18 AAC 50.310. Construction Permits: Application. (effective 1/18/1997)
(a) Application Required.
(b) Operating Permit Coordination.
(c) General Information.
(d) Prevention of Significant Deterioration Information. Table 6. Significant Concentrations
(e) Excluded Ambient Air Monitoring.
(f) Nonattainment Information.
(g) Demonstration Required Near A Nonattainment Area.
(h) Hazardous Air Contaminant Information.
(j) Nonattainment Air Contaminant Reductions.
(k) Revising Permit Terms.
(l) Requested Limits.
(m) Stack Injection.
(n) Ambient Air Quality Information.
18 AAC 50.320. Construction Permits: Content and Duration. (effective 1/18/1997)
18 AAC 50.325. Operating Permits: Classifications. (effective 6/21/1998)
18 AAC 50.330. Operating Permits: Exemptions. (effective 1/18/1997)
18 AAC 50.335. Operating Permits: Application. (effective 6/21/1998)
(a) Application Required.
(b) Identification.
(c) General Emission Information.
(d) Fees.
(e) Regulated Source Information.
(f) Facility-wide Information: Ambient Air Quality.
(g) Facility-wide Information: Owner Requested Limits.
(h) Facility-wide Information: Emissions Trading.
(i) Compliance Information.
(j) Proposed Terms and Conditions.
(k) Compliance Certifications.
(l) Permit Shield.
(m) Supporting Documentation.
(n) Additional Information.
(o) Certification of Accuracy and Completeness.
(p) Renewals.
(q) Insignificant Sources.
(r) Insignificant Sources: Emission Rate Basis.
(s) Insignificant Sources: Category Basis.
(t) Insignificance Sources: Size or Production Rate Basis.
(u) Insignificant Sources: Case-by-Case Basis.
(v) Administratively Insignificant Sources.
18 AAC 50.340. Operating Permits: Review and Issuance. (effective 1/18/1997)
(a) Review of Completeness.
(b) Evaluation of Complete Applications.
(c) Expiration of Application Shield.
18 AAC 50.341. Operating Permits: Reopenings. (paragraphs a, b, c, f, and g)(effective 6/14/1998)
18 AAC 50.345. Operating Permits: Standard Conditions. (effective 6/21/1998)
18 AAC 50.350. Operating Permits: Content. (effective 6/21/1998)
(a) Purpose of Section
(b) Standard Requirements.
(c) Fee Information.
(d) Source-Specific Permit Requirements.
(e) Facility-Wide Permit Requirements.
(f) Other Requirements.
(g) Monitoring Requirements.
(h) Records.
(i) Reporting Requirements.
(j) Compliance Certification.
(k) Compliance Plan and Schedule.
(l) Permit Shield.
(m) Insignificant Sources.
18 AAC 50.355. Changes to a Permitted Facility. (effective 1/18/1997)
18 AAC 50.360. Facility Changes that Violate a Permit Condition. (effective 1/18/1997)
18 AAC 50.365. Facility Changes that do not Violate a Permit Condition. (effective 6/14/1998)
18 AAC 50.370. Administrative Revisions. (effective 6/14/1998)
18 AAC 50.375. Minor and Significant Permit Revisions. (effective 6/21/1998)
18 AAC 50.380. General Operating Permits. (effective 6/14/1998)
18 AAC 50.385. Permit-by-rule for Certain Small Storage Tanks. (effective 6/21/1998)

Article 5. User Fees

18 AAC 50.400. Permit Administration Fees. (effective 6/21/1998)
18 AAC 50.410. Emission Fees. (effective 1/18/1997)
18 AAC 50.420. Billing Procedures. (effective 1/18/1997)

Article 9. General Provisions

18 AAC 50.910. Establishing Level of Actual Emissions. (effective 1/18/1997)
18 AAC 50.990. Definitions. (effective 1/01/2000)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301225; FRL–6829–3]

RIN 2070–AB78

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues ofacetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine in or on citrus dried pulp, citrus fruit group, cotton gin byproducts, cotton undelinted seed, grape, fruiting vegetable group, leafy brassica vegetable group, leafy vegetable (except brassica) group, pome fruit group, and tomato paste; and tolerances for the combined residues of acetamiprid and IM-2-1 N1-[(6-chloro-3-pyridyl) methyl]-N2-cyano-acetamidine in or on fat, meat, and meat byproducts of cattle, hog, horse, goat, and sheep; milk; poultry eggs,fat, liver, and meat. Aventis CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 27, 2002. Objections and requests for hearings, identified by docket control number OPP–301225, must be received on or before May 28, 2002.

