(12) *Crystal River Nuclear Power Plant.* All waters, from surface to bottom, around the Florida Power Crystal River nuclear power plant located at the end of the Florida Power Corporation Channel, Crystal River, Florida, encompassed by a line connecting the following points: 28°56.87′ N, 082°45.17′ W (Northwest corner); 28°57.37′ N, 082°41.92′ W (Northeast corner); 28°56.81′ N, 082°45.17′ W (Southwest corner); and 28°57.32′ N, 082°41.92′ W (Southeast corner).

(13) *Crystal River Demory Gap Channel.* All waters, from surface to bottom, in the Demory Gap Channel in Crystal River, Florida, encompassed by a line connecting the following points: 28°57.61′ N, 082°43.42′ W (Northwest corner); 28°57.53′ N, 082°41.88′ W (Northeast corner); 28°57.60′ N, 082°43.42′ W (Southwest corner); and 28°57.51′ N, 082°41.88′ W (Southeast corner).

(b) *Regulations.* (1) Entry into or remaining within these zones is prohibited unless authorized by the Coast Guard Captain of the Port, Tampa, Florida or that officer's designated representative.

(2) Persons desiring to transit the area of the security zone may contact the Captain of the Port at telephone number 813–228–2189/91 or on VHF channel 16 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or their designated representative.

(c) *Definition.* As used in this section, ''cruise ship'' means a vessel required to comply with 33 CFR Part 120.

(d) *Authority.* In addition to 33 U.S.C. 1231 and 50 U.S.C. 191, the authority for this section includes 33 U.S.C. 1226.

Dated: August 1, 2003.

James M. Farley,

Captain, U.S. Coast Guard, Captain of The Port, Tampa, Florida.

[FR Doc. 03–22370 Filed 9–2–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0299; FRL–7324–1]

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of acetamiprid in or on canola seed and mustard seed. Bayer Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The ownership of this petition has subsequently been transferred to Nippon Soda Company, Ltd.

DATES: This regulation is effective September 3, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0299, must be received on or before November 3, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Akiva Abramovitch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0299. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under 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*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 30, 2001 (66 FR 29313) (FRL–6782–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6082) by Bayer Corporation, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing. Subsequent to the notice of filing, the ownership of this

petition was transferred to Nippon Soda Company, Ltd., 220 East 42nd Street, Suite 3002, New York, NY 10017.

The petition requested that 40 CFR 180.578 be amended by establishing a tolerance for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on canola seed and mustard seed at 0.01 parts 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) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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 of the FFDCA 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) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of acetamiprid on canola seed and mustard seed at 0.01 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 Table 1 of this unit 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 in rats	NOAEL: 12.4/14.6 mg/kg/day (M/F) LOAEL: 50.8/56.0 mg/kg/day (M/F: decreased BW, BW gain and food consumption).
870.3100	90–Day oral toxicity in mice	NOAEL: 106.1/129.4 mg/kg/day (M/F) LOAEL: 211.1/249.1 mg/kg/day (reduced BW and BW gain, decreased glucose and cholesterol levels, reduced absolute organ weights).
870.3150	90–Day oral toxicity in dogs	NOAEL: 13/14 mg/kg/day (M/F) LOAEL: 32 mg/kg/day (reduced BW gain in both sexes).
870.3200	21–Day dermal toxicity in rabbits	NOAEL: 1,000 mg/kg/day (HDT) LOAEL: >1,000 mg/kg/day
870.3700	Developmental toxicity in rats	Maternal NOAEL: 16 mg/kg/day Maternal LOAEL: 50 mg/kg/day (reduced BW and BW gain and food consumption, increased liver weights). Developmental NOAEL: 16 mg/kg/day Developmental LOAEL: 50 mg/kg/day (increased incidence of shortening of the 13th rib)
870.3700	Developmental toxicity in rabbits	Maternal NOAEL: 15 mg/kg/day Maternal LOAEL: 30mg/kg/day (BW loss and decreased food consumption). Developmental NOAEL: 30 mg/kg/day (HDT) Developmental LOAEL: > 30 mg/kg/day

