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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0263; FRL-9940-46]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyazofamid in or on the herb subgroup 19A and the bulb vegetable group 3-07. Interregional Research Project Number 4 (IR-4) requested the herb subgroup 19A tolerances, and ISK Biosciences requested the bulb vegetable group 3-07 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-2015-0263, 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: Susan Lewis, 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 FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0263 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-2015-0263, 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 May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions: One by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077 (PP 5F8352) that requested to establish tolerances in 40 CFR 180.601 for residues of the fungicide cyazofamid and its metabolite (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile) in or on bulb vegetables (crop group 3-07) at 2.0 parts per million (ppm); and one by IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540 (PP 5E8350) that requested to establish tolerances in 40 CFR 180.601 for residues of the fungicide cyazofamid in or on the herb subgroup 19A at 90 ppm and also to remove the existing tolerances for residues of cyazofamid and its metabolite in or on basil, dried leaves at 90 ppm and basil, fresh leaves at 30 ppm upon approval of the herb subgroup 19A tolerances. That document referenced summaries of the two petitions prepared by ISK Biosciences, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notices of filing.

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 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.

The target organ for cyazofamid in rats is the kidney, with an increased incidence of basophilic tubules, increased urinary volume, pH, and protein noted in male rats after subchronic exposure. Female rats were less sensitive, with only a marginal increase in urinary volume, and pH. These findings were noted in a 90-day oral toxicity study, and similar findings were noted in the 28-day oral toxicity range-finding study in rats. In the two-generation reproductive study in rats, there was an increased incidence of inflammation and nephropathy in the high-dose male rats as compared to the controls. Basophilic tubules are indicative of a regenerative process, but they can be more difficult to identify in older animals (i.e., tubular basophilia can be obscured by nephropathy or included as part of the nephropathy constellation). No kidney effects were observed in the chronic oral toxicity study in rats; however, this study did not test up to doses as high as those eliciting kidney effects in the subchronic and two-generation reproduction toxicity studies. The only relevant finding in the dog was an incidence of parathyroid cysts in males at the limit dose in the chronic study.

The pre- and post-natal toxicology database for cyazofamid includes rat and rabbit developmental toxicity studies and a two-generation reproduction toxicity study in rats. The prenatal developmental study in rats showed evidence of increased quantitative susceptibility following *in utero* exposure as a marginally increased incidence of bent ribs was noted in fetuses at the limit dose, whereas no maternal toxicity was noted.

No adverse effects were seen in a route-specific dermal toxicity study. Skin lesions were observed in males following oral exposure in the mouse carcinogenicity study, and are thought to be caused by an allergic reaction to systemic exposure because they did not occur following exposure via the dermal route. Cyazofamid is classified as “not likely to be carcinogenic to humans” based on the lack of evidence for carcinogenicity in mice and rats and a lack of mutagenic potential.

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 http://*www.regulations.gov* in the document titled, “Cyazofamid. Human Health Risk Assessment for Proposed New Uses on Use on Crop Subgroup 19A, Peppers and Tomatoes Grown in Greenhouses, and on Bulb Vegetables Crop Group 03-07” on pp. 32 in docket ID number EPA-HQ-OPP-2015-0263.

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 the NOAEL and the LOAEL are identified. 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for cyazofamid used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Cyazofamid 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)	No appropriate toxicological effect attributable to a single dose was observed. Therefore, a dose and endpoint were not identified for this risk assessment		
Chronic dietary (All populations)	NOAEL= 94.8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.948 mg/kg/day cPAD = 0.948 mg/kg/day	18-Month Mouse Oral Carcinogenicity LOAEL = 985 mg/kg/day based on increased skin lesions

Incidental oral short-term (1 to 30 days)	NOAEL= 171 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Co-critical 90-Day and chronic oral toxicity studies in rats. LOAEL= 295 mg/kg based on increased incidence of basophilic tubules in the kidneys, increased urinary volume, pH, & protein
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 171 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Co-critical 90-Day and chronic oral toxicity studies in rats. LOAEL= 295 mg/kg based on increased incidence of basophilic tubules in the kidneys, increased urinary volume, pH, & protein
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of treatment-related tumors in two adequate rodent carcinogenicity studies		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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 U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

iii. *Cancer*. Based on the data summarized 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 PCT information*. EPA did not use anticipated residue or PCT information in the dietary assessment for cyazofamid. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. Available environmental fate studies suggest cyazofamid is not very mobile and quickly degrades into a number of degradation products under different environmental conditions. The highest estimated chronic drinking water concentrations resulted from modeling which assumed application of 100% molar conversion of the parent into the terminal degradate CTCA. EPA used these estimates of CTCA (4-chloro-5-*p*-tolylimidazole-2-carboxylic acid) in its dietary exposure assessments, a conservative approach that likely overestimates the exposure contribution from drinking water.

The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyazofamid and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyazofamid and its degradates. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.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 the degradate CTCA for chronic exposures are estimated to be 133.5 parts per billion (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 of value 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, termiticide, and flea and tick control on pets).

Cyazofamid is currently registered for use on turf at golf courses, sod farms, seed farms, college and professional sports fields, residential and commercial lawns, and on ornamental

plants in landscapes and those grown in commercial greenhouses and nurseries. EPA assessed residential exposure using the following scenarios:

- Adult handlers. The worst-case scenario was determined to be short-term inhalation exposures from mixing, loading, and applying cyazofamid to turf; and

- Children. The worst-case scenario was determined to be short-term post-application incidental oral exposure from hand-to-mouth activities on turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.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."

EPA has not found cyazofamid to share a common mechanism of toxicity with any other substances, and cyazofamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyazofamid 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://www2.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 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*. The developmental rabbit and two-generation reproduction toxicity study in rats did not show any evidence of increased susceptibility developmental or offspring, respectively. However, there was increased quantitative susceptibility in the rat developmental study; concentrations up to the limit dose did not cause maternal systemic toxicity, but there was an increased incidence of bent ribs. Concern is low based on the following: (1) The increase was marginal, (2) bent ribs are considered a variation

rather than a malformation, (3) the effect was only seen at the limit dose, (4) there is a clear NOAEL for the effect, and (5) the selected endpoints address any concerns for this effect.

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 uncertainty factors (UFs) to account for neurotoxicity.

iii. As noted in Section D.2., there was increased quantitative susceptibility in the rat developmental study, however, concern is low due to the reasons cited.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyazofamid and its degradates 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% 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 14,000 for adults and 6,100 for children 1-2 years old. Because EPA's level of concern for cyazofamid is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term 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

An enforcement method for non-fatty commodities is available, FDA's Multi-residue Protocol D (without cleanup). The method completely recovers (>80% recovery) cyazofamid and its metabolite (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile). In addition, the high-performance liquid chromatography method with ultraviolent 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 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 Aliment-arius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Aliment-arius 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.

There are no Codex MRLs established for cyazofamid in/on the commodities included in this action.

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) and is metabolite (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile) in or on the herb subgroup 19A at 90 ppm; and bulb vegetables, group 3-07 at 2.0 ppm. In addition, the existing tolerances for residues of cyazofamid and its metabolite (4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile) in or on basil, dried leaves and basil, fresh leaves are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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 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 21, 2016.

Susan Lewis,

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, in the table in paragraph (a):

a. Remove the entries for “Basil, dried leaves” and “Basil, fresh leaves”.

b. Add alphabetically entries for “Bulb vegetables, group 3-07” and “Herb subgroup 19A”.

The additions read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General*. * * *

Commodity	Parts per million
*******	
Bulb vegetables, group 3-07	2.0
*******	
Herb subgroup 19A	90
*******	

* * * * *

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