83) then north returning to the point of origin.

(b) *Effective and enforcement period.* This section is effective and will be enforced from 9 p.m. through 11 p.m. on May 26, 2019.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Lake Michigan or a designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port Lake Michigan is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Lake Michigan to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Lake Michigan or an on-scene representative to obtain permission to do so. The Captain of the Port Lake Michigan or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Lake Michigan or an on-scene representative.

Dated: May 2, 2019.

Thomas J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 2019–09417 Filed 5–7–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0532; FRL–9990–60]

Cyflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide cyflumetofen in or on tea, dried. OAT Agrio. Ltd., Tokyo, Japan c/o Landis International, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 8, 2019. Objections and requests for hearings must be received on or before July 8, 2019 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–2017–0532, 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 L. Goodis, P.E., Director, Registration Division (750P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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–2017–0532 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 July 8, 2019. 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–2017–0532, 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 December 15, 2017 (82 FR 59604) (FRL–9970–50), 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 7E8609) by OAT Agrio. Ltd., Tokyo, Japan, c/o Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta,

Georgia 31603–5126. The petition requested that 40 CFR 180.677 be amended by establishing tolerances for residues of the insecticide cyflumetofen, (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), in or on tea at 40 parts per million (ppm). That document referenced a summary of the petition prepared by OAT Agrio. Ltd. c/o Landis International, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* These tolerances were requested to cover residues of cyflumetofen in or on tea resulting from use of this pesticide on tea outside the United States. There is no current U.S. registration for use of cyflumetofen on tea. Four comments were submitted to the docket concerning issues outside the scope of this rulemaking.

Based upon review of the data supporting the referenced petition, EPA is establishing a tolerance for residues of cyflumetofen on tea, dried.

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 cyflumetofen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflumetofen 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.

Cyflumetofen has a low acute toxicity via the acute oral, dermal, and inhalation routes of exposure. It is minimally irritating to the eyes but not to the skin. Cyflumetofen is a skin sensitizer. The major target organ in rats, mice, and dogs following short- and long-term oral administration of cyflumetofen is the adrenal glands characterized by increased organ weight and histopathology (vacuolation and hypertrophy of the adrenal cortical cells).

There is no evidence of increased qualitative or quantitative susceptibility in the rat 2-generation reproduction study; however, the rat and rabbit developmental studies indicate susceptibility in the pups. There is evidence of increased quantitative susceptibility in the rabbit developmental toxicity study, since developmental effects at the limit dose were observed where no maternal toxicity was present. There is evidence of increased qualitative susceptibility in the rat developmental toxicity study as developmental effects were seen at the same dose that caused an increase in adrenal weights and organ-to-body weight ratio in the maternal animals.

There is no evidence of neurotoxicity in any of the submitted studies for cyflumetofen.

Cyflumetofen has been classified as having ''Suggestive Evidence of Carcinogenic Potential'' in accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March 2005). This classification is based on the presence of a single tumor type (thyroid c-cell) in one sex (male) and one species (rat), and the lack of concern for mutagenicity. When there is suggestive evidence of carcinogenicity, the Agency does not attempt a dose-response assessment as the nature of the data generally would not support one. Therefore, the Agency has determined that quantification of risk using a non-linear approach (*i.e.,* the chronic reference dose) will adequately protect for all chronic toxicity, including carcinogenicity, likely to result from exposure to cyflumetofen.

More detailed information on the studies received and the nature of the adverse effects caused by cyflumetofen as well as the NOAEL and the LOAEL from the toxicological studies can be found in the document entitled, ''Cyflumetofen. Human Health Risk Assessment to Support New Uses on Imported Tea,'' dated March 4, 2019, 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–2017–0532. Double-click on the document to view the referenced information.

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 cyflumetofen used for human risk assessment is shown in the Table of this unit.

