Rule

Trifloxystrobin; Pesticide Tolerances

A Rule by the Environmental Protection Agency on 09/03/2014

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ACTION

Final Rule.

SUMMARY

This regulation establishes tolerances for residues of trifloxystrobin in or on pea, dry, seed; pea, field, hay; and pea, field, vines. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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RELATED TOPICS

- Administrative practice and procedure
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Regulations.gov Docket Info

Docket Number
EPA-HQ-OPP-2013-0504

Docket Name
Trifloxystrobin – New use on dry pea, chickpea, and lentil

Supporting/Related Materials
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This regulation is effective September 3, 2014. Objections and requests for hearings must be received on or before November 3, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

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The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0504, 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*.

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SUPPLEMENTARY INFORMATION:

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I. General Information

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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*.

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-2013-0504 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 November 3, 2014. 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-2013-0504, 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

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In the **Federal Register** of October 25, 2013 (78 FR 63938) (FRL-9901-96), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8180) 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 establishing tolerances for residues of the fungicide trifloxystrobin, benzeneacetic acid, (E, *E*)-α-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene] amino]oxy]methyl]-, methyl ester, and the free form of its acid metabolite CGA-321113, (E,E)-methoxyimino-[2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid, calculated as the stoichiometric equivalent of trifloxystrobin, in or on pea, dry, seed at 0.06 parts per million (ppm); pea, field, hay at 15 ppm; pea, field, vines at 4.0 ppm; chickpea, seed at 0.06 ppm; and lentil, seed at 0.06 ppm. That document 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 review of the data supporting the petition, EPA has corrected proposed commodity definitions and eliminated certain proposed crop tolerances. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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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 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 their 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 and a mild dermal and eye irritant. 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. Liver effects characterized by an increase in liver weights and an increased incidence of hepatocellular hypertrophy and/or hepatocellular necrosis were seen in rats, mice, and dogs.

There is no concern for neurotoxicity or immunotoxicity in the database. In the rabbit developmental toxicity study, an increase in the incidence of fused sternabrae was seen at a dose 10 times higher than the maternal lowest observed adverse effect level (LOAEL). In the rat reproduction study, both parents and offspring showed decreases in body weight during lactation. The rat and rabbit developmental and the rat reproduction toxicity data do not demonstrate an increase in susceptibility in the fetus or other offspring.

Trifloxystrobin is classified as: “Not likely to be Carcinogenic to Humans” based on negative results in:

1. The battery of mutagenicicty tests (except at a cytoxic dose in one *in vitro* test), and

2. The long-term carcinogenicity studies in rats and mice.

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 are discussed in the final rule published in the **Federal Register** of June 11, 2010 (75 FR 33190) (FRL-8829-2) and in the document “Trifloxystrobin. Aggregate Human Health Risk Assessment for the Proposed New Uses on Chickpea, Dry Peas, and Lentils with Updated Residential Risk Estimates of All Existing Residential Uses (Lawns/Turf; Gardens and Trees),” dated June 10, 2014, Appendix A, pp. 27-31 in docket ID number EPA-HQ-OPP-2013-0504.

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 was discussed in Unit III B. of the final rule published in the **Federal Register** of June 11, 2010. However, subsequent to that **Federal Register** publication, EPA reassessed the liver effects seen in the 28-day dermal toxicity study according to current policy, and determined that since these effects should not be considered adverse, no toxicity endpoint was identified. The NOAEL for the 28-day dermal study was set at 1,000 mg/kg/day and the LOAEL was not established. Therefore, the endpoints assessed as part of this action exclude the endpoint for dermal exposure identified in the table published in the above-referenced **Federal Register** on June 11, 2010.

