enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 26, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 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 180.434 is amended as follows:

■ a. By revising the expiration date for several commodities in the table in paragraph (a).

■ b. By removing the commodity Corn, stover in the table in paragraph (a).

■ c. By removing the commodity Raspberry in the table in paragraph (b).

§ 180.434 Propiconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration Date
* *	*	* *
Corn, field, forage	12	11/30/08
Corn, field, grain	0.1	11/30/08
Corn, field, stover	12	11/30/08
Corn, sweet, kernel plus cob with husks removed	0.1	11/30/08
* *	*	* *
Peanut	0.2	11/30/08
Peanut, hay	20	11/30/08
* *	*	* *
Pineapple	0.1	11/30/08
Pineapple, fodder	0.1	11/30/08
* *	*	* *

* * * * *

[FR Doc. 04–17509 Filed 8–3–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0100; FRL–7368–8]

Propamocarb hydrochloride; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of propamocarb hydrochloride in or on lettuce, leaf; lettuce, head; vegetable, cucurbit, group 9; vegetable, fruiting, group 8; and tomato paste. Bayer CropScience 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 August 4, 2004. Objections and requests for hearings must be received on or before October 4, 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–2004–100. 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 South 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: Mary Waller, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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 March 10, 2004 (69 FR 11426–11431) (FRL–7340–7), 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 0F6123) by Bayer CropScience, 2TW Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.499 be amended by establishing a tolerance for residues of the fungicide propyl [3-(dimethylamino) propyl] carbamate mono-hydrochloride, also known as propamocarb hydrochloride, in or on the raw agricultural commodities (RACs) lettuce, leaf, at 65 parts per million (ppm), lettuce, head, at 50 ppm, wheat, grain, at 0.05 ppm, wheat, straw, at 0.10 ppm, wheat, forage, at 0.30 ppm, wheat, hay, at 0.30 ppm, vegetable, cucurbit, group 9, at 1.5 ppm, vegetable, fruiting, group 8, at 2.0 ppm, and tomato, paste, at 5.0 ppm. That notice included a summary of the petition prepared by Bayer 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 tolerances for residues of propamocarb hydrochloride on vegetable, cucurbit, group 9 at 1.5 ppm; lettuce, head at 50 ppm; lettuce, leaf at 90 ppm; vegetable, fruiting, group 8 at 2.0 ppm and tomato, paste at 5.0 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 propamocarb hydrochloride are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–day oral toxicity in rodents	NOAEL = 363 mg/kg/day in females and 646 mg/kg/day in males LOAEL = 716 mg/kg/day in females, based on decreased body weight and body weight gain and decreased food efficiency. LOAEL in males is 1,363 mg/kg/day based on decreased food efficiency
870.3150	90–day oral toxicity in nonrodents	NOAEL was not achieved LOAEL = 22.75 mg/kg/day based upon body weight gain depression, decreased food efficiency and focal or multi-focal chronic erosive gastritis
870.3200	21/28–day dermal toxicity in rabbits	NOAEL ≥150 mg/kg/day for both sexes LOAEL = 525 mg/kg/day based on dose-related skin irritation and depressed body weight gain
870.3700	Prenatal developmental toxicity in rats	Maternal NOAEL = 221 mg/kg/day Maternal LOAEL = 740 mg/kg/day based on mortality Developmental NOAEL = 221 mg/kg/day Developmental LOAEL = 740mg/kg/day based on GD 20 fetal death and a possible increase in minor skeletal anomalies
870.3700	Prenatal developmental toxicity in rabbits	Maternal NOAEL = 150 mg /kg/day Maternal LOAEL = 300 mg /kg/day based on decreased body weight gains for GD 6–18 and possible increased abortions Developmental NOAEL = 150 mg/kg/day Developmental LOAEL = 300 mg/kg/day based on increased post-implantation loss
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = 65.41 mg/kg/day for males and 76.78 mg/kg/day for females Parental/Systemic LOAEL = 406.69 mg/kg/day for males and 467.13 mg/kg/day for females based on decreased body weights Reproductive/Offspring NOAEL = 65.41 mg/kg/day for males and 76.78 mg/kg/day for females Reproductive/Offspring LOAEL = 406.69 mg/kg/day for males and 467.13 mg/kg/day for females based on reduced pup weights
870.4100	Chronic toxicity in rodents	NOAEL = ≥25.6 mg/kg/day LOAEL = >25.6 mg/kg/day. There were no signs of toxicity attributable to treatment at any dose level
870.4100	Chronic toxicity in dogs	NOAEL was not achieved. LOAEL = 22.75 mg/kg/day based upon body weight gain depression, decreased food efficiency and focal or multi-focal chronic erosive gastritis
870.4200	Carcinogenicity in rats	NOAEL = 84 mg/kg/day in males, 112 mg/kg/day in females LOAEL = 682 mg/kg/day in males, 871 mg/kg/day in females based on decreased body weight and body weight gain, decreased food consumption, and an increased incidence of vacuolation of choroid plexus ependymal cells in the brain in both sexes and decreased water consumption in the females no evidence of carcinogenicity
870.4200	Carcinogenicity in mice	NOAEL = 12 mg/kg/day in females and ≥690.0 mg/kg/day in males LOAEL = 95 mg/kg/day in females based on decreased body weight and body weight gains no evidence of carcinogenicity
870.5100	Reverse gene mutation assay in bacteria	No evidence of induced mutant colonies over background
870.5375	Cytogenetics *in vitro* mammalian cytogenetics assay	Increases in aberrant metaphases were within the historical control range
870.5395	Bone marrow micronucleus assay	No significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow at any dose tested
870.5395	Bone marrow micronucleus assay	No significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time

