statements, Indians, Intergovernmental relations, Forest and forest products, National forests, Natural resources, Reporting and recordkeeping requirements, Science and technology.

■ Therefore, for the reasons set forth in the preamble, Part 219 of Title 36 of the Code of Federal Regulations is amended as follows:

PART 219–PLANNING

Subpart A—National Forest System Land and Resource Management Planning

■ 1. The authority citation for subpart A continues to read as follows:

Authority: 5 U.S.C. 301; and Secs. 6 and 15, 90 Stat. 2949, 2952, 2958 (16 U.S.C. 1604, 1613).

■ 2. Revise paragraph (d) of § 219.35 to read as follows:

§ 219.35 Transition.

* * * * *

(d) The date by which site-specific decisions made by the responsible official must be in conformance with the provisions of this subpart is extended from November 9, 2003, until the Department promulgates the final planning regulations published as proposed on December 6, 2002 (67 FR 72770).

* * * * *

Dated: September 3, 2003.

David P. Tenny,

Deputy Under Secretary, Natural Resources and Environment.

[FR Doc. 03–22977 Filed 9–9–03; 8:45 am]

BILLING CODE 3410–11–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0244; FRL–7322–7]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of trifloxystrobin in or on leaf petioles subgroup 4B; and vegetable, root, except sugar beet, subgroup 1B, except radish. 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 10, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0244, must be received on or before November 10, 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. 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–2003–0244. 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. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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 March 5, 2003 (68 FR 10469) (FRL–7294–5), 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 a pesticide petition (PP 3E6522) by IR-4, 681 U.S. Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received on this petition.

The petition requested that 40 CFR 180.555 be amended by establishing tolerances for combined residues of the fungicide, trifloxystrobin, (benzeneacetic acid, (*E,E*)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113((*E,E*)-methoxyimino-[2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl] phenyl]acetic acid), in or on the

following commodities: Leaf petioles subgroup 4B at 2.0 parts per million (ppm), and vegetable, root, except sugar beet, subgroup 1B, except radish at 0.10 ppm. The petition was subsequently amended to propose the tolerance for the leaf petioles subgroup 4B at 3.5 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 combined residues of trifloxystrobin and the free form of its acid metabolite CGA-321113 on leaf petioles subgroup 4B at 3.5 ppm, and vegetable, root, except sugar beet, subgroup 1B, except radish at 0.10 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 trifloxystrobin are discussed in Unit III.A. of the final rule on trifloxystrobin, which was published in the **Federal Register** of May 22, 2002 (67 FR 35915) (FRL–7178–6).

B. Toxicological Endpoints

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

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety 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 trifloxystrobin used for human risk assessment is shown in Table 1 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	*Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–49 only.	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 2.5 mg/kg/day	Developmental toxicity-Rat LOAEL = 500 mg/kg/day, based upon increased fetal skeletal anomalies
Acute dietary general population including infants and children.	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment		
Chronic dietary all populations.	Parental NOAEL = 3.8 mg/kg/day UF = 100 Chronic RfD = 0.038 mg/kg/day	FQPA SF = 1X cPAD = cRfD ÷ FQPA SF = 0.038 mg/kg/day	2–generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon decreases in body weight, body weight gains, reduced food consumption and histopathological lesions in the liver, kidneys and spleen
Short-Term Oral (1–30 days). Intermediate-Term Oral (1–6 months)	Offspring NOAEL = 3.8 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	2–Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Short-Term Dermal (1–30 days). Intermediate-term dermal (1–6 months)	Dermal study NOAEL = 100 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	28–Day dermal toxicity study-Rat LOAEL = 1,000 mg/kg/day, based upon increases in mean absolute and relative liver and kidney weights
Long-term dermal (>6 months).	Oral study NOAEL = 3.8 mg/kg/day (dermal absorption rate = 33%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2–Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Short-term inhalation (1–30 days). Intermediate-Term Inhalation (1–6 months) Long-Term Inhalation (> 6 months)	Oral study NOAEL = 3.8 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2–Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Cancer (oral, dermal, inhalation).	Trifloxystrobin is classified as ''Not Likely Human Carcinogen'' based on the lack of evidence of carcinogenicity in mouse and rat cancer studies		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.555) for the residues of trifloxystrobin, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from trifloxystrobin 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. In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Data base (DEEM-FCID®) which incorporates food consumption data as reported by respondents in the 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 assessment: The acute dietary exposure analysis for trifloxystrobin is a Tier I assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin (''100% CT''), and tolerance-level residues were used in the analysis.

