exempt from taxation under section 501(a) to be a shareholder of an S corporation. The temporary regulations under section 444 are also being issued as proposed regulations published elsewhere in this issue of the **Federal Register**.

Explanation of Provisions

The temporary regulations modify the temporary regulations under section 444 to provide that an ESBT and a trust that is described in section 401(a) or section 501(c)(3) that is exempt from taxation under section 501(a) is not a deferral entity for purposes of § 1.444–2T. Therefore, an S corporation with a section 444 election may have an ESBT or a trust that is described in section 401(a) or section 501(c)(3) that is exempt from taxation under section 501(a) as a shareholder. An ESBT is not a deferral entity within the meaning of § 1.444–2T because under section 641(c) the portion of the ESBT consisting of stock in one or more S corporations is taxed to the deemed owner under subpart E, part I, subchapter J of the Code or is subject to taxation at the trust level without a deduction for amounts distributed or required to be distributed from that portion of the trust. A trust described in section 401(a) (other than an employee stock ownership plan described in section 4975(e)(7)), or a trust described in section 501(c)(3) that is exempt from taxation under section 501(a) is not a deferral entity within the meaning of § 1.444–2T because with respect to such trust all items of income, loss, or deduction taken into account under section 1366(a) and any gain or loss on the disposition of the stock in the S corporation is treated as unrelated business taxable income of such trust under section 512(e)(1) and is subject to taxation under section 511. A trust described in section 401(a) that is an employee stock ownership plan described in section 4975(e)(7) is not a deferral entity within the meaning of § 1.444–2T because such trust does not defer taxation but rather is exempt from taxation under section 501(a) and is not treated as having unrelated business taxable income pursuant to section 512(e)(3).

The temporary regulations are effective as of December 29, 2000. However taxpayers may voluntarily apply these temporary regulations to taxable years of S corporations beginning after December 31, 1996, for S corporations that have ESBTs as shareholders, and for taxable years beginning after December 31, 1997, for S corporations that have trusts described in section 401(a) or section 501(c)(3) that are exempt from taxation under section 501(a) as shareholders.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these temporary regulations will be submitted to the Small Business Administration for comment on the regulation's impact on small business.

Drafting Information

The principal authors of these regulations are Bradford Poston and James A. Quinn of the Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.444–4T is also issued under 26 U.S.C. 444(g). * * *

Par. 2. Section 1.444–4T is added under the undesignated centerheading ''Accounting Periods'' to read as follows:

§ 1.444–4T Tiered structure (temporary).

(a) *Electing small business trusts.* For purposes of § 1.444–2T, solely with respect to an S corporation shareholder, the term *deferral entity* does not include a trust that is treated as an electing small business trust under section 1361(e). An S corporation with an electing small business trust as a shareholder may make an election under section 444. This paragraph (a) is applicable beginning December 29, 2000, however taxpayers may voluntarily apply it to taxable years of S corporations beginning after December 31, 1996.

(b) *Certain tax-exempt trusts.* For purposes of § 1.444–2T, solely with respect to an S corporation shareholder, the term *deferral entity* does not include a trust that is described in section 401(a) or section 501(c)(3) that is exempt from taxation under section 501(a). An S corporation with a trust that is described in section 401(a) or section 501(c)(3) that is exempt from taxation under section 501(a) as a shareholder may make an election under section 444. This paragraph (b) is applicable beginning December 29, 2000, however taxpayers may voluntarily apply it to taxable years of S corporations beginning after December 31, 1997.

Approved: December 13, 2000.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Jonathan Talisman,

Acting Assistant Secretary of the Treasury.

[FR Doc. 00–32190 Filed 12–28–00; 8:45 am]

BILLING CODE 4830–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301093; FRL–6760–9]

RIN 2070–AB78

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile in or on grapes, strawberries, dry bulb onions, and green onions. Novartis Crop Protection, Inc. and the Inter-Regional Project Number (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective December 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301093, must be received by EPA on or before February 27, 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–301093 in

the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; and e-mail address: waller.mary@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	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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–301093. 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 August 26, 1998 (63 FR 45497) (FRL–6023–4), 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) for tolerances for fludioxonil on grapes by Novartis Crop Protection, Inc, 410 Swing Road, Greensboro, NC 27419. 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 180.516 be amended by establishing tolerances for residues of the fungicide fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile, in or on grapes at 1.0 ppm.

