PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.960, amend the table by adding in alphabetical order an entry for the polymer ''Acetic acid ethenyl ester, polymer with ethene, N-(hydroxymethyl)-2-propenamide, and 2-propenamide, (AM–E–NMA–VA) minimum number average molecular weight (in amu), 5500'' to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO § 180.960

Polymer	CAS No.
* * * * * * *	
Acetic acid ethenyl ester, polymer with ethene, N-(hydroxymethyl)-2-propenamide, and 2-propenamide, (AM–E–NMA–VA) minimum number average molecular weight (in amu), 5500.	CAS. Reg. No. 49603–78–3.
* * * * * * *	

[FR Doc. 2022–00312 Filed 1–10–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0038; FRL–9086–01–OCSPP]

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trifloxystrobin in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective January 11, 2022. Objections and requests for hearings must be received on or before March 14, 2022, 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–2020–0038, is available at *https://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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2020–0038 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 March 14, 2022. 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–2020–0038, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of September 10, 2020 (85 FR 55810) (FRL–10013–78), 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 9E8792) by Bayer CropScience, 800 N Lindbergh Blvd., St. Louis, MO 63141. The petition requested that 40 CFR 180.555 be amended by establishing tolerances for residues of the fungicide trifloxystrobin in or on the following raw agricultural commodities: Caneberry, Crop Subgroup 13–07A at 3.0 parts per million (ppm); Currant, black and red, at 4.0 ppm; Edible-Podded Legume Vegetables, Crop Subgroup 6A, at 1.5 ppm; Oil, olive, refined at 0.5 ppm; Pea, dry, seed at 0.2 ppm; Succulent shelled pea and bean, Crop Subgroup 6B at 0.15 ppm; and Tropical and Subtropical, Small fruit, edible peel, Crop Subgroup 23A at 0.2 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the petitioner, which is available in the docket for this action, docket ID number EPA–HQ–OPP–2020–0038, at *https://www.regulations.gov.* Two comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances for some commodities at different levels than requested by the petitioner and correcting some of the commodity definitions. Also, EPA is not establishing tolerances for two commodities. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 therein, 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.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for trifloxystrobin, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to trifloxystrobin and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by trifloxystrobin, can be found in the document titled ''Trifloxystrobin. Human Health Aggregate Risk Assessment for Use on Currant, Black and Red; Edible-Podded Legume Vegetables, Subgroup 6A; Succulent Shelled Pea and Bean, Subgroup 6B; Dried Shelled Pea; Caneberry, Subgroup 13–07A; Tropical and Subtropical, Small Fruit, Edible Peel, Subgroup 23A without U.S. Registration.'' dated September 29, 2021, which is available in the docket for this action at *https://www.regulations.gov.*

Toxicological profile. For a discussion of the Toxicological Profile of trifloxystrobin, see Unit III.A. of the trifloxystrobin tolerance rulemaking published in the **Federal Register** of February 15, 2019 (84 FR 4340) (FRL–9985–23) (Docket number EPA–HQ–OPP–2017–0530–0008).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit III.B. of the February 15, 2019 rulemaking.

Exposure assessment. Much of the exposure assessment remains the same since the February 15, 2019 rulemaking, although the new exposure assessment incorporates additional dietary exposures from the petitioned-for tolerances and reevaluates residential exposures based on approved label amendments. These updates are discussed in this section; for a description of the rest of EPA's approach to and assumptions for the exposure assessment, including with respect to residue data, percent crop treated (PCT), processing factors, estimated drinking water concentrations, and the Agency's conclusions about cumulative effects, see Unit III.C. of the February 15, 2019 rulemaking.

EPA's acute and chronic dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from residues of trifloxystrobin on the commodities identified in this action. The acute dietary assessment used the same assumptions described in the February 15, 2019 rulemaking concerning tolerance-level residues, 100% CT and default processing factors. As described in the February 15, 2019 rulemaking, the assumptions for the chronic dietary assessment included average field trial residues for selected crops, tolerance-level residues for all other crop commodities, default and empirical processing factors, and PCT data when available. Tolerance-level residues were used for the commodities identified in this action.

