not justify less than full SIP approval of the rule at this time.

Comment #8: WD–40 commented that the SIP emission credits associated with this rule are based on outdated data and are significantly low if the rule covers more than just metal working facilities.

Response #8: The rule specifically states that it covers all VOC containing fluids used for metalworking and for metal protection. The exact amount of emission credit associated with this rule is not relevant to the action on whether to approve the rule into the federally-enforceable SIP.

Comment #9: WD–40 further stated that rule 1144 does not meet RACT because it: (a) does not exempt small containers; and (b) does not allow low vapor pressure VOCs as do other EPA and CARB regulations.

Response #9: States are not limited to implementing RACT and may, particularly for extreme Ozone nonattainment areas like South Coast, need more stringent requirements to fulfill attainment and other requirements of CAA Sections 110 and part D. See also response to comments 3, 4 and 5.

III. EPA Action

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving these rules into the California SIP.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Volatile organic compounds].

Dated: October 21, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(388)(i)(A) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(388) New and amended regulations for the following APCD were submitted on April 5, 2011 by the Governor's Designee.

(i) Incorporation by reference.

(A) South Coast Air Quality Management District—SCAQMD)

(*1*) Rule 1143, ''Consumer Paint Thinners & Multi-purpose Solvents,'' adopted on March 6, 2009 and amended December 3, 2010.

(*2*) Rule 1144, ''Metal Working Fluids and Direct-Contact Lubricants,'' adopted on March 6, 2009, and amended July 9, 2010.

* * * * *

[FR Doc. 2011–29459 Filed 11–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0866; FRL–9325–4]

Fenamidone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for inadvertent residues of fenamidone in or on the cereal grains crop group 15, except rice and the forage, fodder, and straw of cereal grains crop group 16, except rice. Bayer Crop Science requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 16, 2011. Objections and requests for hearings must be received on or before January 17, 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–2010–0866. 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: Rosemary Kearns, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (703) 305–5611; *email address: kearns.rosemary@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0866 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 January 17, 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–2010–0866, by one of the following methods:

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 15, 2010 (75 FR 78240) (FRL–8853–1), 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 0F7764) by Bayer CropScience, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.547 be amended by establishing tolerances for residues of the fungicide fenamidone, (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-, (S)-), in or on grain, cereal, group 15 (except rice) at 0.1 ppm; grain, forage, group 16 (except rice) at 0.3 ppm; and grain, stover, group 16 (except rice) at 0.5 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

EPA has modified the commodity definitions for which tolerances are being established. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenamidone

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenamidone 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.

Fenamidone has low acute toxicity via the oral, dermal and inhalation routes of exposure. It is a moderate eye irritant, but is not a dermal irritant or a dermal sensitizer. The liver is the target organ in chronic studies in the rat, mouse and dog. The thyroid is also a target organ in the rat. An acceptable guideline immunotoxicity study in rats has been reviewed. While the study showed a potential immunosuppression at the highest dose tested, the existing risk assessment points of departure are lower and are therefore protective of this potential effect. Fenamidone is not likely to be a human carcinogen based on the negative carcinogenic potential of fenamidone in rats and mice and studies indicate that there is no concern for mutagenicity for fenamidone.

Fenamidone did not demonstrate any qualitative or quantitative increased susceptibility of fetuses or offspring in the rat and rabbit developmental toxicity studies or the 2-generation rat reproduction study. In the rat reproduction study (Sprague Dawleyrat), decreased absolute brain weight and pup body weight occurred at the same dose levels as decreased absolute brain weight and parental body weight, food consumption and increased liver and spleen weight. Developmental toxicity (decreased fetal weights and incomplete ossification) was observed in the rat only at the limit dose. Fenamidone did not produce developmental toxicity in the rabbit or reproductive toxicity in the rat.

No treatment-related effects were observed on motor activity or in the functional observation battery (FOB) parameters measured in the subchronic neurotoxicity study in rats. In this subchronic neurotoxicity study, marginal decreases in brain weights were observed only in high dose males. In the acute neurotoxicity study in rats, the most commonly observed clinical sign was staining/soiling of the anogenital region. Other day-1 FOB findings included mucous in the feces, hunched posture and unsteady gait. In a developmental neurotoxicity study in Wistar rats, no neurobehavioral effects and no neuropathological changes were observed at any dose in the offspring, but decreased body weight was observed during pre- and post-weaning.

Specific information on the studies received and the nature of the adverse effects caused by fenamidone 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 docket ID EPA–HQ–OPP–2010–0866 on pages 25–28 of the document titled ''Fenamidone: Human Health Risk Assessment to Support the Label Amendment to Permit Rotation to All Cereal Grain, Except Rice and Establish Revised Tolerances for Inadvertent Residues.''

