

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the designated time period. These deviations from the operating regulations are authorized under 33 CFR 117.35.

Dated: January 11, 2012.

**B.L. Dragon,**

*Bridge Program Director, Seventh Coast Guard District.*

[FR Doc. 2012-1729 Filed 1-26-12; 8:45 am]

**BILLING CODE 9110-04-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0697; FRL-9332-5]

#### Cyazofamid; Pesticide Tolerances for Emergency Exemptions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of cyazofamid in or on basil, fresh and dried. 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 use of the pesticide on basil. This regulation establishes a maximum permissible level for residues of cyazofamid in or on these commodities. The time-limited tolerances expire on December 31, 2014.

**DATES:** This regulation is effective January 27, 2012. Objections and requests for hearings must be received on or before March 27, 2012, 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-2011-0697. All documents in the docket are listed in the docket index available in <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:

Princess Campbell, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; email address: [campbell.princess@epa.gov](mailto:campbell.princess@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:

- 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 provides 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 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocsp> and select "Test Methods and Guidelines."

###### C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (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-2011-0697 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 March 27, 2012. 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-2011-0697, 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. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of the fungicide cyazofamid, in or on fresh basil at 12 parts per million (ppm), and on dried basil at 144 ppm. These time-limited tolerances expire on December 31, 2014.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. \* \* \*

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### III. Emergency Exemption for Cyazofamid on Basil and FFDCA Tolerances

The Illinois Department of Agriculture (IDA) submitted a Section 18 Specific Exemption request (10IL02). After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption were met. EPA has authorized a specific exemption under FIFRA section 18 for the use of

cyazofamid on basil for control of downy mildew (*Peronospora blabarii*) in Illinois. This new food use for cyazofamid triggered the requirement for the establishment of tolerances under FFDCA.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of cyazofamid in or on basil. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although these time-limited tolerances expire on December 31, 2014, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on basil after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether cyazofamid meets FIFRA's registration requirements for use on basil or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of cyazofamid by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Illinois to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for cyazofamid, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

### IV. Aggregate Risk Assessment and Determination of Safety

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerances for combined residues of cyazofamid on fresh basil at 12 ppm, and on dried basil at 144 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

#### A. 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 discussed in Unit III. B. of the final rule published in the **Federal Register** of July 14, 2010 (75 FR 40745) (FRL-8833-1).

#### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cyazofamid, EPA considered exposure under the time-

limited tolerances established by this action 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.* No acute toxicity endpoint was identified for cyazofamid for the general population including infants and children, because no acute effects were observed which could be attributed to a single-dose exposure. Nevertheless, EPA estimated acute exposure for the subpopulation, females 13–49 years, based on the developmental toxicity risk. In estimating acute dietary exposure, 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). Tolerance level residues and 100 percent crop treated (PCT) assumptions were used. Anticipated residues and PCT information were not used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. Tolerance level residues and 100 PCT assumptions were used. Anticipated residues and PCT information were not used.

iii. *Cancer.* Based on the data summarized in Unit III.A., July 14, 2010, and at <http://www.regulation.gov> in document “Cyazofamid. Human Health Risk Assessment for Proposed Section 18 Use on Basil, item 4.4 Dietary Exposure and Risk,” p.14, EPA has concluded that cyazofamid does not pose a cancer risk to humans. Cyazofamid has been classified as “not likely to be carcinogenic in humans,” based on the absence of significant tumor increases in two rodent carcinogenic studies. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the estimated drinking water concentrations (EDWCs) of cyazofamid for acute exposures are estimated to be 136 parts per billion

(ppb) for surface water and 2.18 ppb for ground water. For chronic exposures for non-cancer assessments EDWCs 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. *Sources of 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: Commercially-treated residential turf and ornamentals. EPA assessed residential exposure using the following assumptions: Non-occupational handler exposures are not expected; however, post-application exposure is possible for children and adults. Non-occupational/residential MOEs were estimated for “Day 0” exposure. The post-application children’s aggregate MOE (including incidental oral exposures) is 1,600. The Agency is concerned when MOEs are <100. All MOEs, including the children’s aggregate, are >100, and therefore not a risk concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 Web site at <http://www.epa.gov/pesticides/cumulative>.

### C. 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 (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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. There was some evidence of increased susceptibility following *in utero* exposure to rats in the prenatal developmental toxicity study; the increased incidence of bent ribs in the high dose fetuses was considered adverse and was used for setting the developmental NOAEL/LOAEL.