ADDRESSES: Written objections and hearing requests may besubmitted 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–301225 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Akiva Abramovitch, Registration Division (7505C), Office of Pesticide Programs, EnvironmentalProtection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–8328; e-mail address: abramovitch.akiva@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–301225. 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 May 30, 2001 (66 FR 29213)(FRL–6782–9), 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 0F06082) by Aventis CropScience (formerly Rhone-Poulenc Ag Company), P.O. Box 12014, #2 T.W. Alexander Drive, Research Triangle Park, NC 207709. This notice included a summary of the petition prepared by Aventis CropScience, the registrant. 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 insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on brassica (cole crops) at 1.2 parts per million (ppm), canola seed and mustard seed at 0.01 ppm, citrus at 0.5 ppm, cottonseed at 0.06 ppm, fruiting vegetables at 0.2 ppm, grapes at 0.2 ppm, leafy vegetables at 3.0 ppm, and pome fruits at 0.70 ppm. The Agency will not address the canola seed and mustard seed tolerances at this time.

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 the insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]- N2-cyano-N1-methylacetamidine in or on citrus fruit group at 0.50 ppm, citrus dried pulp and leafy brassica vegetable group at 1.20 ppm each, cotton gin byproducts at 20.0 ppm, cotton undelinted seed at 0.60 ppm, leafy vegetable group (except brassica) at 3.0 ppm, fruiting vegetable group and grape at 0.20 ppm each, pome fruit group at 1.0 ppm, and tomato paste at 0.40 ppm; and tolerances for the combined residues of acetamiprid and IM-2-1 N1-[(6-chloro-3-pyridyl) methyl]-N2-cyano-acetamidine in or on meat and fat of cattle, hog, horse, goat, and sheep at 0.10 ppm each; meat byproducts of cattle, hog, horse, goat, and sheep at 0.20 ppm each; milk at 0.10 ppm; poultry eggs, meat and fat at 0.010 ppm each; and poultry liver at 0.050 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 acetamiprid 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	13–Week Feeding - Rat	NOAEL: 12.4/14.6 mg/kg/day - Male/Female (M/F) LOAEL: 50.8/56.0 mg/kg/day (M/F) based on decreased Body Weight (BW), BW gain and food consumption.

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

Guideline No.	Study Type	Results
870.3100	13–Week Feeding - Mouse	NOAEL: 106.1/129.4 mg/kg/day (M/F) LOAEL: 211.1/249.1 mg/kg/day (M/F) based on reduced BW and BW gain, decreased glucose and cholesterol levels, reduced absolute organ weights.
870.3150	90–Day oral toxicity in nonrodents	NOAEL: 13/14 mg/kg/day (M/F) LOAEL: 32 mg/kg/day based on reduced BW gain in both sexes.
870.3200	21–Day dermal toxicity - rabbit	NOAEL: 1,000 mg/kg/day - Highest Dose Tested (HDT) LOAEL: >1,000 mg/kg/day
870.3700	Prenatal developmental in rodents	Maternal NOAEL: 16 mg/kg/day Maternal LOAEL: 50 mg/kg/day based on reduced BW and BW gain and foodconsumption, increased liver weights. Developmental NOAEL: 16 mg/kg/day Developmental LOAEL: 50 mg/kg/day based on increased incidence of shortening of the 13th rib.
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL: 15 mg/kg/day Maternal LOAEL: 30mg/kg/day based on BW loss and decreased food consumption. Developmental NOAEL: 30 mg/kg/day (HDT) Developmental LOAEL: > 30 mg/kg/day
870.3800	Reproduction and fertility effects	Parental systemic NOAEL: 17.9/21.7 mg/kg/day (M/F) Parental systemic LOAEL: 51.0/60.1 mg/kg/day (M/F) based on decreased BW, BW gain and food consumption. Offspring systemic NOAEL: 17.9/21.7 mg/kg/day (M/F) Offspring systemic LOAEL: 51.0/60.1 mg/kg/day (M/F) based on reductions in pup weight, litter size, viability and weaning indices; delay in age to attain preputial separation and vaginal opening. Reproductive NOAEL: 17.9/21.7 mg/kg/day (M/F) Reproductive LOAEL: 51.0/60.1 mg/kg/day (M/F) based on reductions in litter weights and individual pup weights on day of delivery.
870.4100	Chronic toxicity dogs	NOAEL: 20/21 mg/kg/day (M/F) LOAEL: 55/61 mg/kg/day (M/F) based on initial BW loss and overall reduction in BW gain.
870.4100/870.4200	Chronic toxicity/Carcinogenicity - rats	NOAEL: 7.1/8.8 mg/kg/day (M/F) LOAEL: 17.5/22.6 mg/kg/day (M/F) based on decreases in mean BW and BW gain (F) and hepatocellular vacuolation (M) Evidence of treatment-related increase in mammary tumors.
870.4300	Carcinogenicity mice	NOAEL: 20.3/75.9 mg/kg/day (M/F) LOAEL: 65.6/214.6 mg/kg/day (M/F) based on decreased BW and BW gain andamyloidosis in numerous organs (M) and decreased BW and BW gain (F). Not oncogenic under conditions of study.
870.5100	Reverse gene mutation assay	*Salmonella typhimurium/E. coli* - Not mutagenic under the conditions of the study.
870.5300	Mammalian cells in cultureForward gene mutation assay - CHO cells	Not mutagenic under the conditions of the study.
870.5375	*In vitro* mammalian chromosomal aberrations - CHO cells	Acetamiprid is a clastogen under the conditions of the study.
870.5385	*In vivo* mammalian chromosome aberrations - rat bone marrow	Acetamiprid did not induce a significant increase in chromosome aberrations in bone marrow cells when compared to the vehicle control group.
870.5395	*In vivo* mammalian cytogenetics - micronucleus assay in mice	Acetamiprid is not a clastogen in the mouse bone marrow micronucleus test.
870.5550	UDS assay in primary rat hepatocytes/ mammalian cell culture	Acetamiprid tested negatively for UDS in mammalian hepatocytes *in vivo*.

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

Guideline No.	Study Type	Results
870.6200	Acute neurotoxicity - rat	NOAEL: 10 mg/kg LOAEL: 30 mg/kg based on reduction in locomotor activity.
870.6200	Subchronic neurotoxicity - rat	NOAEL: 14.8/16.3 mg/kg/day (M/F) LOAEL: 59.7/67.6 mg/kg/day (M/F) based on reductions in BW, BW gain, foodconsumption and food efficiency.
N/A	28–day feeding - dog	NOAEL: 16.7/19.1 mg/kg/day (M/F) LOAEL: 28.0/35.8 mg/kg/day based on reduced BW gain.
870.7485	Metabolism - mouse, rat, rabbit Special Study	Male mice, rats or rabbits were administered single doses of acetamiprid by gavage, intraperitoneal injection (i.p.) or intravenous injection (i.v.) up to 60 mg/kg. The animals were assessed for a variety of neurobehavioral parameters. In vitro experiments were also done using isolated ileum sections from guinea pigs to assess contractile responses in the absence and presence of agonists (acetylcholine, histamine diphosphate, barium chloride and nicotine tartrate). Acetamiprid was also assessed via i.v. in rabbits for effects on respiratory rate, heart rate and blood pressure; via gavage in mice for effects on gastrointestinal motility; and via i.p. in rats for effects on water and electrolyte balance in urine, and blood coagulation, hemolytic potential and plasma cholinesterase activity. Based on a number of neuromuscular, behavioral and physiological effects of acetamiprid in male mice, under the conditions of this study, a overall NOAEL of 10 mg/kg (threshold) and LOAEL of 20 mg/kg could be estimated for a single dose by various exposure routes.
870.7485	Metabolism and pharmacokinetics - rat	Extensively and rapidly metabolized. Metabolites 79–86% of administered dose. Profiles similar for males and females for both oral and intravenous dosing. Thirty-seven percent of dose recovered in urine and feces as unchanged test article. Urinary and fecal metabolites from 15–day repeat dose experiment only showed minor differences from single-dose test. Initial Phase I biotransformation: demethylation of parent. 6-chloronicotinicacid most prevalent metabolite. Phase II metabolism shown by increase in glycine conjugate.
870.7600	Dermal absorption	The majority of the dose was washed off with the percent increasing with dose. Skin residue was the next largest portion of the dose with the percent decreasing with dose. In neither case was there evidence of an exposure related pattern. Absorption was small and increased with duration of expure. Since there are no data to demonstrate that the residues remaining on the skin do not enter the animal, then as a conservative estimate of dermal absorption, residues remaining on the skin will be added to the highest dermal absorption value. The potential total absorption at 24 hours could be approximately 30%.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from thetoxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (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 differences.

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 1×10^{-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 acetamiprid used for human risk

assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietarygeneral population including infants and children	NOAEL = 10 mg/kg UF = 100 ..... Acute RfD = 0.10 mg/kg/day	FQPA SF = 1 aPAD = 0.10 mg/kg/day	Acute mammalian neurotoxicity study in the rat LOAEL = 30 mg/kg based on reduction in locomotor activity in males.
Chronic Dietary all populations	NOAEL= 7.1 mg/kg/day UF = 100 ..... Chronic RfD = 0.07 mg/kg/day .	FQPA SF = 3 cPAD = 0.023 mg/kg/day	Chronic/carcinogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced BW and BW gain (females) and hepatocellular vacuolation (males).
Short- and Intermediate-Term Incidental Oral (1 to 30 days and 1 month to 6 months) (Residential)	NOAEL= 15 mg/kg/day	LOC for MOE = 300 (Residential)	Co-critical studies: subchronic oral (rat); subchronic neurotoxicity (rat) developmental toxicity (rat); LOAEL = 50 mg/kg/day based on reductions in BW, BW gain and food consumption.
Short- and Intermediate-TermDermal (1 to 30 days; and 1 month to 6 months) (Residential)	oral study NOAEL= 17.9 mg/kg/day (dermal absorption rate = 30%	LOC for MOE = 100 (Occupational), 300 (Residential)	2-generation reproduction study (rat) LOAEL = 51.0 mg/kg/day based on reductions in pup weights in both generations, reductions in litter size and viability and weaning indices among F_2 offspring, significant delays in age to attain vaginal opening and preputial separation.
Long-Term Dermal (6 months to lifetime) (Residential)	oral study NOAEL= 7.1 mg/kg/day (dermal absorption rate = 30%)	LOC for MOE = 100 (Occupational), 300 (Residential)	Chronic/carcinogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced BW and BWgain (females) and hepatocellular vacuolation (males).
Short- and Intermediate-Term Inhalation (1 to 30 days and 1 month to 6 months)(Residential)	oral study NOAEL= 17.9 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational), 300 (Residential)	2-generation reproduction study (rat) LOAEL = 51.0 mg/kg/day based on reductions in pup weights in both generations, reductions in litter size and viability and weaning indices among F_2 offspring, significant delays in age to attain vaginal opening and preputial separation.
Long-Term Inhalation (6 months to lifetime) (Residential)	oral study NOAEL= 7.1 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational), 300 (Residential)	Chronic/carcinogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced BW and BWgain (females) and hepatocellular vacuolation (males).
Cancer (oral, dermal, inhalation) - not likely to be carcinogenic.	.....	.....	

*The reference to the FQPA Safety Factor refers to any additional safety factor that is retained due to concerns unique to the FQPA. The PAD (Population-adjusted Dose) incorporates the FQPA Safety Factor into the dose for use in risk assessment: PAD = RfD/FQPA SF.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have been established for the residues of acetamiprid, in or on raw agricultural commodities and no tolerances have been established for the combined residues of acetamiprid and IM-2-1 N1-[(6-chloro-3-pyridyl) methyl]-N2-cyano-acetamidine in or on meat, milk, poultry and egg commodities. Risk assessments were conducted by EPA to assess dietary exposures from acetamiprid 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 assessment assumed that 100% of the crops listed on the proposed label were treated and that crops listed on the label and livestock had residues of concern at the tolerance level. For processed commodities without a proposed tolerance, the analysis used the default processing factors provided with the model. A Tier 1 analysis results in highly conservative estimates of exposure and risk. Consideration of processing factors, anticipated residues in foods at the time of consumption, and percent of crop treated would result in

lower exposure and risk estimates than those presented here. Even without such refinement, the acute dietary risk estimates are below the Agency's level of concern [i.e., <100% of the population-adjusted dose (PAD)] for all population subgroups. Dietary (food only) exposure estimates were greatest for the population subgroup composed of children ages 1–6 years old. Acute exposure is estimated to be 0.039606 mg/kg (95th percentile of exposure), which is equal to 40% of the acute population-adjusted dose (aPAD). The results are summarized in the accute dietary exposureportion of Table 3.

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 assessment assumed that 100% of the crops listed on the proposed label were treated and that crops listed on the label and livestock had residues of concern at the tolerance level. For processed commodities without a proposed tolerance, the analysis used the default processing factors provided with the model. A Tier 1 analysis results in highly conservative estimates of exposure and risk. Consideration of processing factors, anticipated residues in foods at the time of consumption, and percent of crop treated would result in lower exposure and risk estimates than those presented here. Even without such refinement the chronic dietary risk estimates are below the Agency's level of concern [i.e., <100% of the population-adjusted dose (PAD)] for all population subgroups. Chronic exposure is estimated to be 0.014687 mg/kg/day, which is equal to 64% of the cPAD. Although there is the potential for incidental ingestion of pesticide residues and soil from treated vegetables and foliage in home gardens via hand-to-mouth transfer, incidental oral exposure was not quantitatively assessed. Toddlers are not expected to spend a significant amount of time in a home garden and any resulting incidental oral exposures would be minimal and not quantifiable. Therefore, the Agency does not believe that incidental oral exposure from the requested homeowner uses will result in significant incidental oral exposures to children. The results are summarized in the chronic exposure portion of Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE AND CHRONIC EXPOSURE TO ACETAMIPRID

Population Subgroup	Acute		Chronic	
	95th percentile Exposure mg/kg	%aPAD	Exposure mg/kg/day	%cPAD
U.S. Population (total)	0.016921	17	0.005395	24
All Infants (<1 year old)	0.038317	38	0.010261	45
Children 1–6 years old	0.039606	40	0.014687	64
Children 7–12 years old	0.022084	22	0.008072	35
Females 13–50	0.011451	11	0.003970	17
Males 13–19	0.011627	12	0.004460	19
Males 20+ years	0.009624	10	0.003673	16
Seniors 55+	0.010242	10	0.004005	17

[1] %aPAD and %cPAD are exposures presented as percentages ofthe acute and chronic population-adjusted doses, respectively. For acetamiprid, the aPAD = 0.1 mg/kg; the cPAD = 0.023 mg/kg/day.

iii. *Cancer*. The Agency classified acetamiprid into the category not likely to be carcinogenic to humans based on the absence of a dose-response and a lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high-dose groups with the controls. Although the incidence exceeded the historical control data from the same lab, it was within the range of values from the supplier.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for acetamiprid 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 acetamiprid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 acetamiprid they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of acetamiprid for acute exposures are estimated to be 17 parts per billion (ppb) for surface water and 0.0008 ppb for ground water. The EECs for chronic exposures are estimated to be 4.0 ppb for surface water and 0.0008 ppb for ground water.

3. *From non-dietary exposure*. The term ''residentialexposure'' 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). Acetamiprid is proposed with this notice to be registered for use on the following residential non-dietary sites: ornamentals, flowers, vegetable gardens, and fruit trees. The risk assessment showed the following: for residential applicators, total MOEs for short- and intermediate-term residential dermal and inhalation exposures range from 1.2×10^5 to 6×10^5. For post-application activities, short- and intermediate-term MOEs range from 1.8×10^4 to 1.8 10^5 for adults and from 2.3×10^4 to 2.2×10^5 for youth ages 10–12 years. The residential uses for acetamiprid are not expected to result in long-term exposures.

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.

EEPA does not have, at this time, available data to determine whether acetamiprid 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, acetamiprid 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 acetamiprid 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 margin of exposure (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*. There is noquantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental studies. In the rat, an increase in the incidence of shortening of the 13th rib was observed in fetuses at the same LOAEL as the dams, which exhibited reduced mean body weight, body weight gain and food consumption and increased liver weights. No developmental toxicity was observed in the rabbit at dose levels that induced effects in the does: body weight loss and decreased food consumption. In the multi-generation reproduction study, qualitative evidence of increased susceptibility of rat pups is observed. The parental and offspring systemic NOAELs are 17.9/21.7 (M/F) mg/kg/day and the offspring/parental systemic LOAELs are 51.0/60.1 mg/kg/day based on a decrease in mean body weight, body weight gain and food consumption in the parents and significant reductions in pup weights in both generations, reductions in litter size, and viability and weaning indices among F_2 offspring as well as significant delays in the age to attain vaginal opening and preputial separation in the offspring. The offspring effects are considered to be more severe than the parental effects.

3. *Conclusion*. There is a complete toxicity data base for acetamiprid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency FQPA Safety Factor Committee recommended that the FQPA safety factor be reduced to 3x in assessing the risk posed by this chemical. The Committee determined that the safety factor is necessary when assessing the risk posed by acetamiprid because there is qualitative evidence of increased susceptibility following prenatal/postnatal exposure to acetamiprid in the 2-generation reproduction study in rats. However, the Committee concluded that the safety factor could be reduced to 3x for acetamidprid because the toxicology database is complete; there is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure of rat and rabbit fetuses; the dietary (food and water) and residential exposure assessments will not underestimate the potential exposures for infants, children, and/or women of childbearing age; and the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study and a safety factor. The Committee recommended that the safety factor be required for all population subgroups when assessing chronic dietary exposures as well as when assessing residential short-, intermediate-, and long-term exposure durations to address the concern for the effects seen following prenatal/postnatal exposure to acetamiprid in the 2-generation reproduction study in rats; the FQPA Safety Factor can be removed (i.e., reduced to 1x) when assessing acute dietary exposure.

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 drinking water level of concerns (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 from food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the population adjusted dose (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 aggregate risk assessment scenario: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (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 acetamiprid will occupy 17% of the aPAD for the U.S. population, 11% of the aPAD for females 13 years and older, 38% of the aPAD for all infants (<1 year old) and 40% of the aPAD for children ages 1–6 years. In addition, there is potential for acute dietary exposure to acetamiprid 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 ACETAMIPRID

Population Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppd)[a]
U.S. Population	0.10	17	0.0008	17	2,900
All Infants (<1 year old)	0.10	38	0.0008	17	620
Children 1–6 years	0.10	40	0.0008	17	600
Children 7–12 years	0.10	22	0.0008	17	780
Females 13–50 years	0.10	11	0.0008	17	2,700
Males 13–19 years	0.10	12	0.0008	17	3,100
Males 20+ years	0.10	10	0.0008	17	3,200
Seniors (55+ years)	0.10	10	0.0008	17	3,100

[a] Drinking Water Level of Comparison = aPAD-Acute DietaryExposure (mg/kg/day) × body weight (kg) × 1,000 μg/mg ÷ water consumption (L/day). Body weight = 70 kg (males and general pop.), 60 kg (females), or 10 kg (infants and children). Consumption = 2 L/day for adults or 1 L/day for infants and children. Values have been rounded to 2 significant figures.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to acetamiprid from food will utilize 24% of the cPAD for the U.S. population, 45% of the cPAD for all infants (< 1 year old) and 64% of the cPAD for children ages 1–6 years. Based on the use pattern, chronic residential exposure to residues of acetamiprid is not expected. In addition, there is potential for chronic dietary exposure to acetamiprid 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 ACETAMIPRID

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppd)[a]
U.S. Population	0.023	24	0.0008	4	620
All Infants (<1 year old)	0.023	45	0.0008	4	130
Children 1–6 years old	0.023	64	0.0008	4	80
Children 7–12 years old	0.023	35	0.0008	4	150
Females 13–50 years old	0.023	17	0.0008	4	670

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppd)[a]
Males 13–19 years old	0.023	19	0.0008	4	650
Males 20+ years old	0.023	16	0.0008	4	680
Seniors (55+ years old)	0.023	17	0.0008	4	670

[a] Chronic Drinking Water Level of Comparison = cPAD-Chronic Dietary Exposure (mg/kg/day) × body weight (kg) × 1,000 µg/mg ÷ water consumption (L/day). Body weight = 70 kg (males and general pop.), 60 kg (females), or 10 kg (infants and children). Consumption = 2 L/day for adults or 1 L/day for infants and children. Values have been rounded to 2 significant figures.

3. *Short-term risk and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently proposed for uses that could result in short-term and intermediate residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term and intermediate exposures for acetamiprid. Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that aggregated food and residential exposures aggregated result in aggregate MOEs of 18,000 for adults, and 23,000 for youth (ages 10–12 years) for the non-oral routes of exposure (i.e., combined dermal and/or inhalation pathways). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of acetamiprid in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM AND INTERMEDIATE-TERM EXPOSURE TO ACETAMIPRID

Population Subgroup	MOE (Food)[a]	Total Non-Oral MOE[b]	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term and Intermediate-Term DWLOC (ppd)[c,d]
U.S. Population	2,780	18,000	4	0.0008	1,500
All Infants (<1 year old)	1,462	N/A[e]	4	0.0008	400
Children 1–6 years old	1,021	N/A	4	0.0008	400
Children 7–12 years old	1,858	23,000	4	0.0008	400
Females 13–50 years old	3,778	18,000	4	0.0008	1,400
Males 13–19 years old	3,363	18,000	4	0.0008	1,600
Males 20+ years old	4,084	18,000	4	0.0008	1,600
Seniors (55+ years old)	3,745	18,000	4	0.0008	1,600

[a] Food MOE = Short-term NOAEL (15 mg/kg/day) ÷Chronic Dietary Exposure (food only)
[b] Total non-oral MOEs are from the Occupational and Residential Risk Assessment. Note that given the currently requested use patterns, incidental oral exposure is an insignificant pathway of exposure and has not been factored into the DWLOCs.
[c] Maximum Water Exposure = Short/Intermediate-term NOAEL (15 mg/kg/day) × (1 ÷ Target MOE) - (1 ÷ Food MOE + 1 ÷ Oral MOE + 1 ÷ Non-Oral MOE)
[d] Short- and Intermediate-term Drinking Water Level of Concern = Maximum Water Exposure (mg/kg/day) × body weight (kg) × 1,000 µg/mg ÷ water consumption (L/day). Body weight = 70 kg (males and general pop.), 60 kg (females), or 10 kg (infants and children). Consumption = 2 L/day for adults or 1 L/day for infants and children. Values have been rounded to 2 significant figures.
[e] N/A = Not Applicable

4. *Aggregate cancer risk for U.S. population*. The Agency classified acetamiprid into the category not likely to be carcinogenic to humans based on the absence of a dose-response and a lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high-dose groups with the controls. Although the incidence exceeded the laboratories historical control data from the same lab: the increase was within the range of values from the supplier.

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 acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Enforcement methods are available for vegetable and non-citrus crops, citrus crops, and livestock commodities. Citrus and livestock methods consist of solvent extraction, followed by solid-phase cleanup, and high performance liquid chromatography/ultraviolet determination of residues. The vegetable and non-citrus crop method differs in that it employs gas chromatography/

electron capture detection determination of residues. The livestock method analyzes acetamiprid and IM-2-1 simultaneously. Limits of quantitation are 0.01 ppm for vegetable and non-citrus fruits, meat, milk, fat, and eggs; and 0.05 ppm for citrus and meat byproducts. Adequate radiovalidation and independent laboratory validation (ILV) data have been received and the method was forwarded to the Analytical Chemistry Laboratory (ACL) for petition method validation (PMV). The petitioner will be required to make any modifications or revision to the proposed enforcement method resulting from PMV. When the PMV is finalized, 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

There are no CODEX, Canadian, or Mexican Maximum Residue Limits for acetamiprid in or on citrus fruit group, citrus dried pulp, cotton, fruiting and leafy, leafy vegetables, tomato paste; and for the combined residues of acetamiprid and IM-2-1 N1-[(6-chloro-3-pyridyl) in or on fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep; milk; poultry eggs, fat, liver, and meat.

C. Conditions

The conditions of the acetamiprid registration contained the following confirmatory data and label requirements: rotational crop storage stability; and radiovalidation data for IM-2-1-amide in ruminant muscle. The storage stability data is considered confirmatory data since the Agency has examined other storage stability data of acetamiprid and found it to be stable upon storage. The Agency decided to impose tolerances on meat and poultry products upon review of the data although tolerances for IM-2-1 were not considered by the registrant in the original submission.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid N1-[(6-chloro-3-pyridyl) methyl]-N2-cyano-N1-methylacetamidine in or on citrus fruit group, citrus dried pulp, cotton undelinted seed, cotton gin byproducts, fruiting vegetable group, grape, leafy vegetable group (except brassica), leafy vegetable brassica group, pome fruit group, and tomato paste; and tolerances for the combined residues of acetamiprid and IM-2-1 N1-[(6-chloro-3-pyridyl) methyl]-N2-cyano-acetamidine in or on fat, meat, and meat byproducts of cattle, hog, horse, goat, and sheep; milk; eggs; fat, liver and meat of poultry.

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–301225 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 May 28, 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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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.

EEPA 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–301225, 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: March 15, 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 180.578 is added to read as follows:

§ 180.578 Acetamiprid; tolerances forresidues.

