scientists critically appraised all the data at that time and came to the conclusion that Mr. Samuels' objection was unwarranted (Ref. 2). However, EPA wishes to make sure all possible areas of disagreement are covered and has reviewed the latest information submitted by the objectors and believes nothing substantive has been added to the body of data known on these chemicals, and no change in the previous exemption is necessary.

VI. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's final decision regarding an objection filed under section 408 of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemakings do not, therefore, apply to this action.

VII. 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, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

VIII. References

1. Letter from Jack L. Samuels to Sue Smith, The White House, Aug. 20, 1998.

2. Letter from J. Andersen to J. Samuels, Oct. 13, 1998.

3. Raiten, D.J. et al., Analysis of Adverse Reactions to Monosodium Glutamate (MSG), American Institute of Nutrition, MD, 1995.

4. e-Mail from J. Samuels to J. Andersen, 7/28/98.

5. Kuznesof, P.M., Expert Report, undated.

6. Stevenson, D.S. Expert Report, undated.

7. Hattan, D.G. Expert Report, undated.

8. Auer, R.N., Expert Report, undated.

9. Olney, J. W. Excitotoxins in Foods. Neurotoxicology 15(3) 535–544, 1994.

10. Olney, J.W., et al., Cytotoxic effects of acidic and sulphur containing amino acids on the infant mouse central nervous system. Exp. Brain Res. 14:61–76, 1971.

11. Martinez, F., et al. Neuroexcitatory amino acid levels in plasma and cerebrospinal fluid during migraine attacks. Cephalalgia. 13:89–93, 1993.

12. Strong, F.C., Why do some dietary migraine patients claim they get headaches from placebos? Clin. Experimental Allergy. 30:739–743, 2000.

13. Geha R. S. et al., Multicenter, double-blind, placebo-controlled, multiple challenge evaluation of reported reactions to monosodium glutamate. J. Allergy Clin. Immunol. 106:973–980, 2000.

14. Anantharaman, K., *In utero* and dietary administration of monosodium L-glutamate to mice: reproductive performance and development in a multigeneration study. *In* ''Glutamic Acid: Advances in Biochemistry.'' L. J. Filer, et al., eds. Raven Press, N.Y., 1979.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative procedure, pesticides and pests.

Dated: October 18, 2004.

James Jones,

Director, Office of Pesticide Programs.

[FR Doc. 04–24041 Filed 10–26–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0331; FRL–7683–5]

Deltamethrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of deltamethrin, isomers trans-deltamethrin and α-R-deltamethrin in or on almond hulls; apples, wet pomace; artichoke, globe; barley, bran; cattle, fat; cattle, meat; cattle, meat byproducts; corn, field, forage; corn, field, refined oil; corn, field, stover; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel + cob with husks removed; corn, sweet, stover; egg; fruit, pome, group 11; goat, fat; goat, meat; goat, meat byproducts; grain, aspirated fractions; grain, cereal, group 15, except sweet corn; hog, fat; horse, fat; horse, meat; horse, meat byproducts; lychee (import tolerance); milk, fat (reflecting 0.02 ppm in whole milk); nut, tree, group 14; onion, dry bulb; onion, green; poultry, fat; poultry, meat; poultry, meat byproducts; radish tops; rapeseed; rice, hulls; rye, bran; sheep, fat; sheep, meat; sheep, meat byproducts; sorghum, grain forage; sorghum, grain stover; soybean, seed; soybean, hulls; starfruit (import tolerance); sunflower seeds; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; vegetable, root, except sugar beet, subgroup IB; vegetable, tuberous and corm, subgroup; IC; wheat, bran. Bayer Crop Science LP, formerly Aventis CropScience, requested these tolerances 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 October 27, 2004. Objections and requests for hearings must be received on or before December 27, 2004.

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 –2004–0331. 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: George LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6100; e-mail address: *larocca.george@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers;

commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 November 7, 2001 (66 FR 56298) (FRL–6808–5), 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 1E6232) (PP 0F6080) by Bayer Crop Science LP, formerly Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.435 be amended by establishing a tolerance for residues of the insecticide deltamethrin, in or on almond hulls; apples, wet pomace; artichokes; brassica, head and stem crop subgroup 5A, excluding cabbage; bulb vegetables ; cabbage (w/wrapper leaves); cabbage (w/o wrapper leaves); carambola (star fruit); corn, field grain; corn, forage (field); corn, fodder/stover (field); corn, refined oil; corn, flour; corn, meal; corn, milled by products; cucurbit vegetables; eggs; fruiting vegetables; leafy vegetables; lichi fruit; milk, fat (reflecting 0.02 ppm in whole milk); mustard greens; pome fruit; poultry, fat; poultry, mbyp; poultry, meat; prunes; rapeseed (including canola and crambe); root vegetable, except sugarbeet (subgroup 1B): roots; ruminant fat; ruminant mbyp; ruminant meat; sorghum, forage; sorghum, fodder/stover; sorghum, grain; soybeans; stone fruit; sunflower seeds; tree nuts; tuberous and corm vegetables subgroup 1C, excluding artichokes; wheat gluten (post harvest); wheat, grain (post harvest); wheat, grain dust (post harvest) at 1.2, 1.2, 0.5, 0.50, 1.5, 1.5, 0.15, 0.2, 0.06, 0.7, 7.0, 0.6, 0.18, 0.12, 0.18, 0.06, 0.02, 0.25, 4.5, 0.2, 0.1, 4.5, 0.2, 0.05, 0.02, 0.02, 2.4, 0.12, 0.15, 0.04, 0.02, 0.02, 0.5, 2.0, 0.5, 0.05, 0.6, 0.05, 4.0, 0.1, 0.04, 1.4, 2.0, and 2.7 parts per million (ppm) respectively . The registrant originally filed petition PP 1E6232 with the Agency, proposing the establishment of regulations for residues of deltamethrin, an insecticide, in or on various food commodities. The petition (PP 1E6232) requested the establishment of proposed tolerances for deltamethrin in/on almond hull, three crop subgroups and rapeseed, and import tolerances for two tropical fruits, as petitioned through the Minor Crop Pest Management program (IR-4). Petition (PP 1E6232) was superceded, at the request of the registrant, by petition (PP 0F6080), including additional tolerances for the above listed crops, and the proposed commodities described in the previous petition (PP 1E6232). The Notice of Filing of November 7, 2001 (66 FR 56298) (FRL–6808–5) identified an inclusive summary of both petitions prepared by Bayer Crop Science LP formerly Aventis CropScience, the registrant. There were no comments received in response to the notice of filing.

