

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: February 12, 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 180.474 is amended by revising the entry for the commodity “Cherry” in the table in paragraph (a)(1) to read as follows:

§ 180.474 Tebuconazole; tolerances for residues.

- (a) *General.* * * *
- (1) * * *

Commodity	Parts per million
* * *	* *
Cherry, sweet, pre- and post-harvest	5.0
Cherry, tart, pre- and post-harvest	5.0
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-1192; FRL-8400-9]

Famoxadone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of famoxadone in or on caneberry subgroup 13-07A; cilantro, leaves; onion, bulb, subgroup 3-07A; onion, green, subgroup 3-07B; spinach; and vegetable, leafy, except *Brassica*, group 4, except spinach. It also removes existing tolerances on lettuce, head; and caneberry, subgroup 13A that are superseded by the new tolerances on vegetable, leafy, except *Brassica*, group 4, except spinach; and caneberry subgroup 13-07A. Interregional Research Project Number 4 (IR-4) requested these amendments under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or before May 4, 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-2007-1192. 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: 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 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 site at <http://www.gpoaccess.gov/ecfr>.

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-2007-1192 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 May 4, 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-2007-1192, 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 March 12, 2008 (73 FR 13225) (FRL-8354-6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 7E7280 and 7E7281) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petitions requested that 40 CFR 180.587 be amended by establishing tolerances for residues of the fungicide, famoxadone, 3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione, in or on leaf petioles, subgroup 4B at 25 parts per million (ppm) (PP 7E7280); leafy greens, subgroup 4A and cilantro at 50 ppm; bulb vegetables, group 3-07 at 40 ppm; and caneberry, subgroup 13-07A at 10 ppm (all in PP 7E7281). IR-4 also proposed in petition 7E7281 to remove the existing tolerances in 40 CFR 180.587 for residues of the fungicide famoxadone in or on the food commodities lettuce, head; and caneberry, subgroup 13A, which would be superseded by the tolerances on leafy, greens, subgroup 4A; and caneberry, subgroup 13-07A. That

notice referenced a summary of the petition prepared on behalf of IR-4 by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has determined that separate tolerances at different levels are needed for the bulb and green onion subgroups of bulb vegetables group 3-07. EPA has also determined that tolerances should be established on "vegetable, leafy, except *Brassica*, group 4, except spinach" at 25 ppm with a separate tolerance of 50 ppm on spinach, rather than the proposed tolerances on subgroups 4A at 50 ppm and 4B at 25 ppm. The reasons for these changes are explained in Unit IV.D.

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 residues of famoxadone on caneberry subgroup 13-07A at 10 ppm; cilantro, leaves at 25.0 ppm; onion, bulb, subgroup 3-07A at 0.45 ppm; onion, green, subgroup 3-07B at 40 ppm; spinach at 50 ppm; and vegetable, leafy, except *Brassica*, group 4, except spinach at 25 ppm. EPA's

assessment of exposures and risks associated with establishing these 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.

Famoxadone has low acute toxicity by the oral, dermal and inhalation routes of exposure. It is a moderate eye and skin irritant but is not a dermal sensitizer. In subchronic and chronic feeding studies in rats, mice, dogs and cynomolgus monkeys, famoxadone generally caused decreased body weights and body weight gains, often accompanied by decreased food consumption and food efficiency. A mild regenerative hemolytic anemia was also regularly observed in these animals as evidenced by decreased erythrocyte counts, hemoglobin and/or hematocrit, increased reticulocytes, and other related changes in hematologic parameters. Famoxadone also induced a mild hepatotoxicity in treated animals characterized by elevated levels of clinical chemistry enzymes indicative of liver damage (increased alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, and/or sorbitol dehydrogenase) and by histopathological lesions in the liver (single cell or focal necrosis, hepatocellular degeneration, diffuse fatty change, foci of eosinophilic cellular alteration, apoptosis and increased mitotic figures). Both the anemia and the hepatotoxicity were mild and did not significantly compromise the overall health status of the treated animals. In repeated dose studies the anemia, which occurred early in the studies, often appeared to be fully compensated for in the latter stages of the studies. Although the hepatotoxicity persisted throughout the duration of the studies, it was mild or moderate in intensity and not severe or life-threatening.

Additional treatment-related effects were observed in dogs that were not observed in other species. In a 13-week feeding study, clinical signs of neurotoxicity (myotonic twitches) were observed in male and female dogs at the highest dose tested throughout the duration of the study. These twitches were not observed, however, at lower doses in the same study or in a 1-year feeding study in dogs. Also, in both

male and female dogs, famoxadone induced treatment-related cataracts in the lens of the eye in the 13-week feeding study and in the 1-year feeding study. The eye effects were observed at dose levels below those at which any other effects were observed in any other species and served as the basis for many of the risk assessments in humans.

