H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This rule is not subject to Executive Order 13211, ''Actions that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 *note*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The requirements of Executive Order 12898 have been previously addressed to the extent practicable in the Regulatory Impact Analysis (RIA) for the regional haze rule (cited above), particularly in chapters 2 and 9 of the RIA. Today's direct final rule makes no changes that would have a disproportionately high and adverse human health or environmental effect on minorities and low-income populations.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the SBREFA, 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. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A ''major rule'' cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(a).

IV. Statutory Provisions and Legal Authority

Statutory authority for today's direct final rule comes from sections 169(a) and 169(b) of the CAA (42 U.S.C. 7545(c) and (k)). These sections require EPA to issue regulations that will require States to revise their SIPs to ensure that reasonable progress is made toward the national visibility goals specified in section 169(A).

List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Carbon monoxide, Nitrogen dioxide, Particulate matter, Sulfur oxides, Volatile organic compounds.

Dated: June 27, 2003.

Christine Todd Whitman,

Administrator.

■ For the reasons set forth in the preamble, part 51 of title 40, Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 42 U.S.C. 7410, 7414, 7421, 7470–7479, 7492, 7601, and 7602.

Subpart P—Protection of Visibility

■ 2. Section 51.309 is amended by revising paragraphs (b)(6) and (d)(5)(i), deleting paragraphs (d)(ii) and (d)(iii), and renumbering (d)(iv) to (d)(ii), to read as follows:

§ 51.309 Requirements related to the Grand Canyon Visibility Transport Commission.

* * * * *

(b)(6) *Continuous decline in total mobile source emissions* means that the projected level of emissions from mobile sources of each listed pollutant in 2008, 2013, and 2018, are less than the projected level of emissions from mobile sources of each listed pollutant for the previous period (*i.e.*, 2008 less than 2003; 2013 less than 2008; and 2018 less than 2013).

* * * * *

(d)(5)(i) Statewide inventories of onroad and nonroad mobile source emissions of VOC, NO_X, SO_2, $PM_{2.5}$, elemental carbon, and organic carbon for the years 2003, 2008, 2013, and 2018.

(A) The inventories must demonstrate a continuous decline in total mobile source emissions (onroad plus nonroad; tailpipe and evaporative) of VOC, NO_X, $PM_{2.5}$, elemental carbon, and organic carbon, evaluated separately. If the inventories show a continuous decline in total mobile source emissions of each of these pollutants over the period 2003–2018, no further action is required as part of this plan to address mobile source emissions of these pollutants. If the inventories do not show a continuous decline in mobile source emissions of one or more of these pollutants over the period 2003–2018, the plan submission must provide for an implementation plan revision by no later than December 31, 2008 containing any necessary long-term strategies to achieve a continuous decline in total mobile source emissions of the pollutant(s), to the extent practicable, considering economic and technological reasonableness and Federal preemption of vehicle standards and fuel standards under title II of the CAA.

(B) The plan submission must also provide for an implementation plan revision by no later than December 31, 2008 containing any long-term strategies necessary to reduce emissions of SO_2 from nonroad mobile sources, consistent with the goal of reasonable progress. In assessing the need for such long-term strategies, the State may consider emissions reductions achieved or anticipated from any new Federal standards for sulfur in nonroad diesel fuel.

(ii) [*text of (iv) retained same as before*]

[FR Doc. 03–16922 Filed 7–2–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0135; FRL–7313–7]

Fludioxonil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fludioxonil in or on Brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; carrot; herb, fresh, subgroup 19A; herb, dried, subgroup 19A; longan; lychee; pulasan; rambutan; spanish lime; and turnip, greens. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This regulation also deletes brassica, leafy, group at 0.01 parts per million (ppm), which is replaced with brassica, leafy greens, subgroup 5B at 10 ppm, and brassica, head and stem, subgroup 5A at 2.0 ppm.

DATES: This regulation is effective July 3, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0135, must be received on or before September 2, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0135. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 2, 2003 (68 FR 16046) (FRL–7299–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6448, 2E6462, 2E6486, and 3E6526) by IR-4, 681 US Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Syngenta Crop Protection, Inc., the registrant.

