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.

X. 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: March 29, 2005.

James Jones,

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), 346a and 371.

■ 2. Section 180.1257 is added to subpart D to read as follows:

§ 180.1257 Paecilomyces lilacinus strain 251; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Paecilomyces lilacinus* strain 251 when used in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 05–7226 Filed 4–12–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0029; FRL–7705–7]

Acetamiprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of acetamiprid in or on tuberous and corm vegetables. Nippon Soda Company c/o Nisso America Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective April 13, 2005. Objections and requests for hearings must be received on or before June 13, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0029. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be

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

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

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, 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 E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of August 4, 2004 (69 FR 47145) (FRL–7369–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F6575) by Nippon Soda Company c/o Nisso America, 42 Broadway, Suite 2120, New York, NY 10006. The petition requested that 40 CFR 180.578 be amended by establishing a tolerance for residues of the insecticide acetamiprid, in or on tuberous and corm vegetables at 0.01 parts per million (ppm). That notice included a summary of the petition prepared by Nisso America, Inc.. There were two comments to the Acetamiprid Notice of Filing and they are addressed in Unit IV.D..

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

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 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 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 FFDCA, for a tolerance for residues of acetamiprid on tuberous and corm vegetables 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 days oral toxicity - rodents	NOAEL: 12.4/14.6 milligrams/kilograms (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.
870.3100	90 days oral toxicity - 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 glucoseand 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 toxicity in rodents	Maternal NOAEL: 16 mg/kg/day Maternal LOAEL: 50 mg/kg/day based on reduced BW and BW gain and food consumption, 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.

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

Guideline No.	Study Type	Results
870.3700	Prenatal developmental toxicity 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. There was an absence of a dose - response and a lack of statistically significant increase in the mammary adenocarcinoma incidence by pair with comparison of the mid- and the high-dose groups with the controls. Although the incidence exceeded the historical control data from the same laboratory, it was within the range of values from the supplier.
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 and amyloidosis 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 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 - 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, food consumption 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.

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

Guideline No.	Study Type	Results
870.7485(SS)	Metabolism - mouse, rat, rabbit Special Study (SS)	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 pharmaco-kinetics - rat	Extensively and rapidly metabolized. Metabolites 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.
870.7600	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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the '' special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 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). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 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[1] and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary General 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 = 0.071 mg/kg/day	FQPA SF = 1 cPAD = 0.071 mg/kg/day	Chronic/oncogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced body weight and body weight 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 = 100 (Residential)	Co-critical studies: subchronic oral (rat); subchronic neurotoxicity (rat) developmental toxicity (rat); LOAEL = 50 mg/kg/day based on reductions in body weight, body weight gain and food consumption.
Short- and Intermediate-Term Dermal (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) 100 (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 F2 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) 100 (Residential)	Chronic/oncogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced body weight and body weight gain (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) 100 (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 F2 offspring, significant delays in age to attain vaginal opening and preputial separation.

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

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF[1] and Endpoint for Risk Assessment	Study and Toxicological Effects
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) 100 (Residential)	Chronic/oncogenicity study in the rat LOAEL = 17.5 mg/kg/day based on reduced body weight and body weight gain (females) and hepatocellular vacuolation (males).
Cancer (oral, dermal, inhalation)	Not likely to be carcinogenic.		

[1] 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.* Tolerances have been established (40 CFR 180.578) for the residues of acetamiprid, in or on a variety of raw agricultural 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 1–day or single exposure.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™ version 1.3), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The assumptions made for the acute exposure assessments are discussed in Unit III.C.1.ii.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

For both the acute and chronic analyses, tolerance-level residues were assumed for all food commodities with current and proposed acetamiprid tolerances, and it was assumed that all of the crops included in the analysis were treated (i.e., 100% crop treated). These assumptions result in highly conservative estimates of dietary exposure and risk. In calculating dietary risk estimates, the Agency has compared the acute and chronic population-adjusted doses (aPAD, cPAD) to the estimated dietary exposures from the models. Typically, the Agency has concerns regarding dietary risk when the exposure estimates exceed 100% of the aPAD and/or cPAD. Even with the conservative assumptions noted above, risk estimates associated with dietary exposure to acetamiprid are below the Agency's LOC.

iii. *Cancer.* Acetamiprid has been classified as not likely to be carcinogenic to humans; therefore, a dietary assessment for cancer risk was not conducted. This classification is 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.

Tier 1 simulated estimated drinking water concentrations (EDWCs) for acetamiprid in surface water using the FQPA Index Resevoir Screening Test (FIRST) to calculate surface water concentrations and screening concentration in ground water (SCI-GROW) to calculate ground water concentrations.

For the surface water assessment, the application rate for citrus was used, which represents the highest label rate for a single application of any crop (0.55 lb a.i./A/season). However, it is important to note that due to limitations imposed by the use of two applications at the highest single application rate (0.25 lb a.i./A), the modeled application rate was equal to only 0.50 lb a.i./A.

