retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications '' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

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 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: September 19, 2002.

James Jones,

Acting Director, 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), 346(a) and 374.

2. Section 180.1221 is added to subpart D to read as follows:

§ 180.1221 Pseudozyma flocculosa strain PF-A22 UL; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

[FR Doc. 02–24651 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0229; FRL–7196–8]

Fenamidone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone, [4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-], in or on lettuce, head at 15 ppm and lettuce, leaf at 20 ppm. Aventis CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer CropScience. Therefore, the registrant is now Bayer CropScience.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0229, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–2002–0229 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a

beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–2002–0229. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of January 4, 2002 (67 FR 592) (FRL–6812–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F06300) by Aventis CropScience, 2 Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by, the registrant. Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer CropScience. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide [4H-Imidazol-4-one, 3,5-dihydro-5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-], fenamidone and its metabolites RPA 412708, RPA 412636 and RPA 410193, in or on letttuce, head at 15 ppm and lettuce, leaf at 20 part per million (ppm).

Section 408(b)(2)(A)(i) of the 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) 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) 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....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of fenamidone on lettuce, head at 15 ppm and lettuce, leaf at 20 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. The nature of the toxic effects caused by fenamidone are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity rodents (rats) Parent compound tested	NOAEL = 29.68/35.39 mg/kg/day in males and females, respectively. LOAEL = 305.48/337.19 mg/kg/day in males and females, respectively, based on decreased body weights, body weight gains, and food consumption in males and females, enlargement and prominent germinal centers in the spleen in males, and periportal vaculation and bile duct hyperplasia in the liver of males.
870.3100	90–day oral toxicity rodents (rats) Parent compound tested	NOAEL = 10.41/12.00 mg/kg/day in males and females, respectively. LOAEL = 68.27/83.33 mg/kg/day based on increased liver weights and incidence of ground glass appearance of the hepatocytes (mostly centrilobular) in the males.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity rodents (rats) RPA 412636 plant metabolite tested	NOAEL = 6.419/7.725 mg/kg/day in males and females, respectively. LOAEL = 32.860/39.111 mg/kg/day in the males and females, respectively, based on increased liver weights, liver enlargement, centrilobular hepatocyte hypertrophy and vacuolation, and follicular epithelial height of the thyroid in males.
870.3100	90–day oral toxicity in rodents (rat) RPA 410193 plant metabolite tested	NOAEL = 9.4/11.5 mg/kg/day in males and females, respectively. LOAEL = 93.3/114.9 mg/kg/day in males and females respectively. based on liver enlargement and increased liver weights and chlolesterol in the males and on incidences of centrilobular hepatocellular hypertrophy in the males and females.
870.3100	90–day oral toxicity in rodents (mice) Parent compound tested	NOAEL = 44.49/54.13 mg/kg/day in males and females, respectively. LOAEL = 220.17/273.86 mg/kg/day in males and females respectively based on mild hepatotoxicity as evidenced by increased liver weights and incidences of pale liver and hepatic microvacuolation in the males and decreased cholesterol and increased incidence of prominent lobulation of the liver in the females.
870.3150	90–day oral toxicity in nonrodents (dogs) Parent compound tested	NOAEL = 500 mg/kg/day for males and females. Highest dose tested (HDT). LOAEL = Not determined.
870.3200	21/28-Day dermal toxicity (rat) Parent compound tested	NOAEL = 1000 mg/kg/day in females. Not established in males. LOAEL = 1000 mg/kg/day in males based on decreased body weight, body weight gain, and food consumption. The LOAEL was not observed in females.
870.3700	Prenatal developmental in rodents (rats) Parent compound tested	Maternal NOAEL = 150 mg/kg/day Maternal LOAEL = 1000 mg/kg/day based on decreased body weight, body weight gains, and decreased food consumption. Developmental NOAEL = 150 mg/kg/day Developmental LOAEL = 1000 mg/kg/day based on decreased fetal weights and incomplete ossification.
870.3700	Prenatal developmental in nonrodents (rabbits) Parent compound tested	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 30 mg/kg/day based on increased liver weights. Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = not observed
870.3800	Reproduction and fertility effects with acid (rat) Parent compound tested	Parental/Systemic NOAEL = 4.04/5.45 mg/kg/day in males and in females Parental/Systemic LOAEL = 68.6/89.2 mg/kg/day in males and females based on decreased absolute brain weight in F1 females. Reproductive/Offspring NOAEL = 4.04/5.45 mg/kg/day in males and females. Reproductive/Offspring LOAEL = 68.6/89.2 mg/kg/day based on decreased absolute brain weight in F2 female pups.
