

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

EPA included the necessary statutory and Executive Order reviews in the December 7, 2007 final rule.

V. 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, Pesticides and pest.

Dated: December 13, 2007.

James Jones,

Acting Assistant Administrator for Prevention, Pesticides, and Toxic Substances.

■ Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.41 is amended by revising the entry for "Gooseberry (*Ribes* spp)" in table 1 to paragraph (c)(15)(ii), and by revising the Crop Group 21 table in paragraph (c)(22)(ii) to read as follows:

§ 180.41 Crop group tables.

* * * * *

(c) * * *

(15) * * *

(ii) * * *

TABLE 1.—CROP GROUP 13-07: BERRY AND SMALL FRUIT CROP GROUP

	Commodities	Related crop subgroups
	* * * * *	
Gooseberry (<i>Ribes</i> spp.)	* * * * *	13-07B, 13-07D, 13-07E, 13-07F

* * * * *

(22) * * *

(ii) * * *

CROP GROUP 21.—EDIBLE FUNGI GROUP—COMMODITIES

Blewitt (*Lepista nuda*)
 Bunashimeji (*Hypsizygus marmoreus*)
 Chinese mushroom (*Volvariella volvacea*) (Bull.) Singer
 Enoki (*Flammulina velutipes*) (Curt.) Singer
 Hime-Matsutake (*Agaricus blazei*) Murill
 Hirneola (*Auricularia auricular*)
 Maitake (*Grifola frondosa*)
 Morel (*Morchella* spp.)
 Nameko (*Pholiota nameko*)
 Net Bearing (*Dictyophora*)
 Oyster mushroom (*Pleurotus* spp.)
 Pom Pom (*Hericium erinaceus*)
 Reishi mushroom (*Ganoderma lucidum*) (Leyss. Fr.) Karst.
 Rodman's agaricus (*Agaricus bitorquis*) (Quel.) Saccardo
 Shiitake mushroom (*Lentinula edodes*) (Berk.) Pegl.)
 Shimeji (*Tricholoma conglabatum*)
 Stropharia (*Stropharia* spp.)
 Truffle (*Tuber* spp.)
 White button mushroom (*Agaricus bisporous*) (Lange) Imbach
 White Jelly Fungi (*Tremella fuciformis*)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0732; FRL-8342-6]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the combined residues of trifloxystrobin, and its free form acid metabolite in or on asparagus; papaya; sapote, black; canistel; sapote, mamey; mango; sapodilla; star apple; vegetable, root, except sugar beet, subgroup 1B; radish, tops; fruit, citrus, group 10; citrus, oil; citrus, dried pulp; and strawberry. Interregional Research Project Number 4 (IR-4), and Bayer Crop Science requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 2, 2008. Objections and requests for hearings must be received on or before March 3, 2008, 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-2006-0732. 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: Shaja R. Brothers, Registration Division (7505P), 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 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 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-2006-0732 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 March 3, 2008.

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-2006-0732, 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 Registers** of September 13, 2006 (71 FR 54058) (FRL-8091-2), and August 22, 2007 (72 FR 47010) (FRL-8142-5), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PPs) 6E7088, 6F7123, 7F7171 by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540; and Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. These petitions requested that 40 CFR 180.555 be amended by establishing tolerances for combined residues of the fungicide trifloxystrobin, (Benzenecetic 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)-ethylideneamino]oxy]methyl)-phenyl]acetic acid, in or on asparagus at