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

Guideline No.	Study Type	Results
870.5575	Other Genotoxicity *Saccharomyces cerevisiae*, mitotic recombination, gene conversion assay	No evidence of gene conversion in the tested strains with activation
870.5575	*Saccharomyces cerevisiae*, mitotic recombination, gene conversion assay	No evidence of gene conversion in the tested strains without activation
870.5575	*Saccharomyces cerevisiae*, mitotic recombination, gene conversion assay	Under the conditions of the study, no evidence of gene conversion
870.6200	Acute neurotoxicity screening battery in rats	NOAEL = 200 mg/kg/day LOAEL =2,000 mg/kg/day based on soiled fur coat (both sexes) and decreased motor activity 8 hours post-dosing (females only)
870.6200	Subchronic neurotoxicity screening battery in rats	NOAEL = 1,320.8 mg/kg/day in males and 1485.6 mg/kg/day in females LOAEL = not observed
870.7485	Metabolism in rats	A higher dose (at least equivalent to levels of human exposure) should have been tested, and the metabolites should have been identified
N/A	Special Study - cholinesterase inhibition study	One male and one female died within 43 min; exhibited tremors, convulsions, respiratory, standstill, and death. ChE inhibition dead animals, plasma - no effect; RBC - 19 - 54%, and brain decrease 10 X the controls. No appreciable decrease in ChE in the surviving dog Conclusion: The cholinesterase inhibition studies were of questionable quality. The chemical does not cause any appreciable inhibition of cholinesterase