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 combined residues of deltamethrin, isomers trans-deltamethrin and α-R-deltamethrin in or on the commodities listed in Unit II. 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 deltamethrin is discussed in Tables 1 and 2 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—rodents	NOAEL = 1.0 and 10 milligrams/kilogram/day (mg/kg/day) for males and females respectively LOAEL = 2.5 mg/kg/day for males based on decreased body weight for males, females was not established.
870.3150	90-Day oral toxicity—non-rodents	NOAEL = 1.0 mg/kg/day males and females LOAEL = 2.5 mg/kg/day based on central nervous system effects diarrhea, vomiting and decreased body weight gain for males and females.
870.3200	21/28-Day dermal toxicity rat	NOAEL > 1,000 mg/kg/day for males and females (limit dose) Dermal NOAEL was not established. Signs of local irritation seen at all doses.
870.3250	90-Day dermal toxicity	NA
870.3465	21-Day inhalation toxicity rat	NOAEL = 3.0 mg/kg/day males and females. LOAEL = 9.6 mg/kg/day based on decreased weight gain, nervous system stimulation and skin irritation for males and females
870.3700	Prenatal developmental—rodents	Maternal NOAEL = 3.3 mg/kg/day Maternal LOAEL = 7.0 mg/kg/day based on decreased body weights and body weight gains and clinical signs of toxicity Developmental NOAEL = greater than 11.0 mg/kg/day Developmental LOAEL = none observed
870.3700	Prenatal developmental—mouse	Maternal NOAEL ≥ 10 mg/kg/day Maternal LOAEL = not observed Developmental NOAEL = 0.1 mg/kg/day Developmental LOAEL = 1.0 mg/kg/day based on decreased fetal weight, and delayed ossification of the sternebrae and paws
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 5.4 and 6.1 mg/kg/day for males and females respectively. Parental/Systemic LOAEL = 21.2 and 23.5 mg/kg/day for males and females respectively. Based on increased mortality and clinical signs, decreased body weights, body weight gains, and absolute food consumption, and gross pathological findings in both sexes. Reproductive NOAEL = 21.2 mg/kg/day for males and females. Reproductive LOAEL = [not established] Offspring NOAEL = 5.8 and 6.7 mg/kg/day for males and females respectively. Offspring LOAEL = 24.9 and 27.2 mg/kg/day for males and females respectiveley. Based on increased mortality and clinical signs, decreased body weights, body weight gains, and absolute food consumption, and gross pathological findings in both sexes.
870.4100	Chronic toxicity—rodents	Same as Chronic Toxicity/Carcinogenicity-rat see below (870.4300)
870.4100	Chronic toxicity—dogs	NOAEL = 1.0 mg/kg/day males and females. LOAEL = 10.0 mg/kg/day males and females. Based on reduced body weight gain, chewing and scratching of extremities, and liquid feces.
870.4200	Carcinogenicity—rats	No evidence of carcinogenicity Same as chronic toxicity/carcinogenicity-rat see below (870.4300).
870.4300	Carcinogenicity—mice	NOAEL = 2,000 mg/kg/day (HDT) LOAEL = not established No evidence of carcinogenicity, HDT assumed to be adequate to characterize the carcinogenic potential based on a 12-week toxicity study in mice showing death and body weight differences (13% decrease) at 3,000 ppm.
870.4300	Chronic/Carcinogenicity-rat	NOAEL = >50 ppm (HDT) for males and females. LOAEL was not determined No evidence of carcinogenicity
870.5100	Bacterial reverse mutation test-*S. typhimurium*	There was no evidence of an induced mutagenic effect up to cytotoxic concentrations ≥38 micro grams/mL -S9; 150 μg/mL +S9). Levels ≥75 micrograms/mL were insoluble.

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

Guideline No.	Study Type	Results
870.5375	*In vitro* mammalian chromosome aberration test- Chinese hamster ovary (CHO) cells	There was no evidence of an induced mutagenic effect up to cytotoxic concentrations (≥38 micrograms/mL -S9; 150 micrograms/mL +S9). Levels ≥75 micrograms/mL were insoluble.
870.5550	Other Genotoxicity Bacterial DNA damage/repair-*E. coli*	There was no evidence of DNA repair/damage up to the limit dose ((5,000 micrograms/well +/-S9). Compound precipitation seen at ≥200 micrograms/well.
870.5550	Other Genotoxicity Unscheduled DNA synthesis in primary rat hepatocytes	There was no evidence that unscheduled DNA synthesis was induced up to insoluble concentrations (≥130 micrograms/mL).
870.6200	Acute neurotoxicity screening battery rats	NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on salivation, soiled fur, impaired motility, no reaction to approach or touch response in the functional observation battery (FOB)
870.6200	Subchronic neurotoxicity screening battery	NOAEL = 14 and 16 mg/kg/day for males and females respectively. LOAEL = 54 and 58 mg/kg/day for males and females respectivley.. Based on mortality, clinical signs, FOB findings, and decreased body weights, body weight gains, and food consumption.
870.6300	Developmental neurotoxicity	NA
870.7485	Metabolism and pharmacokinetics - rats	The test material was relatively well absorbed. Excretion was almost complete within 48 hours. Approximately 36-59% of the dose was found in feces and an approximately equal amount in urine. Absorbed deltamethrin was cleaved by hydrolysis at the ester site followed by rapid sulfate and glucuronide conjugation.
870.7600	Dermal penetration	NA
	Special studies	There were no special studies

TABLE 2.—NON-GUIDELINE TOXICITY STUDIES AND LITERATURE.

Study Type	Results	Citation
Acute Motor Function Oral-male rat	Vehicle: Corn oil ED50 5.1 mg/kg LOAEL 3.0 mg/kg (based on reduced motor function) NOAEL 1.0 mg/kg Vehicle: Methylcellulose ED50 >1,000 mg/kg LOAEL 300 mg/kg (based on reduced motor function) NOAEL 100 mg/kg	Crofton *et al.*, (1995)
Acute Motor Function Oral-male rat	Vehicle: Corn oil LOAEL 2.0 mg/kg (based on reduced motor function) NOAEL Not established	Crofton and Reiter, (1984)
Acute Locomotor Activity Oral- male rat	Vehicle: Corn oil LOAEL 3.0 mg/kg (based on reduced locomotor activity) NOAEL 1.0 mg/kg	Gilbert *et al.*, (1990)
Acute Acoustic Startle Response (ASR) Oral-rats	Vehicle: Corn oil 21-day old rats: LOAEL 1 mg/kg NOAEL Not established Adults: LOAEL 2 mg/kg NOAEL Not established At the ED50 (4 mg/kg), the brain concentration of deltamethrin was ≈2-fold higher in weanlings than in adults	Sheets et al., (1994)

TABLE 2.—NON-GUIDELINE TOXICITY STUDIES AND LITERATURE.—Continued

Study Type	Results	Citation
Acute Behavioral Tests Oral - Mice	Vehicle: 20% Fat Emulsion at 0.7 mg/kg (only dose tested) 17- day old mice No significant changes 4-month old mice Significant changes in locomotion, rearing and activity and a significant decrease in 3HQNB binding sites in the cerebral cortex.	Eriksson and Fredriksson, (1991)
Prenatal developmental—rodents	Maternal NOAEL = 1.0 mg/kg/day Maternal LOAEL = 7.0 mg/kg/day based on slightly reduced body weights Developmental NOAEL = 1.0 mg/kg/day Developmental LOAEL = 10 mg/kg/day based on delayed ossification of the sternebrae	Non-guideline
Prenatal developmental—nonrodents	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = not established Developmental NOAEL = 25 mg/kg/day Developmental LOAEL = 100 mg/kg/day based on increases in the incidences of delayed ossification and skeletal variations	Non-guideline
Prenatal developmental—nonrodents	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 32 mg/kg/day based on decreased bodyweight gain between GD 6 and 21. Developmental NOAEL = >32 mg/kg/day Developmental LOAEL = not established	Non-guideline

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 deltamethrin used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DELTAMETHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population and Females 13-49 years of age)	NOAEL = 1.0 mg/kg/day UF = 100 Acute RfD = 0.01 mg/kg/day	Special FQPA SF = 3X aPAD = acute RfD/ Special FQPA SF = 0.0033 mg/kg/day	Neurotoxicity-Motor Activity (Crofton *et al.*, 1995) LOAEL = 3.0 mg/kg/day based on reduced motor activity
Chronic Dietary (All populations)	NOAEL= 1.0 mg/kg/day UF = 100 Chronic RfD = 0.01 mg/kg/day	Special FQPA SF = 3X cPAD = chronic RfD/Special FQPA SF = 0.0033 mg/kg/day	Chronic Dog Study LOAEL = 10 mg/kg/day based on clinical signs and reduced body weight gain
Incidental Oral Short and Intermediate Term	NOAEL = 1.0 mg/kg/day UF = 100	LOC for MOE = 300	Same as chronic dietary
Dermal All Durations			Not required: No systemic toxicity via the dermal route was seen at the limit dose; there was no evidence of cumulative toxicity; and physical and dermal properties indicate low dermal absorption.
Inhalation All Durations (Residential)	NOAEL = 1.0 mg/kg/day UF = 100= 100%)	LOC for MOE = 300 (Residential)	Same as chronic dietary.
Cancer (oral, dermal, inhalation)			Classification: Not likely to be a human carcinogen.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.435) for the combined residues of deltamethrin, isomers trans-deltamethrin and α-R-deltamethrin, in or on a variety of raw agricultural commodities, including additional meat, milk, poultry and egg tolerances. Risk assessments were conducted by EPA to assess dietary exposures from combined residues of deltamethrin, isomers trans-deltamethrin and α-R-deltamethrin, and tralomethrin 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.