870.4100	Chronic toxicity in dogs (1 year) Parent compound tested	NOAEL = 100 mg/kg/day in males and females respectively. LOAEL = 1000 mg/kg/day in males and females based on increased liver weight, triglycerides, and biliary proliferation in males, and alkaline phosphatase activity in both sexes.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4300	Carcinogenicity in rats Parent compound tested	NOAEL = 2.83/3.63 mg/kg/day in males and females, respectively. LOAEL = 7.07/9.24 mg/kg/day in males and females respectively based on an increase in severity of diffuse thyroid C-cell hyperplasia in both sexes. No evidence of carcinogenicity
870.4200	Carcinogenicity in mice Parent compound tested	NOAEL = 47.5/63.8 mg/kg/day in males and females, respectively. LOAEL = 525.5/690.5 mg/kg/day in males and females, respectively based on decreased body weight, weight gain, food efficiency, increased food consumption and absolute and relative (to body) liver weights and liver nuclear pleomophism in both sexes.
870.5265	Gene Mutation with parent	Fenamidone was non-mutagenic when tested up to or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA102, TA1535 and TA1537.
870.5265	Gene Mutation with RPA 410193	RPA 410193 was non-mutatagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains Ta98, TA100, TA1535, and TA1537 and *E. coli* strain WP2uvrA.
870.5265	Gene Mutation with RPA 412708	RPA 412708 was non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *E. coli* strain WP2uvrA.
870.5265	Gene Mutation with RPA 412636	RPA 412636 was non-mutagenic when tested up to 5,000 μg/plate or cytotoxic levels, in presence and absence of activation, in *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 and *E. coli* strain WP2uvrA.
870.5300	Mouse lymphoma cell/mammalian activation gene forward mutation assay (L5178Y hgprt) with parent	Fenamidone was non-mutagenic at doses up to the limit of solubility (1600 μg/mL) in both the presence and absence of S9 metabolic activation.
870.5300	Mouse lymphoma cell/mammalian activation gene forward mutation assay (l5178Y hgprt) with RPA 412636.	RPA 412636 was non-mutagenic at doses up to the limit of solubility (1600 μg/mL) in both the presence and absence of S9 metabolic activation.
870.5300	Mouse lymphoma cell/mammalian activation gene forward mutation assay (L5178Y hgprt) with RPA 410193.	RPA 410193 was non-mutagenic at doses up to the limit of solubility (800 μg/mL) in both the presence and absence of S9 metabolic activation.
870.5375	*In vitro* mammalian cytogenetics (Chromosomal aberration assay in human peripheral blood) with parent.	There was evidence of chromosome aberrations induce over background both in the presence and absence of S-9 activation.
870.5395	*In vivo* Mouse Micronucleus with parent.	Fenamidone was negative for chromosomal aberrations in the cytogenetic assay when administered singly or for 2 days to CD-1 mice up to 2,000 mg/kg/day.
870.5395	*In vivo* mouse micronucleus with RPA 412636	RPA 412636 was not clastogenic in the mouse micronucleus test up to 350 mg/kg (HDT).
870.5395	*In vivo* mouse micronucleus with RPA 412708	RPA 412708 was not clastogenic in the mouse micronucleus assay when tested once daily for 2 days up to cytotoxic levels of 150 mg/kg.
870.5395	*In vivo* mouse micronucleus with RPA 410193	RPA 410193 was not clastogenic in the mouse micronucleus assay when tested once daily for 2 days up to cytotoxic levels of 2,000 mg/kg.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5550	Unscheduled DNA synthesis with parent	Fenamidone did not produce any evidence of unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), in rat primary hepatocyte cultures exposed up to cytotoxic levels.
870.5550	Unscheduled DNA synthesis with parent	Fenamidone did not produce any evidence of unscheduled DNA synthesis, as determined by radioactive tracer procedures (nuclear silver grain counts), in rat primary hepatocyte cultures exposed up to cytotoxic levels.
870.6200	Acute Neurotoxicity-rat Parent compound tested	NOAEL = 125 mg/kg/day LOAEL = 500 mg/kg/day based on urination, staining/soiling of the anogenital region, mucous in the feces, and unsteady gait in females.
870.6200	Subchronic Neurotoxicity Screening Battery-rat Parent compound tested	NOAEL = 73.5/83.4 mg/kg/day in males and females, respectively. LOAEL = 392.3/414.2 mg/kg/day in males and females based on decreased absolute brain weight in males, and decreased body weight, weight gains, and food consumption in both sexes.
870.7485	Metabolism and pharmacokinetics - rat Parent compound tested	In a rat metabolism with ^{C}14- labeled fenamidone, Sprague-Dawley rats receive doses of 3 mg/kg (single, low dose), 3 mg/kg x 14 days (repeated low dose) and 300 mg/kg (high dose). Fenamidone was well absorbed and rapidly excreted, primarily in the urine and bile, at the low dose and repeated low dose. At 300 mg/kg, biliary excretion was not measured, although fecal excretion was 50-68% of the dose. Tissue levels of radioactivity were primarily found in the liver at the single low dose and in the thyroid in the repeated and high dose studies. Metabolite identification included RPA 408056 (racemic form of RPA 412708) and RPA 717879 (racemic mixture of RPA 412636)
870.7600	Dermal Penetration-rat Parent compound tested	Dermal penetration approximated 10% using the protocol for 10 hours of exposure.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species variations.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fenamidone used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENAMIDONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 125 mg/kg UF = 300 Acute RfD = 0.43 mg/kg	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.43 mg/kg	Acute Neurotoxicity in Rats LOAEL = 500 mg/kg 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 = 300 Chronic RfD = 0.01 mg/kg/day	FQPA SF = 1X cPAD = chr RfD/FQPA SF = 0.01 mg/kg/day	2–Year Chronic Toxicity/Carcinogenicity in Rats LOAEL = 7.07 mg/kg/day based on increase in severity of diffuse thyroid C-cell hyperplasia in both sexes.

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern.
* The reference to the FQPA safety factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. No tolerances have previously been established for the residues of fenamidone. Risk assessments were conducted by EPA to assess dietary exposures from fenamidone in food as follows:

i. *Acute exposure*. Acute dietary 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The Agency notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups which may not be sufficiently represented in the consumption surveys (i.e, nursing infants). Therefore, risks estimated for these subpopulations were included in representative populations having sufficient numbers of survey respondents (i.e., all infants or females 13-50 years old). Thus, the population subgroups listed in Table 3 include those subgroups having sufficient numbers of survey repondents in CSFII food consumption survey. The acute dietary exposure analysis assumed tolerance level residues and 100% crop treated (Tier 1 analysis).

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis incorporated average residues from the field trial studies and assumed 100% crop treated. (Tier 2 analysis) The most highly exposed population subgroup for the chronic analysis was children 7-12 years old at 10% cPAD.

TABLE 3.—SUMMARY OF RESULTS FROM ACUTE AND CHRONIC DEEM™ ANALYSES OF FENAMIDONE

Population Subgroup	Acute Dietary		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	%aPAD	Dietary Exposure (mg/kg/day)	%cPAD
U.S. population - total	0.016993	4	0.000938	9
All Infants (<1 year old)	0.0	<1	0.000016	<1
Children (1–6 years old)	0.016289	4	0.000743	7
Children (7–12 years old)	0.018555	4	0.001047	10
Females (13–50 years old)	0.019273	4	0.001044	10
Males (13–19 years old)	0.014797	3	0.000805	8
Males (20+ years old)	0.015994	4	0.000917	9
Seniors (55+ years old)	0.015981	4	0.000902	9

iii. *Cancer*. Based on the negative carcinogenic potential of fenamidone in rats and mice, the Agency has classified fenamidone as not likely to be carcinogenic in humans by all relevant routes of exposure. Therefore, a cancer dietary analysis is not necessary and has not been conducted.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenamidone in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or

modeling taking into account data on the physical characteristics of fenamidone.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fenamidone they are further discussed in the aggregate risk sections.

Based on the PRZM/EXAM and SCI-GROW models the estimated environmental concentrations (EECs) of fenamidone and its metabolites of concern for acute exposures are estimated to be 49.7 parts per billion (ppb) for surface water and 45.4 ppb for ground water. The EECs for chronic exposures are estimated to be 8.92 ppb for surface water and 45.4 ppb for ground 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 use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether fenamidone has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenamidone has 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The Agency concluded that there is no concern for pre- and/or postnatal toxicity resulting from exposure to fenamidone. No quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental toxicity studies was observed. There was no developmental toxicity in rabbit fetuses up to 100 mg/kg/day (HDT), which resulted in an increased absolute liver weight in the does. 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, maternal toxicity in the form of decreased body weight and food consumption occurred at 1,000 mg/kg/day (limit dose). Also at this same dose, developmental toxicity was observed as decreased fetal body weight and incomplete fetal ossification. The developmental and maternal NOAEL was 150 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 NOAEL was established at 60 ppm (5.45 mg/kg/day) based on decreased absolute brain weight in female F1 adults and female F2 offspring at 1,000 ppm (89.2 mg/kg/day). At 5,000 ppm (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 (HDT).