TABLE —SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYFLUMETOFEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (All Populations)	An acute RfD has not been established for either the general U.S. population or for females 13–49 years of age since there were no appropriate studies that demonstrated evidence of toxicity attributable to a single dose for these populations.		
Chronic dietary (All Populations)	NOAEL = 16.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.17 mg/kg/day. cPAD = 0.17 mg/kg/day	Three co-critical studies: 90-Day Feeding Study in Rats. LOAEL = 1,000 ppm (54.5/62.8 mg/kg/day in males/females) based on hematology and organ weight changes in the liver, adrenal, kidney and ovaries; and histopathology effects in the adrenals and the ovaries. NOAEL = 300 ppm (16.5/19 mg/kg/day in males/females). Chronic Toxicity/Carcinogenicity Study in Rats. LOAEL = 1,500 ppm (49.5/61.9 mg/kg/day in males/females) based on increased adrenal weights and histopathology. NOAEL = 500 ppm (16.5/20.3 mg/kg/day in males/females). Two-Generation Reproduction Study in Rats. Parental: LOAEL = 500 ppm (30.6/46.6 mg/kg/day in males/females) based on increased organ weight and histopathology in adrenals. NOAEL = 150 ppm (9.2/13.8 mg/kg/day in males/females).
Adult and Incidental Oral (Short- and Intermediate-Term).	NOAEL = 16.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100 ...	Same as chronic dietary endpoint.
Dermal (Short- and Intermediate-Term).	No dermal hazard was identified. No appropriate endpoint was selected for risk assessment.		
Inhalation (Short- and Intermediate-Term).	NOAEL = 16.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Occupational and Residential LOC for MOE = <100.	Same as chronic dietary endpoint.
Cancer (Oral, Dermal, and Inhalation)	Classification: ''*Suggestive Evidence of Carcinogenic Potential.*''		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

More detailed information on the toxicological endpoints for cyflumetofen can be found in the document entitled, ''Cyflumetofen. Human Health Risk Assessment to Support New Uses on Imported Tea,'' dated March 4, 2019, 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–2017–0532. Double-click on the document to view the referenced information.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyflumetofen, EPA considered exposure under the petitioned-for tolerances as well as all existing cyflumetofen tolerances in 40 CFR 180.677. EPA assessed dietary exposures from cyflumetofen in food as follows:

i. *Acute exposure.* No acute dietary exposure and risk analysis was performed since there were no appropriate studies identified in the toxicology database that demonstrated evidence of toxicity attributable to a single dose.

ii. *Chronic exposure.* An unrefined chronic dietary analysis was conducted that was based on tolerance-level residues, 100% crop treated (%CT) assumptions, and empirical processing estimates when available or DEEM™ processing factors. Using assumptions considered to be highly protective, the estimated dietary risks ranged from <1% of the cPAD for the general U.S. population to 2.4% of the cPAD for the highest exposed population subgroup of children 1–2 years old. The Agency's LOC is <100% cPAD.

iii. *Cancer.* As explained in unit III.A., quantification of risk using a non-linear approach (*i.e.,* a cPAD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to cyflumetofen.

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

More detailed information on the acute and chronic dietary (food only) exposure and risk assessment for cyflumetofen can be found in the document entitled, ''Cyflumetofen. Human Health Risk Assessment to Support New Uses on Imported Tea,'' dated March 4, 2019, 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–2017–0532. Double-click on the document to view the referenced information.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyflumetofen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyflumetofen. 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.*

The estimated drinking water concentrations (EDWCs) previously used in the dietary risk assessment were incorporated directly into this dietary assessment. The Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) simulations of a NY grapes scenario produced the highest surface-water EDWCs (0.33 ppb for chronic dietary exposure) and an updated EDWC was not required for this assessment since the proposed use on imported tea will not impact the previously provided estimates.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.33 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). The registered uses of cyflumetofen on ornamentals may result in adult residential handler and post-application exposure. This exposure is expected to be only short-term in duration (*i.e.,* 1 to 30 days) as intermediate- or long-term exposures are not likely based on the intermittent nature of applications by homeowners. Since no dermal hazard was identified for cyflumetofen in the toxicological database, only inhalation exposure assessments were conducted. The resulting inhalation margins of exposure (MOEs) for all scenarios are not of concern since they are above the level of concern (LOC) of 100 (MOEs ≥100). Based on the registered use pattern, exposure to children in residential settings is not anticipated. 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 cyflumetofen to share a common mechanism of toxicity with any other substances, and cyflumetofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyflumetofen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased qualitative or quantitative susceptibility in the rat 2-generation reproduction study; however, the rat and rabbit developmental studies indicate susceptibility in the pups. There is evidence of increased quantitative susceptibility in the rabbit developmental toxicity study, since developmental effects (changes in ossicification, paw flexion, and decreased fetal body weights) at the limit dose were observed where no maternal toxicity was present. There is evidence of increased qualitative susceptibility in the rat developmental toxicity study as developmental effects (increased incidence of incompletely ossified sternal centra) were seen at the same dose that caused an increase in adrenal weights and organ-to-body weight ratio in the maternal animals. Notwithstanding, the degree of concern for these effects in infants and children is low because the rat and rabbit developmental effects have clearly defined NOAEL/LOAELs and the dose selected for chronic risk assessment is protective of these effects. Therefore, the PODs based on adrenal effects in rat are health protective of all life stages.