The 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)-1*H*-pyrrole-3-carbonitrile), in or on the following commodities: Brassica, head and stem, subgroup 5A at 1.5 ppm; brassica, leafy greens, subgroup 5B at 9.0 ppm; carrot at 0.5 ppm; herb subgroup 19A at 33 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 2.0 ppm; and turnip, greens at 9.0 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for tolerances for residues of fludioxonil on Brassica, head and stem, subgroup 5A at 2.0 ppm; brassica, leafy greens, subgroup 5B at 10 ppm; carrot at 0.75 ppm; herb, fresh, subgroup 19A at 10 ppm; herb, dried, subgroup 19A at

65 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 1.0 ppm; and turnip, greens at 10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fludioxonil are discussed in Unit III.A. of the final rule on fludioxonil, which published in the **Federal Register** of December 29, 2000 (65 FR 82927) (FRL–6760–9), and August 2, 2002 (67 FR 50354) (FRL–7188–7).

B. Toxicological Endpoints

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fludioxonil used for human risk assessment is Unit III.B.of the final rule on fludioxonil, which published in the **Federal Register** of December 29, 2000 (65 FR 82927) and August 2, 2002 (67 FR 50354).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.516) for the residues of fludioxonil, in or on a variety of raw agricultural commodities. Fludioxonil is registered for foliar application (grape, strawberry, green onion, dry bulb onion, bushberry, caneberry, juneberry, longonberry, pistachio, salal, and watercress), post-harvest application (stone fruit), and for seed treatment purposes (numerous crops) with tolerances for residues of fludioxonil ranging from 0.01-7.0 ppm (40 CFR 180.516(a)). A section 18 registration is also established for post-harvest application to pomegranate with a tolerance for residues of fludioxonil of 5.0 ppm (40 CFR 180.516(b)). Currently there are no tolerances established for residues of fludioxonil in/on livestock. 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 1994–1996, 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: The acute analysis assumed tolerance level residues, 100% crop treatment (CT), and DEEM (ver. 7.76) default processing factors for all registered/proposed commodities (tier 1).

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 1994–1996, 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic analysis assumed tolerance level residues, 100% CT, and DEEM (ver. 7.76) default processing factors for all registered/proposed commodities (tier 1).

iii. *Cancer.* EPA's Cancer Peer Review Committee (CPRC) classified fludioxonil as a Group D - not classifiable as to human carcinogenicity.

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 First 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 Screening Concentration in Ground Water (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. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw

water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fludioxonil they are further discussed in the aggregate risk sections E.

There are no ground or surface water monitoring data available for fludioxonil. Tier I models, FIRST and SCI-GROW, were used to derive the surface water and ground water EECs, respectively. According to the proposed label information, the maximum application rate for fludioxonil is 4 lbs active ingredient (ai)/Acre/year on turf (maximum single application rate of 0.675 lbs ai/Acre). Application to turf provided the high exposure scenario; therefore, the drinking water EECs were derived from the use on turf.

Ground water. SCI-GROW provides a ground water screening exposure value for use in determining the potential risk to human health from drinking ground water contaminated with pesticides. The ground water modeling generated a ground water EEC of 0.11 parts per billion (ppb) for fludioxonil.

Surface water. The predicted index reservoir concentrations for total residues using FIRST for the proposed use of fludioxonil generated acute and chronic surface water EECs of 132 ppb and 49 ppb, respectively.

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: Based on the registered labels, fludioxonil can be used as a protectant fungicide for control of certain diseases of turfgrass and certain foliar, stem and root diseases in ornamentals in residential and commercial landscapes. The risk assessment was conducted using the following residential exposure assumptions: Short- and intermediate-term dermal exposures (adults and toddlers), and short- and intermediate-term incidental ingestion exposures (toddlers).

Fludioxonil is registered for uses on residential lawns and ornamentals; however, it is restricted to professional applicators only. As such, no residential handler (i.e., applicator) exposures are anticipated.