3. *Conclusion*. Other than a developmental neurotoxicity study, there is a complete toxicity data base for fenamidone and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has determined that an additional safety factor of 3X is necessary to protect the safety of infants and children in assessing fenamidone exposures and risks based on the following considerations.

There is a concern for developmental neurotoxicity resulting from exposure to fenamidone due to the clinical signs of neurotoxicity in the mutagenicity studies, abnormal gait and other evidence in the acute neurotoxicity study in rats, the decreased absolute brain weight in the subchronic neurotoxicity study in male rats, and the decreased absolute brain weight in the female F1 adults and female F2 offspring in the 2–generation rat reproduction study. The Agency has determined that an uncertainty factor of

3X (as opposed to a higher value) is sufficiently protective because available DNT data demonstrate that a 3–fold factor is generally sufficient to address the uncertainty that results from a missing DNT study when there are concerns for neurological development (A retrospective analysis of twelve development neurotoxicity studies submitted by the USEPA, Office of Prevention, Pesticides, and Toxic Substances, Presented to the Science Advisory Panel (SAP), December 8-9, 1998). In addition, fenamidone is not a cholinesterase inhibitor and, therefore, the comments made at the June 26-27, 2002 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) SAP meeting on the Determination of the Appropriate FQPA Safety Factor(s) in the Organophosphorous Pesticide Cumulative Risk Assessment: Susceptibility and Sensitivity to the Common Mechanism, Acetylcholinesterase Inhibition should not influence this uncertainty factor decision.

No Special FQPA Safety Factor is necessary because:

i. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with fenamidone, and there is no evidence of increased susceptibility of young rats in the reproduction study with fenamidone;

ii. There are no residual uncertainties identified in the exposure databases as the dietary food exposure assessment is conservative, since tolerance-level residues and 100% crop treated are assumed; and

iii. The dietary drinking water exposure is based on conservative modeling estimates, and there are no registered or proposed residential uses at this time, so these assessments will not underestimate the exposure and risks posed by fenamidone.

Any concern that the additional 3X factor is not sufficiently protective is more than offset by the conservative nature of the exposure estimate. For the following reasons, the exposure estimate, in all likelihood, has overstated potential residue levels by at least a factor of 10. Specifically, in regards to the Agency's dietary food exposure assessment, the Agency has assumed tolerance level residues and 100% crop treated in conducting its acute risk assessment. In conducting the chronic dietary food exposure assessment, the Agency has assumed average residues based on field trial data and 100% crop treated. In July 2001, the U.S. Department of Agriculture issued a report entitled ''Agricultural Chemical Usage, Vegetable Summary,'' in which the Department determined that no greater than 66 percent of the national lettuce crop is treated with any fungicide. Treatment with any one fungicide is lower than this figure and, in most cases, dramatically so. The assumption of 100% crop treated, therefore, is an overestimate and is, therefore, protective. Both the use of tolerance level residues and the use of average residues from field trial data for use in conducting a chronic dietary risk assessment will lead to substantial overstatement of exposure because:

a. Residue levels decline sharply (by a factor of over 200X) within 1 week of treatment at the minimum pre-harvest interval;

b. The average residue calculations assumed consumption of leaf wrappers from head lettuce; data submitted in support of the use of fenamidone on head lettuce indicate that average residues without wrappers, which are typically discarded prior to consumption, are lower than the values used in this assessment by a factor of 6X; and

c. The assessment does not take into account the residue reduction associated with washing of lettuce prior to consumption; fenamidone is not a systemic fungicide and, therefore, residues are likely to be surface residues only and would be reduced through washing.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fenamidone will occupy 4% of the aPAD for the U.S. population, 4% of the aPAD for females and 13–50 and 4% of the aPAD for children 7–12 years old. Children are the population with the greatest potential for exposure to fenamidone. In addition, there is potential for acute dietary exposure to fenamidone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FENAMIDONE

Population Subgroup	aPAD (mg/kg/day)	Food Exposure (mg/kg/day	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.43	0.017	49.7	45.4	14,000
All infants less than 1 year old	0.43	0.000	49.7	45.4	4,300
Children (1–6 years old)	0.43	0.016	49.7	45.4	4,100
Children (7–12 years old)	0.43	0.019	49.7	45.4	4,100
Females (13–50 years old)	0.43	0.019	49.7	45.4	12,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenamidone from food will utilize 10 % of the cPAD for the U.S. population, <1 % of the cPAD for all infants <1 year old and 10 % of the cPAD for children 7–12 years old. There are no residential uses for fenamidone. In addition, there is potential for chronic dietary exposure to fenamidone in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON- CANCER) EXPOSURE TO FENAMIDONE

Population Subgroup	cPAD mg/kg/day	Food Exposure	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.01	0.0009	8.9	45.4	320
All infants less than 1 year old	0.01	0.00002	8.9	45.4	100
Children 7 to 12 years old	0.01	0.001	8.9	45.4	90
Females, 13–50 years old	0.01	0.001	8.9	45.4	270

3. *Short-term risk and intermediate-term risk*. Short-term and intermediate-term aggregate exposure take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fenamidone is not registered for use on any sites that would result in residential exposure. Therefore, short- and intermediate- term risk assessments were not performed.

4. *Aggregate cancer risk for U.S. population*. Fenamidone is not likely to be carcinogenic.

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, and to infants and children from aggregate exposure to fenamidone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Livestock tolerances for residue of fenamidone are not currently necessary; therefore, information pertaining to a livestock enforcement method is not relevant to the current petition.

Fenamidone, RPA 408056, RPA 717979 and RPA 405862 were tested through FDA Multiresidue Method of Protocols. Residues of fenamidone and all three metabolites were completely recovered using Protocol D. Low recoveries of fenamidone were observed from Protocols E (31%) and F (54%). Metabolites RPA 408056, RPA 717879, and RPA 405862 were not recovered using Protocols E and F. Protocol B was not tested because fenamidone and its metabolites are not acids or phenols, and Protocol A was not fully tested because the compounds were not found to naturally fluoresce. These data have been forwarded to the FDA for further evaluation. Adequate method validation, radiovalidation, and independent laboratory validation of the petitioner proposed LC/MS/MS enforcement method have been received. The proposed enforcement method has been forwarded to the ACB for petition method validation. The registrant must make any modifications to the proposed enforcement methods that the Agency finds necessary during its validation of the methods. A successful PMV is necessary before this method can be employed as an enforcement method. Upon successful completion of the validation, the method will be forwarded to FDA for publication for future revision of the Pesticide Analytical Manual, Vol-II (Prior to publication and upon request, the method will be available from the Analytical Chemistry Branch (ACB), BEAD (75053). Contact Francis D. Griffith, telephone (410) 305-2905, e-mail:griffith.francis@epa.gov. Analytical standards are also available from the EPA National Repository at the same location.

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

CODEX, Canada, and Mexico do not have maximum residue limits (MRLs) for residues of fenamidone, in/on head lettuce or leaf lettuce.

V. Conclusion

Therefore, the tolerance is established for residues of [4H-Imidazol-4-one, 3,5-

dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-], fenamidone, in or on head lettuce at 15 ppm and leaf lettuce at 20 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–2002–0229 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 on or before November 26, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlinton, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–2002–0229, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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 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: September 13, 2002.

James Jones,

Acting Director, 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), 346(a) and 374.

2. Section 180.579 is added to read as follows:

§ 180.579 Fenamidone; tolerances for residues.

(a) *General.* Tolerances are established for residues of fenamidone (4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3 (phenylamino)-, (S)-) from the application of the fungicide fenamidone on the following raw agricultural commodities:

Commodity	Parts per million
Lettuce, head	15 ppm
Lettuce, leaf	20 ppm

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 02–24652 Filed 9–26–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0193; FRL–7199–8]

Cyfluthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyfluthrin in or on soybean, seed; soybean, forage; soybean, hay; corn, field, forage; corn, field, stover and corn, pop, stover; grain, cereal, group; corn, field, refined oil; corn, field, milled byproduct; grain, aspirated fractions; wheat milled byproducts, except flour; rice, hulls; rice, bran; barley, bran, oat, bran and rye, bran; milk; milk, fat; cattle, fat, goat, fat, hog, fat, horse, fat and sheep, fat; mustard greens; lettuce, leaf; lettuce, head; brassica, head and stem, subgroup; pea, southern, succulent; and pea, dry. Bayer Corporation and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0193, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0193 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Division (7505C), 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: