

levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal

officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other

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

List of Subjects in 40 CFR Part 180

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

Dated: September 12, 2006.

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 180.511 is amended by alphabetically revising commodities and adding cotton seed to the table in paragraph (a) to read as follows:

§ 180.511 Buprofezin; tolerance for residues

(a) * * *

Commodity	Parts per million	Expiration/revocation dates
Almond hulls	2.0	None
Cotton, gin byproducts	20.0	None
Cotton seed	0.35	None
Tomato	0.40	None

* * * * *
[FR Doc. 06-8065 Filed 9-21-06; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0299; FRL-8093-8]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances 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-trifluoromethylphenyl)ethylideneamino]oxy)methyl) phenyl)acetic acid)) in or on soybean, forage at 10.0 parts per million (ppm), soybean, hay at 25.0 ppm, and soybean, seed at 0.08 ppm. Bayer CropScience requested this tolerance 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 22, 2006. Objections and requests for hearings must be received on or before November 21, 2006, 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-2005-0299. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: 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: janet.whitehurst@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

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 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>

C. Can I File an Objection or Hearing Request?

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. 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-2005-0299 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 21, 2006.

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 your copies, identified by docket ID number EPA-HQ-OPP-2005-0299, 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of January 4, 2006 (71 FR 340) (FRL-7750-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6956) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. 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)ethylideneamino]oxymethyl)phenyl) acetic acid)) in or on soybean, forage at 8.0 ppm, soybean, hay at 20.0 ppm, and soybean, seed at 0.08 ppm. That notice included a summary of the petition prepared by BayerCropScience, the registrant. The petition also proposed a 4.2 ppm tolerance for aspirated grain fractions (AGF) derived from soybean seed. However, this tolerance is not necessary as residues in/on soybean AGF are covered by the existing 5.0 ppm tolerance or AGF, which was established in conjunction with the use of trifloxystrobin on wheat. There were no comments received in response to the notice of filing.

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

aggregate exposure to the pesticide chemical residue. . . .”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see:

<http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>

<http://www.epa.gov/oppfead1/trac/science>

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>

<http://www.epa.gov/pesticides/trac/science/aggregate.pdf>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of trifloxystrobin and CGA 321113 on soybean, forage at 10.0 ppm, soybean, hay at 25.0 ppm, and soybean,

seed at 0.08 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 toxic 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 **Federal Register** of March 29, 2006 (71 FR 15597) (FRL-7759-9).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which 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 LOAEL of concern identified 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at either of the following websites:

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>;

<http://www.epa.gov/oppfead1/trac/science>.

A summary of the toxicological endpoints for trifloxystrobin human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (female 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	Two-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 (1-30 days) and intermed-term (1-6 months) oral	Offspring NOAEL= 3.8 mg/kg/day	LOC for MOE = 100 (residential, includes the FQPA SF)	Two-Generation reproduction study - rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Short-term (1-30 days) and intermed-term (1-6 months) dermal	Dermal study NOAEL = 100 mg/kg/day	LOC for MOE = 100 (occupational) 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 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Two-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

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-term (1-30 days), intermed-term (1-6 months) and long-term >6 months) inhalation	Oral study NOAEL= 3.8 mg/kg/day (Inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes the FQPA SF)	Two-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
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		

¹ UF = uncertainty factor, FQPA SF = Special FQPA SF, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.555) for the combined residues of trifloxystrobin and CGA 321113 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.* 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 conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute dietary exposure analysis for trifloxystrobin is a Tier 1 assessment (assuming 100 percent crop treated (%CT) and tolerance level residues). The acute dietary endpoint was found to be applicable only to the population subgroup females 13-49 years old. An acute dietary endpoint for the general population including infants and children was not identified.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A conservative chronic dietary analysis for

trifloxystrobin was conducted using tolerance-level residues for all commodities with existing and proposed tolerances except for meat byproducts of cattle, goats, horses, and sheep because the metabolite L7a (the taurine conjugate of trifloxystrobin) is included in the risk assessment for liver. For all commodities, 100% CT was used.

iii. *Cancer.* Trifloxystrobin is classified as a "Not Likely Human Carcinogen." Due to the classification, no cancer risk assessment was performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for 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. 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>. EPA determined estimated drinking water concentrations (EDWCs) of trifloxystrobin using the PRZM/EXAMS, FIRST and SCI-GROW models. The highest EDWCs for surface water and ground water acute exposure (92 parts per billion (ppb)) and surface water and ground water chronic exposure (140 ppb) were used in the dietary analysis. The chronic exposure value is higher than the acute exposure value due to some very conservative assumptions in the chronic assessment. These estimates of residues in drinking water were incorporated directly into the DEEM-FCID model of the dietary risk assessment.