The proposed applications of acetamiprid on tuberous and corm vegetables would result in lower EDWCs than citrus, and thus has little effect on the drinking water assessment for this chemical. By using the application rate for citrus crops, the surface and ground water estimated concentrations are conservative estimates for the proposed new use scenarios (tuberous and corm vegetables) because of the higher application rate.

The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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.

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: Ornamentals and flowers. The risk assessment was conducted using the following residential exposure assumptions:

Acetamiprid is currently registered for use on the following residential non-dietary sites: Ornamentals and flowers. No chemical specific data were available to estimate exposure and risk for homeowners applying acetamiprid to ornamentals and flowers. The risk assessment was conducted using the following conservative residential exposure assumptions: Little use of any protective equipment by residential applicators, the use of agricultural transfer coefficients which incorporate larger acreage and greater foliar contact for dermal exposure, and postapplication exposure to the maximum levels of residues on the day of application. Using such assumptions 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 effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA 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 web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of 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 based on reliable data 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. In the developmental toxicity studies in rats and rabbits, the Agency determined that neither quantitative nor qualitative evidence of increased susceptibility of fetuses to in utero exposure to acetamiprid were observed. However, in the multigeneration reproduction study, qualitative evidence of increased susceptibility of rat pups is observed. Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for acetamiprid, the Agency characterized the degree of concern for the effects observed in this study as low, noting that:

i. There is a clear NOAEL for the offspring, and;

ii. 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 is used for short- and intermediate-term dermal and inhalation exposure scenarios. All other toxicology endpoints established for acetamiprid are based on a lower NOAEL than this, and are thus protective of offspring effects.

3. *Conclusion*. The Agency concluded that there is concern for neurotoxicity resulting from exposure to acetamiprid because:

i. Clinical signs of neurotoxicity were observed in the acute neurotoxicity study on the day of dosing, and;

ii. Studies in literature with structurally similar chemicals from the same chemical class (neonicotinoids) suggest that nicotine, when administered to humans and/or animals in utero causes developmental toxicity, including functional deficits.

The Agency concluded that the toxicology database for acetamiprid is not complete for FQPA assessment, since a developmental neurotoxicity (DNT) study in rats is currently under review and has not yet been finalized and is part of a comprehensive evaluation of many DNT studies of various pesticides, some of which have not yet been submitted. The preliminary review of the study indicates the results are not likely to have a significant impact on risks for the currently proposed use, or on existing uses of acetamiprid. Based on weight of the evidence, an uncertainty factor UFDB is not needed (1X) since developmental neurotoxicity data received and reviewed for other compounds in this chemical class indicate that the results of the required DNT will not likely impact the regulatory doses selected for the proposed uses of acetamiprid.

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 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 EPA's 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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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 18 % of the aPAD for the U.S. population, 12 % of the aPAD for females 13 years and older, 44 % of the aPAD for all infants less than one year old, and 61 % of the aPAD for 1–2 years old children. 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 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)
US Population	0.10	18	17	0.0008	2,900
All Infants < 1 year	0.10	44	17	0.0008	540
Children 1–2 years	0.10	61	17	0.0008	370
Children 3–5 years	0.10	42	17	0.0008	560
Children 6–12 years	0.10	22	17	0.0008	790
Youth 13–19 years	0.10	14	17	0.0008	2,600
Adults 20–49 years	0.10	11	17	0.0008	3,100
Adults 50+ years	0.10	10	17	0.0008	3,100
Females 13–49 years	0.10	12	17	0.0008	2,600

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, 16% of the cPAD for all infants <1 year old, and 31% of the cPAD for children 1–2 year old. Based 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 water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in 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)
US Population	0.071	8	4	0.0008	2,300
All Infants < 1 year	0.071	16	4	0.0008	600
Children 1–2 years	0.071	31	4	0.0008	490
Children 3–5 years	0.071	21	4	0.0008	560
Children 6–12 years	0.071	11	4	0.0008	630
Youth 13–19 years	0.071	6	4	0.0008	2,000

TABLE 4.—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 (ppb)
Adults 20–49 years	0.071	5	4	0.0008	2,400
Adults 50+ years	0.071	5	4	0.0008	2,000
Females 13–49 years	0.071	5	4	0.0008	2,400

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-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-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 810–820 for adults male and female. These aggregate MOEs do not exceed the Agency's LOC 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 water and surface water. After calculating DWLOCs and comparing them to- the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM 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-Term DWLOC (ppb)
Adult male	820	100	4	0.0008	5,500
Adult female	810	100	4	0.0008	4,700
Adult 50+	810	100	4	0.0008	4,700

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available for enforcement of tolerances for plant commodities (GC/ECD and HPLC/UV) and animal comodities (HPLC/UV). However, the registrant also proposed that an HPLC/MS method be used for enforcement of plant commodities tolerances. The proposed HPLC/MS/MS enforcement method for plant commodities should undergo independent laboratory validation (ILV) as a condition of registration, and possibly Agency method validation.

