

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: June 26, 2009.

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. The table in paragraph (a)(1) of § 180.518 is amended by removing the commodities "Fruit, citrus, group 10 postharvest" and "Fruit, stone, group 12, except cherry" and alphabetically adding the following commodities to read as follows:

§ 180.518 Pyrimethanil; tolerances for residues.

(a)	*	*	*
(1)	*	*	*
Commodity	Parts per million		
* * * *	*		
Fruit, citrus, group 10, except lemon, postharvest	*	10	
* * * *	*		
Fruit, stone, group 12	*	10	
* * * *	*		
Lemon, preharvest and postharvest	*	11	
* * * *	*		

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0731; FRL-8423-5]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of cyazofamid and its metabolite, CCIM, expressed as cyazofamid in or on fruiting vegetable group 8 and okra. Additionally, it establishes a tolerance with regional restrictions in or on grape. Finally, this regulation removes the established grape import and tomato tolerances, as a regional tolerance on grape and fruiting vegetable group tolerance replaces them, respectively. 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 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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-2008-0731. 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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-2008-0731 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 8, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2008-0731, 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. Petition for Tolerance

In the **Federal Register** of December 3, 2008 (73 FR 73644) (FRL-8386-9), 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 8E7427) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.601 be amended by establishing tolerances for combined 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 fruiting vegetable group 8 and okra at 0.80 parts per million (ppm); and be further amended by establishing a tolerance with regional restrictions in or on grape at 1.5 ppm. Since data were submitted that only supports the use of cyazofamid on grapes grown east of the Rocky Mountains, the proposed tolerance for grape will be restricted to

a regional tolerance under paragraph (c) of § 180.601. This petition additionally requested the removal of the currently established grape import and tomato tolerances. That notice referenced a summary of the petition prepared on behalf of IR-4 by ISK Biosciences Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified some of the proposed tolerances. The reason for these changes 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 the petitioned-for tolerances for combined residues of cyazofamid and its metabolite CCIM, expressed as cyazofamid, on fruiting vegetable, group 8 and okra at 0.40 ppm and grape at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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 cyazofamid exhibited mild or low toxicity with the kidney being the primary target organ. Kidney effects included an increased number of "basophilic kidney tubules" and mild increases in urinary volume, pH, and protein. No adverse kidney effects or any other toxicity findings were noted in chronic toxicity studies in rats.

Similarly, the overall toxicity profile in dogs is unremarkable. In both the 13 week and 1-year dog studies, there were no major toxicity findings up to a dose of 1,000 milligrams/kilograms/day (mg/kg/day). The only possible effect was increased cysts in parathyroids and the pituitary (females only) observed in the high-dose groups of the 1-year study.

Skin lesions, which may be due to systemic allergy, were observed in the males of the 18 month mouse carcinogenicity study. At the high dose, approaching 1,000 mg/kg/day, male mice suffered hair loss due to scratching, which was confirmed at necropsy by increased incidence of body sores (head, neck, trunk, limb, and/or tail) and was correlated histologically with an increased incidence of acanthosis (hyperplasia), chronic active dermatitis, ulceration, and premature death. The sulfonamide moiety in the cyanoimidazole ring might have rendered cyazofamid an allergen, albeit a weak one. This is supported by the findings that cyazofamid is a moderate irritant in the primary rabbit skin test and is a positive weak sensitizer in the guinea pig skin maximization test. There were no skin allergies in the rat feeding study, which may be due possible species variation.

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 reproduction study in rats. There was some evidence of increased susceptibility following *in utero* exposure of rats in the prenatal developmental toxicity study. At the highest dose tested (HDT) (1,000 mg/kg/day), developmental effects (increased incidence of bent ribs) were observed in the absence of maternal toxicity.

There were no indications of treatment-related adverse neurotoxicity

findings. In the acute neurotoxicity study, there were no clinical signs indicating potential neurotoxic effects, no qualitative or quantitative neurobehavioral effects, no changes in brain weight, and no evidence of gross or microscopic pathology. There was no evidence of neurotoxicity in other available studies for cyazofamid as well.

There was no evidence of carcinogenicity in the rat and 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 Fruiting Vegetables and Okra, Grapes East of the Rocky Mountains, Vegetable Greenhouse Transplants, and Commercial Application on Residential Turf and Residential Ornamentals*, pages 47–52 in docket ID number EPA–HQ–OPP–2008–0731.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by

comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 can be found at <http://www.regulations.gov> in document *Cyazofamid. Human Health Risk Assessment for Proposed Uses on Fruiting Vegetables and Okra, Grapes East of the Rocky Mountains, Vegetable Greenhouse Transplants, and Commercial Application on Residential Turf and Residential Ornamentals*, pages 15–16 in docket ID number EPA–HQ–OPP–2008–0731.

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 13–49 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 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 new uses of cyazofamid.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed tolerance-level residues, DEEM default processing factors, and 100 PCT for all commodities.

iii. *Cancer.* Based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies, EPA has classified cyazofamid as “not likely to be carcinogenic to humans;” therefore, a quantitative exposure assessment to evaluate 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 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 professionally managed turf areas, such as golf courses and college/professional sports fields and proposed for use on residential lawns and ornamentals. For the registered uses, short- and intermediate-term postapplication dermal exposure was previously assessed for adult and young golfers and adult athletes, and is not of concern to the EPA. Because it is unlikely for an individual to experience a co-occurrence of activities within a single day, the two scenarios of golfing or using recreational fields were not aggregated with the proposed residential lawn postapplication scenario.

For the proposed use of cyazofamid on residential lawns and ornamentals, application by homeowners to residential turf is prohibited. Therefore, non-occupational (i.e., residential) handler exposure for residential lawns and ornamentals is not expected and was not assessed. A turf transferrable residue (TTR) study, which was submitted for use in assessing postapplication activities, was useful in determining residue dissipation. Short- and intermediate-term postapplication exposure is possible for adults and children in contact with residential lawns and ornamentals after application of cyazofamid. EPA determined there is no significant incidental oral exposure for adults; therefore, only dermal exposure from contact with treated turf and ornamentals was appropriate to analyze for short- and intermediate-term risk for adults. 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. For children, postapplication exposure to treated residential turf was estimated for hand-to-mouth activity, object-to-mouth activity, and soil ingestion. No point of departure was identified for dermal exposures to treated turf for children, since no toxicity was seen in the 28-day

dermal toxicity study at the HDT (1,000 mg/kg/day); therefore, dermal exposure scenarios for children were not assessed. The estimated exposure is believed to be a reasonable high-end estimate based on observations from chemical-specific studies and professional judgment.

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 Food Quality Protection Act of 1996 (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 reproduction toxicity study in rats. The toxicology data for cyazofamid provides no indication of increased susceptibility, as compared to adults, of rabbit fetuses to *in utero* exposure in a developmental study or of rats in the 2-generation reproduction study. There is evidence of

increased quantitative susceptibility following *in utero* exposure to rats in the prenatal developmental study; an increased incidence of bent ribs in fetuses at the HDT was noted in the absence of maternal effects. However, the Agency determined that concern is low because:

- i. The developmental effect is well identified with clear NOAEL/LOAEL.
- ii. The developmental effect (increased bent ribs) is a reversible variation rather than a malformation.
- iii. The developmental effect is seen only at the limit dose of 1,000 mg/kg/day.
- iv. This endpoint is used to establish the acute reference dose for females 13–49.
- v. The overall toxicity profile indicates that cyazofamid is not a very toxic compound.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if 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. 40 CFR part 158 makes immunotoxicity testing (OPPTS Guideline 870.7800) and subchronic neurotoxicity testing (OPPTS 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 testing will result in a NOAEL lower than the regulatory dose for risk assessment. Consequently, EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under FQPA, and an additional database UF 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 *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there is evidence of increased quantitative susceptibility in the prenatal developmental study in rats, the Agency did not identify any residual uncertainties after establishing toxicity

endpoints and traditional UFs to be used in the risk assessment of cyazofamid. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to cyazofamid will occupy <1% of the aPAD for females 13–49 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% 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- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Cyazofamid is currently proposed for uses that could result in short- 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- and intermediate-term residential exposure to cyazofamid.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures (treated residential turf and ornamentals) aggregated result in aggregate MOEs of 1,100 for the general U.S. population and 1,400 for children 1–2 years old. As the aggregate MOEs are greater than 100 for the general U.S. population and children 1–2 years old, short- and intermediate-term aggregate exposure to cyazofamid is not of concern to EPA.

4. *Aggregate cancer risk for U.S. population.* As discussed in unit III.C.1.iii, EPA has classified cyazofamid as “not likely to be carcinogenic to humans,” and it 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

Adequate analytical methodology is available to enforce the tolerances. Cyazofamid and the metabolite CCIM are completely recovered (>80% recovery) using the Food and Drug Administration’s Multi-Residue Protocol D (without cleanup). In addition, an acceptable HPLC/UV method (high performance liquid chromatography method using an ultra violet detector) is available for use as a single analyte confirmatory method. 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; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are currently no maximum residues limits (MRLs) established by Codex or Mexico for cyazofamid. A Canadian MRL has been established for residues of cyazofamid and CCIM at 0.20 ppm for tomatoes. The currently established U.S. MRL for tomato (0.20 ppm) will be replaced by inclusion in fruiting vegetable group 8 (0.40 ppm). At this time, the U.S. fruiting vegetable group tolerance cannot be harmonized with the Canadian tomato MRL because field trial data supporting the group tolerance are higher than 0.20 ppm.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerances on “vegetable, fruiting, group 8” and “okra” should be decreased from 0.80 ppm to 0.40 ppm. EPA revised these tolerance levels based on analysis of the residue field trial data using the Agency’s Tolerance Spreadsheet in accordance with the Agency’s *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*.

V. Conclusion

Therefore, tolerances are established for combined residues of 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 vegetable, fruiting, group 8 at 0.40 ppm; and okra at 0.40 ppm. Additionally, a tolerance with regional restrictions is established in or on grape at 1.5 ppm. Finally, this regulation removes the established grape import and tomato tolerances, as a regional tolerance on grape and fruiting vegetable group tolerance replaces them, respectively.

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: June 26, 2009.

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 as follows:

- i. By removing the commodities “Grape, wine,* import” and “Tomato” and the footnote in the table in paragraph (a).
- ii. By alphabetically adding the following commodities to the table in paragraph (a) and by revising paragraph (c) to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
Okra	0.40
Vegetable, fruiting, group 8	0.40

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for the combined residues of 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 the following commodities:

Commodity	Parts per million
Grape	1.5

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0256; FRL-8422-3]

2-Propenoic acid, 2-methyl-, polymers with Bu acrylate, Et acrylate, Me methacrylate and polyethylene glycol methacrylate C₁₆₋₁₈-alkyl ethers; 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 2-propenoic acid, 2-methyl-, polymers with Bu acrylate, Et acrylate, Me methacrylate and polyethylene glycol methacrylate C₁₆₋₁₈-alkyl ethers; when used as an inert ingredient in a pesticide chemical formulation. BASF Corporation, 100 Campus Drive, Florham Park, NJ 07932 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 2-propenoic acid, 2-methyl-, polymers with Bu acrylate, Et acrylate, Me methacrylate and polyethylene glycol methacrylate C₁₆₋₁₈-alkyl ethers on food or feed commodities.

DATES: This regulation is effective July 8, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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-2009-0256. 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