

consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

### VIII. 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: October 24, 2016.

**Daniel J. Rosenblatt,**

*Acting 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. In § 180.910, add alphabetically the inert ingredient “Iron oxide yellow (CAS Reg. No. 20344–49–4)” to the table to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* * *	* * *
Iron oxide yellow (CAS Reg. No. 20344–49–4).	Not to exceed 0.15% by weight of pesticide formula- tion.	Colorant in pesticide formulations for varroa mite control around bee hives
* * *	* * *	* * *

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2015–0745; FRL–9954–04]

#### Trifloxystrobin; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of trifloxystrobin in or on Cottonseed subgroup 20C; Cotton, gin byproducts; and amends the existing tolerance on Corn, field, forage. Bayer CropScience LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 10, 2016. Objections and requests for hearings must be received on or before January 9, 2017, 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–2015–0745, 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](mailto: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](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–2015–0745 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 January 9, 2017. 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-2015-0745, 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 June 22, 2016 (81 FR 40594) (FRL-9947-32), 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 5F8380) by Bayer CropScience, 2 TW 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 in or on cotton, undelinted seed, (Crop subgroup 20C) at 0.5 parts per million (ppm); cotton, gin byproducts at 3 ppm; and revising the existing tolerance for corn, field, forage from 6 ppm to 8 ppm. That document referenced a summary of the petition prepared by Bayer CropScience LP, the registrant, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has corrected the commodity definitions for the requested cotton commodities. The reason for these changes is 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 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 and a mild dermal and eye irritant. In repeated dose studies in rats, mice, and dogs, liver effects and reduced body weights along with reduction in food consumption are the common findings for trifloxystrobin. Liver effects included an increase in liver weights and an increased incidence of hepatocellular hypertrophy and/or hepatocellular necrosis. 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), while no developmental effects was seen in the rat developmental study at a limit dose. 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 both the negative results in the battery of mutagenicity tests (except at a cytotoxic dose in one in vitro test), and from the long-term carcinogenicity studies in rats and mice. There is no concern for neurotoxicity or immunotoxicity in the database.

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 document "Trifloxystrobin. Human Health Risk Assessment for the Proposed New Use on Cottonseed Subgroup 20C and a Tolerance Amendment on Corn Field Forage.," dated September 13, 2016.

### 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 discussed in Unit III B of the final rule published in the **Federal Register** of June 11, 2010 (75 FR 33192) (FRL-8829-2). 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 these effects should not be considered adverse. The NOAEL for the 28-day dermal study was set at 1,000 mg/kg/day, and a LOAEL was not established. Because the Agency no longer considers there to be a toxic endpoint for dermal exposure, 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 exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA conducted the acute dietary assessment assuming tolerance level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. As to residue levels in food, EPA assumed 100% crop treated, tolerance level residues, average residues for some crops, and default processing factors.

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 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 PRZM/EXAMS (Pesticide Root Zone Model)/(Exposure Analysis Modeling System) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of trifloxystrobin for acute exposures are estimated to be 29 parts per billion (ppb) for surface water and 427 ppb for ground water, respectively. For chronic non-cancer exposure assessments, EDWCs 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: ornamental plants 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 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.* Because 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 for infants and children. 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/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 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 up to or at 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.

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.

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 chronic dietary food exposure assessment was conservatively based on 100%CT 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. The Residential SOPs are based upon reasonable "worst-case" assumptions and are not expected to underestimate risk. These data are reliable and are not expected to underestimate risk to adults or children.

#### *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 trifloxystrobin will occupy 5% of the aPAD for 13–49 year old females, 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 trifloxystrobin from food and water will utilize 71% of the cPAD for 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 of 290 for adults and 130 for children 1–<2 years old. 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). An intermediate-term aggregate risk assessment (1 to 6 months of exposure to trifloxystrobin residues from food, drinking water, and residential pesticide uses) is not expected to occur based on the intermittent nature of homeowner applications, and the short soil half-life of trifloxystrobin (about 2 days). Therefore, an intermediate-term aggregate risk assessment was not performed.

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 for the combined residues of trifloxystrobin and CGA–321113 in plant and livestock commodities. The lowest level of method validation (LLMV) is equivalent to the limit of quantitation (LOQ) which was 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](mailto: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 a MRL for trifloxystrobin on cotton, gin byproducts; cottonseed subgroup 20C; or corn, field, forage.

#### C. Response to Comments

The Agency received one anonymous public comment suggesting that we deny this tolerance because there are “too many toxic chemicals applied to food with no accurate long term tests that show any safety at all.” No supporting data was included to support this comment.

The Agency considered a complete set of scientific data to assess the risk of this chemical and these new uses. These data, along with conservative models/assumptions, were used to assess the safety of these tolerances. The Agency understands the commenter’s concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA 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. The citizen’s comments appear to be directed at the underlying statute and not EPA’s implementation of it; the citizens have made no contention that EPA has acted in violation of the statutory framework.

#### D. Revisions to Petitioned-for Tolerances

The Agency is revising the commodity definitions for the requested tolerances to reflect the common commodity vocabulary currently used by the Agency. Specifically, the requested “Cotton, undelinted seed (Crop subgroup 20C)” was changed to “Cottonseed subgroup 20C”; the requested “Cotton, Gin By-products” was changed to “Cotton, gin byproducts”.

#### V. Conclusion

Therefore, tolerances are established for residues of trifloxystrobin, benzeneacetic acid, (*E,E*)- $\alpha$ -(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]oxymethyl]-phenyl]acetic acid, calculated as the stoichiometric equivalent of trifloxystrobin, in or on cottonseed subgroup 20C at 0.50 ppm; cotton, gin byproducts at 3.0 ppm. The existing corn, field, forage tolerance of 6.0 parts per million (ppm) is increased to 8.0 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: October 21, 2016.

**Michael Goodis,**

*Acting 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. In § 180.555, in the table in paragraph (a):

■ a. Revise the entry for “Corn, field, forage”;

■ b. Add alphabetically entries for “Cotton, gin byproducts” and “Cottonseed subgroup 20C”.

The revisions and additions read as follows:

**§ 180.555 Trifloxystrobin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * *	*
Corn, field, forage .....	8.0
* * * *	*
Cotton, gin byproducts .....	3.0
Cottonseed subgroup 20C ...	0.50
* * * *	*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2015-0631; FRL-9954-58]

#### Di-n-butyl Adipate; Exemption From the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of di-n-butyl adipate (CAS Reg. No. 105-99-7) when used as an inert ingredient (plasticizer) at a concentration of not more than 25% by weight in pesticide formulations intended for varroa mite control around bee hives. Bayer Healthcare, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of di-n-butyl adipate.

**DATES:** This regulation is effective November 10, 2016. Objections and requests for hearings must be received on or before January 9, 2017, 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-2015-0631, 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: [RDfRNtices@epa.gov](mailto:RDfRNtices@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 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](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-2015-0631 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 January 9, 2017. 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-2015-0631, 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. Petition for Exemption

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10838) by Bayer Healthcare, LLC, Animal Health Division, P.O. Box 390 Shawnee Mission, KS 66201. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of di-n-butyl adipate, (CAS Reg. No. 105-99-7) when used as an inert ingredient (plasticizer) intended for varroa mite control around bee hives. That document referenced a summary of the petition prepared by Bayer Healthcare, LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

##### III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and