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) fromthe 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 propamocarb hydrochloride used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PROPAMOCARB HYDROCHLORIDE 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 (females 13–50 years of age)	NOAEL = 150 mg/kg/day UF = 100 Acute RfD = 1.5 mg ai/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 1.5 mg/kg/day	Developmental toxicity study - rabbit developmental LOAEL = 300 mg/kg/day based on increased post-implantation loss
Acute dietary general population including infants and children	NOAEL= 200 mg/kg/day UF = 100 Acute RfD = 2.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = 2.0 mg/kg/day	Acute neurotoxicity screening battery - rat LOAEL = 2000 mg ai/kg/day, based on decreased body weight gain and decreased motor activity
Chronic dietary all populations	NOAEL= 12 mg/kg/day UF = 100 Chronic RfD = 0.12 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD ÷ FQPA SF = 0.12 mg/kg/day	Carcinogenicity study - mouse LOAEL = 95 mg/kg/day, based on decreased body weight and body weight gain in females
Short-term oral (1 – 30 days) (Residential)	NOAEL = 65.41 mg/kg/day	Residential LOC for MOE = 100	2-generation reproduction toxicity study - rat Offspring LOAEL = 406.7 mg/kg/day, based on reduced pup weights in F_0 and F_1 during Day 14 – 21 of lactation
Intermediate-term oral (1 – 6 months)(Residential)	NOAEL = 65.41 mg/kg/day	Residential LOC for MOE = 100	2-Generation reproduction toxicity study - rat Offspring LOAEL = 406.7 mg/kg/day, based on reduced pup weights in F_0 and F_1 during Day 14 – 21 of lactation
Cancer (oral, dermal, inhalation)	''not likely to be carcinogenic to humans''		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.499(a)) for the residues of propamocarb hydrochloride, on potatoes. Risk assessments were conducted by EPA to assess dietary exposures from propamocarb hydrochloride 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: Tolerance-level residues of propamocarb hydrochloride were assumed for all plant commodities with current or proposed propamocarb hydrochloride tolerances. The following residues of propamocarb hydrochloride and the metabolites of concern in livestock *N*-oxide propamocarb, 2-hydroxypropamocarb, and oxazolidine were assumed to be present in livestock commodities: 0.15 ppm in meat, 0.60 ppm in liver, 0.20 ppm in kidney, 0.15 ppm in meat by-products excluding liver and kidney, 0.05 ppm in fat and 0.85 ppm in milk. EPA assumed that all of the crops included in the analysis were treated. Percent crop treated (PCT) and anticipated residue values were not used in the acute risk assessment.

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: Tolerance-level residues of propamocarb hydrochloride were assumed for all plant commodities with current or proposed propamocarb hydrochloride tolerances. The following residues of propamocarb hydrochloride and the metabolites of concern in livestock *N*-oxide propamocarb, 2-hydroxy propamocarb, and oxazolidine were assumed to be present in livestock commodities: 0.15 ppm in meat, 0.60 ppm in liver, 0.20 ppm in kidney, 0.15 ppm in meat by-products excluding liver and kidney, 0.05 ppm in fat and 0.85 ppm in milk. It was assumed that all of the crops included in the analysis were treated. Percent crop treated (PCT) and anticipated residue values were not used in the chronic risk assessment.

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

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/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 ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include 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 propamocarb hydrochloride they are further discussed in the aggregate risk sections in Unit E., *Aggregate Risks and Determination of Safety*, below.

Based on the FIRST and SCI-GROW models, the EECs of propamocarb hydrochloride for acute exposures are estimated to be 972 parts per billion (ppb) for surface water and 2.99 ppb for ground water. The EECs for chronic exposures are estimated to be 77 ppb for surface water and 2.99 ppb for ground water. These EEC's are based on application rates on turf which yield higher projected surfacewater and groundwater concentrations than the proposed application rates on cucurbit vegetables; fruiting vegetables and lettuce.

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).

Propamocarb hydrochloride is currently registered for use on the following residential non-dietary sites: commercial sod farms, greenhouses growing plants for sale, plant nurseries and golf courses. There are two end-use products registered for these uses: Banol (EPA Registration Number 432–942, contains 66.5% propamocarb hydrochloride) and Banol C (EPA Registration Number 432–961, contains 30.5% propamocarb hydrochloride and 30.5% chlorothalonil). An MOE of 100 is assumed to adequately ensure protection from propamocarb hydrochloride via the dermal and inhalation routes for residential exposures. The high-end scenario for residential post-application exposure is to golfers on a course treated with propamocarb hydrochloride. The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential Standard Operating Procedures (SOPs) and recommended approaches by the Health Effects Division's (HED's) Exposure Science Advisory Committee. Short-term post-application exposures are expected for the adult and adolescent golfer (high end exposure scenario). Golfer exposure is expected through minimal hand contact with the golf ball and dermal contact to the lower legs from treated plant surfaces. Since it is assumed that the adolescent golfer would have a proportionally similar exposure to adults, a dermal post-application assessment was performed for the adult golfer only. The calculated MOE for the golfer is 980 and, therefore, does not exceed EPA's level of concern. Since the short- and intermediate-term toxicological endpoints are the same, the golfer post-application exposure assessment is expected to provide adequate exposure estimates for both the short- and intermediate-term exposure scenarios. In the event of intermediate-term exposure, propamocarb hydrochloride residues are expected to dissipate over time. Therefore, this assessment is expected to present a high-end conservative estimate of actual exposure.