In the **Federal Register** of March 29, 2000 (65 FR 45498) (FRL–6495–5), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA announcing the filing of a pesticide petition (PP) for tolerances for fludioxonil on strawberries, bulb vegetables, and stone fruit by the Interregional Research Project Number 4 (IR–4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903. This notice included a summary of the petition prepared by the Interregional Research Project Number 4 (IR–4), the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.516 be amended by establishing tolerances for residues of the fungicide fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile, in or on strawberries at 2.0 ppm; dry bulb onion; great-headed garlic; shallot; and welsh onion at 0.2 ppm; green onion and leek at 7.0 ppm; and stone fruit group at 2.0 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) 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 a tolerance for residues of fludioxonil on grapes at 1.0 ppm, strawberries at 2.0 ppm, dry bulb onions at 0.20 ppm, and green onions at 7.0 ppm. Tolerances are not being established for stone fruit at this time due to additional preliminary residue chemistry data (not yet available to the Agency for review) that indicate that a tolerance of 2.0 ppm may be too low for stone fruit. The Agency will not establish a stone fruit tolerance until the

final set of residue chemistry data are submitted and reviewed. 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 fludioxonil 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
870.3100a	90–Day oral toxicity in rats	NOAEL = 64 mg/kg/day (M) and 70 mg/kg/day (F) LOAEL = 428 mg/kg/day (M) and 462 mg/kg/day (F) based on decreased weight gain (both sexes), chronic nephropathy (M) and centrilobular hepatocyte hypertrophy (F).
870.3100b	90–Day oral toxicity in mice	NOAEL = 445 mg/kg day (M) and 559 mg/kg/day (F) LOAEL = 1052 mg/kg/day (M) and 1307 mg/kg/day (F) based on decreased body weight gain (F), increased alkaline phosphatase (M), increased relative liver weight, increased incidence of nephropathy and centrilobular hypertrophy (both sexes)
870.3100c	90–Day oral toxicity in dogs	NOAEL = 5 mg/kg/day (both sexes) LOAEL = 50 mg/kg/day based on an increased incidence of diarrhea (both sexes).
870.3200	21/28– Day dermal toxicity	NOAEL≥1,000 mg/kg/day for both sexes
870.3250	90–Day dermal toxicity	N/A
870.3465	90–Day inhalation toxicity	N/A
870.3700a	Prenatal developmental in rodents	Maternal NOAEL = 100 mg/kg/day LOAEL = 1,000 mg/kg/day based on reduction in corrected weight gain Developmental NOAEL = 100 mg/kg/day LOAEL = 1,000 mg/kg/day based on increase in the fetal incidence and litter incidence of dilated renal pelvis and dilated ureter.
870.3700b	Prenatal developmental in nonrodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight gain and decreased food efficiency Developmental NOAEL ≥ 300 mg/kg/day
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 22.13 mg/kg/day (M) and 24.24 mg/kg/day (F) LOAEL = 221.61mg/kg/day (M) and 249.67 mg/kg/day (F) based on increased clinical signs, decreased body weights, decreased weight gain, and decreased food consumption in both sexes Reproductive/Offspring NOAEL = 22.13 mg/kg/day (M) and 24.24 mg/kg/day (F) LOAEL = 221.61 mg/kg/day (M) and 249.67 mg/kg/day (F) based on reduced pup weights during lactation
870.4100b	Chronic toxicity dogs	NOAEL = 3.3 mg/kg/day (F) and 33.1 mg/kg/day (M). LOAEL = 35.5 mg/kg/day (F) and 297.8 mg/kg/day (M) based upon decreased weight gain (F) and decreased body weight, reduction in hematological parameters (platelets), increase in cholesterol and alkaline phosphatase, and increased relative liver weight (M)
870.4300	Combined Chronic Toxicity/Carcinogenicity in rats	NOAEL = 37 mg/kg/day (M) and 44 mg/kg/day (F) LOAEL = 113 mg/kg/day (M) and 141 mg/kg/day (F) based on decreased mean body weight gain, slight anemia (F), and increased incidence and severity of liver lesions (degeneration) in both sexes. There was no evidence of carcinogenicity in male rats, but there was a statistically significant increase, both trend and pairwise, of combined hepatocellular tumors in female rats. Classified as ''Group D'' by OPP Cancer Peer Review Committee.
870.4300	Carcinogenicity mice	NOAEL = 11.3 mg/kg/day (M) and 133 mg/kg/day (F)