There was no indication of increased quantitative or qualitative susceptibility of fetuses or offspring to famoxadone exposure in the developmental toxicity studies in rats and rabbits or the 2-generation reproduction toxicity study in rats. In a developmental toxicity study in rats, no developmental toxicity was observed in the fetuses at the highest dose tested. Transient decreases in body weight gain and food consumption were noted in the dams in this study. In a developmental toxicity study in rabbits, an increased incidence of abortions was observed. The does which aborted had markedly decreased body weight, body weight gain and food consumption. There was also an equivocal increase in percent postimplantation loss and mean number of resorptions per doe in this study. In the reproduction toxicity study in rats, offspring toxicity (decreased body weights for F1 and F2 pups throughout lactation) was noted at a dose that also resulted in parental toxicity (decreased body weight, body weight gain, and food consumption; and hepatotoxicity). No reproductive toxicity was observed in this study at the highest dose tested.

In an acute neurotoxicity study in rats, there was equivocal evidence of a possible slight neurotoxic effect at the limit dose. In this study, an increased incidence of palpebral (eyelid) closure was observed, but only in males and only on day one. Other than this equivocal evidence and the clinical observations in the 13-week feeding study in dogs of myotonic twitching in the high dose male and female animals, there was no evidence of treatment-related neurotoxicity in the toxicity studies on famoxadone, including a subchronic neurotoxicity study in rats.

In 28-day immunotoxicity studies in rats and mice, there was no evidence of immunotoxicity following exposure to famoxadone.

In carcinogenicity studies in male and female rats and mice, famoxadone did not demonstrate any biologically significant evidence of carcinogenic potential. Famoxadone is classified as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by famoxadone as well as the no-observed-adverse-effect-level and

the lowest-observed-adverse-effect-level from the toxicity studies can be found at <http://www.regulations.gov> in the document *Famoxadone. Human Health Risk Assessment for the Proposed Food Use of Famoxadone on Bulb Vegetables, Crop Group 3; Leafy Greens, Subgroup 4A; Leaf Petioles, Subgroup 4B; and Cilantro* at page 54 in docket ID number EPA-HQ-OPP-2007-1192.

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-term, intermediate-term, 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 famoxadone used for human risk assessment can be found at <http://www.regulations.gov> in the document *Famoxadone. Human Health Risk Assessment for the Proposed Food*

Use of Famoxadone on Bulb Vegetables, Crop Group 3; Leafy Greens, Subgroup 4A; Leaf Petioles, Subgroup 4B; and Cilantro at page 31 in docket ID number EPA-HQ-OPP-2007-1192.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to famoxadone, EPA considered exposure under the petitioned-for tolerances as well as all existing famoxadone tolerances in 40 CFR 180.587. EPA assessed dietary exposures from famoxadone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for famoxadone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996, and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA used average residues from field trials for most plant commodities and anticipated residues based on the anticipated dietary burdens of livestock for animal commodities. Empirical processing factors were used to refine the residue estimates of processed tomato, pepper, potato and grape commodities. For leafy vegetables, empirically-derived reduction factors were applied to account for reduction of residues from washing and removal of outer leaves. Percent crop treated (PCT) and projected PCT estimates were used to further refine exposure estimates for many of the existing and new uses of famoxadone.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified famoxadone as “not likely to be carcinogenic to humans;” therefore, an exposure assessment for evaluating cancer risk is not needed for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the

tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
 - Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
 - Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.
- In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Cucumbers 5%, peppers 5%, potatoes 5%, pumpkins 5%, squash 1%, tomatoes 10% and watermelons 1%.

In most cases, EPA uses available data from U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency used projected percent crop treated (PPCT) information for certain new crops (celery, lettuce, and spinach) as well as the currently

registered crop, grapes. Since famoxadone has only been registered on grapes for 1 year, PCT estimates based on actual usage data were not deemed sufficient indicators of potential usage on grapes. The following PPCT estimates were used in the chronic dietary exposure assessment: Celery 39%, grapes (wine and table) 5%, grape (juice) 50%, lettuce (head) 67%, lettuce (other) 62%, and spinach 39%.

EPA estimates PPCT for a new pesticide use by assuming that the percent crop treated (PCT) during the pesticide's initial 5 years of use on a specific use site will not exceed the average PCT of the dominant pesticide (i.e., the one with the greatest PCT) on that site over the three most recent surveys. Comparisons are only made among pesticides of the same pesticide type (i.e., the dominant fungicide on the use site is selected for comparison with a new fungicide). The PCTs included in the average may be each for the same pesticide or for different pesticides since the same or different pesticides may dominate for each year selected. Typically, EPA uses USDA/NASS data as the source for raw PCT data because it is publicly available and does not have to be calculated from other available data. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

This estimated PPCT, based on the average PCT of the market leader, is appropriate for use in the chronic dietary risk assessment. This method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use.

