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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-301161; FRL-6797-5]

RIN 2070-AB78

Fludioxonil; Pesticide Tolerances for Emergency Exemptions**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile) in or on pomegranates. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pomegranates. This regulation establishes a maximum permissible level for residues of fludioxonil in this food commodity. The tolerance will expire and is revoked on June 30, 2003.

DATES: This regulation is effective September 12, 2001. Objections and requests for hearings, identified by docket control number OPP-301161, must be received by EPA on or before November 13, 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 VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301161 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially

affected categories and entities may include, but are not limited to:

Categories	NAICS codes	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/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301161. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile), in or on pomegranates at 5.0 parts per million (ppm). This tolerance will expire and is revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the 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 FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .”

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fludioxonil on Pomegranates and FFDCA Tolerances

Losses due to *Botrytis* have increased dramatically over the course of the last 2 years for pomegranate growers and packers. In the 1999 and 2000 packing seasons, growers and packers experienced approximately a 20% loss of fruit after packing for the fresh market due to *Botrytis* mold and had never experienced such frequency of decay before. Previously, they had been able to hold pomegranates for 2 to 3 months, but now have difficulties storing much beyond 2 to 3 weeks. EPA has authorized under FIFRA section 18 the use of fludioxonil on pomegranates for control of gray mold (*Botrytis cinerea*) in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fludioxonil in or on pomegranates. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on June 30, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on pomegranates after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not

exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fludioxonil meets EPA’s registration requirements for use on pomegranates or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fludioxonil by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA’s regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fludioxonil, contact the Agency’s Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 fludioxonil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fludioxonil in or on pomegranates at 5.0 ppm. EPA’s assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

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

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUDIOXONIL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	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	1 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)	1 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 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)	1 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.

B. 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. 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 following assumptions were made for the acute exposure assessments: For the acute DEEM™ analysis (version 7.72), published and proposed tolerances level residues were used. Default processing factors and 100% crop treated (CT) were assumed for all commodities.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the 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: For the chronic DEEM™ analysis (version 7.73), published and proposed tolerances level residues were used. Default processing factors and 100% CT were assumed for all commodities.

iii. *Cancer.* Fludioxonil has been put in “Group D”- not classifiable as to human carcinogenicity via relevant routes of exposure and therefore this risk assessment is not required.

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 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 fludioxonil they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models, the 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 11 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, however, the registrant is seeking registration for the use of fludioxonil by commercial applicators on residential lawns. 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.

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).

C. 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. *Developmental toxicity studies.* In the rat developmental study, the maternal (systemic) NOAEL was 100 mg/kg/day, based on reduction in mean body weight gain in dams during gestation period at the LOAEL of 1,000 mg/kg/day. The developmental (fetal) NOAEL was 100 mg/kg/day, based on increased fetal and litter incidence of dilated renal pelvis and dilated ureter at the LOAEL of 1,000 mg/kg/day. In the rabbit developmental toxicity study, the maternal (systemic) NOAEL was 10 mg/kg/day, based on decreased body weight gains and food efficiency at the LOAEL of 100 mg/kg/day. The developmental (pup) NOAEL was 300 mg/kg/day, the highest dose tested.

iii. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 22.13 mg/kg/day (males)

and 24.24 mg/kg/day (females), based on clinical signs and decreased body weight, body weight gain and food consumption at the LOAEL of 221.6 mg/kg/day (males) and 249.7 mg/kg/day (females). The reproductive/developmental (pup) NOAEL was 22.13 mg/kg/day (males) and 24.24 mg/kg/day (females), based on reduced pup weights at the LOAEL of 221.6 mg/kg/day (males) and 249.7 mg/kg/day (females).

iv. Prenatal and postnatal sensitivity. The toxicological data base for evaluating prenatal and postnatal toxicity for fludioxonil is complete with respect to current data requirements. There are no prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study.

v. Conclusion. EPA concludes that reliable data support the removal of the additional uncertainty factor; the standard hundred-fold uncertainty factor is adequate to protect the safety of infants and children.

D. 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 + chronic non-dietary, non-occupational 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 ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to fludioxonil 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 fludioxonil on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Because the acute endpoint applies to one population subgroup, females (13–50 years old), the acute risk assessment was conducted only for this group. An acute dose and endpoint were 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).