ii. *Chronic exposure.* In conducting this acute dietary risk assessment EPA used the DEEM® software with 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 assessment: The chronic dietary exposure analysis for trifloxystrobin is a Tier I assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin, and tolerance-level residues were used in the analysis.

iii. *Cancer.* The Agency determined that trifloxystrobin should be classified as a ''Not Likely Human Carcinogen.''

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

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 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 I model) before using PRZM/EXAMS (a Tier II 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 LOC.

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 trifloxystrobin they are further discussed in the aggregate risk sections in Unit III.E.

Trifloxystrobin is immobile, and degrades rapidly in soil and aquatic environments to the primary isomer, CGA-321113. EECs were calculated for total trifloxystrobin residues (parent trifloxystrobin plus metabolites) using the FIRST model for surface water and the SCI-GROW model for ground water. EPA's interim method for drinking water estimates for pesticides used in rice paddies was also used to generate surface water EECs.

Surface water concentrations for total trifloxystrobin residues are 92 parts per billion (ppb) for the peak value (acute) and 50 ppb for the chronic value using the FIRST model for terrestrial uses (turfgrass). To estimate surface water concentrations for use on rice, an interim rice paddy model was used. For surface water concentrations from treated rice, the acute estimate for the parent is 48 ppb, and the chronic estimate for the total parent plus degradate is 140 ppb. The rice estimate is considered to be an overestimate of the true value found in the environment due to the assumptions used in the drinking water model for rice. Further, EPA considers the turfgrass estimate to be a more realistic estimate of drinking water residues. The ground water screening concentration used for both acute and chronic assessments is 3.4 ppb. These values represent upper-bound estimates of the concentrations of total residues of trifloxystrobin that might be found in surface water and ground water from uses on turfgrass at the maximum application rate.

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).

Trifloxystrobin is currently registered for use on the following residential non-dietary sites: Turfgrass and ornamental (Compass™). Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. There is potential for dermal exposure to adults and children and oral exposure to children during postapplication activities. Four postapplication exposure scenarios resulting from lawn treatment were assessed, as follows: (1) Dermal exposure from pesticide residues on lawns, (2) incidental non-dietary ingestion of pesticide residues on lawns from hand- to-mouth transfer, (3) incidental non-dietary ingestion of residues from object-to mouth activities (pesticide-treated turfgrass), and (4) incidental non-dietary ingestion of soil from pesticide-treated residential areas. Exposure via incidental non-dietary ingestion involving plant material may occur but is considered negligible. Since the application of trifloxystrobin on turf grass and ornamental is limited to certified pest control operators, an assessment of dermal or inhalation exposure for residential handlers was not performed.

The MOE for adult dermal risk from postapplication exposure is 1,300 and 800 for children. Children's risk from oral exposures range from 1,600 to 220,000. When incidental oral exposure from all possible residential sources are combined (ingestion of residues on turfgrass from hand-to-mouth activities, mouthing turfgrass and eating soil), the result is an MOE of 1,100. Therefore, postapplication exposure and risk estimates for adults and children are considered to be below EPA's LOC.

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 trifloxystrobin 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 trifloxystrobin and any other substances and trifloxystrobin 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 trifloxystrobin 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*. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin.

