



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0832; FRL-10005-85]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyazofamid in or on multiple commodities that are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2018-0832, 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. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

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

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 FFDCFA 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-2018-0832 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2018-0832, 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/where-send-comments-epa-dockets>. 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 Tolerance

In the **Federal Register** of May 9, 2019 (84 FR 20320) (FRL-9992-36), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8718) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, New Jersey 08540. The petition requested that 40 CFR 180.601 be amended by establishing tolerances for residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, in or on brassica, leafy greens, subgroup 4-16B at 15.0 parts per million (ppm); ginseng at 0.2 ppm; kohlrabi at 1.5 ppm; leafy greens subgroup 4-16A at 10.0 ppm; and vegetable, brassica, head and stem, group 5-16 at 1.5 ppm. Upon the establishment of those tolerances, the petition requested the removal of existing tolerances for residues of the fungicide cyazofamid in or on brassica, head and stem, subgroup 5A at 1.2 ppm; brassica, leafy greens, subgroup 5B at 12.0 ppm; leafy greens subgroup 4A at 10 ppm; and turnip, greens at 12.0 ppm. That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, <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 and pursuant to its authority in FFDCCA section 408(d)(4)(A)(i), EPA is establishing three of the tolerances at a different level than requested. 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 FFDCCA 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 FFDCCA 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 FFDCCA 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 FFDCCA section 408(b)(2)(D), and the factors specified in FFDCCA 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 cyazofamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyazofamid 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.

Cyazofamid belongs to a chemical class based on the cyanoimidazole and sulfonamide moieties. It specifically interferes with the cytochrome *bc₁* complex (ubiquinol cytochrome *c* oxidoreductase) in the mitochondrial respiratory chain of oomycetes fungi. The mechanism of toxicity in mammals is not clear. There were no treatment-related adverse effects in the acute and subchronic neurotoxicity studies. However, following repeated administration in more than one species, toxicological effects were observed primarily in the kidney. There were no effects observed up to the limit dose (1000 mg/kg) in the dermal toxicity study. In dogs, there were no major toxicity findings.

In the prenatal developmental toxicity study in rats, there was a marginal increased incidence of bent ribs observed in the high-dose (1000 mg/kg/day) without any maternal effects, indicating quantitative susceptibility following *in utero* exposure.

Cyazofamid is classified as “not likely to be carcinogenic to humans” based on the lack of evidence of carcinogenicity in both the rat and the mouse studies. Additionally, cyazofamid does not appear to be mutagenic, based on several negative *in vivo* and *in vitro* studies.

Specific information on the studies received and the nature of the adverse effects caused by cyazofamid as well as the no-observed-adverse-effect-level (NOAEL) and the

lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <https://www.regulations.gov> in document “Cyazofamid. Human Health Risk Assessment for New Uses of Cyazofamid on Ginseng, and Greenhouse Cucumbers and Crop Group Conversions on Vegetable, Brassica, Head and Stem, Group 5-16; Brassica, Leafy Greens, Subgroup 4-16B; Leafy Greens, Subgroup 4-16A; and to Establish an Individual Tolerance on Kohlrabi” on page 20 in docket ID number EPA-HQ-OPP-2018-0832.

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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

A summary of the toxicological endpoints for cyazofamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of February 3, 2016 (81 FR 5602) (FRL-9940-46).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyazofamid, EPA considered exposure under the petitioned-for tolerances as well as all existing cyazofamid tolerances in 40 CFR 180.601. EPA assessed dietary exposures from cyazofamid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyazofamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA included tolerance-level residues for all crops, default processing factors and assumed that 100% of the crops were treated (100% CT) with cyazofamid.

iii. *Cancer.* Based on the data cited in Unit III.A., EPA has concluded that cyazofamid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyazofamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyazofamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of cyazofamid for chronic exposures for non-cancer assessments are estimated to be 133.5 ppb for surface water and 211 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 211 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).

Cyazofamid is currently registered for the following uses that could result in residential exposures: turf and ornamentals. EPA assumes there is no residential handler exposure

because labels require users to wear personal protective equipment. Post application exposure (to turf and ornamental) from hand-to-mouth exposures was greatest to children 1 to less than 2 years old. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyazofamid and any other substances and cyazofamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyazofamid has 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold

effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the prenatal developmental toxicity study in rats, there was a marginal increased incidence of bent ribs observed at the high-dose (1000 mg/kg/day) without any maternal effects, indicating quantitative susceptibility following *in utero* exposure. There is low concern for this effect because 1) bent ribs are a developmental variation rather than a malformation; 2) the increased incidence was only marginally increased over historical and concurrent controls; 3) similar effects were not seen in the rabbit developmental study; and 4) the effect was only observed at the limit dose.