(a) *General.* (1) Tolerances are established for residues of the insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine in or on the following commodities:

Commodity	Parts per million
Citrus, dried pulp	1.20
Cotton, gin byproducts	20.0
Cotton, undelinted seed	0.60
Fruit, citrus group	0.50
Fruit, pome group	1.0
Grape	0.20
Tomato, paste	0.40
Vegetable, brassica, leafy group	1.20

Commodity	Parts per million
Vegetable, fruiting group	0.20
Vegetable, leafy group, except brassica	3.00

(2) Tolerances are established for the combined residues of the insecticide acetamiprid N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine andN1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-acetamidine in or on the following commodities:

Commodity	Parts per million
Cattle, fat	0.10
Cattle, meat	0.10
Cattle, meat byproducts	0.20
Egg	0.010
Goat, fat	0.10
Goat, meat	0.10
Goat, meat byproducts	0.20
Hog, fat	0.10
Hog, meat	0.10
Hog, meat byproducts	0.20
Horse, fat	0.10
Horse, meat	0.10
Horse, meat byproducts	0.20
Milk	0.10
Poultry, fat	0.010
Poultry, liver	0.050
Poultry, meat	0.010
Sheep, fat	0.10
Sheep, meat	0.10
Sheep, meat byproducts	0.20

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

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

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

[FR Doc. 02–7098 Filed 3–26–02; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 43

[CC Docket Nos. 98–137, ASD File No. 98–91; FCC 99–397]

1998 Biennial Regulatory Review—Review of the Depreciation Requirements for Incumbent Local Exchange Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: This document announces the effective date of the rules published in the **Federal Register** on April 10, 2000. These rules amend the Commission's rules governing the depreciation requirements for price cap incumbent local exchange carriers. The Commission details the reporting and data requirements that the carriers must comply with when they want to change their prescribed depreciation rate.

DATES: Section 43.43 paragraphs (c) and (e) published at 65 FR 18926 (April 10, 2000) became effective on June 29, 2000.

FOR FURTHER INFORMATION CONTACT: Tim Peterson, Deputy Division Chief, Accounting Safeguards Division, Common Carrier Bureau, (202–418–1575).

SUPPLEMENTARY INFORMATION: On June 19, 2000 Office of Management and Budget (OMB) approved the amendment to the depreciation rate rules § 43.43 (c) and (e) pursuant to OMB Control No. 3060–0168. Accordingly, the rules in § 43.43 (c) and (e) became effective on June 29, 2000.

List of Subjects in 47 CFR Part 43

Communications common carriers, Radio, Reporting and recordkeeping requirements, Telegraph, Telephone.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 02–7262 Filed 3–26–02; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 970930235–7235–01; I.D. 032102B]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS closes the commercial hook-and-line fishery for king mackerel in the exclusive economic zone (EEZ) in the southern Florida west coast subzone. This closure is necessary to protect the Gulf group king mackerel resource.

DATES: Effective 12:01 a.m., local time, March 23, 2002, through June 30, 2002.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles, telephone: 727–570–5305, fax: 727–570–5583, e-mail: Mark.Godcharles@noaa.gov.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on April 30, 2001 (66 FR 17368, March 30, 2001) NMFS implemented a commercial quota of 2.25 million lb (1.02 million kg) for the eastern zone (Florida) of the Gulf migratory group of king mackerel. That quota is further divided into separate quotas for the Florida east coast subzone and the northern and southern Florida west coast subzones. On April 27, 2000, NMFS implemented the final rule (65 FR 16336, March 28, 2000) that divided the Florida west coast subzone of the eastern zone into northern and southern subzones, and established their separate quotas. The quota newly implemented for the southern Florida west coast subzone is 1,040,625 lb (472,020 kg). That quota is further divided into two equal quotas of 520,312 lb (236,010 kg) for vessels in each of two groups fishing with hook-and-line gear and run-around gillnets (50 CFR 622.42(c)(1)(i)(A)(*2*)(*i*)).

Under 50 CFR 622.43(a), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification at the Office of the **Federal Register**. NMFS has determined that the commercial quota of 520,312 lb (236,010 kg) for Gulf group king mackerel for vessels using hook-and-line gear in the southern Florida west coast subzone was reached on March 22, 2002. Accordingly, the commercial hook-and-line fishery for king mackerel in the southern Florida west coast subzone is closed effective 12:01 a.m., local time, March 23, 2002, through June 30, 2002, the end of the fishing year.

The Florida west coast subzone is that part of the eastern zone south and west of 25°20.4′ N. lat. (a line directly east from the Miami-Dade County, FL boundary). The Florida west coast subzone is further divided into northern and southern subzones. The southern subzone is that part of the Florida west coast subzone which from November 1