3. *Conclusion*. There is a complete toxicity data base for trifloxystrobin 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:

i. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin. In the developmental and reproduction toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

ii. The Agency determined that a developmental neurotoxicity study in rats is not required.

iii. Although an acute neurotoxicity study is required (the submitted study was unacceptable), the lack of an acute neurotoxicity study does not impact EPA's ability to make an FQPA SF decision.

iv. The acute and chronic dietary food exposure assessments utilize existing and proposed tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

v. The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of trifloxystrobin.

vi. The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which are not likely to be exceeded.

vii. The residential postapplication assessment is based upon the residential Standard Operating Procedures (SOPs). The assessment is based upon surrogate study data. These data are reliable and are not expected to underestimate risk to adults or children. The residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 trifloxystrobin will occupy <1% of the aPAD for females 13–49 years old. An acute dietary endpoint for the general population including infants and children was not identified. In addition, there is potential for acute dietary exposure to trifloxystrobin 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 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLOXYSTROBIN

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	2.5	<1	92 turf 48 rice	3.4	75,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to trifloxystrobin from food will utilize 14% of the cPAD for the U.S. population, 54% of the cPAD for children 1–2 years old, 10% of the cPAD for females 13–49 years old, and 10% of the cPAD for adults 50+ years old. Based on the use pattern, chronic residential exposure to residues of trifloxystrobin is not expected. In addition, there is potential for chronic dietary exposure to trifloxystrobin 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 TRIFLOXYSTROBIN

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.038	14	140 rice 50 turf	3.4	1,100
Children (1–2 years old)	0.038	54	140 rice 50 turf	3.4	170
Females (13–49 years old)	0.038	10	140 rice 50 turf	3.4	1,000
Adults (50+ years old)	0.038	10	140 rice 50 turf	3.4	1,200

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). Trifloxystrobin 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 trifloxystrobin.

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 690 for the U.S. Population; 154 for children 1–2 years old; 970 for females 13–49 years old; and 950 for adults 50+ years old. These aggregate MOEs do not exceed the Agency's LOC for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of trifloxystrobin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's LOC, as shown in Table 4 of this unit:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	690	100	140 rice 50 turf	3.4	1,100
Children 1–2 years old	154	100	140 rice 50 turf	3.4	130
Females 13–50 years old	970	100	140 rice 50 turf	3.4	1,000
Adults 50+ years old	950	100	140 rice 50 turf	3.4	1,200

4. *Intermediate-term risk*. The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 6 months of exposure (30 to 180 days) to trifloxystrobin residues from food, drinking water, and residential pesticide uses. Intermediate-term exposure to trifloxystrobin is not expected to occur based on the chemical's short soil half-life (about 2 days). Therefore, no intermediate-term aggregate risk is expected.

5. *Aggregate cancer risk for U.S. population*. Trifloxystrobin is not expected to pose a cancer risk to humans.

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 trifloxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method using nitrogen/phosphorus detector) 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 maximum residue limits established for trifloxystrobin. Harmonization is thus not an issue at this time.

V. Conclusion

Therefore, the tolerances are established for combined residues of trifloxystrobin, (benzeneacetic acid, (*E,E*)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-, methyl ester) and the free form of its acid metabolite CGA-321113((E,E)-methoxyimino-[2-[1-(3-trifluoromethyl phenyl) ethylideneaminooxymethyl] phenyl]acetic acid) in or on leaf petioles subgroup 4B at 3.5 ppm, and vegetable, root, except sugar beet, subgroup 1B, except radish at 0.10 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–2003–0244 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 10, 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–2003–0244, 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: August 29, 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 180.555 is amended by adding commodities to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Leaf petioles subgroup 4B	3.5
* * *	* *
Vegetable, root, except sugar beet, subgroup 1B, except radish	0.10
* * *	* *

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[FR Doc. 03–23054 Filed 9–9–03; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03–2762, MB Docket No. 02–83, RM–10404]

Digital Television Broadcast Service; Sault Saint Marie, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Scanlan Television, Inc., substitutes DTV channel 9c for DTV channel 56 at Sault Saint Marie, Michigan. *See* 67 FR 20941, April 29, 2002. DTV channel 9c can be allotted to Sault Saint Marie in compliance with the principle community coverage requirements of § 73.625(a) at reference coordinates 46–03–08 N. and 84–06–38 W. with a power of 24, HAAT of 291 meters and with a DTV service population of 84 thousand. Since the community of Sault Saint Marie is located within 400 kilometers of the U.S.-Canadian border, concurrence from the Canadian government has been obtained for this allotment. With this action, this proceeding is terminated.

DATES: Effective October 20, 2003.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MB Docket No. 02–83, adopted August 28, 2003, and released September 4, 2003. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

List of Subjects in 47 CFR Part 73

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.