

Nitrogen dioxide, Ozone, Volatile organic compounds.

Dated: February 21, 2020.

**Kurt A. Thiede,**

*Regional Administrator, Region 5.*

Amend 40 CFR part 52 as follows:

**PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS**

■ 1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.1170, the table in paragraph (e) is amended by revising the three entries for “1997 8-hour ozone” under “Maintenance Plans” to read as follows:

**§ 52.1170 Identification of plan.**

\* \* \* \* \*  
(e) \* \* \*

**EPA-APPROVED MICHIGAN NONREGULATORY AND QUASI-REGULATORY PROVISIONS**

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
*	*	*	*	*
<b>Maintenance Plans</b>				
1997 8-hour ozone .....	Benzie County, Flint, Grand Rapids, Huron County, Kalamazoo-Battle Creek, Lansing-East Lansing, and Mason County.	7/24/2019 .....	3/6/2020, [insert Federal Register citation].	2nd limited maintenance plan.
1997 8-hour ozone .....	Benton Harbor, Cass County, and Muskegon	6/13/2006, 8/25/2006, and 11/30/2006.	5/16/2007, 72 FR 27425.	
1997 8-hour ozone .....	Detroit-Ann Arbor .....	3/6/2009 .....	6/29/2009, 74 FR 30950.	
*	*	*	*	*

\* \* \* \* \*  
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**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2019-0130; FRL-10004-08]

**Trifloxystrobin; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of trifloxystrobin in or on pea and bean, dried shelled, except soybean, subgroup 6C. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 6, 2020. Objections and requests for hearings must be received on or before May 5, 2020, 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-2019-0130, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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 Publishing 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-2019-0130 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 May 5, 2020. 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-2019-0130, 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 7, 2019 (84 FR 26630) (FRL-9993-93), 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 8F8729) by Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide, 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]oxy]methyl)-phenyl]acetic acid) in or on dried shelled pea and bean (except soybean) subgroup 6C at 0.06 parts per million (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 modified the crop group name to be consistent with Agency nomenclature.

## 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.

On February 15, 2019 (84 FR 4340) (FRL-9985-23), EPA published in the **Federal Register** a final rule establishing a tolerance for residues of the fungicide trifloxystrobin in or on flax seed and amending an existing tolerance for aspirated grain fractions based on the Agency’s conclusion that aggregate exposure to trifloxystrobin is safe for the general population, including infants and children. See 84 FR 4340 (FRL-9985-23). That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, and Agency’s determination regarding the children’s safety factor, which have not changed. The Agency conducted a revised risk assessment to incorporate additional exposure to residues of trifloxystrobin approved since that rulemaking and including the use on pea and bean, dried shelled, except soybean, subgroup 6C.

EPA’s exposure assessments have been updated to include the additional exposure from use of trifloxystrobin from use on pea and bean, dried shelled, except soybean, subgroup 6C, *i.e.*, reliance on tolerance-level residues and an assumption of 100 percent crop treated (PCT). EPA’s aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water and from residential sources, although those latter exposures are not impacted by the new uses on pea and bean and thus have not changed since the last assessment. Further information about EPA’s risk assessment and determination of safety supporting the tolerances established in the February 15, 2019 **Federal Register** action, as well as the new trifloxystrobin tolerance can be found at <http://www.regulations.gov> in the document entitled “Trifloxystrobin. Human Health Risk Assessment for the Proposed New Use on Flax Seed and Increase of Established Tolerance on Aspirated Grain Fractions,” dated October 31, 2018, in docket ID EPA-HQ-OPP-2017-0532.

Acute dietary risks are below the Agency’s level of concern: 3.4% of the acute population adjusted dose (aPAD) for females 13 to 49 years old, the only population group of concern. Chronic dietary risks are below the Agency’s level of concern: 58% of the chronic population adjusted dose (cPAD) for all infants less than 1 year old, the group with the highest exposure. There is not expected to be any handler exposure, and there is no adverse systemic hazard via the dermal route of exposure, so the only residential post-application scenario assessed was for the incidental short-term oral exposure of children 1 to less than 2 years old. Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs above the LOC of 100 for all scenarios assessed and are not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information on the subject action to establish a tolerance in or on pea and bean, dried shelled, except soybean, subgroup 6C can be found in the document entitled, “Trifloxystrobin. Human Health Aggregate Risk Assessment for New Use on Dry Beans and Proposed Crop Group Expansion from Dry Pea to Crop

Subgroup 6C” by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0130.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

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

Codex has established a MRL of 0.01 ppm for several of the commodities in subgroup 6C with the exception of broad bean, chickpea, cowpea, guar, lupin, blackeyed pea, crowder pea, pigeon pea and southern pea for which no MRL is established. U.S. tolerances for residues in the commodities of subgroup 6C are not harmonized with Codex. Since the Codex MRL is significantly lower for some commodities, harmonization is not possible because lowering the U.S. tolerance could cause U.S. growers to have violative residues despite legal use of the pesticide.