In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), 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 following assumptions were made for the acute exposure assessments: The acute dietary exposure analysis was a refined probabilistic one. The analysis was refined through the use of projected market share estimates from Agency analysis and anticipated residues (ARs) based on field trial values. At the 99.9th percentile of exposure, the risk estimate for the general U.S. population is 39% of the acute population adjusted dose (aPAD). The most highly exposed population subgroup is All Infants, which utilizes 65% of the aPAD.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), 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 following assumptions were made for the chronic exposure assessments: Chronic exposure analysis was refined through the use of projected market share estimates from Agency analysis and the anticipated residues (ARs) are based on field trial values. The U.S. population and all population subgroups have exposure and risk estimates that are below the Agency's level of concern. The general U.S. population utilizes 3.0% of the chronic PAD (cPAD). The most highly exposed subgroup, Children 1-2 years, utilizes 7.6% of the cPAD.

iii. *Cancer.* Deltamethrin is classified by the Agency as not likely to be carcinogenic in humans.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to

show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of %CT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on %CT.

The Agency used PCT information as follows:

For existing uses of deltamethrin and tralomethrin, the Agency used estimates of PCT for the acute and chronic exposure assessments which were determined using Doanes Market Survey Data (1996–2001). The following deltamethrin PCT data estimates were used for both the acute and chronic dietary exposure assessments: Cotton (14), tomato (19). The following tralomethrin PCT data estimates were used for both the acute and chronic dietary exposure assessments: Broccoli (6.0), lettuce, head (15), lettuce, leaf (22), and soybean (1.0). Tralomethrin is also registered for use on cotton and sunflower. For cotton, the deltamethrin PCT value is higher; therefore, the deltamethrin value was used in the assessment. There is a proposed use for deltamethrin on sunflower, and the projected market share value is higher than the PCT value for tralomethrin. As a result, the projected market share value for deltamethrin was used in the assessment. Since deltamethrin and tralomethrin are essentially the same chemical, it was assumed that both pesticides would not be used on the same crop.

The Agency believes that the three conditions listed in Unit III.C.1.iv. have been met. With respect to Condition 1, PCT estimates are derived from market survey data, which are reliable and have a valid basis.

The Agency used maximum PCT for both acute and chronic dietary exposure estimates. A maximum PCT is unlikely to underestimate exposure to an individual because of the fact that an individual is unlikely to be exposed to more than the maximum PCT either on an acute basis or over a lifetime. For acute assessments, the Agency incorporates PCT information by creating a residue distribution file which includes the measured residue values from field trials, and zero residue values added to account for the percent of crop not treated. This approach is used only for non-blended or partially blended commodities as defined under EPA SOP99.6. For blended commodities, a single-point estimate is created from the residue value multiplied by the upper bound PCT. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation.

For the new uses, the Agency used PCT estimates for both the acute and chronic exposure assessments based on market share projections as follows: Almond (28 %); apple (38 %); canola (1.0 %); cantaloupe (11 %); carrot (22 %); corn (5.0 %); cucumber (10 %); garlic (1.0 %); onion (2.0 %); pear (23 %); pepper (12 %); potato (7.0 %); soybean (1.0 %); squash (2.0 %); sunflower (9.0 %); and walnut (5.0%). The following methods were used to estimate market share for the new uses: The Agency reviewed the proposed new uses for deltamethrin, identified practicable alternatives based on the primary target pest for each use site, and estimated a likely upper-bound for the percent crop treated. The Agency has determined that the alternatives are viable based on the best available EPA data, and assumes they will control the insect pests identified on the proposed label. The Agency believes that the projected market share estimates are upper-bound estimates because it summed the current market share of all chemicals that are currently being used to control the target pest on a particular crop. By doing so, the Agency has made the assumption that deltamethrin will replace all other insecticides that are currently being used on that crop to control the primary target pest that deltamethrin will be used to control. Furthermore, the Agency has made the assumption that deltamethrin will replace all competing insecticides on all of the crops for which projected market share data were used. In addition, the Agency has made the assumption that for many of the crops in the dietary analysis, 100% of the crop would be treated. For the stored grains, the PCT estimates are derived from usage data for chlorpyriphos-methyl, historically the most widely used insecticide for control of insect pests in stored grains. The estimates are as follows: Wheat, oats, and barley (avg: 8.0 %, max: 9.0 %); field corn and pop corn (avg: 3.0 %, max: 6.0 %); sweet corn (avg: 2.1 %, max: 3.5 %); sorghum (avg: 3.2 %, max: 3.7 %); and rice (avg: 2.9 %, max: 3.1 %). For all other new uses, it was assumed that 100% of the crop would be treated.

The Agency believes that the three conditions previously discussed have been met regarding PCT estimates for the new deltamethrin registrations. With respect to Condition 1, EPA finds that the PCT information described in Unit II.C.1.iv. for deltamethrin on almonds, apples, canola, cantaloupe, carrots, corn, cucumbers, garlic, onions, pears, peppers, potatoes, soybeans, squash, sunflowers, walnuts, and stored cereal grains is derived from market survey data, which are reliable and have a valid basis. For almonds, apples, canola, cantaloupe, carrots, corn, cucumbers, garlic, onions, pears, peppers, potatoes, soybeans, squash, sunflowers, and walnuts, the PCT estimates are based on current market share data for all alternative insecticides used to control the primary target pest, and the generous assumption that deltamethrin will replace all of the competing insecticides used to control that target pest. For stored grains, the estimate is derived from usage data for chlorpyrifos-methyl, historically the most widely used insecticide for control of insect pests in stored grains. These estimates should not underestimate actual usage of deltamethrin on the new crops/sites.

