## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2004–0321; FRL–7682–3]**

# Fludioxonil; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fludioxonil in or on bean, dry; bean, succulent; citrus, crop group 10; fruit, pome, group 11; grapefruit, oil; kiwifruit; leafy greens subgroup 4A, except spinach; melon subgroup 9A; and yam, true. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0321. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 South Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Sidney C. Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

## II. Background and Statutory Findings

In the **Federal Register** of March 17, 2004 (69 FR 12680) (FRL–7347–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6551, 3E6639, 3E6701, 3E6742, and 3E6803) by IR–4, 681 US Highway #1 South, New Brunswick, NJ 08902–3390. These petitions 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)-1H-pyrrole-3-carbonitrile, in or on bean, dry and bean, succulent at 0.4 parts per million (ppm) (PP 3E6701); citrus, crop group 10 at 10 ppm; citrus, dried pulp at 20 ppm, citrus, oil at 500 ppm, and pomegranate at 2.0 ppm (PP 3E6803); fruit, pome, group 11 at 5.0 ppm, yam at 8.0 ppm, and melon subgroup 9A at 0.03 ppm (PP 3E6742); kiwifruit at 20 ppm (PP 3E6551); and leafy greens subgroup 4A, except spinach at 30 ppm (PP 3E6639). That notice included a summary of the petitions prepared by Syngenta Crop Protection, Incorporated, the registrant. Subsequently, PP 3E6803 has been amended to delete citrus, dried pulp at 20 ppm, and pomegranate at 2.0 ppm. In addition, ''citrus, oil'' at 500 ppm, and ''yam'' at 8.0 ppm has been translated to ''grapefruit, oil'' at 500 ppm, and ''yam, true'' at 8.0, respectively. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure,

consistent with section 408(b)(2) of FFDCA, for tolerances for residues of fludioxonil on bean, dry; bean, succulent at 0.4 ppm; citrus, crop group 10 at 10 ppm; fruit, pome, group 11 at 5.0 ppm; grapefruit, oil at 500 ppm; kiwifruit at 20 ppm; leafy greens subgroup 4A, except spinach at 30 ppm; melon subgroup 9A at 0.03; and yam, true at 8.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fludioxonil as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed are discussed in the **Federal Register** of December 29, 2000 (65 FR 82927) (FRL–6760–9).

*B. Toxicological Endpoints*

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the ''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand ($1 \times 10^{-5}$), one in a million ($1 \times 10^{-6}$), or one in ten million ($1 \times 10^{-7}$). 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 Table 1. of this unit:

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

| Exposure Scenario | Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF | Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Acute Dietary (Females 13–49 years of age) | NOAEL = 100 mg/kg/day<br>UF = 100<br>Acute RfD = 1.0 mg/kg/day | Special FQPA SF = 1X<br>aPAD = acute RfD ÷ Special FQPA SF = 1.0 mg/kg/day | Developmental Toxicity Study<br>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<br>UF = 100<br>Chronic RfD = 0.03 mg/kg/day | Special FQPA SF = 1X<br>cPAD = chronic RfD ÷ Special FQPA SF = 0.03 mg/kg/day | One year chronic toxicity study - dog<br>LOAEL = 35.5 mg/kg/day based on decreased body weight gain in female dogs |
| Incidental Oral, Short-Term Dermal | Oral study NOAEL = 10 mg/kg/day | LOC for MOE = 100 (Residential) | Rabbit developmental study<br>LOAEL = 100 mg/kg/day based on decreased body weight gain during gestation |

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

| Exposure Scenario | Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF | Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Incidental Oral, Intermediate-Term Dermal | Oral study NOAEL = 3.3 mg/kg/day | LOC for MOE = 100 (Residential) | One year chronic toxicity study - dog<br>LOAEL = 35.5 mg/kg/day based on decreased body weight gain in female dogs |
| Short- and Intermediate-Term Dermal (1–30 days and 1–6 months) (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. Additionally, there were no developmental concerns. There risk assessments are not required | Endpoint was not selected |
| Long-Term Dermal (6 months-lifetime) (Occupational/Residential) | Oral study NOAEL = 3.3 mg/kg/day (dermal absorption rate = 40% when appropriate) | LOC for MOE = 100 (Occupational)<br>LOC for MOE = 100 (Residential) | One year chronic toxicity study - dog<br>LOAEL = 35.5 mg/kg/day based on decreased body weight gain in females dogs |
| Short-Term Inhalation (1 to 30 days) (Inhalation) | Inhalation (or oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%) | LOC for MOE = 100 (Occupational)<br>LOC for MOE = 100 (Residential) | Rabbit developmental study<br>LOAEL = 100 mg/kg/day based on decreased body weight gain during gestation |
| Intermediate-Term Inhalation (1 month–6 months) (Inhalation) | Oral study NOAEL = 3.3 mg/kg/day (inhalation absorption rate = 100%) | LOC for MOE = 100 (Occupational)<br>LOC for MOE = 100 (Residential) | One year chronic toxicity study<br>LOAEL = 35.5 mg/kg/day based on decreased body weight gain in female dogs |
| Long-Term Inhalation (6 months-lifetime) (Occupational/Residential) | Oral study NOAEL= 3.3 mg/kg/day (inhalation absorption rate = 100%) | LOC for MOE = 100 (Occupational)<br>LOC for MOE = 100 (Residential) | One year chronic toxicity study - dog<br>LOAEL = 35.5 mg/kg/day based on decreased body weight gain in female dogs |
| Cancer (oral, dermal, inhalation) | "Group D" - not classified as to human carcinogenicity via relevant routes of exposure | Not applicable | Acceptable oral rat and mouse carcinogenicity studies; evidence of carcinogenic and mutagenic potential |

