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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

DATE: 6/27/01

SUBJECT: PP#9F4875. Request for the Use of Lambda-Cyhalothrin on Imported Avocados; Cereal Grains (except Rice); Fruiting Vegetables (except Cucurbits); Peanut Hay; Peas and Beans, Dried and Succulent Shelled, and Edible Podded; Sorghum Forage and Fodder; and Sugarcane. Evaluation of Analytical Method and Magnitude of the Residue Data.

DP Barcode: D238603
Submission #: S529132
Chemical#:128897
Class: Insecticide
Trade Name: KARATE®
CFR: §180.438

PRAT Case#: 289040
Caswell#: NA
CAS#: 91465-0806
MRID: 44325701-12
EPA Reg#: 10182-96

TO: Arnold Layne/ William Sproat PM 3
Registration Division (7505C)

FROM: William D. Cutchin, Chemist
Registration Action Branch 2
Health Effects Division (7509C)

THRU: Richard Loranger, Branch Senior Scientist
Registration Action Branch 2
Health Effects Division (7509C)

Following is the review of a petition from Zeneca Ag Products requesting establishment of permanent tolerances for residues of the insecticide lambda-cyhalothrin on the following commodities:

Avocados (imported) ..... 0.2 ppm
Cereal grain crop group (except rice, wild rice, and sorghum), forage ... 6.0 ppm

Cereal grain crop group (except rice and wild rice), aspirated grain dust	2.0 ppm
Cereal grain crop group (except rice and wild rice), bran	0.8 ppm
Cereal grain crop group (except rice and wild rice), flour	0.6 ppm
Cereal grain crop group (except rice and wild rice), grain	0.2 ppm
Cereal grain crop group (except rice and wild rice), hay	2.0 ppm
Cereal grain crop group (except rice and wild rice), straw	2.0 ppm
Fruiting vegetable crop group (except cucurbits)	0.2 ppm
Peanut hay	3.0 ppm
Peas & beans - edible podded crop subgroup	0.2 ppm
Peas & beans - succulent shelled crop subgroup	0.01 ppm
Peas & beans - dried shelled crop subgroup (except soybean)	0.1 ppm
Sorghum fodder	0.5 ppm
Sorghum forage	0.3 ppm
Sugarcane	0.05 ppm

The review was performed by the Life Sciences Division of Oak Ridge National Laboratory under the supervision of SIMB and RAB2. The data assessment has undergone secondary review within the branch and has been revised to reflect current HED and OPP policy. If any additional input is needed, please advise.

Executive Summary of Residue Chemistry Deficiencies

- Provide an avocado label for the foreign product that reflects the use pattern of the submitted residue field trials.

- Provide updated labels for succulent and dried shelled pea and bean subgroups, crop subgroups 6B and 6C, restricting the grazing of livestock in treated areas or harvest of vines for forage or hay.

- Remove the requested cereal grain crop group tolerance from Section F.

cc: RAB2 Reading File, PP# 9F4875

RESIDUE CHEMISTRY REVIEW

LAMBDA-CYHALOTHRIN (ICIA0321)

[1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate]

MRIDs 44325701, 44325702, 44325703, 44325704, 44325705, 44325706, 44325707, 44325708, 44325709, 44325710, 44325711, and 44325712

DP Barcode: D238603
Petition #: 7F04875
PC Code: 128897 (cyhalothrin 128867)
EPA Reg. No.: 10182-96
Submission #: S529132
CAS#: 91465-08-6

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
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Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
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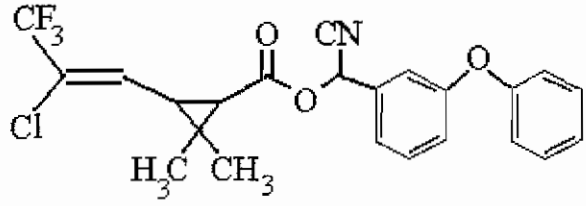
Task Order No. 99-42

Oak Ridge National Laboratory, managed by UT-Battelle, LLC, for the U.S. Dept. of Energy under contract DE-AC05-00OR22725.

