Commodity	Parts per million
Hog, meat	0.1
Hog, meat byproducts, except liver	0.2
Horse, fat	0.1
Horse, liver	0.1
Horse, meat	0.1
Horse, meat byproducts, except liver	0.2
Milk	0.1
Sheep, fat	0.1
Sheep, liver	1.5
Sheep, meat	0.1
Sheep, meat byproducts, except liver	0.2

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

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

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

[FR Doc. 02–24487 Filed 9–26–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0204; FRL–7200–1]

Lambda-cyhalothrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of lambda-cyhalothrin in or on almond, hulls and various other food commodities in 40 CFR 180.438. Syngenta Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0204, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0204 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703–308–8587; e-mail address: *sproat.william@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet home page at *http://www.epa.gov/*. To access this document, on the home page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0204. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 8, 1997 (62 FR 52588–52563) (FRL–5748–6) and May 12, 2000 (65 FR 30591–30596) (FRL–6497–1), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of pesticide petitions (PP 7F4875 and 0F6092) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419–8300.

These notices included a summary of the petition prepared by Syngenta, the registrant. There were no comments received in response to the notice of filing.

The petition(s) requested that 40 CFR 180.438 be amended by establishing a tolerance for residues of the insecticide lambda-cyhalothrin, in or on almond, hulls at 1.5 parts per million (ppm); apple pomace, wet at 2.50 ppm; avocados (imported) at 0.20 ppm; canola, seed at 0.15 ppm; cereal grain crop group (except rice and wild rice), grain, at 0.2 ppm; forage (except sorghum) at 6.0 ppm; hay at 2.0 ppm; straw at 2.0 ppm; aspirated grain dust at 2.0 ppm; bran at 0.8 ppm; flour at 0.6 ppm; fruit, pome, group at 0.3 ppm; fruit, stone, group at 0.50 ppm; nut, tree, group at 0.05 ppm; peanut, hay at 3.0 ppm; peas and beans - dried shelled, (except soybean), subgroup at 0.1 ppm; peas and beans - succulent shelled, subgroup at 0.01 ppm; sorghum, grain, forage at 0.3 ppm; sorghum, grain, stover at 0.5 ppm; sugarcane at 0.05 ppm; vegetables, fruiting, group (except cucurbits) at 0.2 ppm; and vegetables, legumes, edible podded subgroup at 0.2 ppm.

EPA has concluded that the tolerance requests for the cereal grain crop group are unacceptable at this time since additional residue field trial data are necessary in support of these tolerances. PP 0F06092 proposed a tolerance for canola seed of 0.15 ppm, subsequently revised in this final rule to 1.0 ppm on canola and 2.0 ppm in canola oil.

In addition, existing tolerances under § 180.438(a) for tomatoes at 0.1 ppm is no longer needed. It is being replaced with the new tolerance for the vegetables, fruiting, group (except cucurbits) at 0.2 ppm. In addition, existing tolerances for the section 18 emergency exemption under § 180.438(b) for sugarcane at 0.03 ppm is not needed since a tolerance is established by this regulation rule under § 180.438(a) for sugarcane at 0.05 ppm.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of lambda-cyhalothrin on almond, hulls at 1.5 ppm; apple pomace, wet at 2.50 ppm; avocados (imported) at 0.20 ppm; canola, seed at 0.15 ppm; fruit, pome, group at 0.3 ppm; fruit, stone, group at 0.50 ppm; nut, tree, group at 0.05 ppm; peanut, hay at 3.0 ppm; peas and beans - dried shelled, (except soybean), subgroup at 0.1 ppm ; peas and beans - succulent shelled, subgroup at 0.01 ppm; sorghum, grain, forage at 0.3 ppm; sorghum, grain, stover at 0.5 ppm; sugarcane at 0.05 ppm; vegetables, fruiting, group (except cucurbits) at 0.2 ppm; and vegetables, legumes, edible podded subgroup at 0.2 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 lambda-cyhalothrin are discussed in the Table 1 below as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed. Note that studies discussed below were conducted using either cyhalothrin or lambda-cyhalothrin. Cyhalothrin and lambda-cyhalothrin are basically the same chemical, the differences are found in their stereo chemistry and the number of isomers in each mixture. Cyhalothrin consists of four stereo isomers in each mixture. Cyhalothrin consists of four steno isomers while lambda-cyhalothrin is a mixture of the two isomers. The two lambda-cyhalothrin isomers are contained in cyhalothrin and they represent 40% of the cyhalothrin mixture. The major studies submitted to the Agency were conducted with cyhalothrin. However, these studies are used in support of registration for both mixtures. There is evidence, based on subchronic studies in rats, that the two mixtures are not biologically different with respect to their mammalian toxicity.

TABLE 1.—TOXICITY PROFILE OF LAMBDA-CYHALOTHRIN

Guideline No.	Study Type	MRID No. (year)/Classification/ Doses	Results
870.3100	13–Week feeding - rat (cyhalothrin)	00154805 1981/Acceptable 0, 0.5, 2.5, 12.5 mg/kg/day	NOAEL: 2.5 mg/kg/day LOAEL: 12.5 mg/kg/day (decreased body weight gain in males).
870.3100	13–Week feeding - rat (lambda-cyhalothrin)	00153028 1985/Acceptable 0, 0.5, 2.5, 12.5 mg/kg/day	NOAEL: 2.5 mg/kg/day LOAEL: 12.5 mg/kg/day (reduced body weight gain and food consumption in both sexesand food efficiency in females).

TABLE 1.—TOXICITY PROFILE OF LAMBDA-CYHALOTHRIN—Continued

Guideline No.	Study Type	MRID No. (year)/Classification/ Doses	Results
N/A	28–Day feeding - rat (cyhalothrin)	00153029 1984/Acceptable nonguideline 0, 2, 10, 25, 50, 75 mg/kg/day	NOAEL: 2 mg/kg/day LOAEL: 10 mg/kg/day (clinical signs of neurotoxicity). At higher doses, decreases inbody weight gain and food consumption and changes in organ weights.
N/A	28–Day feeding - rat (cyhalothrin)	00154806 1984/Acceptable nonguideline 0, 0.1, 0.5, 1.0, 2.0, 25.0 mg/kg/ day	NOAEL: 1.0 mg/kg/day LOAEL: 2.0 mg/kg/day (decreases in mean body weight gain in females).
N/A	4–Week feeding - mouse (cyhalothrin)	43241901 1981/Acceptable nonguideline 0, 0.65, 3.30, 13.5, 64.2, 309 mg/kg/day (males) 0, 0.80, 4.17, 15.2, 77.9, 294 mg/kg/day (females)	NOAEL: 64.2/77.9 mg/kg/day LOAEL: 309/294 mg/kg/day (mortality, clinical signs of toxicity, decreases in bodyweight gain and food consumption. changes in hematology and organ weights, minimal centrilobularhepatocyte enlargement).
870.3150	26–Week feeding - dog (cyhalothrin)	00154795 1981/Acceptable 0, 1.0, 2.5, 10.0 mg/kg/day	NOAEL: 1.0 mg/kg/day LOAEL: 2.5 mg/kg/day (increase in liquid feces. At 10.0 mg/kg/day, clinical signs ofneurotoxicity).
870.3200	21–Day dermal toxicity - rabbit (cyhalothrin)	00154869 1982/Acceptable 0, 10, 100, 1,000 mg/kg/day for 6 hours/day, 5 days/week for total of 15 applications	NOAEL: 100 mg/kg/day LOAEL: 1,000 mg/kg/day (significant weight loss)
870.3200	21–Day dermal toxicity - rat (lambda-cyhalothrin)	44333802 1989/Acceptable 0, 1, 10 mg/kg/day for 6 hours/ day for 21 consecutive days; 2–3 applications at 100 mg/kg/ day, reduced to 50 mg/kg/day for 21 consecutive days	NOAEL: 10 mg/kg/day LOAEL: 50 mg/kg/day (clinical signs of toxicity, decreased body weight and body weight gain)
N/A	21–Day inhalation toxicity - rat (lambda-cyhalothrin)	41387702 1990/Acceptable nonguideline 0, 0.3, 3.3, 16.7 μg/L; approx. 0, 0.08, 0.90, 4.5 mg/kg/day	NOAEL: 0.08 mg/kg/day LOAEL: 0.90 mg/kg/day (clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctuate foci in cornea, slight reductions in cholesterol in females, slight changes in selected urinalysis parameters).
870.3700	Developmental toxicity - rat (cyhalothrin)	00154800 1981/Acceptable 0, 5, 10, 15 mg/kg/day	Maternal NOAEL: 10 mg/kg/day Maternal LOAEL: 15 mg/kg/day (uncoordinated limbs, reduced body weight gain and food consumption). Developmental NOAEL: 15 mg/kg/day, the highest dose tested (HDT) Developmental LOAEL: >15 mg/kg/day
870.3700	Developmental toxicity - rabbit (cyhalothrin)	00154801 1981/Acceptable 0, 3, 10, 30 mg/kg/day	Maternal NOAEL: 10 mg/kg/day Maternal LOAEL: 30 mg/kg/day (reduced body weight gain and food consumption). Developmental NOAEL: 30 mg/kg/day (HDT) Developmental LOAEL: >30 mg/kg/day
870.3800	3-Generation Reproduction - rat (cyhalothrin)	00154802 1984/Acceptable 0, 0.5, 1.5, 5.0 mg/kg/day	Parental/Offspring NOAEL: 1.5 mg/kg/day Parental/Offspring LOAEL: 5.0 mg/kg/day (decreased parental body weight and body weight gain during premating and gestation periods and reduced pup weight and weight gain during lactation). Reproductive NOAEL: 5.0 mg/kg/day (HDT)
870.4100	1– Year oral - dog (capsule: lambda-cyhalothrin)	40027902 1986/Acceptable 0, 0.1, 0.5, 3.5 mg/kg/day	NOAEL: 0.1 mg/kg/day LOAEL: 0.5 mg/kg/day (clinical signs of neurotoxicity).

TABLE 1.—TOXICITY PROFILE OF LAMBDA-CYHALOTHRIN—Continued

Guideline No.	Study Type	MRID No. (year)/Classification/ Doses	Results
870.4200	Carcinoge nicity - mouse (cyhalothrin)	00150842 1984/Acceptable 0, 3, 15, 75 mg/kg/day	NOAEL: 15 mg/kg/day LOAEL: 75 mg/kg/day (increased incidence of piloerection, hunched posture; decreased body weight gain in males). Not oncogenic under conditions of study. HDT inadequate. New study not required at this time.
870.4300	Chronic/Carcinogenicity - rat (cyhalothrin)	00154803 1984/Acceptable 0, 0.5, 2.5, 12.5 mg/kg/day	NOAEL: 2.5 mg/kg/day LOAEL: 12.5 mg/kg/day (decreases in mean body weight). Not oncogenic under conditions of study.
870.6200	Acute neurotoxicity - rat (lambda-cyhalothrin)	44861510 1999/Acceptable 0, 2.5, 10, 35 mg/kg	NOAEL: 10 mg/kg LOAEL: 35 mg/kg (clinical observations indicative of neurotoxicity and changes in functional observational battery (FOB) parameters).
870.7485	Metabolism and Pharmacokinetics	00151116, 00150852, 00150852, 00150852, 00153036, 00153037 1981, 1984, 1985/Acceptable when combined together	In the rat, approximately 55% of the oral dose is absorbed. It is extensively metabolized when absorbed. After subcutaneous administration, the urinary/fecal excretion ratio is 2.5:1.0. Over 50% of the dose remained in the carcass 7 days after a subcutaneous dose. Metabolism includes cleavage of the ester to cyclopropylcarboxylic acid and a phenoxybenzyl derivative. The distribution patterns and excretion rates in the multiple oral dose studies are similar to the single oral dose studies. There is accumulation of unchanged compound in the fat upon chronic administration. Otherwise, cyhalothrin is rapidly metabolized and excreted. Cyclopropyl carboxylic acid, 3-phenoxybenzoic acid, glucuronide conjugated 3-4′-hydroxyphenoxy benzoic acid and a sulfate conjugate were identified in the urine. Cyhalothrin is taken up slowly by the fat and released slowly. It is rapidly released by blood, kidneys, liver. The rate of metabolism of both enantiomer pairs are likely identical (i.e. PP321 and PP563). The absorption, distribution, metabolism and excretion patterns of PP321 and cyhalothrin following a single dose of 1 mg/kg in the male rat appear to be identical.
870.7485	Metabolis m and Pharmacokinetics	00150843, 00150852 1984/Acceptable when combined together	In the dog, absorption of the C^{14} benzyl label was 80% and absorption of the C^{14} cyclopropyl label was 48%. The metabolite patterns were different, indicating extensive cleavageof the ester bond. Seven metabolites in urine were identified for the benzyl label and 12 metabolites for the isopropyl label. In the feces, a large proportion of the radioactivity was due to unchanged compound. Excretion in urine and feces was rapid (nearly all in 48 hrs.).
870.7600	Dermal penetration	44990402 1991/Acceptable 0.979, 0.099,0.001 and 0.0008 mg/cm^2 for 0.5, 1, 2, 4, 10 and 24 hours	Absorption ranged from 3.46 to 15.89%

TABLE 1.—TOXICITY PROFILE OF LAMBDA-CYHALOTHRIN—Continued

Guideline No.	Study Type	MRID No. (year)/Classification/ Doses	Results
870.7600	Dermal penetration	44333801 1984/Acceptable nonguideline Dermal studies: 1.25 mg/50 cm^2 dermal and 20 mg/800 cm^2 Dermal dose washed quantitatively after 8 hours. Oral study: 5 mg	Mild paraesthesia of varying degrees was observed following dermal dosing. The minimal oral absorption was estimated to be from 50.35 to 56.71%. The minimal dermal absorption was estimated to be from 0.115 to 0.122%. The estimated dermal absorption value of 1% was determined by rounding these values up to the nearest whole number. No metabolites were found near the limit of detection in plasma from the oral dose study. Blood was not analyzed from the dermal study.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for lambda-cyhalothrin used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose (mg/kg/day) UF/MOE	Special FQPA Safety Factor*	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 0.5 UF = 100 Acute RfD = 0.005 mg/kg	FQPA SF = 1 aPAD = acute RfD/FQPA SF = 0.005 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 3.5 mg/kg/day based on clinical signs of neurotoxicity (ataxia) observed from day 2, 3 to 7 hours post-dosing.
Chronic Dietary all populations	NOAEL= 0.1 UF = 100 Chronic RfD = 0.001 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.001 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Incidental OralShort- and Intermediate-Term (1–30 days and 1–6 months) Residential Only	NOAEL= 0.1 MOE= 100	1	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Dermal (All Durations)	Dermal NOAEL= 10 mg/kg/day		21–Day dermal toxicity study in the rat (lambda-cyhalothrin)

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

Exposure Scenario	Dose (mg/kg/day) UF/MOE	Special FQPA Safety Factor*	Study and Toxicological Effects
Residential	MOE = 100	1	LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity (observed from day 2) and decreased body weight and body weight gain
Occupational	MOE = 100	1	
Inhalation (All Durations)	Inhalation NOAEL= 0.3 µg/L (0.08 mg/kg/day)	.....	21–Day Inhalation Study in Rats (lambda-cyhalothrin) LOAEL = 3.3 µg/L (0.90 mg/kg/day) based on clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctuate foci in the cornea, slight reductions in cholesterol in females and slight changes in selected urinalysis parameters.
Residential	MOE = 100	1	
Occupational	MOE = 100	1	
Cancer	Classification: Group D chemical (not classifiable as to human carcinogenicity).		

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.438) for the residues of lambda-cyhalothrin, in or on a variety of raw agricultural commodities. Currently established tolerances for residues of lambda-cyhalothrin are listed under 40 CFR 180.438 and include permanent tolerances on plants ranging from 0.01 ppm on soybeans to 10.0 ppm on hops. Tolerances are also established for aspirated grain fractions, the head and stem Brassica subgroup, corn, cotton seed, dry bulb onions, lettuce, peanuts, soybeans, sorghum, sunflowers, tomatoes, and wheat; and on animal commodities ranging from 0.01 ppm in eggs, poultry meat, and poultry meat by-products to 5.0 ppm in milk fat (reflecting 0.2 ppm in whole milk). A tolerance of 0.01 ppm has been established for residues in foods potentially exposed to the insecticide during treatment of food handling establishments. A temporary tolerance for canola (0.1 ppm) is listed as expired as of 12/31/00.

Lambda-cyhalothrin is used to control a wide range of pests (including aphids, adult Japanese beetles, grasshoppers, and butterfly larvae) in a variety of agricultural applications and crops. For some crop uses, it is applied to soil before crops emerge. Current non-agricultural uses include ornamental gardens, lawns, landscapes, turf, golf courses, and general insect control (spot treatments and crack and crevice treatments) in around and on buildings, structures, and immediate surroundings. It may also be used for structural pest management and in public health applications to control insects such as mosquitoes, cockroaches, ticks, and flies, which may act as disease vectors. Other uses include ear tags and pour-ons for beef cattle.

Risk assessments were conducted by EPA to assess dietary exposures from lambda-cyhalothrin in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A refined Tier 3 probabilistic acute dietary risk assessment was conducted for all currently registered and proposed lambda-cyhalothrin food uses. The acute dietary assessment includes dietary exposures calculated in a previous dietary assessment (Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids, (62 FR 63002, Nov. 26, 1997; FRL–5755–5) as well as dietary exposures calculated for proposed uses.

The following data for the commodities with proposed new uses and tolerances were added to the original analysis: The entire distribution of residue field trial data was used for not-blended or partially-blended commodities; average residue field trial data were used for blended commodities; information from cooking and processing studies were used when available; and market share data for proposed and established tolerances were used.

For this updated analysis, with the exception of peas and beans (Crop Group 6), commodities as part of a crop group for which tolerances were proposed but data on each individual crop were not submitted, were analyzed using tolerance levels and 100%CT. For example, apples and pears, the representative crops for pome fruits, included residue field trial data and market share data which were included in the analysis. The remainder of the crop group was analyzed using tolerance level residues and 100%CT. The exception, peas and beans (Crop Group 6), used the submitted residue field trial data and market share data as appropriate for the entirety of each subgroup. In accordance with present EPA policy, potential residues from uses in food handling establishments were not included in the acute assessment.

The original 1997 analysis included probabilistic methods for acute dietary analyses for cattle (beef and dairy) to select the feed items comprising the potential cattle diets and associated residues. The same livestock information was used for the present analysis since the additional uses are not expected to increase dietary burden.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: This chronic dietary assessment includes dietary exposures calculated in a previous dietary assessment (Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids, (62 FR 63002, Nov. 26, 1997, FRL–5755–5) as well as dietary exposures calculated for proposed uses.

The following data for the commodities with proposed new uses and tolerances were added to the original analysis: average of the residue field trials, information from cooking and processing studies, and market share data.

The original chronic dietary analysis (1997) included dietary burdens calculated using mean field trial residues, adjusted for percent of crop treated and applying appropriate processing factors, for all animal feed items and associated residues. For the updated analysis, with the exception of peas and beans (Crop Group 6), commodities as part of a crop group for which tolerances were proposed but data on each individual crop were not submitted were analyzed using tolerance levels and 100%CT. For example, apples and pears, the representative crops for pome fruits, included residue field trial data and market share data which were included in the analysis. The remainder of the crop group were analyzed using tolerance level residues and 100%CT. The exception, peas and beans (Crop Group 6), used the submitted residue field trial data and market share data as appropriate for the entirety of each subgroup.

In addition, the food handling establishment tolerance was included in the chronic analysis for all foods which did not have individual proposed or established tolerances. Since the tolerance was based on the LOQ, half of the LOQ was used in the chronic dietary analysis.

iii. *Cancer.* The database for carcinogenicity is considered complete, no additional studies are required at this time. The requirements for carcinogenicity studies in the rat and the mouse with lambda-cyhalothrin have been satisfied by a combined chronic/carcinogenicity study in rats and a carcinogenicity study in mice, both conducted with cyhalothrin. Although mice should have been tested at a higher dose, it was determined that there was not enough toxicological concern to warrant a requirement for a new carcinogenicity study in mice. Therefore, a dietary exposure assessment was not conducted. See Unit III.E.5 of this preamble for further discussion.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) 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. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For existing uses, the Agency used estimates of PCT for the acute and chronic exposure assessments which were determined using Doanes market survey data (1998–2000). The following PCT estimates were used for existing registrations: alfalfa 1.8%; broccoli 13.11%; bulb onions/garlic 45.53%; cabbage 31.33%; sweet corn 43.61%; cotton 12.97%; lettuce (head and leaf) 20.47%; rice 10.33%; soybean 0.2%; squash 0.24%; tomatoes 21.03%; wheat 1.13%; and food handling establishments (13.7 %).

The Agency believes that the three conditions listed in Unit III.C.1.iv. of this preamble have been met. With respect to Condition 1, PCT estimates are derived from market survey data, which are reliable and have a valid basis. EPA uses an average PCT for chronic dietary exposure estimates. An average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT 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 nonblended 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 acute and chronic exposure based on market share projections as follows: almonds 11.72%; apples 2.69%; avocados 2.0%; canola seed 1.87%; cherries 17.3%; dried shelled beans and peas 13.41%; edible podded beans and peas 0.40%; hazelnuts 17.91%; peanuts 4.53%; peaches 20.73%; pears 4.84%; pecans 12.5%; peppers 6.24%; sorghum 1.43%; succulent shelled beans and peas 0.84%; sugarcane 3.97%; and walnuts 11.82%.

The Agency believes that the three conditions previously discussed have been met regarding %CT estimates for the new lambda-cyhalothrin uses. With respect to Condition 1, EPA finds that the %CT information described in Unit II.C.1(iv) for lambda-cyhalothrin is reliable and has a valid basis. To support the use of these PCT estimates, the Agency has compared these estimates to existing usage data for currently registered insecticides used on the proposed lambda-cyhalothrin crop sites. Based on this comparison these estimates should not underestimate actual usage of lambda-cyhalothrin on the new crops/sites. The Agency also conducted a DEEM® analysis using the highest percent crop treated for a

competing alternative chemical for apples and peaches, high dietary contributors, and determined no significant increase in the acute RFD. To further support the reliability of these %CT estimates, as a condition of registration, the registrant will be required to agree to report annually on the market share attained for the new uses for which lambda-cyhalothrin is registered. As a condition of registration, they will also be required to agree to mitigate dietary risk as deemed appropriate by the Agency should the market share data raise a concern for increased dietary risk. The Agency will then compare that market share information with the percent crop treated estimates used to evaluate potential dietary risk. In those instances where percent market share is approaching or exceeding the predicted percent crop treated estimate used in the Agency's risk assessment, EPA will conduct a new dietary risk assessment to evaluate the new dietary risk. If the market share data raise a concern for increased pesticide risk, the Agency will act to mitigate that dietary risk and could employ several approaches not limited to production caps, geographical limitations, removal of uses, or other means deemed appropriate by the Agency. 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 lambda-cyhalothrin may be applied in a particular area.

2. *Dietary exposure from drinking water*. Environmental fate studies suggest that lambda-cyhalothrin is moderately persistent in the environment, with laboratory half-lives ranging from 13–73 days and the field half-lives ranging from 12 to 63 days. This chemical has a strong tendency to bind to soil and sediments (Kd=1,970–7,610). The low mobility (due to high Kd) indicates that ground water contamination with the insecticide is highly unlikely. However, under runoff conditions, lambda-cyhalothrin is likely to reach surface water resources bound to soil particles. Once in the water system, lambda-cyhalothrin tends to partition to sediments.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for lambda-cyhalothrin 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 lambda-cyhalothrin.

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to lambda-cyhalothrin they are further discussed in the aggregate risk sections.

Based on the FIRST and SCI-GROW models the EECs of lambda-cyhalothrin for acute exposures are estimated to be 0.62 parts per billion (ppb) for surface water and 0.012 ppb for ground water. The EECs for chronic exposures are estimated to be 0.098 ppb for surface water and 0.012 ppb for ground water. The EECs for lambda-cyhalothrin are based on an application of the insecticide to sweet corn at a maximum of 16 applications per year at a rate of 0.48 lb active ingredient per acre per application.

3. *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).

Lambda-cyhalothrin is currently registered for use on the following residential non-dietary sites: ornamental gardens, lawns, landscapes, turf, golf courses, and general insect control (spot treatments and crack and crevice treatments) in, around, and on buildings, structures, and immediate surroundings. The risk assessment was conducted using the following residential exposure assumptions: A review of current labels indicates that all products, except for one aerosol can product, are limited to use only by certified applicators. As such, this assessment addresses the single residential handler scenario and postapplication scenarios associated with any use in a residential environment. It should be noted that the residential exposure/risk assessment is based on both proposed and existing uses for lambda-cyhalothrin because all potential residential exposures must be considered in the calculation of aggregate risks.

A non-occupational (residential) exposure assessment for lambda-cyhalothrin was completed in 1997 in conjunction with the Risk Assessment for Extension of Tolerances for Synthetic Pyrethroids (62 FR 63002, Nov. 26, 1997, FRL–5755–5). In the 1997 pyrethroid assessment, due to the wide variety of residential uses, it was agreed that flea control (simultaneous use on pets, lawns and indoor surfaces) would serve as a screening level scenario for all residential uses because it was anticipated to represent the highest potential for residential exposure. However, at that time, lambda-cyhalothrin uses did not include indoor surfaces or pets, so only

exposure estimates pertaining to the lawn uses were used as appropriate in the 1997 assessment for lambda-cyhalothrin.

The 1997 lambda-cyhalothrin assessment served as the basis for the current risk calculations. The only modifications have been adjusting the values from the 1997 assessment for appropriate absorption factors. This represents a definitive screening level approach because since that time the Agency has engaged in a series of revisions to its Standard Operating Procedures (SOPs) for Residential Exposure Assessments (i.e., latest on February 22, 2001). Incorporating the revisions to the SOPs would only refine the exposure estimates (i.e., in all cases MOEs would be higher).

For the residential assessment, existing uses on turf, in gardens, on golf courses, and for structural pest control were considered, but a quantitative calculation was only completed for postapplication exposure on treated turf because this scenario is expected to have the highest associated exposures (i.e., this scenario was used as a screening level tool for all residential exposures).

The Agency used a screening level approach to address the risks associated with the use of the aerosol can product of lambda-cyhalothrin that can be purchased and used by homeowners. In this case, a screening level quantitative calculation was only completed for postapplication exposure on treated turf because this scenario is expected to have the highest associated exposures of all residential exposures. In other words, this is a lower tier approach and EPA believes that the selected postapplication assessment on lawns for children is protective for all residential exposures (even the aerosol can handler scenario) because the dose levels for children playing on treated lawns are thought to exceed those expected for all other scenarios (i.e., lawn exposures for children represents the worst case scenario). This approach is based on the following considerations:

- For children on lawns, there was no dissipation of residues from the treated lawn since it was assumed that exposure was determined immediately after application of the lawn product.
- For children on lawns, dermal exposure was high because it was based on a jazzercise scenario which involves a high duration of exposure on the lawn and an intensity of activity that results in a high degree of contact with the treated lawn.
- Low application rate is expected for residential handler.
- Postapplication oral exposure to children on lawns was also calculated which resulted in acceptable MOEs (aggregate MOE = 500), this approach is thought to provide conservative estimates of exposure and it is not a route of consideration for adult handlers.

All residential (non-occupational) MOEs calculated using this screening level approach were well above the Agency target MOE of 100.

The Agency uses the term postapplication to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Lambda-cyhalothrin can be used in many areas that can be frequented by the general population including residential areas such as lawns. As a result, individuals can be exposed by entering these areas if they have been previously treated.

The postapplication assessment for treatment on lawns is based on a screening level approach in which children's and adult's exposure from treated turf were selected to represent the highest anticipated exposure scenarios. In this case, the Agency believes that exposures associated with contact to treated turf represent the high exposure scenario. Adults and children of varying ages can potentially be exposed by dermal and inhalation routes of exposure when they contact previously treated turf. Children may also be exposed by incidental non-dietary ingestion of turf. Each of these elements was considered in the calculation of postapplication exposure for lambda-cyhalothrin on turf. The residential MOEs were aggregated together because, regardless of the exposure route (dermal, inhalation or oral), lambda-cyhalothrin has similar adverse effects (i.e. neurotoxicity).

All residential (non-occupational) MOEs calculated using this screening level approach were well above the Agency target MOE of 100 for the inhalation, dermal, and oral routes and therefore do not exceed EPA's level of concern (range 700 to 14,700). Additionally, when total MOEs were calculated (i.e., each routes added together), MOEs still were not of concern (MOEs for children = 500 and for adults = 3,000).

A quantitative postapplication risk assessment for termiticide use was not performed for this use. Since the IMPASSE TM Barrier is placed under the foundation (poured concrete) of houses the potential for dermal exposure is negligible. The potential for postapplication inhalation exposure is also expected to be extremely minimal. Furthermore, the vapor pressure for lambda-cyhalothrin is very low (1.5 x 10^{-9} mmHg) and therefore EPA does not anticipate any significant air concentrations accumulating of lambda-cyhalothrin.

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

EPA does not have, at this time, available data to determine whether lambda-cyhalothrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, lambda-cyhalothrin 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 lambda-cyhalothrin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. Through the use of bridging data, the toxicology database for lambda-cyhalothrin has been completed using developmental, reproduction, chronic (rodent) and oncogenicity studies conducted with cyhalothrin. With the exception of the developmental neurotoxicity study, the toxicology database for lambda-cyhalothrin, when

bridged with cyhalothrin, is complete and there are no data gaps. The scientific quality is relatively high and the toxicity profile of lambda-cyhalothrin can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to cyhalothrin. The requirement for developmental studies conducted with lambda-cyhalothrin have been satisfied with developmental studies conducted with cyhalothrin. The data demonstrate no indication of increased quantitative or qualitative sensitivity of rats or rabbits to *in utero* exposure to cyhalothrin. No developmental toxicity was observed in either of the developmental toxicity studies in rats and rabbits. Maternal toxicity was observed in the form of clinical signs of neurotoxicity and reduced body weight gain and food consumption in the rat study and reduced body weight gain and food consumption in the rabbit study. In the 3-generation reproduction study in rats, the parental/offspring NOAELs are the same based on decreased parental and pup body weight and body weight gain.

3. *Conclusion.* The cyhalothrins induce clinical signs of neurotoxicity in at least three species (rats, mice and dogs), and a developmental neurotoxicity (DNT) study has been required. A subchronic neurotoxicity study has recently been submitted but has not yet been reviewed; a preliminary review found that the NOAELs are higher than endpoints selected by EPA and this study is not expected to change conclusions of this risk assessment.

EPA has required that a DNT be conducted for lambda-cyhalothrin based upon structure activity relationship (SAR), mode of action, and toxicity information that identifies cyhalothrin and lambda-cyhalothrin as neurotoxic pesticides. Developmental neurotoxicity testing with cyhalothrin is required, to further characterize the potential hazard to the developing animal, in accordance with standard OPP guidance. This determination was based upon a weight-of-evidence evaluation of the database, conducted in accordance with principles first developed at a 1989 Agency workshop on quantitative and qualitative comparability of human and animal developmental neurotoxicity (Levine, T.E and R.E. Butcher (1990) Triggers for developmental neurotoxicity testing. Neurotoxicology and Teratology 12:281-284.), and which have been subsequently reviewed by the FIFRA Scientific Advisory Panel in connection with DNT guideline development (1989), the retrospective analysis of DNT studies submitted to OPPTS (December, 1998), and FQPA 10X guidance (May, 1999).

Although a DNT has been required, EPA evaluated whether the existing reliable toxicity data for lambda-cyhalothrin provided EPA with the confidence to make a safety finding for infants and children using a different safety factor than the default additional safety factor of 10X. For the reasons set forth, EPA has concluded that existing, reliable toxicity data provide reasonable certainty that a risk assessment conducted using no additional factor (1X) will protect the safety of infants and children. First, it is noted that there was no indication, in the developmental or reproductive toxicity studies or in any published literature studies, of increased sensitivity in the offspring of rats or rabbits to *in utero* and/or postnatal exposure to cyhalothrin. Since there is no evidence that immature animals respond more severely than adults to cyhalothrin exposure in these studies, there is less concern regarding the potential for increased sensitivity in a developmental neurotoxicity study.

Second, an extensive evaluation of the data base for the cyhalothrins revealed that no damage to the neurological system (i.e., microscopic lesions, commonly referred to as ''neuropathology'') was observed in the brain of rats or dogs following subchronic or chronic exposure and with formalin fixation of tissues. Even more importantly, in the acute neurotoxicity study with lambda-cyhalothrin, both central and peripheral nervous system tissues were examined following in situ perfusion fixation of tissues (which reduces microscopic artifacts that can result during processing). As per guideline recommendations, this included more extensive sampling and microscopic evaluation of these tissues than is required in standard subchronic or chronic studies. Even with this expanded examination, no treatment-related lesions were observed in the central and peripheral nervous system. (The subchronic neurotoxicity study with lambda-cyhalothrin is currently under review by EPA and was not available at the time of the prior EPA review; however, preliminary evaluation of the neuropathology data by EPA scientists did not reveal the presence of treatment-related lesions.) These findings demonstrate that lambda-cyhalothrin does not alter nervous system structure in adult rats, even at the microscopic level. Additionally, there was no evidence from the prenatal developmental toxicity studies (in rats and rabbits) and the two-generation reproduction study in rats, of malformations or variations of the central nervous system in offspring following *in utero* and/or postnatal exposures. Further, the generally accepted mechanism of action for pyrethroids, sodium channel disruption, has not been traditionally associated with developmental neuropathology. Together with the apparent lack of structural alterations in the nervous system of either adult or developing animals, this line of evidence leads to reduced concern regarding the potential that such effects would be observed in guideline developmental neurotoxicity testing.

Another critical factor in the database that supports EPA's determination that a safety finding can be made without use of an additional safety factor are the data bearing on the level at which neurotoxic effects and non-neurotoxic effects are observed in the rat (the animal used in performing DNTs) and the data pertaining to the level at which neurotoxic effects occur in dogs. While the precise outcome of a DNT study with lambda-cyhalothrin cannot be known prior to completion of the study, the existing toxicity data provide important information on whether any information is likely to emerge from the lambda-cyhalothrin DNT that would change the dose level used in estimating safe exposure levels to lambda-cyhalothrin in the lambda-cyhalothrin risk assessment. Based upon common principles of dose-setting, which utilize data from less complicated studies to inform the design of more complicated studies, it is highly probable that dietary dose levels for the DNT study will be based upon toxicity observed in the reproduction study in rats, considered in context of the complete toxicology database. In the reproduction study, parental and offspring effects consisted solely of body weight and body weight gain reductions at a dietary level of 100 ppm (approximately 5.0 mg/kg/day), and a NOAEL was established at 30 ppm (approximately 1.5 mg/kg/day) which was the mid-dose level on that study. Neurotoxicity effects have only been seen in the rat at significantly higher doses (acute oral neurotoxicity study having a NOAEL of 10 mg/kg/day and a LOAEL of 35 mg/kg/day). In the dog, neurotoxic effects have been found at lower levels (NOAEL of 0.5 mg/kg/day) than the non-neurotoxic effects seen in the rat reproductive study. What this indicates is that the DNT will likely be conducted at dose levels significantly lower than at which any neurotoxic

effects have previously been seen in the rat but still significantly greater than the levels used for assessing acute and chronic risk. Thus, the results from the DNT, even if they show sensitivity in the rat young (which would not be expected), are unlikely to change the levels used for assessing chronic and acute risk.

No quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the developmental studies was observed. No developmental toxicity was observed in either of these studies. No quantitative or qualitative evidence of increased susceptibility was observed in the 3-generation reproduction study in rats. Offspring toxicity (decreased pup weight and pup weight gain) was observed in the reproduction study at the same dose level as parental toxicity (decreased body weight and body weight gain). These effects are not considered to be more severe than the effects in the parents. There are no residual uncertainties for pre- and/or post-natal toxicity in any of the available studies with Cyhalothrin.

This information supports the dose analysis conducted by EPA as well as the removal of the special Food Quality Protection Act (FQPA) Safety Factor required for the protection of infants and children. Therefore, the FQPA Safety Factor (as discussed in the February 2002 OPP 10X guidance document) was reduced to 1X.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to lambda-cyhalothrin will occupy 41% of the aPAD for the U.S. population, 24% of the aPAD for females 13 years and older, 71% of the aPAD for all infants (< year old) and 82% of the aPAD for children 1–6 years old. In addition, there is potential for acute dietary exposure to lambda-cyhalothrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO LAMBDA-CYHALOTHRIN

Population Subgroup	aPAD (mg/kg)	% aPAD	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Infant (<1 year old)	0.005	71	0.62	0.012	14
Child (1–6 years old)	0.005	82	0.62	0.012	9
Adult	0.005	41	0.62	0.012	168

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to lambda-cyhalothrin from food will utilize 8% of the cPAD for the U.S. population, 12% of the cPAD for all infants (<1 year old) and 22% of the cPAD for children 1–6 years old. Based on current use patterns, chronic residential exposure to residues of lambda-cyhalothrin is not expected. In addition, there is potential for chronic dietary exposure to lambda-cyhalothrin in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Infant (<1 year old)	0.001	12	0.098	0.012	9