*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 which includes the following: Brassica, head and stem, Brassica, leafy greens, bushberry, caneberry, carrot, cereal grain, forage, fodder, and straw, cotton gin byproducts, cotton, undelinted seed, flax, seed, grape, grass, forage, fodder and hay, herb and spice group, juneberry, leafy vegetables except Brassica, lingonberry, longan, lychee, non-grass animal feed, dry bulb and green onion, peanut hay, peanut, pistachio, pulasan, rambutan, rapeseed and rapeseed forage, safflower seed, salal, Spanish lime, stone fruit, strawberry, sunflower seed, turnip greens, bulb vegetables, cucurbit vegetables, fruiting legume vegetables, root and tuber vegetables, foliage of legume vegetables, and watercress. 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 one-day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An unrefined, Tier 1 acute dietary exposure assessment used tolerance-level residue values and 100% crop treated (CT) as assumptions for all of the registered and proposed uses.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A partially refined, Tier 2 chronic dietary exposure assessment was conducted for the general U.S. population and related population subgroups. Tolerance-level values and a default of 100% CT were used for all the current and proposed fludioxonil tolerances except for apple, grapefruit, lemon, lime, orange, and pear. Average application rate (AR) values replaced tolerances for apple,

grapefruit, lemon, lime, orange, and pear. In addition, processing factors from processing studies were used for apple juice and citrus juices.

iii. *Cancer*. EPA's Cancer Peer Review Committee (CPRC) classified fludioxonil as a Group D chemical that is considered not classifiable as to human carcinogenicity. Therefore, a cancer risk assessment was not performed.

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 FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 in Unit III.E.1.–4.

Based on the FIRST and SCI-GROW models, the EECs of fludioxonil for acute exposures are estimated to be 132 parts per billion (ppb) for surface water and 0.11 ppb for ground water. The EECs for chronic exposures are estimated to be 49 ppb for surface water and 0.11 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 currently registered for use on the following residential non-dietary sites: Turfgrass and ornamentals in residential landscapes (registered product: Medallion®, EPA Reg. No. 100–769). Medallion® is a wettable powder in water-soluble packets, and the current label indicates that this product is ''for professional use only.'' As such, no residential handler (i.e. applicator) exposures are anticipated. However, short- and intermediate-term dermal (adults and toddlers), and incidental ingestion (toddlers) post-application residential exposures are anticipated based on the use pattern for turfgrass applications detailed on the Medallion label (specifies that the product be applied at 14-day application intervals, with an annual maximum rate of 2 lbs ai/A/yr, which equates to about 3 applications at the maximum per application rate. Also, fludioxonil has half-lives ranging from 95 to 440 days in thatch sod). A residential post-application dermal assessment was not performed since the risks from short- and intermediate-term dermal exposure are negligible. Short- and intermediate-term dermal endpoints were not selected due to the NOAEL of 1,000 mg/kg/day (highest dose tested) in the 28-day dermal toxicity study in rats and also since there were no developmental concerns. EPA has concluded that there are no significant post-application exposures anticipated from treated landscape ornamentals. Therefore, the risk assessment was conducted using the following residential exposure assumption: Post-residential lawn applications for toddler incidental ingestion.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

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

### *D. Safety Factor for Infants and Children*

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility

of rats or rabbits to in utero and/or postnatal exposure.

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

- The toxicology data base is complete.
- The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.
- A developmental neurotoxicity study is not required because there was no evidence of neurotoxicity in the current toxicity data base.
- The exposure assessment approach will not underestimate the potential dietary (food and water) and non-dietary exposures for infants and children resulting from the use of fludioxonil.