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

Guideline No.	Study Type	Results
		LOAEL = 112 mg/kg/day (M) and 417 mg/kg/day (F) based on the increased incidence of mice convulsing when handled (M) and increased absolute liver weight and grossly enlarged livers (F). Statistically significant trend for malignant lymphomas in females.
870.5100	Gene mutation in bacteria	Strains TA 98, 100, 1535, 1537 of *S. typhimurium*, and strain WP2uvrA of E. coli were negative for mutagenic activity when tested from 20 to 5,000 μg/plate in absence and presence of metabolic activation.
870.5300	Gene mutation in mammalian cells in culture	Chinese hamster V79 ovary cells were tested from 0.50 to 60 μg/mL. Negative up to limit of solubility and cytotoxicity.
870.5375	*In vitro* Chromosome aberration	Chinese hamster ovary cells were tested with and without metabolic activation from 1.37 to 700 μg/mL. Positive for nondisjunction of chromosomes both in the presence and absence of activation.
870.5385	Bone marrow chromosome aberrations assay	Chinese hamsters were orally dosed at levels from 1,250 to 5,000 mg/kg. There was no significant increase in the frequency of chromosome aberrations in bone marrow at any dose tested.
870.5395	*In vivo* Mouse micronucleus assay	Both sexes of NMRI mice were dosed up to 5,000 mg/kg/day. There were no significant increases in the number or percentage of micronucleated polychromatic erythrocytes.
870.5395	*In vivo* Rat hepatocyte micronucleus assay	Male rats were orally dosed 1250, 2500 and 5,000 mg/kg and hepatocytes were harvested. Micronucleated hepatocytes were found in Phase II at the low and mid dose levels but not at the high dose level and not in Phase I. Positive for mutagenicity in hepatocytes exposed *in vivo*.
870.5550	*In vitro* unscheduled DNA synthesis assay	There was no evidence of unscheduled DNA synthesis in rat hepatocytes at doses from 4.1 to 5,000 μg/mL.
870.5450	Dominant lethal assay in mice	Male mice singly dosed at 0, 1,250, 2,500, or 5,000 mg/kg/day and mated for 8 consecutive weeks had no evidence of a dominant lethal mutation
870.6200a	Acute neurotoxicity screening battery	Available data do not indicate a need for acute or subchronic neurotoxicity studies
870.6200b	Subchronic neurotoxicity screening battery	Available data do not indicate a need for acute or subchronic neurotoxicity studies
870.6300	Developmental neurotoxicity	Available data do not indicate a need for acute or subchronic neurotoxicity studies
870.7485	Metabolism and pharmacokinetics	C^{14}-Fludioxonil given by gavage and bile duct-cannulation to groups of male and female rats. Absorption was estimated to be between 67–91%. Terminal tissue distribution showed that terminal residues were below the limit of detection for most tissues except the liver, kidneys, blood, and lungs, which showed low levels. The major route of excretion was the feces, with approximately 80% of the administered radioactivity excreted by this route in male and female rats at both the low and high dose. The remaining radioactivity was excreted through urine. In bile duct-cannulated rats, approximately 70% of an administered radioactive dose was excreted via this route, supporting the bile as the origin of the fecal radioactivity. There were no apparent sex- or dose-related differences in the routes of excretion for fludioxonil. Examination of urine for metabolites of fludioxonil showed at least 20 metabolites, each comprising a minor fraction of the administered dose (0.1–3.1%).
870.7600	Dermal penetration	N/A
N/A	Special studies	N/A

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 intra species 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 fludioxonil used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL ENDPOINTS USED FOR HUMAN RISK ASSESSMENT*