As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which deltamethrin may be applied in a particular area.

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

The Agency uses the FQPA 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 SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST, a tier 1 model, before using PRZM/EXAMS, a tier 2 model. The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a 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 deltamethrin they are further discussed in the aggregate risk sections in Unit III.E.

Based on FIRST and SCI-GROW models, the EECs of deltamethrin for acute exposures are estimated to be 0.20 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.067 ppb for surface water and 0.006 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).

Deltamethrin is currently registered for use on lawns, turf, golf courses, sod farms, ornamental gardens, perimeter treatment, indoor broadcast, spot, and crack and crevice surface treatment, and pet collars. The end use products are formulated as ready-to-use sprays, granular, dust, wettable powders and liquids to be applied by commercial applicators and/or homeowners depending on the product. These uses include a wide range of application methods including hose-end sprayers, push-type spreader, shaker can, aerosol can, low/high pressure hand wands, injection, airless sprayers, injection syringe, and paint brush/roller used to treat indoors and outdoors.

No dermal endpoint was selected because no systemic toxicity via the dermal route was seen at the limit dose and therefore a dermal risk assessment for handlers was not required. All inhalation MOEs for residential handlers exposure ranged from 3,300 to 1,800,000 and therefore did not exceed the Agency's level of concern.

Based on the use pattern of residential products, duration of postapplication exposure is expected to be short term. As indicated previously no dermal endpoint was selected and therefore no risk from dermal exposure is expected. The Agency concluded that use of an indoor fogger would result in the worst case scenario for assessing postapplication inhalation exposure. The postapplication inhalation MOEs following use of a fogger were greater than the targeted MOE and therefore the risks were not of concern. Fogger postapplication risks are protective of inhalation risks from other indoor products. Furthermore the vapor pressure of deltamethrin is very low (1.5×10^{-8} mm Hg at 25°) and therefore postapplication inhalation exposure is expected to be minimal for indoor uses.

The following postapplication incidental oral scenarios following application to lawns and indoor surfaces (carpet versus hardwood or vinyl floors) were assessed:

i. Short-term oral hand-to-mouth exposure to toddlers and children from indoor use ;

ii. Short-term oral object to mouth exposure to toddlers and children from ingestion of pesticide treated turf; and

iii. Short-term oral exposure to toddlers and children following soil ingestion.

Since the FQPA safety factor for the protection of children and infants was reduced to 3X, a target MOE value of 300 has been identified for residential assessments. MOE values greater than 300 are not considered to be of concern to the Agency. MOE estimates are based on the NOAEL dose level of 1 mg/kg/day established for short-term oral risk assessment.

TABLE 4.—SUMMARY OF SHORT-TERM RESIDENTIAL POSTAPPLICATION MOES.

Exposure Scenario	Oral Dose (mg/kg/day	Oral MOE
Hand-to-Mouth (Indoor Use)	0.0028	340
Object-to-Mouth (Turf)	0.00049	2,000
Soil Ingestion (Turf)	0.0000065	150,000

Note: Episodic incidental ingestion of granules and paint chips was also assessed and was not considered to be of concern to the Agency.

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.''

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 deltamethrin and any other substances and deltamethrin 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 deltamethrin 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 OPP 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 additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. The toxicology data base for deltamethrin for an FQPA assessment includes developmental toxicity studies in rats, rabbits and mice, a two-generation reproduction toxicity study in rats, acute and subchronic neurotoxicity studies in rats, and studies from the open literature indicating increased susceptibility and neurotoxicity.

Signs of neurotoxicity were seen in guideline acute and subchronic neurotoxicity studies in rats, including salivation, soiled fur, impaired mobility, no reaction to approach and no reaction to touch response observed in the functional observation battery (FOB) in the acute study, and mortality, clinical signs of toxicity, FOB findings, and decreased body weights, body weight gains, and food consumption in the subchronic study. In addition, similar signs of neurotoxicity were observed in several literature studies conducted in rats and mice.

Acceptable developmental toxicity studies in rats and rabbits indicated no evidence of developmental toxicity. In 3 non-guideline multi-species developmental toxicity studies, there is concern for developmental effects that occurred in either the absence of or in the presence of mild maternal toxicity in three species (mice, rats and rabbits). In mice, an increase in delayed ossification in the fetuses was seen in the absence of maternal toxicity at the highest dose tested. In rats, increased delayed ossification was seen in the presence of decreased body weight in the dams. In rabbits, increased fetal death and decreased fetal body weight were seen in the absenceof maternal toxicity at the highest dose tested.

There is qualitative evidence of increased susceptibility only at the highest dose tested in the two-generation toxicity study in rats. Effects were seen in the adults of the F1 generation. These effects were not seen in the P generation or in the F1 rats when they were pups. These effects included increased death, clinical findings (i.e. impaired righting reflexes, hyperactivity, splayed limbs, vocalization, and excessive salivation) and cerebral congestion and/or blood clots at the highest dose tested. Evidence for age-related sensitivity was seen in a published literature study in which the brain concentration of deltamethrin in weanling rats was higher than in adult rats.

