TABLE 10 TO SUBPART EEEE OF PART 63.—CONTINUOUS COMPLIANCE WITH WORK PRACTICE STANDARDS—Continued

For each . . .	For the following standard . . .	You must demonstrate continuous compliance by . . .
	b. Install and, during the loading of organic liquids, operate a vapor balancing system.	i. Except for pressure relief devices, monitoring each potential source of vapor leakage in the system, including, but not limited to pumps, valves, and sampling connections, quarterly during the loading of a transport vehicle or the filling of a container using the methods and procedures described in the rule requirements selected for the work practice standard for equipment leak components as specified in Table 4 to this subpart, item 4. An instrument reading of 500 ppmv defines a leak. Repair of leaks is performed according to the repair requirements specified in your selected equipment leak standards. For pressure relief devices, comply with § 63.2346(a)(4)(v). If no loading of a transport vehicle or filling of a container occurs during a quarter, then monitoring of the vapor balancing system is not required.
	c. Route emissions to a fuel gas system or back to a process.	i. Continuing to meet the requirements specified in § 63.984(b).
* *	* * *	* *
6. Storage tank at an existing, reconstructed, or new affected source meeting any of the tank capacity and vapor pressure criteria specified in Table 2 to this subpart, items 1 through 6.	a. Route emissions to a fuel gas system or back to the process.	i. Continuing to meet the requirements specified in § 63.984(b).
	b. Install and, during the filling of the storage tank with organic liquids, operate a vapor balancing system.	i. Except for pressure relief devices, monitoring each potential source of vapor leakage in the system, including, but not limited to pumps, valves, and sampling connections, quarterly during the loading of a storage tank using the methods and procedures described in the rule requirements selected for the work practice standard for equipment leak components as specified in Table 4 to this subpart, item 4. An instrument reading of 500 ppmv defines a leak. Repair of leaks is performed according to the repair requirements specified in your selected equipment leak standards. For pressure relief devices, comply with § 63.2346(a)(4)(v). If no loading of a transport vehicle or filling of a container occurs during a quarter, then monitoring of the vapor balancing system is not required.

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BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007-0872; FRL–8360–4]

Cyazofamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of cyazofamid and its metabloite CCIM in or on carrot, roots. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 23, 2008. Objections and requests for hearings must be received on or before June 23, 2008, 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–2007–0872. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0872 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 June 23, 2008.

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–2007–0872, 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'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 September 28, 2007 (72 FR 55204) (FRL–8147–1), 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 7E7244) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.601 be amended by establishing a tolerance for combined residues of the fungicide cyazofamid, 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on carrot, roots at 0.06 parts per million (ppm). That notice referenced a summary of the petition prepared 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 the tolerance level for carrot roots. 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 the petitioned-for tolerances for combined residues of cyazofamid and its metabolite CCIM on carrot, roots at 0.09 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. Cyazofamid 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, cyazofamid's overall toxicity profile in dogs seems to be limited. In both the 13 week and one year dog studies, there were no major toxicity findings up to a dose of 1,000 milligrams/kilogram body weight/day (mg/kg/bwt day). The only possible effect was increased cysts in parathyroids of both sexes and the pituitary in females observed in the high dose groups of the one 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 to 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 including clinical signs, qualitative or quantitative neurobehavioral effects, brain weight, or gross/microscopic pathology in the acute neurotoxicity study and no evidence of neurotoxicity in other available studies for cyazofamid.

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 *Human Health Risk Assessment to Support the Registration of Cyazofamid for Use on Carrot* at pages 10 to 17 in docket ID number EPA–HQ–OPP–2007–0872.

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 *Human Health Risk Assessment to Support the Registration of Cyazofamid for Use on Carrot* at pages 18 to 21 in docket ID number EPA–HQ–OPP–2007–0872.

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 50 years old; however, no such effect was identified for the general population, including infants and children.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT for all existing and new uses of cyazofamid. Default processing factors were set to 1x based on the results of processing studies indicating that residues of cyazofamid do not concentrate in processed commodities.

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 in the acute dietary exposure

assessment, EPA assumed tolerance-level residues and 100 PCT for all existing and new uses of cyazofamid and processing factors of 1x for all processed commodities.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified cyazofamid as ''not likely to be carcinogenic to humans.'' Therefore, a cancer exposure assessment was not conducted.