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 propamocarb hydrochloride and any other substances and propamocarb hydrochloride 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 propamocarb hydrochloride 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 (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*. EPA determined that there are no residual concerns for propamocarb for prenatal and postnatal toxicology based on the following:

• There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to propamocarb hydrochloride in developmental toxicity studies. There is no quantitative or qualitative evidence of increased susceptibility to propamocarb hydrochloride following prenatal/postnatal exposure to a 2-generation reproduction study.

• There is no concern for developmental neurotoxicity resulting from exposure to propamocarb hydrochloride. A developmental neurotoxicity study (DNT) is not required.

3. *Conclusion*. There is a complete toxicity data base for propamocarb hydrochloride and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Given the completeness of the data base and the lack of concern for prenatal and postnatal toxicity, EPA concluded that reliable data shows an additional safety factor of 10X is not needed for the protection of infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against 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, 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 propamocarb hydrochloride will occupy 4% of the aPAD for the U.S. population, 6% of the aPAD for females 13 years and older, 2% of the aPAD for infants < 1 year old, and 5% of the aPAD for children between 1 and 2 years of age. In addition, there is potential for acute dietary exposure to propamocarb hydrochloride 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 PROPAMOCARB HYDROCHLORIDE

Population Subgroup	aPAD (mg/kg/day)	%aPAD (food)	Ground Water EEC (µg/L)	Surface Water EEC (µg/L)	Acute DWLOC (µg/L)
U.S. Population	2.0	4	2.99	972	67,000
All infants (<1 year old)	2.0	2	2.99	972	19,000
Children (1–2 years old)	2.0	5	2.99	972	19,000
Children (3–5 years old)	2.0	5	2.99	972	19,000
Children (6–12 years old)	2.0	4	2.99	972	19,000
Youth (13–19 years old)	2.0	4	2.99	972	67,000
Adults (20–49 years old)	2.0	4	2.99	972	67,000
Adults (50+ years old)	2.0	4	2.99	972	67,000
Females (13–49 years old)	1.5	6	2.99	972	42,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to propamocarbhydrochloride from food will utilize 18% of the cPAD for the U.S. population, 11% of the cPAD for infants less than 1 year old, 36% of the cPAD for children between 1 and 2 years of age and 30% of the cPAD for children between 3 and 5 years of age. Based on the use pattern, chronic residential exposure to residues of propamocarb hydrochloride is not expected. In addition, there is potential for chronic dietary exposure to propamocarb hydrochloride 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 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO PROPAMOCARB HYDROCHLORIDE

Population Subgroup	cPAD (mg/kg/day)	%cPAD (Food)	Ground Water EEC (µg/L)	Surface Water EEC (µg/L)	Chronic DWLOC (µg/L)
U.S. Population	0.12	18	2.99	77	3,500
All infants (< 1 year old)	0.12	11	2.99	77	1,100
Children (1–2 years old)	0.12	36	2.99	77	760
Children (3–5 years old)	0.12	30	2.99	77	840
Children (6–12 years old)	0.12	22	2.99	77	930
Youth (13–19 years old)	0.12	16	2.99	77	3,500
Adults (20–49 years old)	0.12	16	2.99	77	3,500
Females (13–49 years old)	0.12	17	2.99	77	3,000
Adults (50+ years old)	0.12	14	2.99	77	3,600

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).

Propamocarb hydrochloride is currently registered for use on golf courses 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 propamocarb hydrochloride.

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 870 for females 13–50 years old, 1,000 for youth 13–19 years old and 980 for the general U.S. population. The short-term aggregate risk assessment estimates risks likely to result from 1–7 day exposure to propamocarb hydrochloride residues in food, drinking water, and residential pesticide uses. High-end estimates of the residential exposure are used in the short-term assessment. Average values are used for food and drinking water exposure. For short-term aggregate exposure risk, the oral and dermal exposures can be combined since both are based on the same toxicity endpoint (decreased body weight). An MOE of 100 is adequate to ensure protection from propamocarb hydrochloride via the dermal route for residential exposures. According to the 1995 RED for propamocarb hydrochloride (Estimated Usage of Pesticide, p. 3), ''almost all usage of propamocarb hydrochloride in the United States is concentrated on golf courses with approximately 100,000 to 200,000 lbs ai applied per year.'' The labels for Banol (EPA Registration Number 432–942) and Banol C (EPA Registration Number 432–961) both state that only protected handlers may be present in the treated area during application. For these reasons, it is assumed that this product will be used by commercial applicators, mainly on golf courses. The high-end scenario for residential post-application exposure is the golf course use of Banol. Therefore, in aggregating short-term risk, the Agency considered background chronic dietary exposure (food and drinking water) and short-term golfer dermal exposure.