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO LAMBDA-CYHALOTHRIN—Continued

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Child (1–6 years old)	0.001	22	0.098	0.012	8
U.S. population	0.001	8	0.098	0.012	32

3. *Short- and Intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Lambda-cyhalothrin is currently registered for use that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short- and intermediate-term exposures for lambda-cyhalothrin.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs listed in Table 5 below. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short- and intermeidate-term DWLOCs were calculated and compared to the EECs for chronic exposure of lambda-cyhalothrin in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short- and itermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

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

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Infant	315	149	0.098	0.012	7
Child	239	172	0.098	0.012	6
General Population	867	113	0.098	0.012	31

5. *Aggregate cancer risk for U.S. population*. The database for carcinogenicity is considered complete, no additional studies are required at this time. The requirements for carcinogenicity studies in the rat and the mouse with lambda-cyhalothrin have been satisfied by a combined chronic/carcinogenicity study in rats and a carcinogenicity study in mice, both conducted with cyhalothrin. Although mice should have been tested at a higher dose, it was determined that there was not enough toxicological concern to warrant a requirement for a new carcinogenicity study in mice. Lambda-cyhalothrin is classified as a Group D chemical (not classifiable as to human carcinogenicity).

Under the conditions of the studies, lambda-cyhalothrin is not considered to be carcinogenic in either rats or mice. However, there has been a question concerning a slight but not statistically significant increase in mammary tumors in the mouse study. In that study, the dose levels were not sufficiently high to totally rule these out. Nevertheless, it is determined that there is not a sufficient toxicological concern to ask for a new study for the following reasons: an examination of the evidence of carcinogenicity with other pyrethroids showed no increases in mammary tumors with any other pyrethroid. In addition, from a mode of action standpoint, the primary effect of the pyrethroids is on the neuromuscular system. Pyrethroids generally stimulate nerve cells to produce repetitive discharges which are caused by their action on the sodium channel. Mammary gland carcinogenesis in the rodent can be caused by either mutagenesis or by a hormonal imbalance leading to elevated or prolonged exposure to estrogen. There is no evidence that the pyrethroid mode of action leads to a hormonal imbalance and lambda-cyhalothrin has not been shown to be a DNA reactive mutagen. For these reasons, it is unlikely that a repeat mouse study on lambda-cyhalothrin would provide any additional evidence. Therefore, a risk assessment for potential carcinogenicity to humans is not required.

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 lambda-cyhalothrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in plant and animal commodities. ICI Method 81 (PRAM 81) is used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices and ICI Method 86 is used to determine residues of lambda-cyhalothrin and its epimer in animal matrices. Both methods have been validated by EPA as adequate enforcement methods for determination of parent lambda-cyhalothrin and its epimer in the respective matrices. ICI Method 96 is used to determine lambda-cyhalothrin metabolites in meat, milk, poultry and eggs. The LOQ for all three methods is 0.01 ppm.

B. International Residue Limits

There are currently no Mexican, Canadian or Codex maximum residue limits (MRLs) for lambda-cyhalothrin.

There are MRLs for cyhalothrin from which lambda-cyhalothrin is derived as an enriched isomer.

C. Magnitude of Residue

Residue field trial data are adequate to support the established and proposed lambda-cyhalothrin tolerances. The Monte Carlo methods for acute dietary analyses for cattle (beef and dairy) to select the feed items comprising the potential cattle diets and associated residues have been previously reviewed and found acceptable. The nature of the residues of lambda-cyhalothrin in plants and animals is understood. Quantifiable residues are expected on most treated commodities.

V. Conclusion

Therefore, the tolerance is established for residues of lambda-cyhalothrin, in or on almond, hulls at 1.5 ppm; apple pomace, wet at 2.50 ppm; avocados (imported) at 0.20 ppm; canola, seed at 0.15 ppm; fruit, pome, group at 0.3 ppm; fruit, stone, group at 0.50 ppm; nut, tree, group at 0.05 ppm; peanut, hay at 3.0 ppm; peas and beans - dried shelled, (except soybean), subgroup at 0.1 ppm ; peas and beans - succulent shelled, subgroup at 0.01 ppm; sorghum, grain, forage at 0.3 ppm; sorghum, grain, stover at 0.5 ppm; sugarcane at 0.05 ppm; vegetables, fruiting, group (except cucurbits) at 0.2 ppm; and vegetables, legumes, edible podded subgroup at 0.2 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0204 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 26, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0204 to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735,

October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 20, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.438 is amended by adding new commodities to the table in paragraph (a)(1) to read as follows, and by removing the entry for ''sugarcane'' from the table in paragraph (b).

§ 180.438 Lambda-Cyhalothrin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Almond, hulls	1.5
Apple pomace, wet	2.50
* * * * *	
Avocados (imported)	0.20
* * * * *	
Canola	1.0
Canola, oil	2.0
* * * * *	
Fruit, pome, group	0.30
Fruit, stone, group	0.50
* * * * *	
Nut, tree, group	0.05
* * * * *	
Pea and bean, dried shelled,(except soybean), subgroup	0.10
Pea and bean, succulent shelled, subgroup	0.01
Peanut, hay	3.0
* * * * *	
Sorghum, grain, forage	0.30
Sorghum, grain, stover	0.50
* * * * *	
Sugarcane	0.05
* * * * *	
Vegetables, fruiting, group (except cucurbits)	0.20
Vegetables, legume, edible podded, subgroup	0.20
* * * * *	

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