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. Such effects were identified for trifloxystrobin. In estimating acute dietary (food and water) exposure for females 13-49 years old, EPA conducted an analysis using the Dietary Exposure Evaluation Model (DEEM-FCID) Version 3.16. This model uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). An acute dietary assessment was conducted assuming tolerance level residues (plus the

additional metabolite residues as noted in this paragraph) and 100 percent crop treated (PCT) for all commodities. For the dietary assessment, a value of 0.20 ppm for the metabolite L7a was added to the tolerance level for meat byproducts of cattle, goats, horses, and sheep to account for the higher residues in liver; therefore, these commodities were assessed in the dietary assessments at 0.3 ppm. Pork was assessed in the DEEM at the established tolerance level of 0.05 ppm; pork, liver was assessed at 0.16 ppm to account for the residues of the metabolite L7a. DEEM version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model (DEEM-FCID) Version 3.16. This model uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). A chronic dietary exposure assessment was conducted assuming 100 PCT, anticipated residues (ARs) for grapes, apples, oranges, and pears, and tolerance level residues for the rest of the commodities, including additional metabolite residues as noted in this paragraph. A value of 0.20 ppm for the metabolite L7a was added to the tolerance level for meat byproducts of cattle, goats, horses, and sheep to account for the higher residues in liver; therefore, these commodities were assessed in the dietary assessments at 0.3 ppm. Pork was assessed in the DEEM at the established tolerance level of 0.05 ppm; pork, liver was assessed at 0.16 ppm to account for residues of the metabolite L7a. DEEM version 7.81 default processing factors were assumed except for where tolerances were established for processed commodities.

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 (AR) and 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.

EPA used anticipated residue information in the chronic dietary assessment for trifloxystrobin for grapes, apples, oranges, and pears.

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) and PRZMGround Water (PRZM-GW) models, the estimated drinking water concentrations (EDWCs) of total toxic residues of trifloxystrobin and its major degradation product for acute exposures are estimated to be 29 parts per billion (ppb) for surface water and 427 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 23 ppb for surface water and 365 ppb 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 427 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 365 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).

Trifloxystrobin is currently registered for the following uses that could result in residential exposures: Ornamentals and turfgrass. EPA assessed residential exposure from relevant registered trifloxystrobin products using the Agency's 2012 Residential Standard Operating Procedures (SOPs) along with updates in dermal risk assessment hazard and policy regarding body weight in addition to the following assumptions:

i. *Residential handler exposures.* Residential handler exposure is expected to be short-term only. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Dermal handler exposures were not assessed since no adverse systemic dermal hazard was identified for trifloxystrobin.

ii. *Residential post-application exposures.* Since dermal hazard has not been identified for trifloxystrobin, a

quantitative post-application assessment for dermal exposure is not necessary and the only exposure scenarios quantitatively assessed are for children 1 to <2 years old who may experience short-term incidental oral exposure to trifloxystrobin from treated turf. Incidental oral granule ingestion is not applicable because there is no endpoint identified for the acute dietary duration. Intermediate-term incidental oral post-application exposures are not expected because trifloxystrobin is not persistent in soil or water; furthermore, the short-term incidental oral risk estimates would be protective of the possible intermediate-term incidental oral exposures because the POD for both durations is the same. Post-application inhalation exposure is expected to be negligible for the proposed residential uses.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: *http://www.epa.gov/pesticides/science/residential-exposure-sop.html*

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 Web site 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 quantitative or qualitative susceptibility to trifloxystrobin in rats or rabbits. In the prenatal developmental study in rats, there was no developmental toxicity at and up to the limit dose. In the prenatal developmental study in rabbits, developmental toxicity was seen at a dose that was higher than the dose causing maternal toxicity. In the multigeneration study, offspring and parental LOAELs are at the same dose level.