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 propamocarb hydrochloride 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 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PROPAMOCARB HYDROCHLORIDE

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground/ Water EEC (ppb)	Short-Term DWLOC (ppb)
General US Population	980	100	2.99	77	47,000
Females 13–49 years old	870	100	2.99	77	40,000
Youth 13–19 years old	1,000	100	2.99	77	48,000

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The short-term aggregate assessment adequately addresses both the short- and intermediate-term golfer dermal exposures. The short- and intermediate-term dermal endpoints were chosen from the 21–day dermal rabbit toxicity study. The short-term golfer exposure was calculated assuming 1 to 7 days exposure to propamocarb hydrochloride. The intermediate-term aggregate risk assessment estimates risks likely to result from 7 days to 3 months of exposure. In the event of intermediate-term exposure, propamocarb hydrochloride residues are

expected to dissipate over time. Therefore, the short-term aggregate assessment is expected to present a high-end conservative estimate of intermediate-term risk. As the short-term aggregate risk assessment represents the high-end scenario, an intermediate-term assessment was not performed.

5. *Aggregate cancer risk for U.S. population*. A quantitative cancer risk analysis was not performed since there is no concern for mutagenic potential and there is no evidence of carcinogenic potential in either the rat or mouse. Propamocarb has been classified as ''not likely to be carcinogenic in humans.''

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 propamocarb hydrochloride residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography/nitrogen-phosphorus detection (GC/NPD) method (Xenos Report Number: XEN97–37) has been submitted. This method has undergone a successful independent laboratory validation (ILV) and petition method validation (PMV). The GC/NPD has been sent to the Food and Drug Administration (FDA) and is currently listed in the Pesticide Analytical Manual (PAM) Vol. II for determining residues of propamocarb hydrochloride in plant commodities.

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

The Codex Alimentarius Commission (Codex) has established tolerances (maximum residue levels) for propamocarb hydrochloride in the following raw agricultural commodities: Beetroot at 0.2 ppm, brussel sprouts at 1.0 ppm, cabbage (head) at 0.1 ppm, cauliflower at 0.2 ppm, celery at 0.2 ppm, cucumber at 2.0 ppm, lettuce (head) at 10 ppm, pepper (sweet) at 1.0 ppm, radish at 5.0 ppm, strawberry at 0.1 ppm and tomato at 1.0 ppm.

Proposed tolerances for vegetable, cucurbit, Group 9, lettuce head; vegetables, fruiting, group 8; and tomato paste vary from established Codex MRL's due to varying agricultural practices and environmental conditions.

V. Conclusion

Therefore, tolerances are established for residues of propamocarb hydrochloride on vegetable, cucurbit, group 9 at 1.5 ppm; lettuce, head at 50 ppm; lettuce, leaf at 90 ppm; vegetable, fruiting, group 8 at 2.0 ppm; tomato, paste at 5.0 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–2004–0100 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 October 4, 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. *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–2004–100, 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: July 19, 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 180.499 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.499 Propamocarb Hydrochloride; tolerances for residues.

(a) * * *

Commodity	Parts per million
Lettuce, head	50
Lettuce, leaf	90
* * * *	*
Vegetable, cucurbit, group 9	1.5
Vegetable, fruiting, group 8	2.0
Tomato, paste	5.0

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0283; FRL–7358–4]

Propanoic Acid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of propanoic acid, and its calcium and sodium salts on all raw agricultural commodities; changes the chemical name from propionic acid to propanoic acid; reorganizes the existing tolerance exemptions; and reorganizes the current tolerance exemptions when used as an inert ingredient. Nayfa Industries, Inc. requested an exemption from the requirement of tolerances for sugar beets, potatoes, and sweet potatoes under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).