

End-use	Substitute	Decision	Further information
Rigid polyurethane slabstock and other foams.	Transcend™ Technologies as an additive to other SNAP-approved foam blowing agents for this end use as substitutes for CFCs and HCFCs.	Acceptable	Decision only applies where the foam blowing blend makes up to 5% by weight of the total foam formulation.
Polyurethane integral skin foam	Transcend™ Technologies as an additive to other SNAP-approved foam blowing agents for this end use as substitutes for CFCs and HCFCs.	Acceptable	Decision only applies where the foam blowing blend makes up to 5% by weight of the total foam formulation.
Polyurethane: extruded sheet	Transcend™ Technologies as an additive to other SNAP-approved foam blowing agents for this end use as substitutes for CFCs and HCFCs.	Acceptable	Decision only applies where the foam blowing blend makes up to 5% by weight of the total foam formulation.

Fire Suppression and Explosion Protection

Total flooding	Uni-light AFFF 1% as a substitute for Halon 1301.	Acceptable	This agent is intended for use on-board ships and in off-shore installations. Appropriate personal protective equipment should be worn during manufacture or in the event of a release. Personal protective equipment should include safety goggles, protective gloves, and a self-contained breathing apparatus. Supply bottles for the foam should be clearly labeled with the potential hazards associated with the use of the chemicals in the foam, as well as handling procedures to reduce risk resulting from these hazards. Use should conform with relevant OSHA requirements, including 29 CFR part 1910, subpart L, §§ 1910.160 and 1910.163. EPA has no intention of duplicating or displacing OSHA coverage related to the use of personal protection equipment (e.g., respiratory protection), fire protection, hazard communication, worker training or any other occupational safety and health standard with respect to halon substitutes.
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0299; FRL-7759-9]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance 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) pesticide petition (PP 4F6892) in or on corn, sweet, kernel plus cob with husks removed at 0.04 parts per million (ppm), corn, sweet, forage at 0.6 ppm, corn, sweet, stover at 0.25 ppm, and corn, sweet, cannery waste at 0.6 ppm; (PP 3E6769) oat, forage at 0.3 ppm, oat, grain at 0.05 ppm, oat, hay at 0.3 ppm, oat, straw at 5.0 ppm, barley, grain at 0.05 ppm, barley, hay at 0.3 ppm, barley, straw at

5.0 ppm. Bayer Crop Science 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 March 29, 2006. Objections and requests for hearings must be received on or before May 30, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** 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 on the

www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Janet Whitehurst, Registration Division (7505C), 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.

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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

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 pesticide petition (PP 4F6892) by Bayer Crop Science, P.O. Box 12014, 2T.W. Alexander Drive, 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*)- α -(methoxyimino)-2-[[[1-(3-(trifluoromethyl)phenyl]ethylidene]amino]oxy)methyl]-, methylester) and the free form of its acid metabolite CGA-321113 ((*E,E*)-methoxyimino-[2-[1-(3-(trifluoromethyl)phenyl)-ethylideneamino]oxy)methyl]-phenyl)acetic acid), (PP 4F6892) in or on corn, sweet, kernel plus cob with husks removed at 0.04 ppm, corn, sweet, forage at 0.6 ppm, corn, sweet, stover at 0.25 ppm, and corn, sweet, cannery waste at 0.6 ppm. That notice included a summary of the petition prepared by Bayer Crop Science, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of January 18, 2006 (71 FR 2929) (FRL-7756-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP 3E6769) by the Interregional Research Project Number 4 (IR-4), 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390. The petition requested that 40 CFR 180.555 be amended by establishing a tolerance for residues of the fungicide trifloxystrobin, in or on the following raw agricultural commodities: barley,

grain at 0.05 parts per million (ppm); barley, hay at 0.3 ppm; barley, straw at 5.0 ppm; oat, forage at 0.3 ppm; oat, grain at 0.05 ppm; oat, hay at 0.3 ppm; and oat, straw at 5.0 ppm. That notice included a summary of the petition prepared by IR-4. There were no comments received on 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. . . ."

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 (PP 4F6892) in or on corn, sweet, kernel plus cob with husks removed at 0.04 ppm, corn, sweet, forage at 0.6 ppm, corn, sweet, stover at 0.25 ppm, and corn, sweet, cannery waste at 0.6 ppm; (PP 3E6769) oat, forage at 0.3 ppm, oat, grain at 0.05 ppm, oat, hay at 0.3 ppm, oat, straw at 5.0 ppm, barley, grain at 0.05 ppm, barley, hay at 0.3 ppm, barley, straw at 5.0 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 and CGA-321113 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 May 22, 2002 (67 FR 35915)(FRL-7178-6).

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable

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

of the human population as well as other unknowns.

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.

A summary of the toxicological endpoints for trifloxystrobin and CGA-321113 used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL ENDPOINTS FOR USE IN HUMAN HEALTH RISK ASSESSMENT¹

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 only)	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 1X aPAD = aRfD FQPA SF = 2.5 mg/kg/day	Developmental Toxicity-Rat LOAEL = 500 mg/kg/day, based upon increased fetal skeletal anomalies
Acute Dietary General Population including infants and children	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic Dietary all populations	Parental NOAEL = 3.8 mg/kg/day UF = 100 Chronic RfD = 0.038 mg/kg/day	FQPA SF = 1X cPAD = cRfD FQPA SF = 0.038 mg/kg/day	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- (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- (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
Short- (1-30 days), Intermed-(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

TABLE 1.—SUMMARY OF TOXICOLOGICAL ENDPOINTS FOR USE IN HUMAN HEALTH RISK ASSESSMENT¹—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
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 and CGA-321113 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.

Such effects were identified in the toxicological studies for trifloxystrobin and CGA-321113 applicable only to Females 13-49 years old. In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDTM), 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: One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin (100% CT) and tolerance-level residues were used in the analysis. The acute dietary endpoint (increased fetal incidence of fused sternebrae) is only applicable to the population subgroup females 13-49 years old. An acute dietary endpoint for the general population including infants and children was not identified. The highest estimate for acute drinking water exposure, 92 ppb, was used in the analysis.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCIDTM, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following

assumptions were made for the chronic exposure assessments: One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin (100% CT) and tolerance-level residues were used in the analysis. The chronic dietary endpoint applies to all population subgroups including infants and children. The highest estimate for chronic drinking water exposure, 140 ppb, was used in the analysis.

iii. *Cancer.* EPA determined that trifloxystrobin should be classified as a “Not Likely Human Carcinogen.” Due to the classification, no cancer exposure assessment was performed.

2. *Dietary exposure from drinking water.* Based on the FIRST, and Screening Concentrations in Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of trifloxystrobin and CGA-321113 for acute exposures are estimated to be 92 parts per billion (ppb) for surface water and 34 ppb for ground water. The EECs for chronic exposures are estimated to be 50 ppb for surface water and 3.4 ppb for ground 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 use on the following residential non-dietary sites: Turfgrass and ornamentals. The risk assessment was conducted using the following residential exposure assumptions: There is potential for dermal (adults and children) and incidental oral exposure (children only) during postapplication activities. The following postapplication exposure scenarios resulting from lawn treatment were assessed:

- a. Dermal exposure from pesticide residues on lawns,
- b. Incidental non-dietary ingestion of pesticide residues on lawns from hand-to-mouth transfer,
- c. Incidental non-dietary ingestion of residues from object-to-mouth activities (pesticide-treated turfgrass), and

d. Incidental non-dietary ingestion of soil from pesticide-treated residential areas. Postapplication 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.

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 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 (SF) value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The EPA concluded that the toxicology database was complete for Food Quality Protection Act (FQPA) purposes and that there are no residual uncertainties for prenatal/postnatal toxicity.

3. *Conclusion.* EPA determined that the 10X SF to protect infants and children should be reduced to 1X. The FQPA, SF is reduced because:

- i. There is a complete toxicity data base for trifloxystrobin.
- ii. 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;
- iii. EPA determined that a developmental neurotoxicity study in rats is not required;
- iv. Although an acute neurotoxicity study is required (the submitted study was unacceptable), the lack of an acute neurotoxicity study does not impact EPA's ability to make an FQPA safety factor decision because upgrading the study would not result in a lower NOAEL than what is present for the acute RfD;
- v. The acute and chronic dietary food exposure assessments utilize existing and proposed tolerance level residues

and 100% crop treated information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated;

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

vii. The residential postapplication assessment is based upon the residential 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 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 acute risk estimate for females 13-49 years, resulting from aggregate exposure to trifloxystrobin in food and drinking water is below Health Effects Division (HED)'s level of concern. The food and water exposure estimates for females 13-49 yrs old is <1% aPAD.

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 chronic population adjusted doses (cPADs) are all below 100%). The exposure to the U.S. population was 21% cPAD and the most highly exposed subgroup, children 1-2 yrs old, at 62% 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.* The short-term aggregate risk assessment estimates risks likely to result from 1- to 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 possible to combine dietary/incidental oral exposure with dermal exposure.

A short-term risk assessment was not required for adults, because no incidental oral exposure is expected for adults. A short-term risk assessment is required for infants and children because there are residential postapplication 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. Table 2 summarizes short-term aggregate risk from incidental oral and dietary food and water sources for children.

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

Population	Short-Term Scenario				
	NOAEL mg/kg/day	LOC MOE ¹	Average Food + Water Exposure mg/kg/day	Residential Exposure ² mg/kg/day	Aggregate MOE (food and residential) ³
U.S. population	3.8	100	0.008030	N/A	470
Youth (13-19 years)	N/A	N/A	0.005867	N/A	650
All Infants (>1 year)	N/A	N/A	0.021883	0.00642	130
Children (1-2 years)	N/A	N/A	0.023429	0.00642	130

TABLE 2.—SHORT-TERM AGGREGATE RISK (FOOD, WATER AND INCIDENTAL ORAL EXPOSURE)—Continued

Population	Short-Term Scenario				
	NOAEL mg/kg/day	LOC MOE ¹	Average Food + Water Exposure mg/kg/day	Residential Exposure ² mg/kg/day	Aggregate MOE (food and residential) ³
Females (13-49 years old)	N/A	N/A	0.006312	N/A	600

¹ The level of concern (LOC) MOE is 100, based on inter- and intra-species safety factors totaling 100.

² Residential Exposure = Incidental Oral exposure from all possible sources. No residential oral exposure is expected for adults.

³ Aggregate MOE = NOAEL (3.8 mg/kg/day) ÷ (Avg Food Exposure + Residential Exposure).

As shown above in Table 2, the aggregate short-term MOE for all infants less than 1 yr old and children 1-2 years old at 130 does not exceed EPA's level of concern, a MOE of 100. It should be noted that the maximum surface water concentration, which is included in the average food and water exposure, results from the use on rice, is considered to be an overestimate of the true value found in the environment due to the intricacies of the drinking water model, and should be viewed as very conservative. Further, EPA considers the turfgrass estimate (50 ppb) to be a more realistic estimate of drinking water residues. EPA does not consider short-term aggregate risk for children to be a concern.

4. *Intermediate-term risk.* An intermediate-term aggregate risk (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).

5. *Aggregate cancer risk for U.S. population.* 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, and to infants and children from aggregate exposure to trifloxystrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method using nitrogen/phosphorus detector) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for trifloxystrobin in/on corn and barley grain. The U.S. tolerances are

not compatible with the Codex MRLs because the U.S. and Codex tolerance expressions are different. The current U.S. tolerance for corn grain (i.e., field corn) is set at 0.05 ppm, while we are proposing a tolerance of 0.04 ppm for sweet corn. Both of these U.S. tolerances are not compatible with the Codex MRL for maize, because the U.S. and Codex tolerance expressions are different. The U.S. and Codex residue definitions differ in that the U.S. tolerance includes the acid metabolite whereas the Codex does not. Although non-quantifiable residues of each compound were observed in both the North American and European field trials, the U.S. tolerance on sweet corn (0.04 ppm) is being established at twice the level of Codex MRL for maize (0.02 ppm). For barley, the European GAP use rate is almost four times the U.S. use rate, which partly explains the much higher Codex MRL (0.5 ppm).

The Canadian MRLs have been established for wheat, oats and barley at 0.05 ppm. The U.S. tolerances for barley and oats are being established at 0.05 ppm and the wheat tolerance has already been established at 0.05 ppm. Harmonization is thus not an issue.

