has harmonized the residue level with established Codex MRLs on cherry and peach, but notes that it is not possible to harmonize the tolerance expression at this time as the Codex MRL includes parent only. Additionally, it is not possible to harmonize with the codex MRL for plums as the established Codex MRL of 0.2 ppm is too low to cover residues that could result from the use of hexythiazox in the U.S.

V. Conclusion

Therefore, the tolerance for residues of hexythiazox, in or on plum, prune, dried is revised from 0.4 ppm to 1.3 ppm; and the tolerance for fruit, stone, group 12, except plum is revised to read fruit, stone, group 12. The established tolerances for plum and for plum, prune, fresh can be removed as these commodities are addressed by the stone fruit group tolerance.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: July 1, 2010.

Lois Rossi,

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 § 180.448, the table in paragraph (a) is amended as follows:

i. Remove the entry for plum at 0.10 ppm and for plum, prune, fresh at 0.10 ppm;

ii. Revise the entry for Fruit, stone, group 12, except plum; and

iii. Revise the entry for plum, prune, dried.

The revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

Commodity	Parts per million
* * * * *	
Fruit, stone, group 12	1.0
* * * * *	
Plum, prune, dried	1.3
* * * * *	

* * * * *

[FR Doc. 2010–17034 Filed 7–13–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0801; FRL–8833–1]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyazofamid in or on Brassica, head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B; turnip, greens; spinach; and hop, dried cones. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0801. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available,

e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr*.

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–2009–0801 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 September 13, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0801, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7615) by IR-4, 500 College Road East, Suite 201 W., Princeton, NJ 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, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, expressed as cyazofamid, in or on Brassica, head and stem, subgroup 5A at 1.2 parts per million (ppm); Brassica, leafy greens, subgroup 5B at 12.0 ppm; turnip, greens at 12.0 ppm; spinach at 9.0 ppm; and hops at 10.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by ISK Biosciences, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA has revised the tolerance expression for all established commodities to be consistent with current Agency policy. The reason for this change is explained in Unit IV.C.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 has a low order of acute toxicity via the oral, dermal, and inhalation routes of exposure. It produces minimal but reversible eye irritation, is a slight dermal irritant, and is a weak dermal sensitizer. In subchronic toxicity studies in rats, the kidney appeared to be the primary target organ, with kidney effects including an increased number of basophilic kidney tubules and mild increases in urinary volume, pH, and protein. No adverse kidney effects were noted in chronic toxicity studies in rats. There were no toxicity findings up to the limit dose in a subchronic toxicity study in dogs; in the chronic dog toxicity study, increased cysts in parathyroids were observed in males at the highest dose tested (HDT).

There were no maternal or developmental effects observed in the prenatal developmental toxicity study in rabbits and no maternal, reproductive, or offspring effects in the 2-generation reproductive toxicity study in rats. There was evidence of increased susceptibility following *in utero* exposure of rats in the prenatal developmental toxicity study at the HDT; developmental effects, including an increased incidence of bent ribs, were observed in the absence of maternal toxicity.

There was no evidence of neurotoxicity in any study in the exposure database for cyazofamid. Skin lesions, which may be due to a systemic allergy, were observed in male mice in a carcinogenicity study. There was no evidence of carcinogenicity in the rat or mouse carcinogenicity studies and no evidence that cyazofamid is mutagenic in several *in vivo* and *in vitro* studies. Based on the results of these studies, EPA has classified cyazofamid as "not likely to be carcinogenic to humans."

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 document: "Cyazofamid. Human Health Risk Assessment for Proposed Uses on Brassica (Cole) Leafy Vegetables Crop Group 5, Turnip Greens, Spinach, and Hops," pp 34-38 in docket ID number EPA–HQ–OPP–2009–0801.

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 cyazofamid used for human risk assessment is shown in the following Table.

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 (General population including infants and children)	No adverse effects were observed which could be attributed to a single dose exposure for the general population.		
Acute dietary (Females 13–49 years of age)	NOAEL = 100 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.0 mg/kg/day aPAD = 1.0 mg/kg/day	Rat Prenatal Developmental Toxicity Study LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
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 Study LOAEL = 985 mg/kg/day based on increased skin lesions.
Incidental oral, short-term (1 to 30 days) and intermediate-term (1-6 months)	NOAEL= 30 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day Rat Oral Toxicity Study LOAEL = 295 mg/kg/day based on increased number of basophilic tubules of the kidneys, increased urinary volume, pH, and protein.
Dermal, short-term (1 to 30 days) and intermediate-term (1-6 months)	For Children: No toxicity was found at 1,000 mg/kg/day in a 28–day dermal toxicity study; therefore, in the absence of hazard identified for this population, a dermal risk assessment is not necessary.		

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYAZOFAMID FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
	For Adults: Dermal (or oral) study NOAEL = 100 mg/kg/day (dermal absorption rate = 37 %) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Rat Prenatal Developmental Toxicity Study LOAEL = 1,000 mg/kg/day based on developmental toxicity findings of increased incidence of bent ribs.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. 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.

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. EPA identified such an effect (increased incidence of bent ribs in the rat prenatal developmental toxicity study) for the population subgroup females 13 to 49 years old; however, no such effect was identified for the general population, including infants and children.

In estimating acute dietary exposure for females 13 to 49 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994 to 1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues, Dietary Exposure Evaluation Model (DEEM) default processing factors and 100 percent crop treated (PCT) for all existing and proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994 to 1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues, DEEM default processing factors and 100 PCT for all existing and proposed 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 and/or PCT information in the dietary assessment for cyazofamid. Tolerance level residues and/or 100 PCT 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 *http://www.epa.gov/oppefed1/models/water/index.htm.*

Available environmental fate studies suggest cyazofamid is not very mobile and quickly degrades into a number of degradation products under different environmental conditions. Among the three major degradates for cyazofamid (CCIM, CCIM-AM and CTCA), the two terminal degradates are CCIM and CTCA. The highest estimated 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 in its dietary exposure assessments, a conservative approach that likely overestimates the exposure contribution from drinking water. Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model for surface water and the Screening Concentration in Ground Water (SCI-GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of CTCA for acute exposures are estimated to be 136 parts per billion (ppb) for surface water and 2.18 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 133 ppb for surface water and 2.18 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 136 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 133 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 use on residential turf and ornamentals and on professionally managed turf areas, such as golf courses and college/professional sports fields. For the use of cyazofamid on professionally managed turf areas, short-term and intermediate-term postapplication dermal exposure was assessed for adult and youth golfers and adult athletes. However, because it is unlikely for an individual to experience a co-occurrence of activities within a single day, the scenarios of golfing and/or using recreational fields were not aggregated with the residential turf and ornamental scenarios.

For the use of cyazofamid on residential turf and ornamentals, application by homeowners is

prohibited; therefore, residential handler exposure is not expected and was not assessed. However, short-term and intermediate-term postapplication exposure is possible for adults and children. Adults were assessed for short-term and intermediate-term postapplication dermal exposure from contact with treated turf and ornamentals. The adult population of concern for dermal risk assessment is females of childbearing age (13+), based on the developmental toxicity findings of increased incidence of bent ribs; thus, the estimated risk for this population is protective of all adult population subgroups. Children were assessed for short-term and intermediate-term postapplication incidental oral exposure to treated residential turf and ornamentals, including hand-to-mouth activity, object-to-mouth activity, and soil ingestion. No POD was identified for dermal exposures to treated turf or ornamentals for children, since no toxicity was seen in the 28–day dermal toxicity study at the HDT (1,000 mg/kg/day); therefore, dermal postapplication exposure scenarios for children were not assessed.

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://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 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*. The prenatal and postnatal toxicology database for cyazofamid includes rat and rabbit developmental toxicity studies and a 2-generation reproductive toxicity study in rats. There was no indication of increased susceptibility, as compared to adults, of rabbit fetuses to *in utero* exposure in a developmental study or of rat pups in the 2-generation reproductive toxicity study. There is evidence of increased quantitative susceptibility following *in utero* exposure of rats to cyazofamid in the prenatal developmental study; an increased incidence of bent ribs in fetuses at the HDT was noted in the absence of maternal effects.