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*. 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 ones 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) and Screening Concentration in Ground Water (SCI-GROW) models, 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; the EDWCs of CTCA for 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 the following uses that could result in residential exposures: Disease control on professionally managed turf areas, such as golf courses and college/professional sports fields. EPA assessed residential exposure using the following assumptions: Application by homeowners to residential turf is prohibited. Therefore, non-occupational (i.e., residential) handler exposure is not expected and was not assessed. Short and intermediate term post-application dermal exposure is possible for recreational golfers or players of various sports who use college/professional athletic fields after cyazofamid has been applied. EPA assessed post-application exposure of adult golfers as well as young golfers (children 6-12 and children 3-5 years old). Post-application exposures on college/professional sports fields were assessed only for adults, since children are not expected to play on these types of athletic fields. The post-application exposure assessment was conducted using conservative assumptions, and the resulting exposure estimates are considered to represent high-end exposures.

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 pre-natal and post-natal 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. *Pre-natal and post-natal sensitivity*. The pre- and post-natal toxicology database for cyazofamid includes rat and rabbit developmental toxicity studies and a 2–generation reproduction toxicity study in rats. In the prenatal developmental toxicity study in rabbits, there were no maternal or developmental effects at any dose up to the limit dose of 1,000 mg/kg/day. Similarly, in the 2–generation reproduction study, the HDT (>1,000 mg/kg/day) did not cause maternal systemic, reproductive or offspring toxicity. There was some evidence of increased susceptibility following *in utero* exposure of rats in the prenatal developmental toxicity study. At the HDT (1,000 mg/kg/day), developmental effects (increased incidence of bent ribs) were observed in the absence of maternal toxicity.

EPA concluded that the concern is low for the quantitative susceptibility seen in the rat developmental toxicity study and that there are no residual uncertainties 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 RfD for Females 13-49; and

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 the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyazofamid is complete.

ii. There is no indication that cyazofamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that cyazofamid results in increased susceptibility in *in utero* rabbits in the prenatal developmental study or in young rats in the 2–generation reproduction study. Although there is quantitative evidence of increased susceptibility in the pre-natal developmental study in rats, the degree of concern for pre-natal toxicity is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of cyazofamid.

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 post-application exposure of children (young golfers). 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 13–50 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 1.1% 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-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 aggregated result in aggregate MOEs of 330 for adults, 7,100 for children 3–5 years old and 9,100 for children 6–12 years old. The aggregate MOE for adults includes post-application exposures on athletic fields treated with cyazofamid, the worst-case post-application exposure scenario. The aggregate MOEs for children include post-application exposure of young golfers on treated golf courses.

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). Cyazofamid is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to cyazofamid through food and water with intermediate-term exposures for cyazofamid. Since the endpoints and points of departure (NOAELs) are identical for short and intermediate-term exposures, the aggregate MOEs for intermediate-term exposure are the same as those for short-term exposure (330 for adults, 7,100 for children 3–5 years old and 9,100 for children 6–12 years old).

5. *Aggregate cancer risk for U.S. population*. EPA has classified cyazofamid into the category ''Not likely to be carcinogenic to humans''. Cyazofamid is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methodology is available to enforce the tolerance on carrot roots. Cyazofamid and the metabolite CCIM are completely recovered (>80% recovery) using FDA's Multi-Residue Protocol D (without cleanup). In addition, the petitioner has submitted the results of an Independent Laboratory Validation (ILV) for an HPLC/UV method (high performance liquid chromatography method using an ultra violet detector) which can be used as a single analyte confirmatory method. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no maximum residue limits (MRLs) established by Codex, Canada or Mexico for cyazofamid.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA determined that the proposed tolerance on ''carrot, roots'' should be increased from 0.06 ppm to 0.09 ppm. EPA revised the tolerance level 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, a tolerance is established for combined residues of cyazofamid, 4-chloro-2-cyano-*N*,*N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide, and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, expressed as cyazofamid, in or on carrot, roots at 0.09 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, *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: April 10, 2008.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.601 is amended by alphabetically adding the following commodity to the table in paragraph (a) to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
Carrot, roots	0.09
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0003; FRL–8359–7]

Pyraclostrobin; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl) pyrazol-3-yl]oxy]o-tolyl]carbamate), expressed as parent compound, in or on Belgian endive. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing post harvest use of the pesticide on endive, Belgian to control the fungal pathogen, *Sclerotinia sclerotiorum*. This regulation establishes a maximum permissible level for residues of pyraclostrobin in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2009.

DATES: This regulation is effective April 23, 2008. Objections and requests for hearings must be received on or before June 23, 2008, 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–2008–0003. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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