0.07 parts per million (ppm); papaya at 0.7 ppm; sapote, black at 0.7 ppm; canistel at 0.7 ppm; sapote, mamey at 0.7 ppm; mango at 0.7 ppm; sapodilla at 0.7 ppm; star apple at 0.7 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.1 ppm; and radish, tops at 10 ppm (6E7088); fruit, citrus, group 10 at 0.4 ppm; citrus, oil at 36 ppm; citrus, dried pulp at 1.0 ppm (6F7123); and strawberry at 1.1 ppm (6F7171). These notices referenced a summary of the petitions prepared by Bayer CropScience, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. One comment was received from a private citizen on the notice of filing concerning the tolerances for strawberry and citrus. EPA’s response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has increased the tolerances on fruit, citrus, group 10 from 0.4 to 0.6 ppm, and citrus, oil from 36 to 38 ppm. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 on asparagus at 0.07

ppm; papaya at 0.7 ppm; sapote, black at 0.7 ppm; canistel at 0.7 ppm; sapote, mamey at 0.7 ppm; mango at 0.7 ppm; sapodilla at 0.7 ppm; star apple at 0.7 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.1 ppm; and radish, tops at 10 ppm; fruit, citrus, group 10 at 0.6 ppm; citrus, oil at 38 ppm; citrus, dried pulp at 1.0 ppm; and strawberry at 1.1 ppm. EPA's assessment of exposures and risks associated with establishing these 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. 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 Uses on Asparagus; Vegetable, Root Except Sugar Beet, Subgroup 1B; Radish (Tops); and Papaya, Black Sapote, Canistel, Mamey Sapote, Mango, Sapodilla, and Star Apple, Citrus Fruits, Crop Group 10; Citrus, Oil; and Citrus, Dried Pulp, and Strawberry* on pages 16 and 17 for docket ID number EPA-HQ-OPP-2006-0732.

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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for trifloxystrobin used for human risk assessment can be found at <http://www.regulations.gov> in the *Trifloxystrobin: Human Health Risk Assessment for Section 3 Uses on Asparagus; Vegetable, Root Except Sugar Beet, Subgroup 1B; Radish (Tops); and Papaya, Black Sapote, Canistel, Mamey Sapote, Mango, Sapodilla, and Star Apple, Citrus Fruits, Crop Group 10; Citrus, Oil; and Citrus, Dried Pulp, and Strawberry* on pages 16 and 17 for docket ID number EPA-HQ-OPP-2006-0732.

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 tolerance level residues and 100 percent crop treated (PCT) was performed for trifloxystrobin.

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 tolerance level residues and 100 PCT was performed for trifloxystrobin. PCT and/or anticipated residues were not used.

iii. *Cancer.* Trifloxystrobin is classified as a “not likely carcinogen”; therefore, quantification of human cancer risk is not required and a cancer dietary exposure assessment was not performed.

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/oppefed1/models/water/index.htm>.

Trifloxystrobin is immobile in soil. It degrades and transforms rapidly in soil and aquatic environments. The primary degradate is CGA-321113. Estimated drinking water concentrations (EDWCs) were calculated for total trifloxystrobin residues (parent trifloxystrobin plus the major degradate CGA-321113) using the Agency's First Index Reservoir Screening Tool (FIRST) model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water. The interim method for drinking water estimates for pesticides used in rice paddies was also used to generate EDWCs. The use site with the highest application rate is turf, with a maximum label rate of 1.078 pounds active ingredient/acre/year (lb ai/A/yr) (three applications at 0.359 lb ai/A/yr). Drinking water estimates were also provided for rice paddies that may be treated with trifloxystrobin.

The Agency determined that the highest EDWC for both acute and chronic analysis should use 140 parts per billion (ppb) based on the model for the use on rice. Because this model does not account for degradation of the chemical or dilution with uncontaminated water outside of the rice paddy, the calculated EDWCs (140 ppb) are expected to exceed concentrations likely to be found in drinking water derived from surface water sources.

Based on the FIRST, and SCI-GROW models, the estimated environmental concentrations (EECs) of trifloxystrobin for acute and chronic exposures for surface water are estimated at 140 ppb. Acute and chronic exposure for ground water is estimated at 3.4 ppb.