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

Guideline No.	Study Type	Results
870.3800	2–Generation reproduction in rats	Parental systemic NOAEL: 17.9/21.7 mg/kg/day (M/F) Parental systemic LOAEL: 51.0/60.1 mg/kg/day (M/F) (decreased body weight, body weight 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: 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: 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: initial BW loss and overall reduction in BW gain).
870.4200	Carcinogenicity in mice	NOAEL: 20.3/75.9 mg/kg/day (M/F) LOAEL: 65.6/214.6 mg/kg/day (M/F: decreased BW and BW gain and amyloidosis in numerous organs (M) and decreased BW and BW gain (F)). Not oncogenic under conditions of study.
870.4300	Carcinogenicity in rats	NOAEL: 7.1/8.8 mg/kg/day (M/F) LOAEL: 17.5/22.6 mg/kg/day (M/F, decreases in mean BW and BW gain (F) and hepatocellular vacuolation (M)) Evidence of treatment-related increase in mammary tumors. There was an absence of a dose-response and a lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair with 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.
870.5100	*Salmonella typhimurium/E. coli* Reverse gene mutation assay	Not mutagenic under the conditions of the study.
870.5300	Mammalian cells in culture Forward 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*.
870.6200	Acute neurotoxicity in rats	NOAEL: 10 mg/kg LOAEL: 30 mg/kg (reduction in locomotor activity).
870.6200	Subchronic neurotoxicity in rats	NOAEL: 14.8/16.3 mg/kg/day (M/F) LOAEL: 59.7/67.6 mg/kg/day (M/F: reductions in BW, BW gain, food consumption and food efficiency).
N/A	28–Day feeding in dogs	NOAEL: 16.7/19.1 mg/kg/day (M/F) LOAEL: 28.0/35.8 mg/kg/day (reduced BW gain).

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

Guideline No.	Study Type	Results
870.7485	Metabolism in rats	Extensively and rapidly metabolized. Metabolizes 79–86% of administered dose. Profiles similar for males and females for both oral and intravenous dosing. Three to 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-chloronicotinic acid most prevalent metabolite. Phase II metabolism shown by increase in glycine conjugate.
870.7485	Metabolism in mice, rats, and rabbits (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.
870.7600	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 exposure. 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 the toxicology 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 intraspecies 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 factors (SF) 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 SF.

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 acetamiprid used for human risk assessment is shown in the following Table 2 of this unit:

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 dietary (general population including infants and children)	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.10 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/FQPA SF = 0.10 mg/kg/day	Acute neurotoxicity study LOAEL = 30 mg/kg/day based on decrease 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 = 1X cPAD = chronic RfD/FQPA SF = 0.07 mg/kg/day	Chronic feeding/oncology study in rats. LOAEL = 17.5 mg/kg/day based on decrease in body weight/body weight gain and hepatocellular vacuolation.
Short-term (1 to 30 days) and intermediate-term (1 to 6 months) Incidental Oral	NOAEL= 15 mg/kg/day	LOC for MOE = 100 (Residential)	13–Week feeding study in rats; subchronic neurotoxicity in rats; developmental toxicity in rats. LOAEL = 50 mg/kg/day based on decrease in body weight/body weight gain, food consumption, and food efficiency.
Short-term (1 to 30 days) and intermediate-erm (1 to 6 months) dermal	Oral NOAEL = 17.9 mg/kg/day (dermal absorption factor = 30%)	LOC for MOE = 100 (Residential) LOC for MOE = 100 (Occupational)	2–Generation reproduction study. LOAEL = 51 mg/kg/day based on delay in preputial separation, vaginal opening, eye opening and pinna unfolding; reduced litter size, viability and weaning indices in offspring.
Long-term dermal (> 6 months)	Oral NOAEL= mg/kg/day (dermal absorption factor = 30%)	LOC for MOE = 100 (Residential) LOC for MOE = 100 (Occupational)	Chronic feeding/oncology study in rats. LOAEL = 17.5 mg/kg/day based on decrease in body weight/body weight gain and hepatocellular vacuolation.
Short-term (1 to 30 days) and intermediate-term (1 to 6 months) Inhalation	Oral NOAEL = 17.9 mg/kg/day (inhalation absorption factor = 100%)	LOC for MOE = 100 (Residential) LOC for MOE = 100 (Occupational)	2–Generation reproduction study. LOAEL = 51 mg/kg/day based on delay in preputial separation, vaginal opening, eye opening and pinna unfolding; reduced litter size, viability and weaning indices in offspring.
Long-term inhalation (> 6 months)	Oral NOAEL = 7.1 mg/kg/day (inhalation absorption factor = 100%)	LOC for MOE = 100 (Residential) LOC for MOE = 100 (Occupational)	Chronic feeding/oncology study in rats. LOAEL = 17.5 mg/kg/day based on decrease in body weight/body weight gain and hepatocellular vacuolation.
	Cancer (oral, dermal, inhalation) - Not likely to be carcinogenic.		