3. *Conclusion.* EPA has determined that reliable data show that 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 sufficient to characterize the hazard, to conduct FQPA assessment, and to select toxicity endpoints for risk assessment. Under current data requirement guidelines, functional immunotoxicity data (OPPTS 780.7800) is a data gap. However, the cyazofamid toxicology database does not show any evidence of biologically relevant effects on the immune system that relate to this chemical. The Agency does not believe that conducting a functional immunotoxicity study will result in a lower NOAEL than the regulatory dose for this risk assessment, and an additional uncertainty factor (UF) for the data gap is unnecessary.

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 for this time-limited tolerance.

iii. There was some evidence of increased susceptibility following *in utero* exposure to rats in the prenatal developmental toxicity study. As described earlier, the increased incidence of bent ribs in the high dose fetuses was considered adverse and was used for setting the developmental NOAEL/LOAEL. EPA considers this approach conservative and highly protective because bent ribs are a reversible developmental anomaly rather than a malformation.

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 as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyazofamid.

#### *D. 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 cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* 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 13–49 years, the only subpopulation assessed. For the population of concern, the acute dietary (food and drinking water) risk assessment represents acute aggregate risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyazofamid from food and water will utilize <1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3. regarding residential use patterns, chronic residential exposure to residues of cyazofamid is not expected.

3. *Short-term and intermediate term risk.* Short-term and intermediate-term risks have been assessed together because both scenarios have the same endpoints and PODs. Short-intermediate term aggregate exposure takes into account short-intermediate term residential exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Cyazofamid is currently registered for uses that could result in short-term and/or intermediate term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-intermediate term residential exposures to cyazofamid.

Using the exposure assumptions described in this unit for short-intermediate term exposures, EPA has concluded the combined short-intermediate term food, water, and residential exposures result in aggregate MOEs of >100 for all scenarios. Because EPA's level of concern for cyazofamid is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent (both the rat and the mouse) 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.

#### **V. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodologies are available to enforce the tolerance expression. Cyazofamid its and metabolite CCIM are completely recovered (≤80% recovery) using FDA's Multiresidue Protocol D (without cleanup). In addition, an acceptable high performance liquid chromatography/ultraviolet/detector (HPLC/UV) method ("Independent Laboratory Validation of the Residue Method for IKF-916 and CCIM in Tomatoes", Document Number 013033-0, Pyxant Labs Inc., with slight modification) 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; email address: [residuemethods@epa.gov](mailto: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.

The Codex has not established a MRL for cyazofamid on basil.

#### **VI. Conclusion**

Therefore, time-limited tolerances are established for residues of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1*H*-imidazole-1-sulfonamide, and its metabolites and degradates in or on basil, fresh, at 12 ppm, and basil, dried, at 144 ppm. These tolerances expire on December 31, 2014.

#### **VII. Statutory and Executive Order Reviews**

This final rule establishes time-limited tolerances under sections 408(e) and 408(l)(6) of FFDCA. 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 in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This 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) (Pub. L. 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).

**VIII. 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.

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 18, 2012.

**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 revising paragraph (b) to read as follows:

**§ 180.601 Cyazofamid; tolerances for residues.**

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited 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 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, calculated as the stoichiometric equivalent of cyazofamid, resulting from use of the pesticide under FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Basil, dried .....	144	12/31/14
Basil, fresh .....	12	12/31/14

\* \* \* \* \*

[FR Doc. 2012–1815 Filed 1–26–12; 8:45 am]

**BILLING CODE 6560–50–P**

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**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Parts 2 and 95**

[ET Docket No. 09–36; RM–11404; FCC 11–176]

**Additional Spectrum for the Medical Device Radiocommunication Service**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

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**SUMMARY:** This document expands the Commission’s Medical Device

Radiocommunication (MedRadio) Service rules to permit the use of new wideband medical implant devices that employ neuromuscular microstimulation techniques to restore sensation, mobility, and other functions to paralyzed limbs and organs. These medical devices hold enormous promise to advance the state of medical care, lower health costs, and improve the quality of life for countless Americans. The rules will allow these new types of MedRadio devices to access 24 megahertz of spectrum in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands on a secondary basis.

**DATES:** Effective February 27, 2012.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Nicholas Oros, Office of Engineering and Technology, 202–418–063, [Nicholas.oros@fcc.gov](mailto:Nicholas.oros@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Report and Order, ET Docket No. 09–36; RM 11404, FCC 11–176, adopted November 30, 2011 and released November 30, 2011. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission’s copy contractor, Best