



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0215; FRL-9955-97]

Tioxazafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tioxazafen in or on corn, field, forage; corn, field, grain; corn, field, stover; cotton, gin byproducts; cotton, undelinted seed; soybean, forage; soybean, hay; soybean, meal; soybean, seed. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0215, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

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

Under FFDCCA 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-2015-0215 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0215, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *<http://www.epa.gov/dockets>*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8339) by Monsanto Company, 1300 I Street NW, Suite 450 East, Washington, DC 20005. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the nematicide tioxazafen, in or on cattle, fat at 0.01 parts per million (ppm); cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; corn, field, forage at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.01 ppm; soybean, forage at 0.15 ppm; soybean, hay at 0.30 ppm; soybean, meal at 0.05 ppm; and soybean, seed at 0.04 ppm. That document referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available in the docket, *<http://www.regulations.gov>*. One comment was received in

response to the notice of filing. The Agency's response to that comment is contained in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerance levels for corn, field, forage; corn, field, grain; and cotton, undelinted seed that differ from what the petitioner requested. In addition, the Agency determined tolerances were not necessary on cattle, fat; cattle, meat; cattle, meat byproducts; goat, fat; goat, meat; goat, meat byproducts; horse, fat; horse, meat; horse, meat byproducts, milk; sheep, fat; sheep, meat; and sheep, meat byproducts because of no expectation of residues. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other

relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tioxazafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tioxazafen 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.

Tioxazafen has low acute toxicity by the oral, dermal and inhalation routes of exposure. It is a mild eye irritant, nonirritating to the skin, and is not a dermal sensitizer.

The adrenal gland in male and female rats was the primary target organ in subchronic and chronic oral toxicity studies. These effects were also observed in the dermal and inhalation (28- and 90-day) toxicity studies. In male rats, adrenal effects included increased adrenal weights and adrenal vacuolation. Although female rats exhibited decreased rather than increased adrenal weights, there were no corresponding histological effects in adrenals of females in the 2-generation reproductive study or the chronic toxicity study to indicate adversity of the finding. The available studies suggest that the male rat may be more sensitive than females to the adrenal effects of tioxazafen.

Evidence of neurotoxicity (i.e., decreased locomotor activity) was observed in the acute neurotoxicity study in the rat. Decreased hindlimb splay observed in the rat

subchronic neurotoxicity study was not considered adverse, and there was no evidence of neurotoxicity in the rest of the database and no corroborating neuropathology.

Tioxazafen did not result in developmental effects in either rats or rabbits, and therefore, there is no quantitative or qualitative susceptibility. In rats, the only maternal effects were decreased adrenal weights, and decreased food consumption. No histology was performed on the adrenal to assess potential functional effects. There were no maternal effects in the rabbit of toxicological significance. No offspring toxicity was noted up to 60 milligram/kilogram/day (mg/kg/day) (highest dose tested (HDT)) in the 2-generation reproductive toxicity study.

In an immunotoxicity rat study, decreased serum IgM response (not statistically significant) was noted at the high dose and decreasing median values exhibited a clear dose-response. These findings provide an indication of perturbation/dis-regulation of the immunologic response.

Long-term dietary exposure to high doses of tioxazafen was associated with the development of malignant thoracic hibernomas in female rats, hepatocellular tumors in male and female mice, and hemangiosarcomas in male mice. Based on the observation of tumors in 2 species and both sexes without an adequate mode of action, EPA classified tioxazafen as “likely to be carcinogenic to humans” with a linear cancer slope factor (Q1*) of $9.63 \times 10^{-3} \text{ (mg/kg/day)}^{-1}$. Tioxazafen is not considered to be a mutagen.

Specific information on the studies received and the nature of the adverse effects caused by tioxazafen 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 the document, “Tioxazafen. Human Health Risk

Assessment for the First Food Uses on Corn, Cotton, and Soybean Seeds” (K. Rickard, 10/06/2016) in docket ID number EPA-HQ-OPP-2015-0215.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological Point of Departures (PODs) 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 the NOAEL and the LOAEL are identified. 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 tioxazafen used for human risk assessment is shown in Table 1 of this unit.

Table 1. --Summary of Toxicological Doses and Endpoints for Tioxazafen 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 (General population including infants and children)	LOAEL = 250 mg/kg/day UF _A = 10 UF _H = 10 FQPA SF/ UF _L = 10x	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Acute neurotoxicity - Rat LOAEL = 250 mg/kg/day based on decreased total motor and ambulatory activity counts (observed at time of peak)
Chronic dietary (All populations)	Parental NOAEL= 5.0 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Two-Generation Reproductive - Rat LOAEL = 20 mg/kg/day based on adrenal effects (increased weight and vacuolation of the adrenal gland) in males
Cancer (Oral, dermal, inhalation)	Classification: "Likely to be Carcinogenic to Humans" based on female mouse liver combined adenoma and/or carcinoma tumor rates. A linear low dose extrapolation model for risk assessment will be used with a unit risk, $Q^{1*} = 9.63 \times 10^{-3} (\text{mg/kg/day})^{-1}$ for female mouse liver combined adenoma and/or carcinoma tumor rates.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tioxazafen, EPA considered exposure under the petitioned-for tolerances in 40 CFR 180.