In the new chronic dietary exposure assessment, EPA assumed average field trial residues for apples, rice and commodities in subgroups 4A, 4B, 5A, 5B and 19A. The following average PCT estimates were used in the chronic dietary risk assessment for the crops for which trifloxystrobin is currently registered: Apples: 25%, apricots: 10%, cantaloupes 5%, carrots 2.5%, cotton:

10%, cherries: 25%, pop, sweet, and field corn: <2.5%, cucumbers: <2.5%, dry beans/peas: <1%, grapefruit: 30%, grapes: 25%; hazelnuts: 65%, oranges: 5%, peaches: <2.5%, peanuts: 5%, pears: 10%, pecans: 15%, peppers: 5%, plums/prunes: <2.5%, potatoes: <1%, pumpkins: 5%, rice: 15%, soybeans: 5%, squash: <2.5%, strawberries: 5%, sugar beets: 5%, sweet corn: <2.5%, tangerines: 5%, tomatoes: <2.5%, watermelons: 5%, and wheat: <2.5%. One hundred percent (100%) CT was assumed for the remaining commodities. Due to uncertainty in PCT data from California, PCT for almonds, walnuts, pistachio, celery, artichokes, and nectarine were set to 100%.

Anticipated residue and percent crop treated information. Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a 100 PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that Conditions a, b, and c discussed above have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which trifloxystrobin may be applied in a particular area.

Estimated drinking water concentrations have not changed since the February 15, 2019 rulemaking, because there will be no U.S. registrations for use of trifloxystrobin on the commodities identified in this action. The non-dietary (*i.e.,* residential) exposure assessment reevaluated residential exposures and risk based on approved label amendments reflecting a lower representative single maximum application rate of 0.34 lb ai/A for products with residential turf use sites. There was no adverse systemic hazard via the dermal route of exposure. The updated residential post-application risk estimates for children 1 to less than 2 years old were not of concern.

Safety factor for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children is adequately protected if the Food Quality Protection Act (FQPA) safety factor is reduced from 10X to 1X for all routes of exposure other than inhalation. The FQPA safety factor of 10X has been retained for inhalation endpoints only to account for the lack of the subchronic inhalation toxicity study for trifloxystrobin at this time. The reasons for this determination are articulated in Unit III.D. of the February 15, 2019 rulemaking.

Assessment of aggregate risks. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD: They are 3.4% of the aPAD at the 95th percentile of exposure for females 13 to 49 years old, which is the population subgroup with the highest exposure estimate. No other subpopulations were evaluated. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD: They are 58% of the cPAD for infants less than 1 year old, which is the population subgroup with the highest exposure estimate. Moreover, the short-term aggregate risk for the population subgroup with the highest total exposure (children 1 to less than 2 years old) is represented by an aggregate MOE of 120, which is not a risk of concern because EPA considers MOEs of 100 or less to be of concern; short-term aggregate risk calculations are protective of the intermediate-term duration of exposure. Chronic aggregate risk is equivalent to chronic dietary (food and drinking water) risk estimates, which are not of concern. Trifloxystrobin is classified as ''not likely to be carcinogenic to humans'' based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies; therefore, cancer exposure and risk assessments were not conducted at this time.

Determination of safety. 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 tolerances in or on Caneberry, subgroup 13–07A; Currant; Vegetable, legume, edible podded, subgroup 6A; Pea and bean, succulent shelled, subgroup 6B; and Tropical and subtropical, small fruit, edible peel, subgroup 23A can be found in the document entitled, ''Trifloxystrobin. Human Health Aggregate Risk Assessment for Use on Currant, Black and Red; Edible-Podded Legume

Vegetables, Subgroup 6A; Succulent Shelled Pea and Bean, Subgroup 6B; Dried Shelled Pea; Caneberry, Subgroup 13–07A; Tropical and Subtropical, Small Fruit, Edible Peel, Subgroup 23A without U.S. Registration.'' dated September 29, 2021 at *www.regulations.gov,* under docket ID number EPA–HQ–OPP–2020–0038.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the February 15, 2019 rulemaking.

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). Codex 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 tolerances for trifloxystrobin are not harmonized with Codex for every commodity identified in this action. No Codex MRLs have been established for residues of trifloxystrobin in or on Caneberry, subgroup 13–07A and Currant. The U.S. tolerance level for Vegetable, legume, edible-podded, subgroup 6A (1.5 ppm), calculated using the Organisation for Economic Co-operation and Development (OECD) MRL procedure, is much higher than the Codex MRL (0.01 ppm), and thus harmonization is not possible. Similarly, the U.S. tolerance level for Pea and bean, succulent shelled, subgroup 6B (0.2 ppm) is much higher than the Codex MRL (0.01 ppm for lima beans only), and thus harmonization is not possible. The U.S. tolerance level for Tropical and subtropical, small fruit, edible peel, subgroup 23A, is harmonized with the Codex MRL established in or on olives, a member of subgroup 23A, at 0.3 ppm.