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for fenamidone used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations).	NOAEL = 125 milligrams/kilograms/day (mg/kg/day). UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day	Acute Neurotoxicity in Rats: LOAEL = 500 mg/kg/day based on urination, staining/soiling of the anogenital region, mucous in the feces, and unsteady gait in the females.
Chronic dietary (All populations).	NOAEL= 2.83 mg/kg/day .. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0283 mg/kg/day. cPAD = 0.0283 mg/kg/day	2 Year Chronic Toxicity/Carcinogenicity in Rats: LOAEL = 7.07/9.24 mg/kg/day (M/F) based on increase in severity of diffuse thyroid C-cell hyperplasia in both sexes.
Cancer (Oral, dermal, inhalation).	Based on the negative carcinogenic potential of fenamidone in rats and mice, EPA has classified fenamidone as ''not likely'' to be a human carcinogen by all relevant routes of exposure.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to fenamidone, EPA considered exposure under the petitioned-for tolerances as well as all existing fenamidone tolerances in 40 CFR 180.579. EPA assessed dietary exposures from fenamidone 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.

Such effects were identified for fenamidone. 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). As to residue levels in food, EPA conducted a conservative acute dietary risk assessment which used maximum field trial residue values and assumed 100 percent crop treated for all 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 to residue levels in food, EPA conducted a conservative acute dietary risk assessment which used maximum field trial residue values and assumed 100 percent crop treated for all commodities.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that fenamidone does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue 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.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fenamidone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenamidone. 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) and Screening Concentration in Ground Water (SCI–GROW) models the estimated drinking water concentrations (EDWCs) of fenamidone for acute exposures are estimated to be 47.88 parts per billion (ppb) for surface water and 178 ppb for ground water. For chronic exposures for non-cancer assessments these levels are estimated to be 12.86 ppb for surface water and 178 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For both acute and chronic dietary risk assessments, the water concentration value of 178 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).

Fenamidone 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 fenamidone to share a common mechanism of toxicity with any other substances, and fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fenamidone 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.*

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 pre- and postnatal toxicity database for fenamidone includes rat and rabbit developmental toxicity studies, a rat developmental neurotoxicity study (DNT), and a 2-generation reproduction toxicity study in rats. No evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to in utero exposure was observed in the developmental toxicity studies. There was no developmental toxicity in rabbit fetuses up to 100 milligrams/kilogram/day (mg/kg/day), the highest dose tested (HDT); whereas an increase in absolute liver weight was observed in the dose at 30 and 100 mg/kg/day. Since the liver was identified as one of the principal target organs in rodents and dogs, the occurrence of this finding in rabbits at 30 and 100 mg/kg/day was considered strong evidence of maternal toxicity. In the rat developmental study, developmental toxicity manifested as decreased fetal body weight and incomplete fetal ossification in the presence of maternal toxicity in the form of decreased body weight and food consumption at the limit dose (1,000 mg/kg/day). The effects at the limit dose were comparable between fetuses and dams. No quantitative or qualitative evidence of increased susceptibility was observed in the 2-generation reproduction study in rats. In that study, both the parental and offspring LOAELs were based on decreased absolute brain weight in female F1 adults and female F2 offspring at 89.2 mg/kg/day. At 438.3 mg/kg/day, parental effects consisted of decreased body weight and food consumption, and increased liver and spleen weight. Decreased pup body weight was also observed at the same dose level of 438.3 mg/kg/day. There were no effects on reproductive

performance up to 438.3 mg/kg/day (highest dose tested; HDT).

The results of the DNT study indicated an increased susceptibility of offspring. There was no maternal toxicity at the HDT (429 mg/kg/day). Effects in the offspring included decreased body weight (9–11%) and body weight gain (8–20%) during preweaning and decreased body weight (4–6%) during post-weaning at 429 mg/kg/day (LOAEL). There were no neurobehavioral effects and no neuropathological changes at any dose in the offspring. The concern for the increased susceptibility observed in the DNT is low because:

i. There were no neurobehavioral or neuropathological changes in the offspring at any dose;

ii. A clear NOAEL for the adverse effects in the study was identified;

iii. The endpoints used for the various risk assessment scenarios are much more sensitive than that of the decreased bodyweight of the offspring occurring at almost half the limit-dose (429 mg/kg/day); and

iv. The NOAEL of 2.83 mg/kg/day used for the long-term risk assessment is 33x lower than the offspring NOAEL of 92.3 mg/kg/day in the DNT.