Based on clinical signs indicative of neurotoxicity observed in adult animals, concern for the effects seen in the two-generation reproduction study and structural-activity relationship concerns, a developmental neurotoxicity study (DNT) has been required for deltamethrin. The study protocol indicates that the proposed lowest dose in the study is 1 mg/kg/day, which is equivalent to the NOAELs currently selected for dietary and non-dietary risk assessment.

3. *Conclusion*. The hazard-based FQPA Safety Factor has been reduced to 3x for all population subgroups including those comprised of infants and children.

Previously, the Agency determined that the overall FQPA Safety Factor should be retained at 10x due to the lack of an acceptable pre-natal toxicity study in rabbits; the lack of the required developmental neurotoxicity (DNT) study; an overall degree of concern for the qualitative and quantitative evidence of increased susceptibility observed in mice; and residual uncertainties for pre/post-natal toxicity. The default 10x factor encompassed the database uncertainty factor and the Special FQPA Safety Factor.

The Agency has since received and reviewed an acceptable pre-natal developmental toxicity study in rabbits which does not show evidence (quantitative or qualitative) of increased susceptibility. A dose analysis indicated no need for a database uncertainty factor for the lack of a DNT since this study is not expected to lower the doses currently used for the overall risk assessment. Therefore, there is no need for a database uncertainty factor. However, the Special FQPA Safety Factor is needed since there is still a concern for the qualitative evidence of increased susceptibility observed in mice. A Special FQPA Safety Factor of 3X (as opposed to a 10X) was determined to be adequate based on the following weight-of-evidence considerations.

i. The endpoint of concern for risk assessment is already based on the most sensitive endpoint (i.e., clinical signs indicative of neurotoxicity),

ii. In the acute and subchronic neurotoxicity studies, no damage to the neurological system (e.g., neuropathology or alterations in brain weight) was seen, and there was no evidence of malformations or variations of the central nervous system of the fetuses in the pre-natal studies or to offspring in the post-natal study,

iii. The generally accepted mechanism of action for pyrethroids, sodium channel disruption, has not been traditionally associated with developmental neuropathology, and

iv. A dose that was four-fold higher than the dose used for risk assessment was required to cause the two-fold difference in brain concentration of deltamethrin in weanling rats.

The NOAEL of 1.0 mg/kg/day currently used for overall risk assessment is protected by a safety factor of 3X which yields an extrapolated dose of 0.3 mg/kg/day. This dose is an order of magnitude lower than the dose that caused the two-fold decrease in brain concentrations of deltamethrin in the weanling rats. Therefore, a half-log reduction (3X) in the Special FQPA Safety Factor is considered to be sufficiently protective of the concerns for the qualitative susceptibility seen in mice.

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 youth 13-19), 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 deltamethrin will occupy 39% of the aPAD for the U.S. population, 28% of the aPAD for females 13 to 49, 65% of the aPAD for All Infants (< 1 year old), and 60% of the aPAD for Children 1-2 years old. In addition, there is potential for acute dietary exposure to deltamethrin 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 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO DELTAMETHRIN

Population Subgroup	Exposure (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
General U.S. Population	0.001305	39	0.20	0.006	71
All Infants (< 1 year old)	0.002175	65	0.20	0.006	12
Children 1-2 years old	0.001992	60	0.20	0.006	13
Children 3-5 years old	0.002135	64	0.20	0.006	12
Children 6-12 years old	0.001555	47	0.20	0.006	18
Youth 13-19 years old	0.001010	30	0.20	0.006	70
Adults 20-49 years old	0.000830	25	0.20	0.006	88
Adults 50+ years old	0.000836	25	0.20	0.006	87
Females 13-49 years old	0.000937	28	0.20	0.006	72

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to deltamethrin from food will utilize 3 % of the cPAD for the U.S. population, 7.6 % of the cPAD for Children 1-2 years old. Based on the use pattern, chronic residential exposure to residues of deltamethrin is not expected. In addition, there is potential for chronic dietary exposure to deltamethrin 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 Table 6 of this unit:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DELTAMETHRIN

Population Subgroup	Exposure mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.000099	3.0	0.067	0.006	110
All Infants (< 1 year old)	0.000157	4.7	0.067	0.006	32
Children 1-2 years old	0.000252	7.6	0.067	0.006	31
Children 3-5 years old	0.000238	7.1	0.067	0.006	31
Children 6-12 Years	0.000149	4.5	0.067	0.006	32

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DELTAMETHRIN—Continued

Population Subgroup	Exposure mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Youth 13-19 Years	0.000086	2.6	0.067	0.006	97
Adults 20-49 Years	0.000076	2.3	0.067	0.006	110
Adults 50+ Years	0.000078	2.3	0.067	0.006	110
Females 13-49	0.000077	2.3	0.067	0.006	98

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

Deltamethrin 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 deltamethrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 2600 for the U.S. Population, 2700 for Females 13-49, 338 for all infants <1 year old, 328 for Children 1-2 years old, and 329 for Children 3-5 years old. These aggregated MOEs include average exposure from deltamethrin residues in food as well as inhalation exposure of adults; oral (hand-to-mouth) exposure of infants and children from the residential uses of deltamethrin resulting from spot, and crack and crevice use and surface treatments to carpet and vinyl surfaces. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of deltamethrin in ground and surface water. After calculating DWLOCs and comparing them to- the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 7 of this unit:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO DELTAMETHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
U.S. Population	2,600	300	0.067	0.006	100
Females 13-49	2,700	300	0.067	0.006	89
All infants (<1 year)	338	300	0.067	0.006	3.8
Children 1-2	328	300	0.067	0.006	2.8
Children 3-5	329	300	0.067	0.006	3.0

4. *Intermediate-term risk*. Intermediate term residential exposures are not anticipated from the registered and proposed uses of deltamethrin, therefore, an intermediate term risks are not expected.