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50	NOAEL = 100 mg/kg/day; UF = 100; Acute RfD = 1.0 mg/kg/day	FQPA SF = 1X; aPAD = acute RfD/FQPA SF = 1.0 mg/kg/day	Developmental Toxicity Study - rat Developmental LOAEL = 1,000 mg/kg/day based on increased incidence of fetuses and litters with dilated renal pelvis and dilated ureter
Chronic Dietary all populations	NOAEL= 3.3 mg/kg/day; UF = 100; Chronic RfD = 0.03 mg/kg/day	FQPA SF = 1X; cPAD = chronic RfD/FQPA SF = 0.03 mg/kg/day	One year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Short-Term Dermal (1–7 days) (Occupational/Residential)	none	No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) in the 28–day dermal toxicity study in rats. This risk assessment is not required.	Endpoint was not selected
Intermediate-Term (1 week - several months) Dermal (Occupational/Residential)	Oral study NOAEL= 64 mg/kg/day (dermal penetration = 40%)	LOC for MOE = 100 (Occupational); LOC for MOE = 100 (Residential)	13 Week Oral Feeding Study - rat Systemic LOAEL = 428 mg/kg/day based on decreased body weight gain in both sexes, chronic nephropathy in males, and centrilobular hepatocyte hypertrophy in females
Long-Term (several months-lifetime) Dermal (Occupational/Residential)	Oral study NOAEL = 3.3 mg/kg/day (dermal penetration = 40%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	one year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Short-Term (1–7 Days) Inhalation (Occupational/Residential)	NOAEL = 64 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational); LOC for MOE = 100 (Residential)	13 Week Oral Feeding Study - rat Systemic LOAEL = 428 mg/kg/day based on decreased body weight gain in both sexes, chronic nephropathy in males, and centrilobular hepatocyte hypertrophy in females
Intermediate-term (1 week - several months) Inhalation (Occupational/Residential)	NOAEL = 64 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential)	13 Week Oral Feeding Study - rat Systemic

TABLE 2.—SUMMARY OF TOXICOLOGICAL ENDPOINTS USED FOR HUMAN RISK ASSESSMENT*—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
			LOAEL = 428 mg/kg/day based on decreased body weight gain in both sexes, chronic nephropathy in males, and centrilobular hepatocyte hypertrophy in females
Long-Term (several months-lifetime) Inhalation (Occupational/Residential)	NOAEL = 3.3 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational); LOC for MOE = 100 (Residential)	one year chronic toxicity study - dog LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs
Cancer (oral, dermal, inhalation)	''Group D''- not classifiable as to human carcinogenicity via relevant routes of exposure	not applicable	Acceptable oral rat and mouse carcinogenicity studies; evidence of carcinogenic and mutagenic potential.

* UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern. The FQPA factor being referenced is the factor unique to the FQPA and does not include FQPA factors related to data uncertainty.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.516) for the residues of fludioxonil, in or on a variety of raw agricultural commodities. Fludioxonil is the active ingredient in registered products used as a seed treatment for many crops (with the exception of tree crops and berries). In addition, several Section 18 emergency exemptions for use as a foliar spray on strawberries, caneberries and as a post-harvest spray treatment on apricots, nectarines, peaches, and plums have been approved. Risk assessments were conducted by EPA to assess dietary exposures from fludioxonil 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 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 acute analysis was performed for the females 13–50 years old population subgroup using published and proposed tolerance levels, default concentration factors, and 100% CT assumptions for all commodities. The acute dietary exposure estimate at the 95th percentile of exposure for females 13–50 years old is 0.004512 mg/kg/day, representing 0.5% of the aPAD.

For acute dietary risk estimates, EPA's level of concern is >100% aPAD. The results of the acute analysis indicate that at the 95th percentile of exposure, the acute dietary risk associated with the proposed uses of fludioxonil is below EPA's level of concern.

ii. *Chronic exposure.* The chronic DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–92 nationwide CSFII and accumulated exposure to the chemical for each commodity using published and proposed tolerance levels, default concentration factors, and 100% crop treated (CT) assumptions for all commodities. Chronic dietary exposure estimates ranged from 0.000609 mg/kg/day (2.0% of the cPAD) for males 13–19 years old, up to 0.003506 mg/kg/day (12% of the cPAD) for all infants (< 1 year old). All other population subgroups fell in between these two figures, including the U.S. population (0.001107 mg/kg/day; 3.7% of the cPAD), children 1–6 years old (0.002934 mg/kg/day; 9.8% of the cPAD), children 7–12 years old (0.001522 mg/kg/day; 5.1% of the cPAD), females 13–50 years old (0.000823 mg/kg/day; 2.7% of the cPAD), males 20+ years old (0.000726 mg/kg/day; 2.4% of the cPAD), and seniors 55+ years old (0.000961 mg/kg/day; 3.2% of the cPAD).