LAMBDA-CYHALOTHRIN



PERMANENT TOLERANCE PETITION FOR LAMBDA-CYHALOTHRIN IN/ON:

IMPORTED AVOCADOS, CEREAL GRAIN CROP GROUP (EXCEPT RICE), FRUITING VEGETABLE CROP GROUP (EXCEPT CUCURBITS), PEANUT HAY, PEAS & BEANS - DRIED SHELLED CROP SUBGROUP, PEAS & BEANS - EDIBLE PODDED CROP SUBGROUP, PEAS & BEANS - SUCCULENT SHELLED CROP SUBGROUP, SORGHUM FORAGE & FODDER, AND SUGARCANE (DP Barcode D238603)

Shaughnessy No. 128897

INTRODUCTION

Zeneca Ag Products, the petitioner, has submitted a petition for the establishment of permanent tolerances for residues of the pyrethroid insecticide, lambda-cyhalothrin, in/on numerous crops. Specifically, the petitioner has proposed the establishment of tolerances for lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and the lambda-cyhalothrin epimer, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, in/on the following commodities:

Avocados (imported)	0.2 ppm
Cereal grain crop group (except rice, wild rice, and sorghum), forage	6.0 ppm
Cereal grain crop group (except rice and wild rice), aspirated grain dust	2.0 ppm
Cereal grain crop group (except rice and wild rice), bran	0.8 ppm
Cereal grain crop group (except rice and wild rice), flour	0.6 ppm
Cereal grain crop group (except rice and wild rice), grain	0.2 ppm
Cereal grain crop group (except rice and wild rice), hay	2.0 ppm
Cereal grain crop group (except rice and wild rice), straw	2.0 ppm
Fruiting vegetable crop group (except cucurbits)	0.2 ppm
Peanut hay	3.0 ppm
Peas & beans - edible podded crop subgroup	0.2 ppm
Peas & beans - succulent shelled crop subgroup	0.01 ppm
Peas & beans - dried shelled crop subgroup (except soybean)	0.1 ppm
Sorghum fodder	0.5 ppm
Sorghum forage	0.3 ppm
Sugarcane	0.05 ppm

The "import" tolerance for avocados would be a tolerance without a domestic registration. The establishment of the tolerance for avocados grown in Mexico would allow their legal import into the United States.

Lambda-cyhalothrin is a synthetic pyrethroid insecticide and acaricide used to control a wide range of pests (including aphids, adult Japanese beetles, grasshoppers, and butterfly larvae) in a variety of applications. 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. Another of its uses is as SABER® Pour-On Insecticide, which is applied down the backline of beef cattle for control of lice and horn flies. Lambda-cyhalothrin is compatible with most other insecticides and fungicides. For some of its uses, it is applied to soil before crops emerge.

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 6.0 ppm on alfalfa hay, corn forage, and tomato pomace (dry or wet). Tolerances are also established on animal commodities ranging from 0.01 ppm in eggs, poultry meat, and poultry meat by-products (mbyp) to 5.0 ppm in milk fat (reflecting 0.2 ppm in whole milk).

The following volumes of residue chemistry data were submitted with this petition: MRIDs 44325701, 44325702, 44325703, 44325704, 44325705, 44325706, 44325707, 44325708, 44325709, 44325710, 44325711, and 44325712. Their citations are provided at the end of this document.

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Product chemistry data for lambda-cyhalothrin were reviewed in 1992. There are no toxicological concerns for any of the lambda-cyhalothrin impurities. CBTS recommended that the IUPAC names for lambda-cyhalothrin and its epimer (rather than the Chemical Abstract names) appear in the regulation. KARATE® 1E Insecticide (EPA Reg. No. 10182-96), the formulation used in all proposed uses, with the exception of avocados, contains 13.1% ai. It is an emulsifiable concentrate that contains 1 lb ai per gallon, or 0.0078 lb ai per fl oz. Also available in the U.S. is WARRIOR® T (formulation number WF2616; EPA Reg No. 10182-434) a capsule suspension that contains 1 lb ai per gallon. ICIA0321 (lambda-cyhalothrin) Technical (EPA Reg. No. 10182-131) contains a minimum of 81% ai.

OPPTS GLN 860.1200: Proposed Uses

2a. **The proposed use directions are adequate for all commodities except for avocados and succulent and dried shelled pea and bean subgroups, crop subgroup 6B and 6C.** Although the proposed use directions for small grains, specifically for the cereal grains, crop group 15 (excluding field corn, sweet corn, popcorn, rice, wild rice, and sorghum) are adequate for evaluation of crop field test results, insufficient data were presented to justify establishing tolerances on additional small grains in the entire crop group.