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 ornamentals. The risk assessment was conducted using the following residential exposure assumptions: Trifloxystrobin is currently registered for residential uses including disease control in turfgrass and ornamentals. Up to three applications may be made in a season, with the shortest interval between applications being 5-7 days. Because FQPA requires consideration of aggregate exposure to all likely non-occupational uses, this assessment uses non-occupational post-application contact with trifloxystrobin following use on turfgrass as the most common and worst case contributor to such exposures. There is potential for dermal (adults and children) and incidental oral exposure (children only) during post-application activities. The following post-application exposure scenarios resulting from lawn treatment were assessed: 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 turfgrass), 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. The exposure via incidental non-dietary ingestion involving other plant material may occur but is considered negligible. Intermediate and chronic, or long-term exposures are not expected.

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

2. *Conclusion.* The Agency found that because the toxicology database are complete for FQPA purposes and that there are no residual uncertainties for prenatal/postnatal toxicity, the 10X FQPA Safety Factor (SF) can be reduced

to 1x. The FQPA SF is reduced to 1X because:

- 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;
- The EPA determined that a developmental neurotoxicity study in rats is not required;
- The acute and chronic dietary food exposure assessments utilize existing and proposed tolerance level residues and 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated;
- 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;
- 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; and
- The residential postapplication assessment is based upon using 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

1. *Acute risk.* The aggregate acute risk estimates include exposure to residues of trifloxystrobin in food and drinking water, and does not include dermal, inhalation or incidental oral exposure. Since the dietary exposure assessment already includes the highest acute exposure from the drinking water modeling data, no further calculations are necessary. The food and drinking water exposure estimates for females 13-49 years old is <1% acute population adjusted dose (aPAD). The acute risk estimate for females 13-49 years, resulting from aggregate exposure to trifloxystrobin in food and drinking water is below EPA's level of concern.

2. *Chronic risk.* The aggregate chronic risk assessment takes into account average exposure estimates from dietary consumption of trifloxystrobin (food and drinking water) and residential

uses. Since the exposure from turf is considered short-term, the aggregate chronic assessment included food and drinking water only. Since the dietary exposure assessment already includes the highest chronic exposure from the drinking water modeling data, no further calculations are necessary. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's level of concern (i.e., the percentages of the cPADs are all below 100%). The exposure to the U.S. population was 21% of the cPAD and the most highly exposed subgroup, children 1-2 years old, was at 62% of the cPAD. Therefore, chronic risk estimates resulting from aggregate exposure to trifloxystrobin in food and drinking water are below EPA's level of concern from all population subgroups.

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). The short-term aggregate risk assessment estimates risks likely to result from 1-30 day exposure to trifloxystrobin residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the short-term assessment, while average values are used for food and drinking water exposure (i.e. chronic exposures).

Different endpoints were identified by EPA for short-term incidental oral and dermal risk assessment (the basis for the oral endpoint is reduced pup body weights and the dermal endpoint is based on increases in liver and kidney weights). Therefore, it is not reasonable, as a toxicological matter, to combine dietary/incidental oral exposure with dermal exposure. A short-term aggregate risk assessment for dietary plus incidental oral exposure is needed for toddlers because there are residential postapplication incidental oral exposure scenarios. Toddlers' incidental oral exposure is assumed to include hand-to-mouth exposure, object-to-mouth exposure and exposure through incidental ingestion of soil. Because toddlers also have post-application dermal exposure as a result of the residential use and because it is not scientifically appropriate to combine oral and dermal exposures for trifloxystrobin, a separate short-term aggregate risk assessment is needed for toddlers to assess the risk of dermal exposure. This separate risk assessment only takes into account dermal exposure and compares this exposure to the dermal endpoint. The short-term aggregate oral exposure to all other

population groups is from dietary exposure alone (i.e. from food and drinking water) because these population groups do not have incidental oral exposures. As with

toddlers, a separate short-term aggregate risk assessment has been conducted for dermal exposure. Table 2 summarizes short-term aggregate risks. All short-term aggregate risk estimates result is

MOEs greater than 100. Therefore, EPA does not consider short-term aggregate risk to be a concern.