The predominant factors that bear on whether the estimated PPCT could be exceeded are whether the new pesticide use is more efficacious or controls a broader spectrum of pests than the dominant pesticide(s), whether there are concerns with pest pressures as indicated in emergency exemption requests (<http://www.epa.gov/opp001/section18/>) or other readily available information, and/or other factors based on analysis of additional information. All information readily available has been considered for famoxadone on celery, lettuce and spinach, and it is the opinion of EPA that it is unlikely that actual PCTs for famoxadone on these sites will exceed the corresponding estimated PPCTs during the next 5 years.

A discussion of the factors considered in making this determination can be found in the document *PPCT for the Use of Fungicide Famoxadone (PC 113202)*

on celery (DP 357845), lettuce and spinach (DP 357847), and grapes (no BEAN). Additional Factors Revised in this Memorandum. The referenced document is available at www.regulations.gov in docket ID number EPA-HQ-OPP-2007-1192.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which famoxadone may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for famoxadone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of famoxadone. 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 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 famoxadone for acute exposures are estimated to be 6.2 parts per billion (ppb) for surface water and 0.01 ppb for ground water. EDWCs of famoxadone for chronic exposures for non-cancer assessments are estimated to be 0.189 ppb for surface water and 0.01 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For

chronic dietary risk assessment, the water concentration of value 0.189 ppb was used to assess the contribution to drinking water. As explained in Unit III.C.1.i. an acute dietary risk assessment for famoxadone is unnecessary.

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). Famoxadone is not registered for any specific use patterns that would result in residential exposure.

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 famoxadone to share a common mechanism of toxicity with any other substances, and famoxadone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that famoxadone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for famoxadone includes rat and rabbit developmental toxicity studies and a 2-generation reproduction

toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of *in utero* rats or rabbits in the developmental toxicity studies or of offspring in the rat reproduction study.

3. *Conclusion.* EPA has determined that the FQPA safety factor of 10X must be retained as a database uncertainty factor for the chronic dietary exposure assessment. That decision is based on the following findings:

i. Although the toxicity database for famoxadone is complete, there is uncertainty related to the 13-week feeding study in dogs that was selected to assess chronic dietary exposures to famoxadone. EPA has determined that the 10X FQPA safety factor must be retained to account for the uncertainty arising due to the lack of a NOAEL in this study and extrapolation from a subchronic to chronic exposure duration. A 10X uncertainty factor is considered to provide an adequate margin of safety during development, based on several considerations. First, the LOAEL appeared to be a threshold effect level based on the minimal findings observed. The endpoint (microscopic lens lesions, cataracts, in the eyes of female dogs) was of minimal severity at the lowest dose tested (1.4 milligrams/kilogram/day (mg/kg/day)). This finding would probably have very little effect on vision, and no evidence of cataracts was observed in the ophthalmologic examination. Second, although the microscopic data in the chronic dog study were not considered acceptable due to fixation artifact, there was no evidence of cataracts in the ophthalmologic examination at a similar dose (1.2 mg/kg/day), suggesting that progression with time was minimal at that dose. Finally, there was no evidence of cataracts in monkeys administered famoxadone for 1-year at doses up to 1,000 mg/kg/day. The lack of cataracts in a primate species provides suggestive evidence that humans may be less sensitive than dogs for this effect.

ii. There was equivocal evidence of a slight neurotoxic effect (eyelid closure) at the limit dose in the acute neurotoxicity study in rats, and myotonic twitching was noted at the high dose in male and female dogs in the 13-week feeding study. In this same study, one female dog in the high dose group also had convulsions and ataxia on day 34. Since there was no evidence of treatment-related neurotoxicity at lower doses in these studies or in any other famoxadone toxicity studies, including a subchronic neurotoxicity study in rats and the 1-year feeding study in dogs, EPA has concluded that

there is not a concern for neurotoxicity from exposure to famoxadone, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that famoxadone 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.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were refined for most commodities using reliable PCT/PPCT information and anticipated residue values calculated from valid field trial data. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to famoxadone in drinking water. Residential exposure to famoxadone is not expected. These assessments will not underestimate the exposure and risks posed by famoxadone.

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-term, intermediate-term, 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. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, famoxadone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to famoxadone from food and water will utilize 65% of the cPAD for adult males, 20 years and older, the population group receiving the greatest exposure. There are no residential uses for famoxadone.

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). Famoxadone is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to famoxadone through food and water and will not be greater than the chronic aggregate risk.

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). Famoxadone is not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to famoxadone through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Famoxadone is classified as “not likely to be carcinogenic to humans” and is, therefore, 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 famoxadone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Gas Chromatography with Nitrogen Phosphorus Detection (GC/NPD)) is available to enforce the tolerance expression. 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 no CODEX maximum residue limits (MRLs) established for famoxadone on the commodities associated with these petitions.