B. International Residue Limits

There are no CODEX, or Canadian Maximum Residue Limits for acetamiprid on tuberous and corm vegetables.

C. Conditions

A Developmental Neurotoxicity study (DNT) study is currently under review.

The proposed HPLC/MS/MS enforcement method for plant commodities should undergo independent laboratory validation (ILV) as a condition of registration, and possibly Agency method validation.

D. Response to Comments

One commenter expressed a general objection to the approval of pesticide tolerances and also criticized the use of animal testing to determine the safety of pesticides. This commenter's concerns have been addressed in previous tolerance documents. See the **Federal Register** of October 29, 2004, (69 FR 63083) (FRL–7681–9). The other comment was from the WTO (World Trade Organization) Enquiry Point in China and asked for extra time to translate the document and prepare comments. This comment was received after the close of the comment period on Sepember 7, 2004 via e-mail. On February 28, 2005 EPA contacted the commenter and requested that if it had any comments to submit them by March 15, 2005. No further response was received by EPA.

V. Conclusion

Therefore, the tolerance is established for residues of acetamiprid, in or on tuberous and corm vegetables at 0.01 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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 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–2005–0029 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 June 13, 2005.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0029, 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 **ADDRESSES**. 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 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 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 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: April 1, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

§ 180.578 Acetamiprid; tolerances for residues.

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

Commodity	Parts per million
* * *	* *
Tuberous and Corm Vegetables	0.01
* * *	* *

* * * * *

[FR Doc. 05–7225 Filed 4–12–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 22, and 90

[WT Docket Nos. 03–103, 05–42; FCC 04–287]

Air-Ground Telecommunications Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (''Commission'') revises rules governing the four megahertz of dedicated spectrum in the 800 MHz commercial Air-Ground Radiotelephone Service band. The Commission adopts a flexible regulatory approach to determine the configuration of the band; adopts rules that enable interested parties to bid on spectrum licenses according to the band configuration that they believe will best meet their needs for the provision of air-ground services; makes available nationwide air-ground licenses in three configurations: band plan 1, comprised of two overlapping, shared, cross-polarized 3 MHz licenses (licenses A and B, respectively), band plan 2, comprised of an exclusive 3 MHz license and an exclusive 1 MHz license (licenses C and D, respectively), and band plan 3, comprised of an exclusive 1 MHz license and an exclusive 3 MHz license (licenses E and F, respectively), with the blocks at opposite ends of the band from the second configuration; and finally, the Commission revises and eliminates certain Public Mobile Services (PMS) rules that are no longer warranted as a result of technological change, increased competition in Commercial Mobile Radio Services (CMRS), supervening changes to related Commission rules, or a combination of these factors.

DATES: Effective May 13, 2005.

FOR FURTHER INFORMATION CONTACT: Richard Arsenault, Chief Counsel, Mobility Division, Wireless Telecommunications Bureau, at 202–418–0920 or via e-mail at *Richard.Arsenault@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order portion (*Report and Order*) of the Commission's *Report and Order and Notice of Proposed Rulemaking,* FCC 04–287, in WT Docket Nos. 03–103 and 05–42, adopted December 15, 2004, and released February 22, 2005. Contemporaneous with this document, the Commission publishes a Notice of Proposed Rulemaking (*Notice*) (summarized elsewhere in this publication). The full text of this document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, 445 12th St., SW., Room CY–A257, Washington, DC 20554. The complete text may be purchased from the Commission's duplicating contractor: Best Copy & Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 800–378–3160, facsimile 202–488–5563, or via e-mail at *fcc@bcpiweb.com.* The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365 or at *Brian.Millin@fcc.gov.*

Synopsis of the Report and Order

A. 800 MHz Air-Ground Radiotelephone Service

1. The Commission initiated this proceeding, *inter alia,* to reexamine the 800 MHz Air-Ground Radiotelephone Service band plan and service rules. Although the Commission initially licensed six 800 MHz air-ground nationwide licensees, only one licensee (Verizon Airfone) continues to provide service in the band, and our current technical rules allow it to provide only a limited range of narrowband voice and data services. This circumstance led us to question in the *Notice of Proposed Rulemaking* in this proceeding, 68 FR 44003, July 25, 2003, whether our existing rules were impeding the provision of telecommunications services desired by the public onboard aircraft. Nearly all parties commenting on these issues agree that our existing band plan and rules have hindered the efficient, competitive provision of air-ground services desired by the public. Based on our review of the record in this proceeding, we find that the public interest will be served by adopting flexible rules that will enable interested parties to bid on licenses in three possible band configurations. Each of the three band configurations includes at least one spectrum block that will permit the provision of high-speed telecommunications services to the public onboard aircraft.

2. In reexamining the current band plan and service rules, we must address both competitive issues (*i.e.*, how many competitors can the spectrum and the market support) and technical