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 cyflumetofen is complete and adequate to characterize potential pre- and/or post-natal risk for infants and children.

ii. There are acute and subchronic neurotoxicity studies available. There is no indication that cyflumetofen is a neurotoxic chemical in any of the submitted studies for cyflumetofen, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. While there is evidence of increased susceptibility in the rabbit and rat developmental studies, these studies have clearly defined NOAEL/LOAELs based on the explanation in Unit III.D.2. above.

iv. There are no residual uncertainties identified in the exposure database. Since the dietary and residential exposure estimates were based on conservative assumptions, EPA is confident that this assessment does not underestimate dietary (food and water) or residential exposure.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate dietary risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No acute dietary exposure and risk analysis was performed since there were no appropriate studies identified in the toxicology database that demonstrated evidence of toxicity attributable to a single dose.

2. *Chronic risk.* Using the exposure assumptions described in the unit for chronic exposure, EPA has concluded that chronic exposure to cyflumetofen from food and water will utilize 2.4% of the cPAD for children 1–2 years 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 cyflumetofen 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). Cyflumetofen is currently registered for use on ornamentals that result in residential handler exposure. Residential handler exposure is expected to be short-term in duration as intermediate- or long-term exposures are not likely because of the intermittent nature of applications by homeowners, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyflumetofen.

Since no dermal hazard was identified for cyflumetofen in the toxicological database, only inhalation exposure assessments were conducted for residential handlers. The most conservative residential exposure scenario was chosen for the adult population which reflects inhalation exposure from mixing/loading/applying the liquid cyflumetofen formulation with a backpack sprayer. For background dietary exposure, the adult sub-population with the highest exposure (adults 50–99) was chosen since this is protective for all other adult sub-populations. There are no residential exposures expected for children; therefore, a short-term aggregate risk assessment for children is equal to the chronic food and drinking water exposure and risk estimates and is not of concern. 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 above the LOC of 100 for all scenarios assessed and 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 adverse effect was identified; however, cyflumetofen is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for cyflumetofen.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA concluded that the nonlinear approach for assessing potential cancer risk from exposure to cyflumetofen is appropriate. As noted in this Unit, the chronic risk aggregate exposure to cyflumetofen is below the Agency's level of concern; therefore, the Agency concludes that there is not a cancer risk of concern from exposure to cyflumetofen.

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 cyflumetofen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology is available to enforce the HED-recommended tolerances for cyflumetofen in plant commodities. The high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) method has been adequately validated, has undergone a successful ILV (independent laboratory validation), is considered adequately radio-validated and has been reviewed by the Agency for appropriateness as an enforcement method. The method limit of detection (LOD) for residues of cyflumetofen in tea is 0.01 ppm. Cyflumetofen has also been subjected to analysis by the Food and Drug Administration (FDA) multi-residue method (MRM) protocols. Cyflumetofen is not adequately recovered through any of the FDA multi-residue protocols.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established maximum residue limits (MRLs) for residues of cyflumetofen in tea commodities; therefore, there are no harmonization issues.

C. Revisions to Petitioned-For Tolerances

To conform with to the Agency's preferred commodity vocabulary, EPA is establishing the tolerance for tea on ''tea, dried'', which will cover residues on all tea commodities.

V. Conclusion

Therefore, a tolerance is established for residues of the insecticide cyflumetofen, (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), in or on tea at 40 ppm.

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 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: April 26, 2019.

Donna Davis,

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 § 180.677, add alphabetically the commodity ''tea, dried'' to the table in paragraph (a) to read as follows:

§ 180.677 Cyflumetofen; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Tea, dried [1]	40
* * * * *	

[1] There are no U.S. registrations for this commodity as of May 8, 2019.

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