the following food commodities.

Commodity	Parts per million	Expiration/ revocation date
Onion, dry bulb	0.60	12/31/03
Onion, green	4.0	12/31/03
Strawberry	5.0	12/31/03

* * * * *

[FR Doc. 01–15620 Filed 6–21–01 8:45 a.m.]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301141; FRL–6788–4]

RIN 2070–AB78

Tebufenozide; Re-establish Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation re-establishes time-limited tolerances for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide in or on eggs at 0.01 part per million (ppm); grass, forage at 5 ppm; grass, hay at 18 ppm; hogs, liver at 1 ppm; hogs, mbyp at 0.1 ppm; peanuts at 0.05 ppm; peanut, hay at 5 ppm; peanut, meal at 0.15 ppm; peanut, oil at 0.15 ppm; poultry, fat at 0.1 ppm; poultry, meat at 0.01 ppm; and poultry, mbyp at 0.05 ppm for an additional 2–year period. These tolerances will expire and are revoked on June 30, 2003. 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 peanuts and pasture. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the FIFRA.

DATES: This regulation is effective June 22, 2001. Objections and requests for hearings, identified by docket control number OPP–301141, must be received by EPA on or before August 21, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301141 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone