

follows: Artichoke, globe from 0.05 ppm to 0.1 ppm; asparagus from 0.1 ppm to 0.15 ppm; brassica head and stem, subgroup 5-A from 0.05 ppm to 0.1 ppm; and grape from 0.05 ppm to 0.1 ppm.

The tolerances for artichoke, globe; brassica head and stem, subgroup 5-A; and grape were determined based on the sum of the method Limits of Quantitation (LOQ) for parent pendimethalin (0.05 ppm) and its regulated metabolite (0.05 ppm), since no detectable residues were found in the submitted residue field trials.

The tolerance for asparagus was determined using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

Therefore, tolerances are established for combined residues of pendimethalin, *N*-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and its metabolite, 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on artichoke, globe at 0.1 ppm; asparagus at 0.15 ppm; brassica head and stem, subgroup 5-A at 0.1 ppm; and grape at 0.1 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule,

the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: September 7, 2007.

**Lois Rossi,**

*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), 346a and 371.

■ 2. Section 180.361 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**180.361 Pendimethalin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Artichoke, globe .....	0.1
Asparagus .....	0.15
Brassica head and stem, subgroup 5-A .....	0.1
Grape .....	0.1

[FR Doc. E7-18259 Filed 9-18-07; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0539; FRL-8147-3]

**Trifloxystrobin; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of Trifloxystrobin and the acid metabolite CGA-321113 in or on grass, forage and grass, hay. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 19, 2007. Objections and requests for hearings must be received on or before November 19, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0539. To access the electronic docket, go to <http://>

[www.regulations.gov](http://www.regulations.gov), select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Janet Whitehurst, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6129; e-mail address: [whitehurst.janet@epa.gov](mailto:whitehurst.janet@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be

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

###### B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0539 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 as required by 40 CFR part 178 on or before November 19, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0539, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### II. Petition for Tolerance

In the **Federal Register** of August 1, 2007 (72 FR 42072) (FRL-8138-1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F7024) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.555 be amended by establishing a tolerance for combined residues of the fungicide Trifloxystrobin, (benzeneacetic acid, (E,E)- $\alpha$ -(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)-ethylideneamino]oxymethyl]-phenyl] acetic acid, in or on grass, forage at 10 parts per million (ppm) and grass, hay at 14 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. below.

Based upon review of the data supporting the petition, EPA has modified the tolerances proposed for grass, forage and grass, hay. The appropriate tolerances for grass forage and hay were calculated to be 12 and 17 ppm, respectively. Although residue data were also provided for grass straw and seed screenings, tolerances are not required on these commodities as the Agency no longer considers them to be significant livestock feedstuffs. The recommended tolerance levels for grass forage and hay were determined considering recent Agency Guidance (Guidance for Setting Pesticide Tolerances Based on Field Trial Data).

##### III. Aggregate Risk Assessment and Determination of Safety

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 FFDCFA 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 FFDCFA 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...." These provisions were added to the FFDCFA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for combined residues of trifloxystrobin, (benzeneacetic acid, (E,E)- $\alpha$ -(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)-ethylideneamino]oxy]methyl]-phenyl] acetic acid (hereinafter referred to as Trifloxystrobin) on grass, forage at 12 ppm and grass, hay at 17 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the adverse effects caused by Trifloxystrobin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies

can be found in the *Trifloxystrobin: Human Health Risk Assessment for Section 3 Registration for the Proposed Uses on Grasses Grown for Seed*. at <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0539 in that docket.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account 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. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/oppfead1/trac/science>; <http://www.epa.gov/pesticides/factsheets/riskassess.htm>; <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>

A summary of the toxicological endpoints for Trifloxystrobin used for human risk assessment can be found at <http://www.regulations.gov> in document *Trifloxystrobin: Human Health Risk Assessment for Section 3 Registration for the Proposed Uses on Grasses Grown for Seed*. *Petition No: 6F7024* at page 16

in docket ID number EPA-HQ-OPP-2007-0539.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to Trifloxystrobin, EPA considered exposure under the petitioned-for tolerances as well as all existing Trifloxystrobin tolerances in (40 CFR 180.555). EPA assessed dietary exposures from Trifloxystrobin in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and 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 estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100% crop treated (CT) and tolerance level residues for each commodity.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA assumed 100% CT and tolerance level residues for each commodity.

iii. *Cancer*. The Agency classified trifloxystrobin as a "not likely carcinogen;" therefore, quantification of human cancer risk is not required and a cancer dietary assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information*. The Agency did not use anticipated residue estimates or PCT information in the trifloxystrobin dietary exposure assessment.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring 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 environmental fate characteristics of Trifloxystrobin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppfead1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), Screening Concentration in Ground Water (SCI-GROW) models, and rice paddies

method the estimated environmental concentrations (EECs) of Trifloxystrobin and the metabolite CGA-321113 for acute exposures are estimated to be 92 parts per billion (ppb) for surface water and 3.4 ppb for ground water. The EECs for chronic exposures are estimated to be 140 ppb for surface water and 3.4 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 92 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 140 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Trifloxystrobin is currently registered for the following residential non-dietary sites: Turfgrass and ornamentals. EPA assessed residential exposure using the following assumption: Non-occupational postapplication contact with trifloxystrobin following Compass® use on turfgrass is the most common and worst case contributor to such exposures.

4. *Cumulative effects from 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."

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 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 ("10X") 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* In the prenatal developmental study in rats there was no developmental toxicity at the Limit Dose. In the prenatal developmental study in rabbits, developmental toxicity was seen at a dose that was higher than the dose that caused maternal toxicity. In the 2-generation reproduction study, there was no offspring toxicity at the highest dose tested.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for Trifloxystrobin is complete except for an acute neurotoxicity study which is classified as unacceptable. The toxicity database contains developmental toxicity studies in two species (rats and rabbits) and a 2-generation reproduction study in rats which are adequate to assess pre and/or post natal susceptibility to infants and children. Although the available, submitted acute neurotoxicity study was found to be unacceptable, based on a weight-of-the evidence review of the available data, the lack of this study does not impact the Agency's ability to make an FQPA safety factor decision. Given that there was no evidence of neurotoxicity in this study at the Limit Dose nor in the other subchronic and chronic studies in the database there is not an uncertainty concerning neurotoxic effects and EPA has reliable data to show that removal of the FQPA safety factor is safe for children. Additionally, these data demonstrate that a developmental neurotoxicity study is not required for this pesticide.

ii. There is no residual concern for pre- or post-natal toxicity or increased sensitivity in infants and children. In both the rat developmental study and the 2-generation reproduction study there were no effects in fetal animals or offspring at the highest dose tested. Although developmental effects were seen in the rabbit developmental study, there was a clear NOAEL identified for these effects and that NOAEL was used in setting the aPAD. Moreover, adverse effects were seen in the adult animals in this study at a lower level.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues Conservative ground water and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by Trifloxystrobin].

#### *E. Aggregate Risks and Determination of Safety*

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to Trifloxystrobin will occupy <1% of the aPAD for the population group (females 13–49 years old) receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to Trifloxystrobin from food and water will utilize 81% of the cPAD for the population group (children 1–2 years old, the most highly exposed subgroup). Based on the use pattern, chronic residential exposure to residues of Trifloxystrobin is not expected.

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 uses 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, water, and residential exposures aggregated result in aggregate MOEs greater than 100 for adults and children 1–2 years. Therefore, the Agency does not consider short term aggregate risk to be of concern.

#### 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).

Though residential exposure could occur intermediate-term aggregate risk is not expected based on the short soil half-life (about 2 days). Therefore, an intermediate-term aggregate risk assessment was not performed.

5. *Aggregate cancer risk for U.S. population.* The Agency classified trifloxystrobin as a “not likely” human carcinogen. Therefore, trifloxystrobin is not expected to pose a cancer risk.

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

### IV. Other Considerations

#### A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography with a nitrogen phosphorus detector (GC/NPD method (Method AG–659A)) 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](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

There are currently no Canadian Maximum Residue Levels (MRLs) for trifloxystrobin. Codex and Mexican MRLs have been established for trifloxystrobin in/on various commodities; however, there are no MRLs for the commodities associated with the proposed use of trifloxystrobin in/on grasses grown for seed. Also, the residue definition for both Codex and Mexican MRLs includes only parent compound in plant commodities, but the definition for Codex MRLs in livestock commodities includes parent

and the acid metabolite, CGA321113. Therefore, harmonization in plant commodities is not possible at this time as the current U.S. tolerance definition includes the combined residues of trifloxystrobin and its free acid metabolite. Harmonization of the tolerance level in meat by-products of cattle, goats, and sheep is not possible at this time as the U.S. tolerance in meat by-products reflects higher potential exposures to various feedstuffs.

#### C. Response to Comments

One comment was received from B. Sachau. Ms. Sachau’s comments regarding general exposure to pesticides contained no scientific data or evidence to rebut the Agency’s conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to trifloxystrobin, including all anticipated dietary exposures and other exposures for which there is reliable information. This comment as well as her comments regarding animal testing have been responded to by the Agency on several occasions. For examples, see the **Federal Register** issues of January 7, 2005 (70 FR 1349) (FRL–7691–4) and October 29, 2004 (69 FR 63083) (FRL–7681–9).

### V. Conclusion

Therefore, the tolerance is established for combined residues of Trifloxystrobin, (benzeneacetic acid, (E,E)- $\alpha$ -(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)-ethylideneamino]oxymethyl]-phenyl) acetic acid in or on grass, forage at tolerance level 12 ppm and grass, hay at tolerance level 17 ppm.

### VI. 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, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety*

*Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCa. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and

other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: September 10, 2007.

**Daniel J. Rosenblatt,**

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

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

**PART 180—[AMENDED]**

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

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

■ 2. Section 180.555 is amended by alphabetically adding the following commodities in the table in paragraph (a):

**§ 180.555 Trifloxystrobin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* *
Grass, forage .....	12
Grass, hay .....	17
* * *	* *

\* \* \* \* \*

[FR Doc. E7-18371 Filed 9-18-07; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**EPA-HQ-OPP-2006-0297; FRL-8146-8]**

**Desmedipham; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of desmedipham in or on beet, garden, roots; beet, garden, tops and spinach. The Interregional Research Project No. 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 19, 2007. Objections and

requests for hearings must be received on or before November 19, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0297. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

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

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

*B. How Can I Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0297 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 as required by 40 CFR part 178 on or before November 19, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA