

EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE NEW MEXICO SIP

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/effective date	EPA approval date	Explanation
* Interstate transport for the 1997 ozone and PM _{2.5} NAAQS.	* New Mexico	* 09/17/07	* 06/11/10 [insert FR page number where the document begins].	* 06/11/10 Approval for revisions to prohibit significant contribution to nonattainment in any other State.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0278; FRL-8829-2]

Trifloxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases existing tolerances for residues of trifloxystrobin in or on corn, field, forage; corn, sweet, forage; and corn, sweet, stover. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Additionally, EPA is removing several tolerances which have expired.

DATES: This regulation is effective June 11, 2010. Objections and requests for hearings must be received on or before August 10, 2010, 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-2009-0278. All documents in the docket are listed in the docket index available at <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: Tawanda Maignan, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8050; e-mail address: maignan.tawanda@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).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

To access the harmonized test guidelines referenced in this document electronically, please go <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, 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-2009-0278 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 10, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0278, 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 Facility'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. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 19, 2009 (74 FR 41898) (FRL-8426-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7487) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.555 be amended by increasing existing tolerances for residues of the fungicide trifloxystrobin, benzenoacetic acid, (*E,E*)- α -(methoxyimino)-2-[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-methyl ester), in or on corn, field, forage at 6.0 parts per million (ppm); corn, sweet, forage at 7.0 ppm; and corn, sweet, stover at 4.0 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon the review of the data supporting the petition, the Agency is increasing the existing meat, fat and meat byproduct of cattle, goats, horses, and sheep tolerances to 0.1 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with section 408(b)(2)(D) of FFDCFA, and the factors specified in section 408(b)(2)(D) of FFDCFA, 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 trifloxystrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trifloxystrobin 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.

Trifloxystrobin exhibits very low toxicity following single oral, dermal and inhalation exposures. It is a strong dermal sensitizer. In repeated dose tests in rats, the liver is the target organ for trifloxystrobin; toxicity is induced following oral and dermal exposure for 28 days. In the available toxicity studies on trifloxystrobin, there was no estrogen, androgen, and/or thyroid mediated toxicity. The toxicological database for trifloxystrobin does not show any evidence of treatment-related effects on the immune system. Further, there was no evidence of neurotoxicity at the limit dose in an unacceptable acute neurotoxicity study or in the other subchronic and chronic studies in the database. There is no evidence of increased susceptibility following pre-natal exposure to rats and rabbits and post-natal exposures to rats. Trifloxystrobin was determined not to be carcinogenic in mice or rats following long-term dietary administration. Trifloxystrobin is positive for mutagenicity in Chinese Hamster V79 cells, albeit at cytotoxic

dose levels. However, trifloxystrobin is negative in the remaining mutagenicity studies.

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 at <http://www.regulations.gov> in document "Trifloxystrobin. Human Health Risk Assessment for a Section 3 Petition Proposing Increased Tolerances for Residues in/on Field, Sweet and Pop Corn" at pages 17 to 21 in docket ID number EPA-HQ-OPP-2009-0278.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. 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/pesticides/factsheets/riskassess.htm>.

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

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLOXYSTROBIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–49 years of age)	NOAEL = 250 milligrams/kilograms/day (mg/kg/day) UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day aPAD = 2.5 mg/kg/day	Developmental Toxicity-Rabbit. LOAEL = 500 mg/kg/day based on increased fetal skeletal anomalies.
Chronic dietary (All populations)	NOAEL = 3.8 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.038 mg/kg/day cPAD = 0.038 mg/kg/day	Two-Generation reproduction study-Rat. LOAEL = 55.3 mg/kg/day based on decreases in body weight, body weight gains, reduced food consumption and histopathological lesions in the liver, kidneys and spleen.
Incidental Oral Short- (1 to 30 days) and Intermediate- (1-6 months) Term	Offspring NOAEL = 3.8 mg/kg/day UF _A = NA UF _H = NA FQPA SF = NA	LOC for MOE = 100	Two-Generation reproduction study-Rat. LOAEL = 55.3 mg/kg/day based on reduced pup body weights during lactation.
Dermal Short- (1 to 30 days) and Intermediate- (1 to 6 months) Term	Dermal study NOAEL = 100 mg/kg/day UF _A = NA UF _H = NA FQPA SF = NA	LOC for MOE = 100	28-Day Dermal Toxicity Study-Rat. LOAEL = 1,000 mg/kg/day based on increases in mean absolute and relative liver and kidney weights.
Inhalation Short- (1 to 30 days), and Intermediate- (1 to 6 months) Term	Oral study NOAEL = 3.8 mg/kg/day (inhalation absorption rate = 100%) UF _A = NA UF _H = NA FQPA SF = NA	LOC for MOE = 100	Two-Generation reproduction study-Rat. LOAEL = 55.3 mg/kg/day based on 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.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. 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.* 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 for females 13 to 49 years old, EPA conducted an analysis using the Dietary Exposure Evaluation Model (DEEMTM7.81), which 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). EPA used tolerance level residues. EPA assumed all

commodities with established or proposed tolerances were treated with 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 to be included in DEEM. As to residue levels in food, EPA used tolerance level residues for all commodities with the exception of apples, oranges and grapes. For these commodities EPA used anticipated residues. EPA assumed all commodities with established or proposed tolerances were treated with trifloxystrobin.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that trifloxystrobin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of

pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trifloxystrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport 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>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), GENERIC Estimated Exposure Concentration (GENEEC), and/or Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of trifloxystrobin for the proposed new application are higher than those previously assessed for corn; however, the EDWCs for both corn rates are less than those previously estimated, via GENEEC, for turf use.

Based on the PRZM/EXAMS, GENEEC, and/or SCI-GROW models, the EDWCs of trifloxystrobin plus its major degradation product, CGA-321113 for acute exposures are estimated to be 47.99 parts per billion (ppb) and 47.31 ppb for chronic exposures. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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 uses that could result in residential exposures: ornamentals and turfgrass. EPA assessed residential exposure using the following assumptions: adult post application dermal exposure; child's post application dermal and/or hand to mouth. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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."

EPA has not found trifloxystrobin to share a common mechanism of toxicity with 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 assumed that trifloxystrobin does not have 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(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin. In the prenatal developmental study in rats, there was no developmental toxicity at the limit dose. In the prenatal developmental study in rabbits, developmental toxicity was seen at a dose that was higher than the dose that caused maternal toxicity. In the two generation reproduction study, there was no offspring toxicity at the highest dose tested.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for trifloxystrobin is complete except for neurotoxicity and immunotoxicity testing. Recent changes to 40 CFR part 158 make neurotoxicity and immunotoxicity testing required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Although acute and subchronic neurotoxicity and immunotoxicity studies are needed to complete the database, there are no concerns for immunotoxicity or neurotoxicity based on the results of the existing studies. The toxicological database for trifloxystrobin does not show any evidence of treatment-related effects on the immune system. There was a decrease in the incidence of hemosiderosis in the spleen of F0 and F1 parental males and females in the 2-generation reproduction study. The

effect was not seen in any other toxicity studies, and it was not a primary effect on the spleen. This decrease may indicate a decrease of red blood cell turnover; but it is not an effect on the immune system. Further, there was no evidence of neurotoxicity at the limit dose in an unacceptable acute neurotoxicity study or in the other subchronic and chronic studies in the database. The EPA does not believe that conducting neurotoxicity or immunotoxicity studies will result in a dose less than the PODs already used in this risk assessment and an additional database uncertainty factor for potential neurotoxicity and/or immunotoxicity does not need to be applied.

ii. There is no indication that trifloxystrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that trifloxystrobin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments utilize existing and proposed tolerance level residues and 100% crop treated information for all commodities, except for apples, oranges, and grapes which utilized anticipated residue levels for the chronic dietary. By using these screening-level assessments with minor refinement, actual exposures/risks from residues in food will not be underestimated. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to trifloxystrobin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of 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

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate

PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 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-term risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trifloxystrobin from food and water will utilize 15% of the cPAD for the general U.S. population and 43% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of trifloxystrobin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term 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 exposure through food and water with short-term residential exposures to trifloxystrobin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,200 for adults (dermal residential + dietary food and drinking water exposures); 680 for children 1 to 2 years old (dermal residential + dietary food and drinking water exposures); and 170 for children 1 to 2 years old (incidental oral + dietary food and drinking water exposures). Because EPA's level of concern for trifloxystrobin is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Trifloxystrobin is not expected to pose an intermediate-term risk based on a short soil half-life (approximately 2 days).

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, trifloxystrobin is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen phosphorus detection (GC/NPD)), Method AG-659A is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established a MRL for trifloxystrobin in or on maize fodder (dry) at 10 ppm. Canada has a proposed (not yet established) MRL of 0.02 for corn grain, sweet corn, popcorn grain for parent and metabolite. Since the Codex MRL is for a commodity that is not recognized domestically and would normally not be transported across international borders, there is no concern for international harmonization. Also, since the Canadian MRL has not been established, there is no concern for international harmonization.

C. Revisions to Petitioned-For Tolerances

Trifloxystrobin tolerances for crop commodities listed in 40 CFR 180.555(a)(1) are expressed in terms of the residues of the fungicide trifloxystrobin, benzenoacetic acid, (*E,E*)- α -(methoxyimino)-2-[[[1-[3-(trifluoromethyl) phenyl]ethylidene] amino]oxy]methyl]-, methyl ester, and the free form of its acid metabolite CGA-321113, (*E,E*)-methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino]oxy]methyl]-phenyl]acetic acid. EPA has revised the trifloxystrobin tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured.

EPA's analysis of the adequacy of the existing tolerances for meat, fat and meat byproduct of cattle, goats, horses, and sheep tolerances based on the proposed tolerances as well as existing tolerances indicates they need to be increased to 0.1 ppm from 0.05 ppm. Also, EPA is removing from paragraph (b), tolerances for soybean, forage; soybean, hay; and soybean, seed which expired and were revoked on December 31, 2009.

V. Conclusion

Therefore, existing tolerances in 40 CFR 180.555(a) are increased for residues of trifloxystrobin, benzenoacetic acid, (*E,E*)- α -(methoxyimino)-2-[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-methyl ester, in or on corn, field, forage at 6.0 ppm; corn, sweet, forage at 7.0 ppm; and corn, sweet, stover at 4.0 ppm. EPA is also removing paragraph (b) tolerances for soybean, forage; soybean, hay; and soybean, seed which expired December 31, 2009.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *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 tolerances 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 9, 2000) do not apply to this final rule. In addition, this final 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: May 27, 2010.

Daniel J. Rosenblatt, 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. Amend § 180.555 as follows:

a. Revise the introductory text of paragraph (a).

b. Revise the following entries in the table in paragraph (a): cattle, fat; cattle, meat; cattle, meat byproducts; corn, field, forage; corn, sweet, forage; corn, sweet, stover; goat, fat; goat, meat; goat, meat byproducts; horse, fat; horse, meat; horse, meat byproducts; and sheep, fat; sheep, meat; and sheep, meat byproducts.

c. Revise paragraph (b).

The revisions read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) General. Tolerances are established for residues of trifloxystrobin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of trifloxystrobin, benzeneacetic acid, (E,E)-α-(methoxyimino)-2-[[[1-[3-(trifluoromethyl) phenyl]ethylidene] amino]oxy]methyl]-, methyl ester, and the free form of its acid metabolite CGA-321113, (E,E)-methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneamino]oxy]methyl-phenyl]acetic acid, calculated as the stoichiometric equivalent of trifloxystrobin, in or on the commodity.

Table with 2 columns: Commodity and Parts per million. Lists various agricultural products like Cattle, Corn, Goat, Horse, and Sheep with their respective parts per million values.

(b) Section 18 emergency exemptions. [Reserved]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

Defense Federal Acquisition Regulation Supplement; New Designated Country—Taiwan—DFARS Case 2009-D010

AGENCY: Defense Acquisition Regulations System; Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is adopting, as final, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to add Taiwan as a designated country, due to the accession of Taiwan to membership in the World Trade Organization Government Procurement Agreement.

DATES: Effective date: June 11, 2010.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, Defense Acquisition