Modeled estimates of drinking water concentrations were directly entered

into the dietary exposure model. For the acute and chronic dietary risk assessments, the water concentration values of 140 ppb (acute and chronic) were 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: Compass™ is registered for residential use on turf grass and ornamentals disease control. However, this product may only be applied by a Certified Pest Control Operator (PCO). Therefore, an assessment for residential handlers was not performed.

There is potential for dermal (adults and children) and oral exposure (children only) during post-application activities. EPA assessed residential post-application exposure using the following assumptions:

- i. Dermal exposure from pesticide residues on lawns;
- ii. Incidental non-dietary ingestion of pesticide residues on lawns from hand-to-mouth transfer;
- iii. Incidental non-dietary ingestion of residues from object-to-mouth activities (pesticide-treated turf grass); and
- iv. Incidental non-dietary ingestion of soil from pesticide-treated residential areas.

Post-application exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. Exposure via incidental non-dietary ingestion involving other plant material may occur but is expected to result in much less exposure than the four exposure scenarios listed above.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 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 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.* 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.

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 prenatal and/or postnatal 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. Since 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

no 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 prenatal or postnatal toxicity or increased sensitivity in infants and children. In both the rat developmental study and the 2-generation reproduction studies 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 PCT and tolerance-level residues. Conservative ground water and surface water modeling estimates were used. Similarly, conservative assumptions 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 females 13 to 49 years old.

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 52% of the cPAD for all infants less than 1 year old. Based on the use pattern, chronic residential exposure to residues of trifloxystrobin is not expected to underestimate risk to adults or children.

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 dermal MOEs of 1,200 and 670 for the U.S. population and all infants <1 year old, respectively, and an oral MOE of 150 for all infants <1 year old.

4. *Intermediate-term risk.* Intermediate-term exposure (1 to 6 months) to the parent trifloxystrobin is not expected to occur in residential settings due to its short half-life (about 2 days based on soil and aquatic metabolism studies). Therefore, an intermediate-term aggregate risk assessment was not performed.

5. *Aggregate cancer risk for U.S. population.* EPA has classified trifloxystrobin as a "not likely human carcinogen," and EPA considers trifloxystrobin to pose no greater than a negligible 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

An adequate gas chromatography with nitrogen phosphorus detector (GC/NPD) method (Method AG-659A) is available for enforcing tolerances for the combined residues of trifloxystrobin and CGA-321113 in plant commodities.

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 currently no Canadian maximum residue levels (MRLs) for trifloxystrobin. Codex and Mexican MRLs have been established for trifloxystrobin in or on various commodities; however, there are no Mexican MRLs for the commodities associated with the proposed uses. Codex MRLs have been established on

carrots (0.1 ppm) and strawberry (0.2 ppm), which differs from the MRL calculated by the MRL spreadsheet for strawberry (1.1 ppm). 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. 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.

C. Response to Comments

One comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency has received this same comment from this commenter on numerous previous occasions and rejects it for the reasons previously stated in the **Federal Register** of 70 FR 1349, 1354 (January 7, 2005).

D. Explanation of Tolerance Revisions

Bayer CropScience requested a reduction in the pre-harvest interval from 30 to 7 days for citrus and a corresponding modification of the tolerance. The submitted field trial data and processing studies are adequate to support this request. As a result, tolerance expressions have been revised from 0.4 to 0.6 ppm for fruit, citrus, group 10; and 36 to 38 ppm for citrus, oil.

V. Conclusion

Therefore, the tolerances are established for combined residues of trifloxystrobin, Benzeneacetic acid, (*E,E*)- α -(methoxyimino)-2-[[[1-[3-(trifluoromethyl)p 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)-ethylidene aminooxymethyl]-phenyl]acetic acid, in or on asparagus at 0.07 ppm; papaya at 0.7 ppm; sapote, black at 0.7 ppm; canistel at 0.7 ppm; sapote, mamey at 0.7 ppm; mango at 0.7 ppm; sapodilla at 0.7 ppm; star apple at 0.7 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.1 ppm; and radish, tops at 10 ppm; fruit, citrus, group 10 at 0.6 ppm; citrus, oil at 38 ppm; citrus, dried pulp at 1.0 ppm; and strawberry at 1.1 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: December 20, 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. In § 180.555, the table to paragraph (a) is amended by revising the entries for “Citrus, dried pulp” “Citrus, oil” and “Fruit, citrus, group 10,” and by alphabetically adding new commodities to read as follows:

§ 180.555 Trifloxystrobin.