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.578) for the residues of acetamiprid, in or on a variety of raw agricultural commodities. Tolerances for acetamiprid range from 0.2 to 20 ppm in plant commodities and range from 0.01 to 0.2 ppm in livestock 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 proposed crops and all other crops having acetamiprid tolerances were treated and that all treated crops and livestock had residues of concern at the tolerance level. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the aPADs are all below 100%). The most highly exposed subgroup is children 1 to 6 years of age, which utilizes 40% of the aPAD.

ii. *Chronic exposure.*In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide 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 proposed crops and all other crops having acetamiprid tolerances were treated and that all treated crops and livestock had residues of concern at the tolerance level. The general U.S. population and all population subgroups have exposure and risk estimates which are below EPA's LOC (i.e., the cPADs are all below 100%). The most highly exposed subgroup is children 1 to 6 years of age, which utilizes 21% of the cPAD.

iii. *Cancer*. EPA has determined that acetamiprid is not likely to be a human carcinogen and EPA, therefore, does not expect it to pose a cancer risk. As a result, a quantitative cancer dietary exposure analysis was not performed.

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 Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. 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 in Unit III.E.

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 ppb for surface water and 0.0008 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).

Acetamiprid is currently registered for use on the following residential non-dietary sites: As an outdoor insecticide on ornamentals, flowers, vegetable gardens, and fruit trees. The risk assessment was conducted using the following residential exposure assumptions: Residential handlers (homeowners) are assumed to make the maximum number of applications at maximum use rates with little use of any protective equipment. Potential dermal and inhalation doses that homeowners may receive during applications of pesticides to the garden, around walkways, driveways, foundations, vegetables, and ornamentals were considered; therefore, exposures and risks are calculated for both dermal and inhalation exposures. This scenario assumes that pesticides are available for inhalation or have the potential to come in contact with the skin of adults and youths during the mixing/loading and application of pesticides used around the garden. The short- and intermediate-term handler MOEs for the residential uses of acetamiprid for both age groups of adults and youth are at or greater than 120,000 for all exposure scenarios, and therefore represent risks that are below EPA's level of concern.

Postapplication exposures were calculated assuming dermal exposure to adults and children while working in treated gardens or with various fruit trees and ornamentals. Inhalation exposure was not quantitatively addressed because exposure by inhalation is considered minimal due to the air exchange that occurs in outdoor scenarios. In addition, 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, EPA does not believe that incidental oral exposure from the registered homeowner uses will result in significant incidental oral exposures to children. This scenario assumes that pesticide residues are transferred to the skin of adults and youth who enter treated gardens for gardening or other homeowner activities. The short- and intermediate-term postapplication MOEs for the residential uses of acetamiprid for both age groups of adults and youth are at or greater than 18,000 for all exposure scenarios, and therefore represent risks that are below EPA's level of concern.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether acetamiprid has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to acetamiprid and any other substances, and 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 policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA 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.* Neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in the developmental toxicity studies in rats and rabbits. In the multigeneration reproductive study, qualitative evidence of increased susceptibility of rat pups is observed since the offspring effects are considered to be more severe than the parental effects. However, quantitative evidence of increased susceptibility of rat pups was not observed since the parental and offspring NOAELs and LOAELs are at the same doses.

Since there is qualitative evidence of increased susceptibility of the young following exposure to acetamiprid in the rat reproduction study, EPA performed a Degree of Concern analysis to determine the level of concern for the effects observed when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of this chemical. If residual uncertainties are identified, EPA examines whether these residual uncertainties can be addressed by a special FQPA safety factor and, if so, the size of the factor needed.

The multigeneration reproduction study in rats was used for the Degree of Concern analysis. In that rat reproduction study, qualitative susceptibility was evidenced as 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 presence of lesser maternal toxicity (reductions in body weight, body weight gain and food consumption) at the highest dose tested. Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for acetamiprid, the EPA characterized the degree of concern for the effects observed in this study as low, noting that there is a clear NOAEL for the offspring effects observed and that these effects occurred in the presence of parental toxicity and only at the highest dose tested. No residual uncertainties were identified. The NOAEL for offspring effects in this reproduction study (17.9 mg/kg/day) is used as the basis for short- and intermediate-term dermal and inhalation exposure scenarios. For all other toxicity endpoints established for acetamiprid, a NOAEL lower than this offspring NOAEL is used.

For the reasons stated above, EPA has concluded that there is low concern for prenatal and/or postnatal toxicity resulting from exposure to acetamiprid.

3. *Conclusion.* The toxicology data base is not complete for FQPA purposes. EPA has determined that a developmental neurotoxicity study in rats should be conducted. The need for a developmental neurotoxicity study is based on the consideration that clinical signs of neurotoxicity were observed on the day of dosing in the acute neurotoxicity study in rats. In addition, acetapmiprid is structurally related to thiamethoxam and imidacloprid, both of which are neonicotinoids. Imidacloprid is a chloronicotinyl compound and is an analog to nicotine. Studies in the published literature suggest that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*. With imidacloprid, there is evidence that administration causes clinical signs of neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2–year carcinogenicity study. With thiamethoxam, there was also evidence of clinical signs of neurotoxicity in the acute neurotoxicity study. There are also indications that thiamethoxam may affect the endocrine system.

Recently, EPA has received objections to tolerances for residues of acetamiprid from the Natural Resources Defense Council (NRDC). NRDC asserted that EPA is missing data bearing on oral exposure to acetamiprid from residential uses of the pesticide. The **Federal Register** notice on the contested acetamiprid tolerance notes that ''incidental oral exposure is an insignificant pathway of exposure'' for acetamiprid (67 FR 14649, 14657; March 27, 2002). As noted above, little or no incidental oral exposure is expected since acetamiprid's residential uses are limited to ornamentals, flowers, vegetable gardens, and fruit trees. Incidental oral exposure to pesticides can occur when young children engage in ''mouthing'' behavior (i.e. repeatedly placing their hands or other objects in their mouth) in a location where a pesticide is present. EPA assumes that incidental oral exposure to a pesticide may occur when a pesticide is used to treat a home lawn because young children frequently play on home lawns. EPA, however, considers it unlikely that young children would spend an extended time in flower, vegetable, or ornamental gardens, and thus treatment of such gardens with a pesticide is not likely to lead to a significant exposure to children by the incidental oral route.

The NRDC also claimed that a 10X safety factor should be used to account for the lack of the developmental neurotoxicity study. However, it has been noted that reliable developmental neurotoxicity data received and reviewed for other structurally-related compounds in this chemical class (neonicotinoids), including thiacloprid, clothianidin, and imidacloprid, demonstrated that the developmental neurotoxicity had no effect on the regulatory endpoint for those pesticides. Therefore, EPA believes that the results of the required developmental neurotoxicity study will not likely impact the regulatory doses selected for acetamiprid. It is further noted that the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young (e.g., neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring). On this basis, EPA concluded that a data base uncertainty factor is not needed to account for the lack of the developmental neurotoxicity study with acetamiprid, and that reliable data support removing the additional safety factor for the protection of infants and children.

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: 2 liter (L)/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 ground water 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 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 infants less than 1 year of age and 40% of the aPAD for children 1 to 6 years of age. 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 3 of this unit:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.10	17	17	0.0008	2,900
All Infants (< 1 year)	0.10	38	17	0.0008	620
Children 1 to 6 years	0.10	40	17	0.0008	600
Females 13 to 50 years	0.10	11	17	0.0008	2,700

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 8% of the cPAD for the U.S. population, 15% of the cPAD for infants less than 1 year of age and 21% of the cPAD for children 1 to 6 years of age. Based upon 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 4 of this unit:

TABLE 4.—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 (ppb)
U.S. population	0.07	8	4	0.0008	2,260
All infants (< 1 year)	0.07	15	4	0.0008	600
Children 1 to 6 years	0.07	21	4	0.0008	550

3. *Short- and intermediate-term risk*. Short- 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 registered for use that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short- and intermediate-term exposures for acetamiprid.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 18,000 for U.S. population and 23,000 for children 7 to 12 years of age. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short- and intermediate-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- and intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT- AND INTERMEDIATE-TERM EXPOSURE TO ACETAMIPRID

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-/Intermediate-Term DWLOC (ppb)
U.S. population	18,000	100	4	0.0008	1,500
Children 7 to 12 years	23,000	100	4	0.0008	400

5. *Aggregate cancer risk for U.S. population*. Acetamiprid has been classified as a ''not likely human carcinogen.'' Therefore, it is not expected to pose a cancer risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (solvent extraction followed by gas chromatography/electron capture detection (GC/ECD) determination of residues) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels (MRLs) have been established for residues of acetamiprid.

V. Conclusion

Therefore, the tolerance is established for residues of acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on canola seed and mustard seed at 0.01 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2002–0299 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 3, 2003.

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 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, 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 20460–0001.

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 20460–0001.

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.1. Mail your copies, identified by docket ID number OPP–2002–0299, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. 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. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this 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 section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 section 408(n)(4) of the FFDCA. 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. Congressional Review Act

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: August 22, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.578 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Canola, seed	0.010
* * * * *	
Mustard, seed	0.010
* * * * *	

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[FR Doc. 03–22313 Filed 9–2–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0288; FRL–7323–9]

Bifenthrin; Pesticide Tolerance for Emergency Exemption; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendment.

SUMMARY: EPA issued a final rule in the **Federal Register** of September 27, 2001, to establish a time-limited tolerance for residues of bifenthrin in or on sweet potato. This action was in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sweet potato. This document is being issued to correct typographical errors in that original document.

DATES: This document is effective on September 3, 2003.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: *conrath.andrea@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:

- Crop Production (NAICS Code 111)
- Animal Production (NAICS Code 112)
- Food Manufacturing (NAICS Code 311)
- Pesticide Manufacturing (NAICS Code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0288. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under 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.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Does this Technical Amendment Do?

EPA issued a final rule in the **Federal Register** of September 27, 2001 (66 FR 49300)(FRL–6801–5), to establish a time-limited tolerance for residues of bifenthrin in or on sweet potato. This action was in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on sweet potato. The amendment to establish the tolerance for bifenthrin inadvertently added the tolerance for ''sweet potato'' to 40 CFR 180.442(a). However, 40 CFR 180.442(a) is not designated for section 18 emergency exemptions; consequently, the entry for sweet potato could not be added to § 180.442(a) by the Office of the Federal Register. This technical amendment is being issued to correctly add the tolerance for sweet potato to the table in § 180.442(b), which is designated for time-limited tolerances associated with section 18 emergency exemptions.

In addition to correctly adding the tolerance to paragraph (b) of § 180.442, based on a final rule issued by EPA in the **Federal Register** of July 1, 2003 (68 FR 39427)(FRL–7308–9), EPA is also changing the commodity term ''sweet potato'' to read ''sweet potato, roots.''

III. Why is this Technical Amendment Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical amendment final without prior proposal and opportunity for comment, because EPA is merely correcting the placement of a tolerance already issued and previously published as a final rule, and the commodity term. EPA finds that this