EPA assessed dietary exposures from tioxazafen 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 for tioxazafen. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined acute dietary assessment using tolerance-level residues, 100 PCT assumptions, and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA conducted an unrefined chronic dietary assessment, using tolerance-level residues, 100 PCT assumptions, and default processing factors.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that tioxazafen should be classified as “Likely to be Carcinogenic to Humans” and a linear

approach has been used to quantify cancer risk. Unrefined cancer dietary assessments were conducted using tolerance-level residues, 100 PCT assumptions, and default processing factors.

iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for tioxazafen. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tioxazafen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tioxazafen. 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 in Water Calculator (PWC v1.52) consisting of a graphical user interface shell integrating PRZM v.5.02 and VVWMv.1.02.1, the estimated drinking water concentrations (EDWCs) of tioxazafen for acute exposures are estimated to be 4.89 parts per billion (ppb) for surface water and 0.0756 ppb for ground water. For chronic exposures for non-cancer assessments the EDWCs are estimated to be 0.61 ppb for surface water and there was no breakthrough for ground water. Chronic exposures for cancer assessments are estimated to be 0.38 ppb for surface water and there was no breakthrough for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 4.89 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 0.61 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 0.38 ppb was used to assess the contribution to drinking water.

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

Tioxazafen is not registered for any specific use patterns that would result in residential exposure.

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 tioxazafen to share a common mechanism of toxicity with any other substances, and tioxazafen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tioxazafen 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 Food Quality Protection Act Safety Factor (FQPA 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.* No evidence of quantitative or qualitative increased susceptibility, as compared to adults, was observed in fetuses as a result of *in utero* exposure in developmental toxicity studies in rats or rabbits, or in offspring as a result of potential *in utero* or postnatal exposure in a reproduction study in rats.

3. *Conclusion.* EPA is retaining the 10X FQPA SF for acute exposure scenarios to account for extrapolation to a NOAEL from a LOAEL. For other exposure durations and routes, 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 based on the following findings:

- i. The toxicology database for tioxazafen is complete.
- ii. Tioxazafen did not result in developmental effects in either rats or rabbits, therefore, there is no evidence of increased qualitative or quantitative susceptibility in the developing fetus. No offspring toxicity was noted up to 60 mg/kg/day (highest dose tested) in the 2-generation reproductive toxicity study.
- iii. There is low concern for neurotoxicity. In the acute neurotoxicity study in the rat, decreased locomotor activity was noted and decreased hind limb splay was observed

in the rat subchronic neurotoxicity study at week 3 evaluations; however, this effect was not considered adverse since there was no dose response relationship, the response was variable, nonpersistent, and not observed in the 90-day subchronic rat oral toxicity study, and no additional neurotoxicity data are required.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tioxazafen in drinking water. These assessments will not underestimate the exposure and risks posed by tioxazafen.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tioxazafen will occupy <1% of the aPAD for all infants <1-year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tioxazafen from food and

water will utilize <1% of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for tioxazafen.

3. *Short-term risk.* Because there are no residential exposures to tioxazafen, a short-term aggregate risk assessment was not conducted.

4. *Intermediate-term risk.* Because there are no residential exposures to tioxazafen, an intermediate-term aggregate risk assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* Using a linear low-dose extrapolation model (Q_1^*) was used to estimate cancer risk, with a $Q_1^* = 9.63 \times 10^{-3}$ (mg/kg/day)⁻¹, the Agency estimates cancer risk to Adults 20-49 years old to be 5×10^{-7} . EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible.

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 tioxazafen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available to enforce the proposed tolerances for tioxazafen and benzamidine in plant commodities. The proposed plant enforcement method, Method 115G8064A, employs a single extraction and determinative step for both analytes. This method was successfully validated by an independent laboratory.

Adequate enforcement methodology (electrospray ionization liquid chromatography with mass spectrometric detection (ESI LC-MS/MS) in positive ion mode) is available to enforce the tolerance expression.

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 FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for tioxazafen.

C. Response to Comments

EPA received one comment on the Notice of Filing objecting, without any supporting information, to the establishment of these tioxazafen tolerances for concerns about the toxicity of chemicals generally. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned from use on agricultural crops. The existing legal framework provided by section 408 of the FFDC, however, states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. EPA has evaluated the available data, assessed the effects of this chemical on human health, and determined that aggregate exposure to it will be safe. The commenter has not provided any information to support altering that safety finding.

D. Revisions to Petitioned-For Tolerances

Some of the petitioned-for tolerance levels in the Notice of Filing differ from those currently being set by the Agency. Specifically, the Agency has determined that no livestock tolerances are needed as there is no reasonable expectation of finite residues in those commodities. Further, for corn and cotton raw agricultural commodities, the appropriate tolerance level needs to be the sum of the level of quantification of tioxazafen and benzamidine (0.02 ppm) rather than 0.01 ppm.

V. Conclusion

Therefore, tolerances are established for residues of tioxazafen, in or on corn, field, forage at 0.02 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm; soybean, forage at 0.15 ppm; Soybean, hay at 0.30 ppm; soybean, meal at 0.05 ppm and soybean, seed at 0.04 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: April 10, 2017.

Richard P. Keigwin, Jr.,

Acting Director, 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. Add § 180.692 to subpart C to read as follows:

§ 180.692 Tioxazafen; tolerances for residues.

(a) *General.* Tolerances are established for residues of tioxazafen, 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 the combined residues of tioxazafen [3-phenyl-5-(2-thienyl)-1,2,4-oxadiazole] and benzamidine, expressed as tioxazafen in or on the commodity.

Commodity	Parts per million
Corn, field, forage	0.02
Corn, field, grain	0.02
Corn, field, stover	0.02
Cotton, gin by-products	0.02
Cotton, undelinted seed	0.02
Soybean, forage	0.15
Soybean, hay	0.30
Soybean, meal	0.05
Soybean, seed	0.04

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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