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. The Agency has waived requirements for a subchronic neurotoxicity study because:

a. Trifloxystrobin was not neurotoxic in the acute neurotoxicity study, nor in any of the repeated dose studies in the available data,

b. There is no evidence of neurotoxicity in the existing trifloxystrobin database or that of other strobilurin pesticides, and

c. Because endpoints and PODs used for risk assessment are likely to be protective of neurotoxicity concerns. EPA has also waived requirements for subchronic inhalation testing. Trifloxystrobin exhibits low toxicity (Category IV) via inhalation route of exposure.

ii. There is no indication that trifloxystrobin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Adverse effects were not seen up to the limit dose in an acute neurotoxicity study. There is no evidence of neurotoxicity in subchronic and chronic toxicity studies (rats, dogs, mice), in developmental toxicity studies (rats, rabbits), or in a reproductive toxicity study (rats). There is no concern for neurotoxicity of trifloxystrobin based on the available database.

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 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are complete or are estimated based on data that reasonably account for potential exposures. The exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of trifloxystrobin. The acute and chronic dietary food exposure assessment was conservatively based on 100 PCT assumptions

and conservative ground water drinking water modeling estimates. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations, and are not likely to be exceeded. In addition, the residential post-application assessment is based upon the residential SOPs employing surrogate study data and reasonable "worst-case" assumptions. These data and assessments are reliable and are not expected to underestimate exposure and risk posed by trifloxystrobin to adults or children as well as incidental oral exposure of young children (1-2 years old).

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. With the exception of the subpopulation group, females 13 to 49 years old, 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 1.3% of the aPAD for females 13-49 years old.

2. *Chronic 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 32% of the cPAD for the general U.S. population and 78% for all infants <1 year 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 for adults of 300 (from food, water and residential inhalation exposures) and for children 120 (from food, water and residential incidental/hand-to-mouth oral exposure). 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).

Although the Agency identified an intermediate-term endpoint, the Agency does not expect trifloxystrobin to result in intermediate-term residential exposure, due to the intermittent nature of homeowner applications and its short soil half-life (about 2 days). Therefore, the Agency relies on the chronic risk assessment to account for intermediate-term risk and concludes that trifloxystrobin does not pose an intermediate-term aggregate risk.

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

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A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method with nitrogen phosphorus detection (GC/NPD), Method AG-659A) is available to enforce the tolerances for the combined residues of trifloxystrobin and CGA-321113 in plant and livestock commodities. Subject crops under this action were analyzed for residues of trifloxystrobin and CGA-321113 using a high performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS). The lowest level of method validation (LLMV) is equivalent to the limit of quantitation (LOQ) which is 0.010 ppm for each analyte in/on all matrices.

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; email 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 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for trifloxystrobin on the crops subject to this action.

C. Revisions to Petitioned-For Tolerances

EPA determined that the proposed tolerances for chickpea hay and vines are not needed since both commodities are not significant livestock feed items. In addition, the proposed tolerances on chickpea seed and lentil seed are not needed since pea, dry, seed under the definition in 40 CFR 180.1 includes these commodities.

To reflect the correct commodity definitions, EPA revised the proposed commodity listings for “pea, dry, hay” and “pea, dry, vines” to read: “pea, field, hay” and “pea, field, vines”, respectively.

V. Conclusion

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Therefore, tolerances are established for 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-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl]acetic acid, calculated as the stoichiometric equivalent of trifloxystrobin, in or on pea, dry, seed at 0.06 ppm; pea, field, hay at 15 ppm; and pea, field, vines at 4 ppm.

VI. Statutory and Executive Order Reviews

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This final rule 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 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 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 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 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 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) (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 of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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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

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- Environmental protection
- Administrative practice and procedure
- Agricultural commodities

Pesticides and pests

- Reporting and recordkeeping requirements

Dated: August 25, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

begin regulatory text

PART 180—[AMENDED]

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

Authority:

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

2. In § 180.555, add alphabetically the following entries to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerance for residues.

(a) * * *

Commodity	Parts per million
*****	
Pea, dry, seed	0.06
Pea, field, hay	15
Pea, field, vines	4
*****	

* * * * *

end regulatory text

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