5. *Aggregate cancer risk for U.S. population*. Deltamethrin is classified by the Agency as not likely to be carcinogenic in humans, therefore, deltamethrin 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 deltamethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods based on gas chromatography (GC) with electron capture detection (ECD) are available for enforcing tolerances for residues of deltamethrin. These methods are used for the determination of cis-deltamethrin, trans-deltamethrin, and alpha-R-deltamethrin in various raw agricultural, animal-derived, and processed commodities. In addition, cis-deltamethrin is completely recovered and its trans isomer is partially recovered by one of the multiresidue methods utilized by the Food and Drug Administration for monitoring of pesticide residues. 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

Codex Maximum Residue Limits (MRL's) are established on a variety of commodities for residues of deltamethrin in terms of the cis-isomer only. This definition is not compatible with the U.S. tolerances, which also include the trans and alpha-R isomers. However, the cis-isomer is consistently present at much higher levels than the other two isomers in crop field trials. Thus, in numerical terms there is not a significant difference in the tolerance definitions. Therefore, the Agency concludes that it is reasonable to harmonize U.S. tolerance levels numerically with Codex MRL's where feasible. The commodities for which the

U.S. tolerances have been raised for harmonization purposes are meat byproducts of cattle, goats, horses, and sheep (to match the 0.05 ppm Codex MRL for edible mammalian offal); cereal grains; soybean seed (0.1 ppm Codex MRL for legume vegetables); sunflower seed (0.1 ppm Codex MRL on oilseeds); cucurbit vegetables; and wheat bran. The U.S. tolerances on barley bran and rye bran have also been increased since they are based on the data for wheat bran. The data for dry bulb onions in the U.S. support setting the tolerance at the same level as the Codex bulb vegetable tolerance. The following U.S. tolerances can not be harmonized numerically with Codex MRL's due to residues being higher from the requested uses in the U.S. or the tolerances being based on the sum of the analytical method limits of quantitation for the three deltamethrin isomers (versus only the cis-isomer included in Codex MRL's): globe artichoke; meat of cattle, goats, horses, and sheep; stover of field corn, pop corn, sweet corn, and grain sorghum; eggs; pome fruit; green onion; poultry meat and meat byproducts; rapeseed; fruiting vegetables; root vegetables; and tuberous and corm vegetables.

V. Conclusion

Therefore, the tolerance is established for combined residues of deltamethrin, isomers trans-deltamethrin and α-R-deltamethrin, in or on almond hulls; apples, wet pomace; artichoke, globe; barley, bran; cattle, fat; cattle, meat; cattle, meat byproducts; corn, field, forage; corn, field, refined oil; corn, field, stover; corn, pop, stover; corn, sweet, forage; corn, sweet, kernel + cob with husks removed; corn, sweet, stover; egg; fruit, pome, group 11; goat, fat; goat, meat; goat, meat byproducts; grain, aspirated fractions; grain, cereal, group 15, except sweet corn; hog, fat; horse, fat; horse, meat; horse, meat byproducts; lychee (import tolerance); milk, fat (reflecting 0.02 ppm in whole milk); nut, tree, group 14; onion, dry bulb; onion, green; poultry, fat; poultry, meat; poultry, meat byproducts; radish tops; rapeseed; rice, hulls; rye, bran; sheep, fat; sheep, meat; sheep, meat byproducts; sorghum, grain forage; sorghum, grain stover; soybean, seed; soybean, hulls; starfruit (import tolerance); sunflower seeds; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; vegetable, root, except sugar beet, subgroup IB; vegetable, tuberous and corm, subgroup; IC; wheat, bran at 2.5, 1.0, 0.5, 5.0, 0.05, 0.02, 0.05, 0.7, 2.5, 5.0, 5.0, 10, 0.03, 15, 0.02, 0.2, 0.05, 0.02, 0.05, 65, 1.0, 0.05, 0.05, 0.02, 0.05, 0.2, 0.1, 0.1, 0.1, 1.5, 0.05, 0.02, 0.02, 4.0, 0.2, 2.5, 5.0, 0.05, 0.02, 0.05, 0.5, 1.0, 0.1, 0.2, 0.2, 0.1, 0.2, 0.3, 0.2, 0.04, 5.0 parts per million (ppm) respectively .

At the request of the registrant (Bayer Crop Science LP, formerly Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709]) the following crop tolerances were voluntarily withdrawn from the original petition: head & stem brassica vegetables, leafy vegetables and stone fruits.

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–2004–0331 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 December 27, 2004.

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. *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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0331, 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: September 30, 2004.