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 except for immunotoxicity and subchronic neurotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OSCPP Harmonized Guideline 870.7800) and subchronic neurotoxicity testing (OSCPP Harmonized Guideline 158.500) required for pesticide registration; however, the available data for cyazofamid do not show potential for immunotoxicity. Further, there is no evidence of neurotoxicity in any study in the toxicity database for cyazofamid. EPA does not believe that conducting neurotoxicity and immunotoxicity studies will result in a NOAEL lower than the regulatory dose for risk assessment. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database uncertainty factor does not need to be applied.

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. There is no evidence that cyazofamid results in increased susceptibility in rabbits in the prenatal developmental study or in young rats in the 2-generation reproductive toxicity study. Although there is evidence of increased quantitative susceptibility in the prenatal developmental study in rats, the Agency determined that concern is low because:

a. The developmental effect (increased bent ribs) is well identified with a clear NOAEL and LOAEL.

b. Increased bent ribs are considered a reversible variation rather than a malformation.

c. The effect was noted only at the limit dose of 1,000 mg/kg/day.

d. This endpoint was used to establish the acute reference dose (aRfD) for females 13–49.

e. The overall toxicity profile indicates that cyazofamid is not a very toxic compound.

Therefore, there are no residual concerns regarding developmental effects in the young.

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 in drinking water. EPA used similarly conservative assumptions to assess postapplication 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-term, intermediate-term 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*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyazofamid will occupy 1.2% of the aPAD for females 13 to 49 years old, the population group of concern for acute effects. Cyazofamid is not expected to pose an acute risk to the general population, including infants and children.

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 1.2% of the cPAD for infants less than 1 year 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 and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-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 and intermediate-term postapplication residential exposure to adults and children. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposure to cyazofamid.

Using the exposure assumptions described in this unit for short-term and intermediate-term exposures, EPA has concluded the combined short-term and intermediate-term food, water, and residential exposures (treated residential turf and ornamentals) aggregated result in MOEs of 1,000 for the general U.S. population, 1,400 for children 3 to 5 years old, and 1,500 for children 6 to 12 years old. As the MOEs are greater than 100 for all population subgroups, short-term and intermediate-term aggregate exposure to cyazofamid is not of concern.

4. *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.

5. *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 adequate analytical methodology is available to enforce the proposed tolerances. Cyazofamid and the metabolite CCIM are completely recovered (>80% recovery) using FDA's Multi-Residue Protocol D (without cleanup). In addition, a high performance liquid chromatography/ultraviolet detector (HPLC/UV) method is available for use as a single analyte confirmatory method. These 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; e-mail 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 U.N. 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 currently no Codex or Canadian MRLs established for residues of cyazofamid in or on commodities associated with this petition.

C. Revisions to Petitioned-For Tolerances

The EPA has revised the tolerance expression to clarify: 1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of cyazofamid not specifically mentioned; 2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

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 its metabolite 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on Brassica, head and stem, subgroup 5A at 1.2 ppm; Brassica, leafy greens, subgroup 5B at 12.0 ppm; turnip, greens at 12.0 ppm; spinach at 9.0 ppm; and hop, dried cones at 10.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 section 408(d) of FFDCA, 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 final rule 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 section 408(n)(4) of FFDCA. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: July 1, 2010.

Lois Rossi,

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. Section 180.601 is amended by:

i. Revising the introductory text and alphabetically adding the following commodities to the table in paragraph (a):

ii. Revising the introductory text in paragraph (c) to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide cyazofamid, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide and its metabolite, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on the following commodities:

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	1.2
Brassica, leafy greens, subgroup 5B	12.0
* * * * * * *	
Hop dried cones	10.0
* * * * * * *	
Spinach	9.0
Turnip, greens	12.0
* * * * * * *	

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the fungicide cyazofamid, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide and its metabolite, 4-chloro-5-(4-methylphenyl)-1*H*-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, in or on the following commodities:

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0231; FRL–8834–4]

Castor Oil, Ethoxylated, Oleate; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of castor oil, ethoxylated, oleate (CAS Reg. No. 220037–02–5) with a minimum number average molecular weight (in amu) of 1,600 when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. SciReg. Inc. on behalf of Rhodia, Inc, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of castor oil, ethoxylated, oleate on food or feed commodities.

DATES: This regulation is effective July 14, 2010. Objections and requests for hearings must be received on or before September 13, 2010 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0231. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are