(a) * * *

Commodity	Parts per million
* * *	* *
Asparagus	0.07
* * *	* *
Canistel	0.7
* * *	* *
Citrus, dried pulp	1.0
Citrus, oil	38
* * *	* *
Fruit, citrus, group 10	0.6
* * *	* *
Mango	0.7
* * *	* *
Papaya	0.7
* * *	* *
Radish, tops	10
* * *	* *
Sapodilla	0.7

Commodity	Parts per million
Sapote, black	0.7
Sapote, mamey	0.7
* * *	* *
Star apple	0.7
Strawberry	1.1
* * *	* *
Vegetable, root, except sugar beet, subgroup 1B	0.1
* * *	* *

* * *

[FR Doc. E7–25396 Filed 12–31–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260 and 261

[EPA–HQ–RCRA–2002–0002; FRL–8511–5]

RIN 2050–AE78

Regulation of Oil-Bearing Hazardous Secondary Materials From the Petroleum Refining Industry Processed in a Gasification System To Produce Synthesis Gas

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is revising its hazardous waste management regulations under the Resource Conservation and Recovery Act (RCRA) to further promote the environmentally sound recycling of oil-bearing hazardous secondary materials generated by the petroleum refining industry. Specifically, EPA is amending an existing exclusion from the definition of solid waste for oil-bearing hazardous secondary materials when they are processed in a gasification system at a petroleum refinery for the production of synthesis gas. We are finalizing this exclusion so that the gasification of these materials will have the same regulatory status (they are all excluded from the definition of solid waste under RCRA) as oil-bearing hazardous secondary materials that are reinserted into the petroleum refining process. This action serves what we believe is a national interest by capturing as much energy from a barrel of oil as possible to maximize production efficiencies at petroleum refineries in an energy constrained world.

DATES: This final rule is effective on February 1, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2002–0002. All

documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, because, for example, it may be Confidential Business Information (CBI) or other information, the disclosure of which is restricted by statute. Certain material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the RCRA Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the RCRA docket is (202) 566–0270.

FOR FURTHER INFORMATION CONTACT:

Elaine Eby, Waste Minimization Branch, Hazardous Waste Minimization and Management Division, Office of Solid Waste (5302P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8449, fax number: (703) 308–8433, e-mail address: eby.elaine@epa.gov.

SUPPLEMENTARY INFORMATION:

A. Does This Action Apply to Me?

This rule may apply to entities regulated under RCRA, in the petroleum refining industry, identified as Standard Industrial Classification (SIC) 2911. To determine whether your facility, company, or business is affected by this action, you should carefully examine 40 CFR Parts 260 through 271. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding “**FOR FURTHER INFORMATION CONTACT**” section.

B. Table of Contents

- I. Statutory Authority.
- II. Summary of This Action.
- III. Background.
- IV. Development of This Final Rule.
 - A. How Many Gasification Systems Are Currently Operating at Petroleum Refineries?
 - B. What Conclusions Have We Drawn About Gasification Systems Operating at Petroleum Refineries?
- V. This Final Rule.
 - A. Does the Conditional Exclusion Include a Definition for a Gasification System Used at a Petroleum Refinery?
 - B. Does the Conditional Exclusion Include a Synthesis Gas Specification?
 - C. Does the Conditional Exclusion Prohibit Oil-Bearing Hazardous Secondary Material From Being Placed on the Land