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 180.435 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.435 Deltamethrin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond hulls	2.5
Apples, wet pomace	1.0
Artichoke, globe	0.5

Commodity	Parts per million
Barley, bran	5.0
Cattle, fat	0.05
Cattle, meat	0.02
Cattle, meat byproducts	0.05
Corn, field, forage	0.7
Corn, field, refined oil	2.5
Corn, field, stover	5.0
Corn, pop, stover	5.0
Corn, sweet, forage	10
Corn, sweet, kernel + cob with husks removed	0.03
Corn, sweet, stover	15
* * * * *	
Egg	0.02
Fruit, pome, Group 11	0.2
Goat, fat	0.05
Goat, meat	0.02
Goat, meat byproducts	0.05
Grain, aspirated fractions	65
Grain, cereal, Group 15, except sweet corn	1.0
Hog, fat	0.05
Horse, fat	0.05
Horse, meat	0.02
Horse, meat byproducts	0.05
Lychee*	0.2
Milk, fat (reflecting 0.02 ppm in whole milk)	0.1
Nut, tree, Group 14	0.1
Onion, dry bulb	0.1
Onion, green	1.5
Poultry, fat	0.05
Poultry, meat	0.02
Poultry, meat byproducts	0.02
Radish tops	4.0
Rapeseed	0.2
Rice, hulls	2.5
Rye, bran	5.0
Sheep, fat	0.05
Sheep, meat	0.02
Sheep, meat byproducts	0.05
Sorghum, grain forage	0.5
Sorghum, grain stover	1.0
Soybean, seed	0.1
Soybean, hulls	0.2
Starfruit*	0.2
Sunflower seed	0.1
* * * * *	
Vegetable, cucurbit, Group 9	0.2
Vegetable, fruiting, Group 8	0.3
Vegetable, root, except sugar beet, Subgroup IB	0.2
Vegetable, tuberous and corm, Subgroup IC	0.04
Wheat, bran	5.0

*There are no U.S. registrations for use of deltamethrin on starfruit and lychee.

* * * * *

[FR Doc. 04–24040 Filed 10–26–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15, 74, 78, and 101

[ET Docket Nos. 00–258, 95–18; FCC 04–219]

Advanced Wireless Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission found that the bands 1915–1920 MHz paired with 1995–2000 MHz and 2020–2025 MHz paired with 2175–2180 MHz were well suited to provide additional spectrum for AWS use and designated these paired bands for such use. The Commission also modified the rules pertaining to unlicensed PCS service in the 1920–1930 MHz band in order to provide additional flexibility to users of the band to offer both voice and data services using a variety of technologies. The *Third Memorandum Opinion and Order* denies petitions for rulemaking related to the reallocation to AWS in previous rulemakings and the *Fifth Memorandum Opinion and Order* clarifies rules governing relocation of FS licensees.

DATES: Effective November 26, 2004.

FOR FURTHER INFORMATION CONTACT: Shameeka Hunt or Priya Shrinivasan, Office of Engineering and Technology, (202) 418–2472.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Sixth Report and Order, Third Memorandum Opinion and Order, and Fifth Memorandum Opinion and Order,* ET Docket Nos. 00–258 and 95–18, FCC 04–219, adopted September 9, 2004, and released September 22, 2004. The full text of this Commission decision is available on the Commission's Internet site at *http://www.fcc.gov.* It is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Room CY-B402, 445 12th Street, SW., Washington, DC 20554. Alternate formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Summary of the Report and Order

1. In the *Sixth Report and Order (Sixth R&O and Third MO&O*) in ET Docket No. 00–258, the Commission continues its ongoing efforts to promote spectrum utilization and efficiency by evaluating spectrum that may be suitable for the provision of new services, including Advanced Wireless Services (AWS). In the *Sixth R&O,* we find that the bands 1915–1920 MHz paired with 1995–2000 MHz and 2020–2025 MHz paired with 2175–2180 MHz—which were all previously reallocated for Fixed and Mobile services—are well suited to provide additional spectrum for AWS use and we designate these paired bands for such use. This action will provide an additional twenty megahertz of spectrum for the introduction of new services and technology. We also modified the rules pertaining to unlicensed PCS services in the 1920–1930 MHz band in order to provide additional flexibility to users of the band to offer both voice and data services using a variety of technologies.

2. The *Sixth R&O* identifies two five + five megahertz spectrum blocks that are especially well suited for AWS use, and find that such a designation will maximize the potential use of the spectrum and promote the deployment of high value service offerings. Specifically, we redesignate the 1915–1920 MHz and 1995–2000 MHz, as well as the 2020–2025 MHz and 2175–2180 MHz spectrum blocks as paired bands suitable for the introduction of new technologies.

A. 1915–1920 MHz and 1995–2000 MHz Bands

3. The Commission concludes that AWS operations in the 1915–1920 MHz band are technically feasible with a ten megahertz frequency separation between Broadband PCS mobile and base operations. We recognize, that additional technical constraints may need to be placed on AWS to avoid impairing incumbent PCS operations. Although we conclude here that this band will be designated for AWS, one goal of the *AWS 2 GHZ Service Rules NPRM* is to adopt technical rules that will protect existing PCS operations from interference.

4. The Commission also concluded that AWS operations can be deployed in the 1995–2000 MHz band. Several parties contend that technical constraints will need to be placed on new AWS operations in the 1995–2000 MHz band in order to avoid interference to adjacent MSS operations in the 2020–2025 MHz band. However, we note that prior to the reallocation of MSS spectrum in the 1990–2000 MHz band to fixed and mobile services, existing Broadband PCS was immediately adjacent to the MSS. Thus, by redesignating the 1995–2000 MHz band