EPA did not select short- or intermediate-term dermal endpoints; subsequently, no residential post-application dermal assessment is included. Additionally, due to the low vapor pressure of fludioxonil, no significant post-application inhalation exposure is anticipated. As a result, there are no significant post-application exposures anticipated from treated landscape ornamentals. Therefore, the residential component of this assessment only includes a post-application assessment for toddler incidental ingestion exposures related to residential lawn applications.

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

EPA does not have, at this time, available data to determine whether fludioxonil has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 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 Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. 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 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 milligram/kilogram (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

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

When EECs for surface water and 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 1% of the aPAD for females 13-49 years old. Fludioxonil is not expected to pose an acute dietary risk for the general population (including children and infants). 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 for females 13–49 years old, as shown in Table 1 of this unit:

TABLE 1.—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 (13-49 years old)	1.0	1	132	0.11	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 11% of the cPAD for the U.S. population, 30% of the cPAD for all infants (<1 year old) and 38% of the cPAD for children 1–2 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 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUDIOXONIL

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.3	11	49	0.11	940
All infants (<1 year old)	0.3	30	49	0.11	210
Children (1-2 years old)	0.3	38	49	0.11	190
Females (13-49 years old)	0.3	8	49	0.11	830

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 460 for all infants < 1 year old; 410 for children 1–2 years old; 490 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 3 of this unit:

TABLE 3.—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)	460	100	49	0.11	780
Children (1-2 years old)	410	100	49	0.11	760
Children (3-5 years old)	490	100	49	0.11	800

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 200 for all infants <1 year old; 180 for children 1–2 years old; and 220 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 4 of this unit:

TABLE 4.—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)	Short-Term DWLOC (ppb)
All infants (< 1 year old)	200	100	49	0.11	130
Children (1-2 years old)	180	100	49	0.11	140
Children (3-5 years old)	220	100	49	0.11	180

5. *Aggregate cancer risk for U.S. population*. EPA's Cancer Peer Review Committee (CPRC) classified fludioxonil as a Group D - not classifiable as to human carcinogenicity.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

The methods used in the field trial studies were similar to a method validated by the Analytical Chemistry Branch. Since adequate method validation and concurrent recoveries were attained in the field trial studies, EPA concludes that the ACB validated method is appropriate for enforcement of the tolerances associated with this petition. No further validation is necessary.

Adequate enforcement methodology (high pressure liquid chromatography method AG–597B) 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

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

V. Conclusion

Therefore, the tolerances are established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on brassica, head and stem, subgroup 5A at 2.0 ppm; brassica, leafy greens, subgroup 5B at 10 ppm; carrot at 0.75 ppm; herb, fresh, subgroup 19A at 10 ppm; herb, dried, subgroup 19A at 65 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 1.0 ppm; and turnip, greens at 10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0135 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 September 2, 2003.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0135, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

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

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 25, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.516 is amended by removing the entry for ''Vegetable, brassica, leafy, group'' and by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) * * *

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10
* * * * *	
Carrot	0.75
* * * * *	
Herb, dried, subgroup 19A	65
Herb, fresh, subgroup 19A	10
* * * * *	
Longan	1.0
Lychee	1.0
* * * * *	
Pulasan	1.0
* * * * *	
Rambutan	1.0
* * * * *	
Spanish lime	1.0
* * * * *	
Turnip, greens	10
* * * * *	

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[FR Doc. 03–16931 Filed 7–2–03; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 10

RIN 1024–AC84

Native American Graves Protection and Repatriation Act Regulations—Civil Penalties; Correction

AGENCY: Department of the Interior.

ACTION: Final rules correction.

SUMMARY: This document corrects the final rule that was published on Thursday, April 3, 2003. This final rule outlines procedures for assessing civil penalties on museums that fail to comply with applicable provisions of the Native American Graves Protection and Repatriation Act of 1990 (''the Act'' or ''NAGPRA'').

EFFECTIVE DATE: May 5, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. John Robbins, Assistant Director, Cultural Resources, National Park