TABLE 2.—SHORT-TERM AGGREGATE RISK (FOOD, DRINKING WATER AND RESIDENTIAL EXPOSURE)

Population	Short-Term Scenario					
	NOAEL mg/kg/day	LOC MOE ¹	Average Food + Water Exposure mg/kg/day	Oral Residential Exposure ² mg/kg/day	Dermal Residential Exposure mg/kg/day	Aggregate MOE ³
U.S. population/adults oral	3.8	100	0.008145	NA	NA	470
U.S. population/adults dermal	100	100	NA	NA	0.079	1300
Youth (13-19 years old)	3.8	100	0.005969	NA	NA	640
Children (1-2 years old) oral	3.8	100	0.023704	0.00642	NA	130
Children (1-2 years old) dermal	100	100	NA	NA	0.130	770
Females (13-49 years old)	3.8	100	0.006396	NA	NA	590

¹ The LOC MOE is 100, based on inter-species and intra-species safety factors totaling 100.

² Oral Residential Exposure = Incidental Oral exposure from all possible sources.

³ Aggregate MOE = NOAEL ÷ (All exposures appropriate to the assessment).

4. *Intermediate-term risk.* An intermediate-term aggregate risk assessment (1 to 6 months of exposure to trifloxystrobin residues from food, drinking water, and residential pesticide uses) is not expected to occur 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.* EPA determined that trifloxystrobin should be classified as a “Not Likely Human Carcinogen.” EPA does not expect trifloxystrobin 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, and to infants and children from aggregate exposure to trifloxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate Gas Liquid Chromatography/Nitrogen Phosphorous (GC/NPD) method, Method AG-659A, is available for enforcing tolerances for the combined residues of trifloxystrobin and the free form of its acid metabolite (CGA-321113) in plant and livestock commodities. This method was validated by the and forwarded to FDA for inclusion in PAM Vol. II.

In the current soybean field trials and processing study, residues of trifloxystrobin and CGA-321113 were

determined using a LC/MS/MS method (Bayer Report No. 200177), which was previously developed for the analysis of residues in tomatoes and peppers. This method uses the same extraction procedures as the current tolerance enforcement method, but uses different clean up procedures and detection by LC/MS/MS. This method is adequate for collecting residue data on trifloxystrobin and CGA-321113 in soybean commodities.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican MRL’s or tolerances for trifloxystrobin on soybeans. Therefore, international harmonization is not an issue for this petition.

V. Conclusion

Therefore, the tolerance is 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-trifluoromethylphenyl) ethylideneamino]oxy)methyl)phenyl) acetic acid)) in or on soybean, forage at 10.0 ppm, soybean, hay at 25.0 ppm, and soybean, seed at 0.08 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 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the

distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: September 14, 2006.

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 180.555 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Soybean, forage	10.0
Soybean, hay	25.0
Soybean, seed	0.08
* * * * *	*

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[FR Doc. 06-8060 Filed 9-21-06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[Docket ID No. EPA-HQ-SFUND-1994-0009; FRL-8221-6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Direct Final Notice of Deletion of the Army Materials Technology Laboratory Superfund Site from the National Priorities List.

SUMMARY: EPA Region 1 is publishing a direct final notice of deletion of the Army Materials Technology Laboratory Superfund Site (Site), located in Watertown, Massachusetts, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA is publishing this direct final notice of deletion with the concurrence of the Commonwealth of Massachusetts, through the Department of Environmental Protection (MADEP), because EPA determined that all appropriate response actions under CERCLA—other than operation and maintenance and five-year reviews—have been completed and further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final deletion will be effective November 21, 2006 unless EPA receives adverse comments by October 23, 2006. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-SFUND-1994-0009, by one of the following methods:

- www.regulations.gov: Follow the on-line instruction for submitting comments.
- E-mail: keckler.kymerlee@epa.gov.
- Fax: (617) 918-0385.
- Mail: Kymerlee Keckler, Remedial Project Manager, U.S. Environmental Protection Agency, Region 1, 1 Congress Street, Suite 1100 (HBT), Boston, Massachusetts 02114-2023.
- Hand delivery: 1 Congress Street, Suite 1100 (HBT), Boston,