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 cyazofamid is complete.
- ii. There is no indication that cyazofamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. Although there is evidence of quantitative susceptibility in the developmental rat study, the concern is low because the effects occur at the limit dose and are well-

characterized with clearly established no observed adverse-effect level (NOAEL)/lowest-observed adverse-effect level (LOAEL) values and selected endpoints address the observed effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT, default processing factors and assumed tolerance-level residues for all crops. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyazofamid in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyazofamid.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyazofamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyazofamid from food and water will utilize 2.0% 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 cyazofamid 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). Cyazofamid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to cyazofamid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 6,200 for children 1 to less than 2 years old for dietary exposure (which is considered a background exposure) and incidental oral (hand-to-mouth) exposure from contact with treated turf. Because EPA's level of concern for cyazofamid is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, cyazofamid 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 cyazofamid.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, cyazofamid is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyazofamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available to determine residues of cyazofamid and its metabolite CCIM (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile) in various commodities. An enforcement method for non-fatty commodities is available, FDA's Multiresidue Protocol D (without cleanup). The method completely recovers cyazofamid and its metabolite CCIM. In addition, the high-performance liquid chromatography method with ultraviolet light detection (HPLC/UV) method is acceptable for use as a single analyte enforcement method provided a confirmatory method such as the liquid chromatography method with tandem mass-spectrometric detection (LC/MS/MS) method is used.

The methods 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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for cyazofamid in or on Brassica (cole or cabbage) vegetables, head cabbage, and flowerhead Brassicas at 1.5 ppm; leaves of Brassicaceae at 15 ppm; and leafy vegetables (except Brassica leafy vegetables) at 10 ppm. The U.S. tolerances being established are harmonized with these Codex MRLs, specifically vegetable, brassica, head and stem, group 5-16 at 1.5 ppm; kohlrabi at 1.5 ppm; brassica leafy greens, subgroup 4-16B at 15 ppm; and leafy greens subgroup 4-16A at 10 ppm. There is no Codex MRL for ginseng.

C. Response to Comments

EPA received two comments to the Notice of Filing, generally opposed to any cyazofamid residues on leafy greens. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. These comments appear to be directed at the underlying statute and not EPA's implementation of it; the comments provide no information relevant to the Agency's safety determination.

D. Revisions to Petitioned-For Tolerances

EPA is establishing tolerances for Brassica, leafy greens, subgroup 4-16B and Leafy greens subgroup 4-16A at different levels than requested to be consistent with the Organisation for Economic Cooperation and Development (OECD) rounding class practice. For ginseng, the petitioner's proposed tolerance was adjusted because storage stability data indicated a decline in residues of CCIM. Organization for Economic Cooperation and Development (OECD) statistical calculation procedures applied to the corrected residue data provided a different value (0.3 ppm) than the proposed value (0.2 ppm). Therefore, EPA is establishing the tolerance for ginseng at 0.3 ppm.

V. Conclusion

Therefore, tolerances are established for residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, in or on Brassica, leafy greens, subgroup 4-16B at 15 ppm; Ginseng at 0.3 ppm; Kohlrabi at 1.5 ppm; Leafy greens subgroup 4-16A at 10 ppm; and Vegetable, brassica, head and stem, group 5-16 at 1.5 ppm. Additionally, EPA is removing the established tolerances for Brassica, head and

stem, subgroup 5A at 1.2 ppm; Brassica, leafy greens, subgroup 5B at 12.0 ppm; Leafy greens subgroup 4A at 10 ppm; and Turnip, greens at 12.0 ppm. Finally, as a housekeeping measure, EPA is removing the expired exemption in paragraph (b) Section 18 emergency exemptions for Basil, dried at 144 ppm, as it expired on December 31, 2014.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), 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 tolerances 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 FFDCIA 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: March 2, 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 §180.601:

a. In the table in paragraph (a):

i. Remove the entries: Brassica, head and stem, subgroup 5A; and Brassica, leafy greens, subgroup 5B;

ii. Add alphabetically the entries: Brassica, leafy greens, subgroup 4-16B; Ginseng; and Kohlrabi;

iii. Remove the entry Leafy greens subgroup 4A;

iv. Add alphabetically the entry Leafy greens subgroup 4-16A;

v. Remove the entry Turnip, greens; and

vi. Add alphabetically the entry Vegetable, brassica, head and stem, group 5-16; and

b. Remove and reserve paragraph (b).

The additions and revision read as follows:

§180.601 Cyazofamid; tolerances for residues.

(a) * * *

Table to Paragraph (a)

Commodity	Parts per million

Brassica, leafy greens, subgroup 4-16B	15

Ginseng	0.3

Kohlrabi	1.5

Leafy greens subgroup 4-16A	10
Vegetable, brassica, head and stem, group 5-16	1.5

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