#### V. Conclusion

Therefore, tolerances are established for residues of trifloxystrobin in or on pea and bean, dried shelled, except soybean, subgroup 6C at 0.06 ppm.

Additionally, the existing tolerance on “pea, dry, seed” is removed as unnecessary since it is part of the new subgroup 6C tolerance.

#### VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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: February 6, 2020.

**Michael Goodis,**

*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, amend the table in paragraph (a) as follows:

- a. Add alphabetically the entry for “Pea and bean, dried shelled, except soybean, subgroup 6C”; and
- b. Remove the entry for “Pea, dry, seed”.

The addition reads as follows:

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

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Pea and bean, dried shelled, except soybean, subgroup 6C ....	0.06
* * * * *	*

[FR Doc. 2020-04208 Filed 3-5-20; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 710

[EPA-HQ-OPPT-2018-0320; FRL-10005-48]

RIN 2070-AK21

### Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

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

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing requirements for regulated entities to substantiate certain confidential business information (CBI) claims made under the Toxic Substances Control Act (TSCA) to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory, and the Agency's plan for reviewing certain CBI claims for specific chemical identities. The substantiation requirements describe the applicable procedures and provide instructions for regulated entities. The Agency's plan sets out the review criteria and related procedures that EPA will use to complete the reviews within the five-year timeframe set in TSCA.

**DATES:** This final rule is effective on May 5, 2020.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0320, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. 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 OPPT Docket is (202) 566-0280. Please review

the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

*For technical information contact:* Scott M. Sherlock, Environmental Assistance Division (Mail code 7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-8257; email address: [sherlock.scott@epa.gov](mailto:sherlock.scott@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

##### A. What action is the Agency taking?

This final rule establishes the CBI substantiation requirements for manufacturers (which under TSCA includes importers) and processors who claimed specific chemical identities as CBI in previously filed Notices of Activity (NOAs) Form A (Ref. 1) in accordance with the 2017 TSCA Inventory Notification (Active-Inactive) Requirements rule (hereinafter "2017 Active-Inactive Rule," which is summarized in more detail in Unit III and codified in 40 CFR part 710, subpart B) (Ref. 2). This final rule also amends the existing CBI substantiation requirements for manufacturers and processors who have filed or will file NOAs Form B (Ref. 3) and claimed or claim specific chemical identities as CBI. Manufacturers and processors who previously provided substantiations in NOAs Form A or B for CBI claims for specific chemical identities pursuant to the 2017 Active-Inactive Rule will be required to supplement those substantiations to include responses to two new questions related to a specific chemical identity's susceptibility to reverse engineering. All substantiations must be submitted to the Agency using EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal.

This final rule describes the Agency's plan to review the CBI claims for specific chemical identities that were asserted in NOAs Form A during the one-time retrospective reporting period under the 2017 Active-Inactive Rule, including procedures for the Agency's publication of annual review goals and results. EPA will review each specific chemical identity CBI claim and substantiation, and approve or deny each claim consistent with the procedures and substantive criteria in

TSCA sections 8(b)(4) and 14 and 40 CFR part 2, subpart B.

EPA is amending the existing regulations in 40 CFR part 710, subpart B, and is adding provisions about the NOA Form A substantiation process and the Agency's review plan to a new subpart C.

##### B. What is the Agency's authority for taking this action?

EPA is issuing this rule pursuant to the authority in TSCA section 8(b), 15 U.S.C. 2607(b).

##### C. Why is the Agency taking this action?

TSCA section 8(b)(4)(C) requires EPA to promulgate a rule that establishes the Agency's plan to review all CBI claims for the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory that were asserted in an NOA Form A pursuant to the one-time retrospective reporting under the 2017 Active-Inactive Rule. The 2017 Active-Inactive Rule required any reporter who sought to maintain an existing CBI claim for a specific chemical identity to assert that claim as part of the submission of an NOA Form A, but the rule did not require substantiation of those claims at that time. This final rule implements the statutory substantiation and review requirements so as to ensure that only those specific chemical identities that currently qualify for confidential treatment are protected from disclosure by the Agency.

This final rule also addresses a Federal court remand of the 2017 Active-Inactive Rule by amending that rule to add two substantiation questions which will be applicable to all NOA Form B reporters who seek to maintain an existing CBI claim for a specific chemical identity, and by including the same two questions in the newly finalized substantiation requirements for NOA Form A reporters who seek to maintain an existing CBI claim for a specific chemical identity. These substantiation questions address whether a specific chemical identity is readily discoverable through reverse engineering and will ensure the submission of information that EPA will use to evaluate CBI claims for specific chemical identities.

##### D. Who does this action apply to?

You may be affected by this action if you reported a confidential chemical substance under the 2017 Active-Inactive Rule using an NOA Form A or NOA Form B and sought to maintain an existing CBI claim for a specific chemical identity. You may also be affected by this action if you anticipate