2b. The proposed use directions, Section B, for the KARATE® EC Insecticide formulation of lambda-cyhalothrin for use on avocados to be imported from Mexico, are not completely reflected in the submitted label. In Mexico, KARATE® EC has activity of lambda-cyhalothrin equivalent to 70 g ai/L (0.58 lb ai/gal). This product is intended for foliar application at a maximum individual application rate of 35 g ai/ha (0.031 lb ai/A) to control or suppress the leaf miner, whitefly, leaf hopper, and thrips. However, the label does not specify a maximum seasonal application rate, a retreatment interval, and a preharvest interval. **The petitioner should submit a revised label that shows the proposed use directions, a PHI of 7 days, an interval between applications of approximately 30 days, and a maximum total application rate per season of 0.12 lb ai/A.**

2c. Lambda-cyhalothrin is proposed for use as a foliar spray on small grains, which are described by the petitioner as cereal grains, crop group 15 (but excluding field corn, sweet corn, popcorn, rice, wild rice, and sorghum) to control or suppress numerous insect species, including cutworms, armyworms, and flea beetles. In the absence of adequate data to set tolerances on all small grains (Conclusions 11b(2) and 11b(3)), the expanded use on these crops should be deleted from the label. The existing uses on wheat, wheat hay, and triticale may be retained.

2d. Lambda-cyhalothrin is proposed for use as a foliar application on edible-podded legume vegetables (i.e., crop subgroup 6A) and the succulent shelled pea and bean subgroup (i.e., crop subgroup 6B) to control or suppress numerous insects species. The maximum application rate per treatment is 0.03 lb ai/A, and the maximum application rate per season is 0.12 lb ai/A, with a PHI of 7 days. Since there are animal feed items of regulatory interest for croup group 6B, notably cowpea hay and forage, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for succulent shelled pea and bean subgroup, crop subgroup 6B: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

2e. Lambda-cyhalothrin is proposed for use as a foliar application on the dried shelled pea and bean (except soybean), crop subgroup 6C, to control or suppress numerous insects species. The maximum application rate per treatment is 0.03 lb ai/A, and the maximum application rate per season is 0.12 lb ai/A, with a PHI of 21 days. Since there are animal feed items of regulatory interest for croup group 6C, notably cowpea hay and forage, and field pea vine and hay, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for dried shelled pea and bean subgroup, crop subgroup 6C: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

OPPTS GLN 860.1300: Nature of the Residue - Plants

3. No new studies were submitted with this application. Based on metabolism studies conducted on cotton, cabbage, soybeans and wheat, the nature of the residue in plants is adequately understood. Lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropanecarboxylic acids and the corresponding phenoxybenzoic acids or alcohols. In most cases the parent compound is the principal constituent of the

residue. However, in the cabbage metabolism study the cis- and trans-cyclopropanecarboxylic acids were the major constituents. HED has decided that the plant metabolites need not appear in the tolerance expression at this time due to lack of toxicological concern and low concentrations found from residue studies. The residue to be regulated is lambda-cyhalothrin and its epimer R157836.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

4. No new studies were submitted with this application. Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been reviewed. Lambda-cyhalothrin is the major component of the residue in them, except for kidney and liver of ruminants and liver of poultry, where, in addition to the plant metabolites, 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBAcid) may be present in significant quantities. A residue transfer study in which cows were fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that, at $\leq$ 8 ppm, OH-CPA levels in tissue would not exceed 0.01 ppm. As with plants, the residue to be regulated is lambda-cyhalothrin and its epimer R157836. HED has determined that animal metabolites do not need to appear in the tolerance expression at this time. CBTS decided earlier not to require further animal metabolism data to support uses for lambda-cyhalothrin on alfalfa, lettuce or the Brassica crop group.

OPPTS GLN 860.1340: Analytical Methods - Plants

5a. Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in all plant commodities. ICI Method 81 is used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices. ICI Method 81, which is also called PPRAM 81, has undergone an EPA method validation for soybeans and was found to be adequate for enforcement purposes. This method involves acetone:hexane 1:1 (v/v) extraction, followed by liquid-liquid chromatography to remove lipids and florisil column cleanup. Quantification uses capillary gas chromatography (GC) with electron capture detection (ECD). The limits of quantification were 0.01 ppm for both lambda-cyhalothrin and its enantiomer. ICI Method 81 has been determined to be an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on plants.

5b. In analytical studies of all crops besides avocados, and in the processing study on sugarcane, the procedure used was based on methods PPRAM 81 and PPRAM 70. PPRAM 81 and PPRAM 70 are identification symbols of two ICI Plant Protection Division Reports. This procedure identified both lambda-cyhalothrin and its epimer R157836, and the limit of quantitation was 0.01 ppm for both residues. In the PPRAM 81/PPRAM 70 method, lambda-cyhalothrin and R157836 are extracted from the sample with a 1:1 (v/v) acetone:hexane mixture. The acetone is removed by partitioning with deionized water. An acetonitrile liquid-liquid column cleanup is used to remove extracted lipids, and Florisil adsorption chromatography is used to remove interfering endogenous materials. Quantification by capillary GC/ECD uses an external standardization technique. The reference standard used for cyhalothrin (also called

ICIA0321) had reference number ASY/Cyhalothrin/No242 and purity of 91.1% (containing 57.7% w/w R157836 & 33.4% w/w ICIA0321).