C. Response to Comments

Comments were received from a private citizen objecting to EPA's reliance on animal toxicity testing on the basis that it is inhumane and not indicative of the potential for pesticides to cause toxicity in humans. The Agency disagrees with the commenter's claims regarding animal testing. Since humans and animals have complex

organ systems and mechanisms for the distribution of chemicals in the body, as well as processes for eliminating toxic substances from their systems, EPA relies on laboratory animals such as rats and mice to mimic the complexity of human and higher-order animal physiological responses when exposed to a pesticide. EPA is committed, however, to reducing the use of animals whenever possible. EPA-required studies include animals only when the requirements of sound toxicological science make the use of an animal absolutely necessary. The Agency's goal is to be able to predict the potential of pesticides to cause harmful effects to humans and wildlife by using fewer laboratory animals as models and EPA has been accepting data from alternative (to animals) test methods for several years. As progress is made on finding or developing non-animal test models that reliably predict the potential for harm to humans or the environment, EPA expects that it will need fewer animal studies to make safety determinations. Finally, because the commenter has not provided the Agency with a specific rationale (including supporting information) as to why the Agency's action is inconsistent with the legal standards in section 408 of FFDCA, EPA can not provide any more detailed response to the commenter's disagreement with the Agency's decision.

D. Revisions to Petitioned-For Tolerances

IR-4 proposed a tolerance of 40 ppm on the crop group “vegetable, bulb, group 3.” Based on the results of field trials showing a greater than 5-fold difference in residues on bulb and green onions, EPA determined that separate tolerances are required for these subgroups. Therefore, EPA is establishing tolerances of 0.45 ppm on onion, bulb, subgroup 3-07A and 40 ppm on onion, green, subgroup 3-07B. EPA determined the appropriate tolerance levels for bulb and green onions based on analyses 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*.

IR-4 proposed tolerances on leaf petioles, subgroup 4B at 25 ppm and on leafy greens, subgroup 4A and cilantro, leaves at 50 ppm. Based on the results of field trial data indicating higher residues in spinach than the other members of subgroup 4A, EPA determined that a tolerance of 25 ppm would be adequate for members of the entire crop group 4 (including

subgroups 4A and 4B), except spinach, and cilantro leaves. Therefore, EPA is establishing tolerances of 25 ppm on vegetable, leafy, except *Brassica*, group 4, except spinach; 25 ppm on cilantro, leaves; and 50 ppm on spinach.

V. Conclusion

Therefore, tolerances are established for residues of famoxadone, 3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione, in or on caneberry subgroup 13-07A at 10 ppm; cilantro, leaves at 25.0 ppm; onion, bulb, subgroup 3-07A at 0.45 ppm; onion, green, subgroup 3-07B at 40 ppm; spinach at 50 ppm; and vegetable, leafy, except *Brassica*, group 4, except spinach at 25 ppm.

VI. Statutory and Executive Order Reviews

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

Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the 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) (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: February 12, 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 180.587 is amended by removing the tolerances for Caneberry, Subgroup 13A and Lettuce, head; and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.587 Famoxadone; tolerances for residues.

(a) * * *

Commodity	Parts per million
Caneberry subgroup 13-07A	10
Cilantro, leaves	25
Onion, bulb, subgroup 3-07A	0.45
Onion, green, subgroup 3-07B	40
Spinach	50
Vegetable, leafy, except <i>Brassica</i> , group 4, except spinach	25

* * * * *

[FR Doc. E9-4357 Filed 3-3-09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2007-1106; FRL-8402-7]

Chlorothalonil; Pesticide Tolerances**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite in or on lychee and starfruit. The United States Department of Agriculture (USDA) requested that EPA establish these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 4, 2009. Objections and requests for hearings must be received on or before May 4, 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-2007-1106. 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: 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 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>.

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-2007-1106 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 May 4, 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-2007-1106, 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

In the **Federal Register** of December 3, 2008 (73 FR 73632) (FRL-8390-1), EPA issued a proposed rule pursuant to sections 408(e) of FFDCA, 21 U.S.C. 346a(d)(3). The rule proposed that 40 CFR 180.275 be amended by establishing tolerances for combined residues of chlorothalonil and its 4-hydroxy metabolite in or on lychee at 15 parts per million (ppm) and starfruit at 3.0 ppm. The USDA requested that EPA establish these tolerances. Because USDA did not submit a petition in support of establishing these tolerances, EPA did not publish a Notice of Filing of a petition for these tolerances. Rather, EPA issued a proposed rule that included a summary of the exposure assessment prepared by the Agency and explained the basis for EPA's conclusion that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to chlorothalonil. The proposal established a 60-day public comment period. Comments were received in response to the proposed rule. EPA's response to these comments is discussed in Unit III.