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fludioxonil will occupy 0.7% of the aPAD for females (13–50 years old). In addition, despite the potential for acute dietary exposure to fludioxonil in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of fludioxonil in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—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	0.7	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 5.5% of the cPAD for the U.S. population, 22% of the cPAD for all infants <1 year old) and 14% of the

cPAD for children 1 to 6 years old. Based on the use pattern, chronic residential exposure to residues of fludioxonil is not expected. In addition, despite the potential for chronic dietary exposure to fludioxonil in drinking water, after calculating DWLOCs and

comparing them to conservative model of EECs fludioxonil in 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 FLUDIOXONIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.03	5.5	11	0.35	990
All infants (<1 year old)	0.03	22	11	0.35	230
Children (1 to 6 years old)	0.03	14	11	0.35	260

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children (7 to 12 years old)	0.03	8.2	11	0.35	280
Females (13–50 years old)	0.03	3.8	11	0.35	870
Males (13–19 years old)	0.03	3.2	11	0.35	1,000
Males (20+ years old)	0.03	3.5	11	0.35	1,000
Seniors (55+ years old)	0.03	5.1	11	0.35	1,000

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

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

For the U.S. population and all infants (<1 year old) population subgroups, the total food and residential short-term aggregate MOEs are 1,900 and 995, respectively. As these values are greater than 100, the short-term food and residential aggregate risks for the U.S. population and all infants (<1 year old) population subgroups are below the Agency’s level of concern. Because the all infants (<1 year old) population subgroup has the highest exposure to

fludioxonil residues from dietary sources, including all infants (<1 year old) is adequately protective of the children 1–6 and 7–12 years old population subgroups.

In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of fludioxonil in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency’s level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. population	1,900	100	11	0.35	21,000
All infants (<1 year old)	995	100	11	0.35	5,800

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

Though residential exposure could occur with the use of fludioxonil, no residential exposure scenarios for fludioxonil are expected to have intermediate-term durations. Therefore, an intermediate-term aggregate risk assessment is not required.

5. *Aggregate cancer risk for U.S. population.* Fludioxonil has been put in “Group D”- not classifiable as to human carcinogenicity via relevant routes of exposure and therefore this risk assessment is not required.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. 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; 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 (MRLs) for fludioxonil on pomegranates.

VI. Conclusion

Therefore, the tolerance is established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile), in or on pomegranates at 5.0 ppm.

VII. 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-301161 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 13, 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 VII.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 the docket control number OPP-301161, 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time-limited tolerance under FFDCA section 408. 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 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 FIFRA section 18 exemption under FFDCA section 408, such as the [tolerance/exemption] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCFA 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."

Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

IX. 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: August 14, 2001.

Peter Caulkins, Acting
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.516 is amended by alphabetically adding the following commodity to the table in paragraph (b) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

* * * * *
(b) * * *

Commodity	Parts per million	Expiration/revocation date
Pomegranate	5.0	6/30/03

* * * * *
[FR Doc. 01-22524 Filed 9-11-01; 8:45 am]
BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS-1160-F]

RIN 0938-AK41

Medicare Program; Requirements for the Recredentialing of Medicare+Choice Organization Providers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule changes the requirement for recredentialing providers who are physicians or other health care professionals for

Medicare+Choice Organizations (M+COs) from at least every 2 years to at least every 3 years. This change is consistent with managed care industry recognized standards of practice and quality, and with standards already adopted by nationally recognized private quality assurance accrediting organizations. This change simplifies administrative requirements by retaining consistency with the private accrediting processes. This rule benefits M+COs and providers within the M+COs who must be recredentialled, while continuing to address quality issues of Medicare beneficiaries.

DATES: The effective date of this rule is October 12, 2001.

FOR FURTHER INFORMATION CONTACT: Siera Gollan, (410) 786-6664.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1851 through 1859 of the Social Security Act (the Act) established Part C of the Medicare program, known as the "Medicare+Choice (M+C) Program." On June 26, 1998, we

published a comprehensive interim final rule (63 FR 34968) in the **Federal Register** to implement the M+C Program. That interim final rule set forth the M+C regulations in 42 CFR Part 422—Medicare+Choice Program. We published a subsequent final rule with comment period in the **Federal Register** on June 29, 2000 (65 FR 40170).

When these rules were promulgated, we established a 2-year recredentialing cycle consistent with standards adopted by nationally recognized private quality assurance accrediting organizations. Under § 422.204(b)(2)(ii), Medicare+Choice Organizations (M+COs) are required to recredential providers who are physicians or other health care professionals (including members of physicians groups) at least every 2 years. The recredentialing updates information obtained during initial credentialing, considers performance indicators such as those collected through quality assurance programs, utilization management systems, handling of grievances and appeals, enrollment satisfaction surveys,