Since the FQPA factor was reduced to 1x for all population subgroups, the Agency's level of concern is 100% cPAD = 100% cRfD. The results of this analysis indicate that the chronic dietary risk associated with the existing uses and the proposed uses of fludioxonil is below EPA's level of concern.

iii. *Cancer.* EPA has classified Fludioxonil as a Group D - not classifiable as to human carcinogenicity. The evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect. In one mouse study, there was a significant trend for malignant lymphomas in female mice up to 3,000 ppm. However, in a second study up to 7,000 ppm, the limit dose, there was no evidence of carcinogenicity for either sex. In rats, fludioxonil produced a significant trend and pair-wise increase in hepatocellular tumors, combined, in female rats at doses adequate to assess carcinogenicity. EPA determined that based on the increase in liver tumors in female rats that was statistically significant for combined adenoma/carcinoma only, the lack of tumorogenic response in male rats or in either sex of mice, and the need for additional mutagenicity studies, a Group D classification was appropriate.

Fludioxonil was not mutagenic in the tests for gene mutations. However, because of the powerful induction of polyploidy in the *in vitro* Chinese hamster ovary cell cytogenetic assay and the suggestive evidence of micronuclei induction in rat hepatocytes *in vivo*, additional mutagenicity testing was performed in an *in vivo* study specifically designed for aneuploidy analysis.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fludioxonil 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 fludioxonil.

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %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 fludioxonil they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of fludioxonil for acute exposures are estimated to be 46 parts per billion (ppb) for surface water and 0.35 ppb for ground water. The EECs for chronic exposures are estimated to be 32 ppb for surface water and 0.35 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).

Fludioxonil is not currently registered for residential (outdoor, non-food) uses. The registrant is seeking registration for the use of fludioxonil by commercial applicators on residential lawns.

There is potential residential postapplication exposure to adults and children entering residential areas treated with fludioxonil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate-term dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected. Short-term non-dietary oral exposures for toddlers were not assessed since the acute dietary endpoint for fludioxonil is only relevant for females 13–50 years old. Intermediate-term, non-dietary ingestion exposure for toddlers is possible and was assessed using the intermediate-term dose and endpoint identified from the 13 week oral feeding study in rats. Intermediate-term exposure is not expected from the proposed ornamental uses of fludioxonil.

There are no chemical-specific data available to determine the potential risks from post-application activities associated with the proposed uses of fludioxonil. The exposure estimates are based on assumptions and generic data as specified by the newly proposed Residential SOPs. The MOEs for postapplication exposures from full lawn uses are 2,000 and 1,200 for adults and children, respectively. The dermal MOE for postapplication exposure for the hand to mouth scenario is 13,000. The aggregate intermediate MOE for postapplication residential exposure to toddlers is 1,100. These estimates indicate that the potential intermediate-term risks from residential uses of fludioxonil do not exceed the Agency's level of concern. The Agency's level of concern is for MOEs below 100.

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 fludioxonil 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, fludioxonil 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 fludioxonil 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

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*. The rat and rabbit developmental toxicity studies were tested at doses that produced maternal toxicity. There were no developmental findings in rabbits. The findings in the rat developmental toxicity studies were considered to be related to maternal toxicity, rather than an indication of increased susceptibility. In the reproductive study, maternal and reproductive/ offspring toxicity occurred at the same dose indicating no evidence of susceptibility.

iii. *Conclusion*. There is a complete toxicity data base for fludioxonil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Accordingly, taking into account the data on pre- and post-natal toxicity, EPA determined that an additional tenfold safety factor was not necessary to protect infants and children.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used 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 groundwater 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.* The acute dietary exposure estimate at the 95th percentile of exposure for females 13–50 years old is 0.004512 mg/kg/day, representing 0.5% of the aPAD. An acute dose and endpoint was not selected for the U. S. population (including infants and children) because there were no effects of concern observed in oral toxicology studies, including maternal toxicity in the developmental toxicity studies in rats and rabbits, that are attributable to a single exposure dose. In addition, there is potential for acute dietary exposure to fludioxonil in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	1.0	0.5%	46	0.35	30,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fludioxonil from food will utilize 3.7% of the cPAD for the U.S. population, 12% of the cPAD for all infants (< 1 year old) and 9.8% of the cPAD for children 1–6 years old. Based the use pattern, chronic residential exposure to residues of fludioxonil is not expected. In addition, there is potential for chronic dietary exposure to fludioxonil 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 4:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)*	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.3	3.7	11	0.35	1,000
All infants (<1 year old)	0.3	12	11	0.35	260
Children 1–6 years old	0.3	9.8	11	0.35	270
Children 7–12 years old	0.3	5.1	11	0.35	280
Females 13–50 years old	0.3	2.7	11	0.35	880
Males 13–19 years old	0.3	2.0	11	0.35	1,000
Males 20 + years old	0.3	2.4	11	0.35	1,000
Seniors 55 + years old	0.3	3.2	11	0.35	1,000

*GENEEC model estimated 56–day (average) concentration was divided by a factor of 3 prior to comparison with the DWLOC; 32/3 = 11.