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 toxicology database for fenamidone is complete for purposes of the characterization of potential pre-natal and/or post-natal risks to infants and children.

ii. There was no evidence of neurotoxicity in the subchronic neurotoxicity study submitted for fenamidone. There was evidence of neurotoxicity (urination, staining/soiling of the anogenital region, mucous in the feces and unsteady gait in females) in the acute neurotoxicity study, and EPA used the NOAEL from this study to assess acute dietary exposure. There was also evidence of neurotoxicity (decreased absolute brain weights) in the 2-generation rat reproduction study; however, there was no indication of increased susceptibility of offspring with regard to these effects. Finally, there was no evidence of neurotoxicity at any dose in the submitted DNT study. Based on the results of these studies, EPA concluded that there is no need for additional UFs to account for neurotoxicity.

iii. No qualitative or quantitative increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental toxicity studies was observed. There was no qualitative or quantitative increased susceptibility in the two generation reproduction study (rat). There is low concern for residual uncertainties in the DNT study in the rat since there is a well established offspring NOAEL for the reasons noted in Unit III.D.2.

iv. Residue values used in the dietary risk assessments are unlikely to underestimate risk. Dietary exposure assessments were conducted using maximum field trial residue values and assumed 100% crop treated. Therefore, the acute and chronic dietary, food only, exposure is considered an upper bound conservative estimate. The contribution from drinking water is minimal. EPA concludes that the acute and chronic exposure estimates in this analysis are unlikely to underestimate actual exposure. The drinking water component of the dietary assessment utilizes water concentration values generated by modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, 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 fenamidone will occupy 5% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenamidone from food and water will utilize 90% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. There are no residential uses for fenamidone.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fenamidone is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and/or intermediate-term risk is assessed based on short- and/or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fenamidone.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fenamidone 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 fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatographic method coupled with tandem mass spectrum detection (LC/MS/MS)) 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; *email address: residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States

is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for fenamidone in cereal crops (crop group 15 and 16, except rice).

C. Revisions to Petitioned-For Tolerances

EPA has modified the commodity definitions that were proposed in the Notice of Filing to (1) be consistent with Agency policy and nomenclature and (2) to have all of crop group 16 under a single tolerance instead of separated into separate ones as proposed.

EPA is removing the tolerances for corn, field forage; corn, field, grain; corn, field, stover; corn, sweet, forage, corn, sweet, plus cob with husks removed; corn, sweet, stover; wheat, grain; wheat, hay; wheat, forage; and wheat, straw from paragraph (d) that are covered by the newly created crop group tolerances.

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

V. Conclusion

Therefore, tolerances are established for indirect or inadvertent residues of fenamidone (4–H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino, (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on grain, cereal, group 15, except rice at 0.1 ppm; and grain, cereal, forage, fodder and straw, group 16, except rice at 0.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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).

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: October 27, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.579, revise paragraphs (a)(1) introductory text, (a)(2) introductory text, (c) introductory text, and paragraph (d) to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide, fenamidone, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring only fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-,(S)-), in or on the commodities:

* * * * *

(2) Tolerances are established for residues of the fungicide fenamidone, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-,(S)-), and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), in or on the commodities:

* * * * *

(c) *Tolerances with regional registrations.* A tolerance with regional registration as defined in § 180.1(l) is established for residues of the fungicide fenamidone, including its metabolites and degradates, in or on the following commodities. Compliance with the

tolerance levels is to be determined by measuring only fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-,(S)-), in or on the commodity:

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide fenamidone, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels is to be determined by measuring fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-,(S)-), and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), in or on the following commodities when present therein as a result of application of fenamidone to the crops in paragraph (a)(1).

Commodity	Parts per million
Grain, cereal, group 15, except rice	0.1
Grain, cereal, forage, fodder and straw, group 16, except rice	0.5
Soybean, forage	0.15
Soybean, hay	0.25
Soybean, seed	0.02
Strawberry	0.15

[FR Doc. 2011–29618 Filed 11–15–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[[EPA–HQ–OPP–2011–0606; FRL–8892–1]

Polyethylene Glycol; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of α-Hydro-ω-hydroxypoly(oxyethylene), minimum number average molecular weight (in amu), 17,000; also known as polyethylene glycol, when used as an inert ingredient in a pesticide chemical formulation. Clariant Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of α-Hydro-ω-hydroxypoly(oxyethylene), minimum number average molecular weight (in amu), 17,000 on food or feed commodities.

DATES: This regulation is effective November 16, 2011. Objections and requests for hearings must be received on or before January 17, 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–2011–0606. 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: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8560; *email address: fertich.elizabeth@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.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2011–0606 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 January 17, 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–2011–0606, 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