V. Conclusion

Therefore, the tolerance is established for combined residues of trifloxystrobin and CGA-321113, (PP 4F6892) in or on corn, sweet, kernel plus cob with husks removed at 0.04 ppm, corn, sweet, forage at 0.6 ppm, corn, sweet, stover at 0.25 ppm, and corn, sweet, cannery waste at 0.6 ppm; (PP 3E6769) oat, forage at 0.3 ppm, oat, grain at 0.05 ppm, oat, hay at 0.3 ppm, oat, straw at 5.0 ppm, barley, grain at 0.05 ppm, barley, hay at 0.3 ppm, barley, straw at 5.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178.

Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number 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 May 30, 2006.

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

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA-HQ-OPP-2005-0299, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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.

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 20, 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
* * *	* *
Barley, grain	0.05
Barley, hay	0.3
Barley, straw	5.0
* * *	* *
Corn, sweet, cannery waste	0.6
Corn, sweet, forage	0.6
Corn, sweet, kernel plus cob with husks re- moved	0.04
Corn, sweet, stover	0.25
* * *	* *
Oat, forage	0.3
Oat, grain	0.05
Oat, hay	0.3
Oat, straw	5.0
* * *	* *

* * *

[FR Doc. 06-2978 Filed 3-28-06; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2004-0132; FRL-7769-1]

Flonicamid; Pesticide Tolerance

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a
tolerance for combined residues of
flonicamid and its metabolites in or on
head and stem brassica and mustard
greens. ISK Biosciences Corporation
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
March 29, 2006. Objections and requests

for hearings must be received on or
before May 30, 2006.

ADDRESSES: To submit a written
objection or hearing request follow the
detailed instructions as provided in
Unit VI. of the **SUPPLEMENTARY
INFORMATION.** EPA has established a
docket for this action under Docket
identification (ID) number EPA-HQ-
OPP-2004-0132. All documents in the
docket are listed on the
www.regulations.gov web site.
(EDOCKET, EPA's electronic public
docket and comment system was
replaced on November 25, 2005, by an
enhanced Federal-wide electronic
docket management and comment
system located at [http://
www.regulations.gov/](http://www.regulations.gov/). Follow the on-
line instructions.) Although listed in the
index, some information is not publicly
available, i.e., 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 either electronically in
EDOCKET or in hard copy at the Public
Information and Records Integrity
Branch (PIRIB), Rm. 119, Crystal Mall
#2, 1801 S. Bell St., Arlington, VA. This
docket facility is open from 8:30 a.m. to
4 p.m., Monday through Friday,
excluding legal holidays. The docket
telephone number is (703) 305-5805.
FOR FURTHER INFORMATION CONTACT: Ann
Sibold, Registration Division (7505C),
Office of Pesticide Programs,
Environmental Protection Agency, 1200
Pennsylvania Ave., NW., Washington,
DC 20460-0001; telephone number:
(703) 305-6502; e-mail address:
sibold.ann@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 and Other Related Information?

In addition to using EDOCKET ([http://
www.epa.gov/edocket/](http://www.epa.gov/edocket/)), you may access
this **Federal Register** document
electronically through the EPA Internet
under the “**Federal Register**” listings at
<http://www.epa.gov/fedrgstr/>. A
frequently updated electronic version of
40 CFR part 180 is available on E-CFR
Beta Site Two at [http://
www.gpoaccess.gov/ecfr/](http://www.gpoaccess.gov/ecfr/).

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004
(69 FR 40916) (FRL-7362-5), 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 4F6832) by ISK
Biosciences Corporation, 7470 Auburn
Road, Suite A, Concord, Ohio 44077.
The petition requested that 40 CFR
180.613 be amended by establishing a
tolerance for combined residues of the
insecticide flonicamid [N-
(cyanomethyl)-4-(trifluoromethyl)-3-
pyridinecarboxamide] and its
metabolites TFNA [4-
trifluoromethylnicotinic acid], TFNA-
AM [4-trifluoromethylnicotinamide]
TFNG [N-(4-
trifluoromethylnicotinoyl)glycine] in or
on the raw agricultural commodities
brassica, head and stem, subgroup 5A at
1.5 parts per million (ppm) and mustard
greens at 11 ppm. That notice included
a summary of the petition prepared by
ISK Biosciences Corporation, the
registrant. There were no comments
received in response to the notice of
filing. There was one comment received
in response to the final rule published
in the **Federal Register** of August 31,
2005 (70 FR 51604) (FRL-7731-6),
which is referenced in today's rule. The
Agency's response is set forth in Unit
IV.C.