3. *Short-term risk*. In aggregating short-term risk, the Agency considers background chronic dietary exposure (food + drinking water) and short-term inhalation and dermal exposures from residential uses. EPA did not identify a dermal endpoint of concern for the short-term duration. Short-term inhalation endpoints were identified, however, they are not relevant for the short-term aggregate risk since homeowners would not be applying fludioxonil. The registrant indicated that the requested residential uses are only for professional applications. Therefore, the short-term aggregate risk assessment is not required.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

For adults, post-application exposures may result from dermal contact with treated turf. For toddlers, dermal and non-dietary oral post-application exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,200 for the U.S. population and 530 for infants/children. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of fludioxonil in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Inter-mediate-Term DWLOC (ppb)
U.S. Population	1,200	100	11	0.35	1,100
Infants/Children	530	100	11	0.35	220

5. *Aggregate cancer risk for U.S. population*. The EPA classified Fludioxonil as a Group D - not classifiable as to human carcinogenicity. The evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect. In one mouse study, there was a significant trend for malignant lymphomas in female mice up to 3,000 ppm. However, in a second study up to 7,000 ppm, the limit dose, there was no evidence of carcinogenicity for either sex. In rats, fludioxonil produced a significant trend and pair-wise increase in hepatocellular tumors, combined, in female rats at doses adequate to assess carcinogenicity. The EPA determined that based on the increase in liver tumors in female rats that was statistically significant for combined adenoma/carcinoma only, the lack of tumorogenic response in male rats or in either sex of mice, and the need for additional mutagenicity studies, a Group D classification was appropriate.

However, the Agency has since received the additional mutagenicity studies and based on the negative preliminary findings of the studies, the fact that the statistical increase in liver tumors in female rats occurred only at the highest dose, the lack of tumorigenic response in male rats and mice, the Agency has concluded that fludioxonil does not pose a significant cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fludioxonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The registrant has proposed high performance liquid chromatography using ultraviolet detection Method AG–597B as the analytical enforcement method. This method is a reissue of Method(s) AG–597/AG–597A which has successfully undergone an ILV trial as well as Agency petition method validation (PMV). The original method is available for enforcement purposes until the new method is validated. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460. Office location and telephone number: Rm. 101FF, CM # 2, 1921 Jefferson Davis Hwy, Arlington, VA, (703) 305-5229.

B. International Residue Limits

There are no Codex Maximum Residue Limits (MRLs) for fludioxonil. Therefore, international harmonization is not an issue at this time.

C. Conditions

Registration is conditional upon submission of the two dry bulb onion residue trials in Regions 5 and 12.

V. Conclusion

Therefore, the tolerance is established for residues of fludioxonil 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrilein or on grapes at 1.0 ppm, strawberries at 2.0 ppm, dry bulb onions at 0.20 ppm, and green onions at 7.0 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 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–301093 on 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 February 27, 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–301093, 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 file format 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 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).

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: December 18, 2000.

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 180.516 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) *General.* A tolerance is established for residue of the fungicide fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Grape	1.0
* * * * *	
Onion, dry bulb	0.20
Onion, green	7.0
* * * * *	
Strawberry	2.0
* * * * *	

* * * * *

[FR Doc. 00–33168 Filed 12–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301098; FRL–6762–7]

RIN 2070–AB78

Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II of this document. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act 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.

DATES: This regulation is effective December 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301098, must be received by EPA on or before February 27, 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–301098 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: See the listing below for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366.

Pesticide/CFR cite	Contact person
2,4-D (§ 180.142)	Beth Edwards
Paraquat (§ 180.205)	Libby Pemberton
Lambda-cyhalothrin (§ 180.438).	Andrew Ertman
Bifenthrin and difenoconazole (§ 180.442 and § 180.475, respectively).	Andrea Conrath
Fenbuconazole (§ 180.480).	Dan Rosenblatt
Sulfentrazone and imazamox (§ 180.498 and § 180.508, respectively).	Barbara Madden

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	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