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fludioxonil will occupy 0.13% of the aPAD for females 13 years and older. 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 Table 2. of this unit:

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) |
|---|---|---|---|---|---|
| Female 13–49 years old | 1.0 | 0.13 | 132 | 0.11 | 26,000 |

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 39.4% of the cPAD for the U.S. population, 43.7% of the cPAD for all infants < 1 year old, 65.2% of the cPAD for children 1–2 years old, and 39.4% of the cPAD for females 13–49 years old. Based on 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 Table 3. of this unit:

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 | 39.4 | 49 | 0.11 | 630 |
| All infants < 1 year old | 0.03 | 43.7 | 49 | 0.11 | 170 |
| Children 1–2 years old | 0.03 | 65.2 | 49 | 0.11 | 100 |
| Females 13–49 years old | 0.03 | 39.4 | 49 | 0.11 | 570 |

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 currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to

aggregate chronic food and water and short-term exposures for fludioxonil.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 390 for all infants < 1 year old, 300 for children 1–2 years old, and 320 for children 3–5 years old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-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 short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4. of this unit:

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) |
|---|---|---|---|---|---|
| All infants < 1 year old | 390 | 100 | 49 | 0.11 | 740 |
| Children 1–2 years old | 300 | 100 | 49 | 0.11 | 670 |
| Children 3–5 years old | 320 | 100 | 49 | 0.11 | 690 |

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). Fludioxonil is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for fludioxonil.

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 160 for all infants < 1 year old, 120 for children 1–2 years old, and 130 for children 3–5 years old. 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 Table 5. of this unit:

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) | Intermediate-Term DWLOC (ppb) |
|---|---|---|---|---|---|
| All infants < 1 year old | 160 | 100 | 49 | 0.11 | 100 |
| Children 1–2 years old | 120 | 100 | 49 | 0.11 | 30 |
| Children 3–5 years old | 130 | 100 | 49 | 0.11 | 50 |

5. *Aggregate cancer risk for U.S. population.* EPA has classified fludioxonil in ''Group D'' - not classifiable as to human carcinogenicity. Based on available data, the Agency concludes that the proposed use of fludioxonil does not present discernable aggregate 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*

Adequate enforcement methodology is available to enforce the tolerance expression. Apple, pear, kiwifruit, cantaloupe, yam, citrus, and pomegranate were analyzed for fludioxonil using Syngenta tolerance enforcement method AG–597B, Analytical Method for the Determination of CGA–219417 in Crops by High Performance Liquid Chromatography Including Validation Data, with Modifications. Head and leaf lettuce, lima bean, dry bean, and snap bean were analyzed for fludioxonil using Novartis working method AG–631B, Determination of Residues of CGA–219417 in Crops by High Performance Liquid Chromatography with Column Switching.

Adequate enforcement methodology (liquid chromotography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

### *B. International Residue Limits*

There are no CODEX, Canadian, or Mexican tolerances/maximum residue levels (MRLs) for fludioxonil residues on kiwifruit, yam, bean, dry and bean, succulent, citrus, leafy greens except spinach, melons, or pome fruit. Thus, harmonization is not an issue at this time.

## V. Conclusion

Therefore, the tolerances are established for residues of fludioxonil,

4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile, in or on bean, dry; bean, succulent at 0.4; citrus, crop group 10 at 10 ppm; fruit, pome, group 11 at 5.0 ppm; grapefruit, oil at 500 ppm; kiwifruit at 20 ppm; leafy greens subgroup 4A, except spinach at 30 ppm; melon subgroup 9A at 0.03; and yam, true at 8.0 ppm.

## VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0321 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 29, 2004.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0321, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have

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

### VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 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), 346a and 371.

■ 2. Section 180.516 is amended as follows:

a. By alphabetically adding commodities to the table in paragraph (a).

b. By removing the commodities ''Apricot,'' ''Caneberry,'' ''Nectarine,'' ''Peach,'' and ''Plum'' in the table in paragraph (b).

**§ 180.516 Fludioxonil; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| Bean, dry | 0.4 |
| Bean, succulent | 0.4 |
| * * * | * * |
| Citrus, crop group 10 | 10 |
| * * * | * * |
| Fruit, pome, group 11 | 5.0 |
| * * * | * * |
| Grapefruit, oil | 500 |
| * * * | * * |
| Kiwifruit | 20 |
| Leafy greens subgroup 4A, except spinach | 30 |
| * * * | * * |
| Melon subgroup 9A | 0.03 |
| * * * | * * |
| Yam, true | 8.0 |

* * * * *

[FR Doc. 04–21803 Filed 9–28–04; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–2004–0312; FRL–7681–6]**

### Methoxyfenozide; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of methoxyfenozide (benzoic acid, 3-methyl-2-methyl-,2-(3,5-methylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) in or onblack sapote; canistel; coriander, leaves; mamey sapote; mango; papaya; pea and bean, succulent shelled, subgroup 6B; peppermint; sapodilla; spearmint; star apple; strawberries; vegetable, foliage of legume (except soybean), subgroup 7A; vegetable, leaves of root and tuber, group 2; vegetable, legume, edible podded, subgroup 6A; vegetable, root, subgroup 1A. Interregional Research Project Number 4 (IR-4) and Dow AgroSciences are requesting these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

**ADDRESSES** : To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2004–0312. All documents in the docket are listed in the EDOCKET index at*http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6411; e-mail address:*tavano.joseph@epa.gov*.

**SUPPLEMENTARY INFORMATION:**