C. Response to Comments

We received two comments regarding this import tolerance. A comment was received on September 10, 2020 regarding the absence of an analytical method and obtaining additional data. Analytical enforcement methodology is available for trifloxystrobin and is described in Unit IV.A. of the February 15, 2019 rulemaking (84 FR 4340) (FRL–9985–23). A risk assessment was conducted by EPA based on the well-characterized toxicology database for this active ingredient, and no risks of concern were identified. Tolerances are being set based on residue data and calculations using the OECD MRL calculation procedures.

An anonymous comment was received October 13, 2020, supporting the pesticide regulation. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the trifloxystrobin tolerances are safe.

D. Revisions to Petitioned-For Tolerances

The Agency is setting a tolerance for residues of trifloxystrobin in or on Caneberry, subgroup 13–07A at 2 ppm rather than the requested 3.0 ppm; in or on Currant at 3 ppm instead of the requested 4.0 ppm; and in or on Pea and bean, succulent shelled, subgroup 6B at 0.2 ppm rather than the requested 0.15 ppm based on values determined in accordance with the OECD MRL calculation procedures. A tolerance in or on Currant is being set rather than the petitioned-for ''Currant, black and red'' based on standard commodity definitions. Based on crop group revisions, the terminology Pea and bean, succulent shelled, subgroup 6B is used instead of the petitioned-for ''Succulent shelled pea and bean, subgroup 6B'' and Vegetable, legume, edible podded, subgroup 6A is used instead of the petitioned-for ''Edible-podded legume vegetables, subgroup 6A.'' The petitioned-for tolerance on ''Pea, dry seed'' is not being set because this commodity is covered by a tolerance that is already established for Pea and bean, dried shelled, except soybean, subgroup 6C. The tolerance in or on Tropical and subtropical, small fruit, edible peel, subgroup 23A tolerance is being set at 0.3 ppm rather than the petitioned-for 0.2 ppm to harmonize with the Codex MRL. The petitioned-for tolerance in or on Olive, oil is not being established because this commodity is covered by the tolerance established in this action for subgroup 23A.

V. Conclusion

Therefore, tolerances are established for residues of trifloxystrobin including its metabolites and degradates in or on Caneberry, subgroup 13–07A at 2 parts per million (ppm); Currant at 3 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.2 ppm; Tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.3 ppm; and Vegetable, legume, edible podded, subgroup 6A at 1.5 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). 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 tolerances for residues 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: January 5, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 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) by:

■ a. Adding in alphabetical order the entries for ''Caneberry, subgroup 13–07A''; ''Currant''; ''Pea and bean, succulent shelled, subgroup 6B''; ''Tropical and subtropical, small fruit, edible peel, subgroup 23A''; and ''Vegetable, legume, edible podded, subgroup 6A''.

■ b. Add footnote 4.

The additions read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Caneberry, subgroup 13–07A [4]	2
* * * * * * *	
Currant [4]	3
* * * * * * *	
Pea and bean, succulent shelled, subgroup 6B [4]	0.2
* * * * * * *	
Tropical and subtropical, small fruit, edible peel, subgroup 23A [4]	0.3
* * * * * * *	
Vegetable, legume, edible podded, subgroup 6A [4]	1.5
* * * * * * *	
[3] * * * * * * *	

[4] There are no U.S. registrations on this commodity as of January 11, 2022.

* * * * *

[FR Doc. 2022–00311 Filed 1–10–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1008

Medicare and State Health Care Programs: Fraud and Abuse; Procedures Regarding the Submission of Advisory Opinion Requests to, and the Issuance of Advisory Opinions by, OIG

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: OIG is amending the regulations governing the procedures for the submission of advisory opinion requests to, and the issuance of advisory opinions by, OIG.

DATES: This final rule is effective February 10, 2022.

FOR FURTHER INFORMATION CONTACT: Christina Hinkle, Office of Counsel to the Inspector General, (202) 465–6245.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 1128D of the Social Security Act (the Act),[1] HHS, through OIG, publishes advisory opinions regarding the application of the Federal anti-kickback statute [2] and the safe harbor provisions, as well as OIG's administrative sanction authorities, to parties' proposed or existing arrangements. More specifically, in consultation with the Department of Justice (DOJ) OIG issues written advisory opinions to requesting parties with regard to: (1) What constitutes prohibited remuneration under the Federal anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Act, or established by regulation (*i.e.,* safe harbors),[3] for activities that do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or

[1] 42 U.S.C. 1320a–7d.

[2] Section 1128B of the Act; 42 U.S.C. 1320a–7b(b).

[3] The safe harbor regulations are set forth at 42 CFR 1001.952.