5c. In the analytical studies on avocados, the method of analysis was Analytical Method 081/03, and the only residue detected was lambda-cyhalothrin. Analytical Method 081/03 appears to be a recent modification of the EPA-validated method PPRAM 81. In Method 081/03, following extraction in acetone:hexane, an aliquot is sampled and evaporated to dryness. The aliquot is then redissolved in hexane and cleaned up by absorption chromatography on a Silica Bond Elut chromatography column. Quantitative determination is by capillary gas-liquid chromatography with ECD or mass-spectrometric detection. The LOQ is 0.01 ppm.

5d. The petitioner submitted concurrent recovery studies for all crops. The 46 uncorrected recoveries of lambda-cyhalothrin had a mean of 95.2% with a SD of 26.1%, and the 45 uncorrected recoveries of R157836 had a mean of 87.6% with a SD of 9.8%. The lowest concurrent fortification levels for lambda-cyhalothrin and R157836 tended to be slightly below (0.007 ppm) and slightly above (0.013 ppm), respectively, the LOQ of 0.01 that was applied for both residues. Limited but adequate sample chromatograms were provided for the concurrent method recoveries by the analytical laboratory (Zeneca Ag Products at Richmond, CA). However, no lambda-cyhalothrin calibration curves were presented, and there was no mention of the LOD. With a few exceptions, control matrices showing interferences for lambda-cyhalothrin, R157836, or both were below the LOQ.

OPPTS GLN 860.1340: Analytical Methods - Animals

6a. Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in animal commodities. ICI Method 86 is used to determine residues of lambda-cyhalothrin in animal matrices. Parent lambda-cyhalothrin is extracted from milk or animal tissue with 50% acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate. Cleanup uses Florisil column chromatography. Determination of residue is accomplished using packed column GC and a ^{63}Ni electron capture detector. The LOQ is 0.01 ppm. ICI Method 86 has been validated by EPA as an adequate enforcement method for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk.

6b. ICI Method 96 is used to determine lambda-cyhalothrin metabolites in meat, milk, poultry and eggs. Samples are extracted with acetonitrile:hydrochloric acid or methanol, the extract is diluted with water, and parent lambda-cyhalothrin is removed on a C_{18}-bonded silica cartridge. The eluate is evaporated and refluxed for 4 hours with concentrated hydrochloric acid. The hydrolysate is then partitioned into dichloromethane. For 3-PBAcid and/or 4'-OH-3-PBAcid analyses, the extracts are evaporated, reconstituted in 50% methanol and passed through a C_{18} column. The eluate is evaporated and redissolved in dichloromethane. 3-PBAcid is methylated with diazomethane prior to GCMS with selected ion monitoring (SIM). CPA is benzylated with benzyl bromide and purified on a Florisil column prior to GC with an electron capture detector. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The LOQ is 0.01 ppm.

OPPTS GLN 860.1360: Multiresidue Method

7. The petitioner has determined recoveries of cyhalothrin and its metabolites PP890 and 3-PBAcid under FDA's multiresidue protocols. As of 11/2/90, these results had not been listed in FDA's summary. On the basis of the recoveries made, this requirement is considered to have been met.

OPPTS GLN 860.1380: Storage Stability Data - Plants

8. No new studies were submitted with this application. Previous freezer storage stability data demonstrated that residues of lambda-cyhalothrin and its epimer are stable in peach, pea, oilseed rape, wheat grain, sugar beet roots, cottonseed, apple, cabbage and potato when stored at -18 °C for periods up to 26 months. Storage stability data were also earlier reviewed and found to be adequate for alfalfa and lettuce. Alfalfa forage and hay samples were stored frozen at <-15 °C for 126-956 days from sampling to extraction and an additional 2-22 days from extraction to analysis. Recoveries reported for alfalfa samples were acceptable (90-123% for lambda-cyhalothrin and 82-129% for its enantiomer). Leaf lettuce samples were stored frozen at <-15° C for 503-720 days from sampling to extraction and an additional 1-7 days from extraction to analysis. Recoveries reported for leaf lettuce were acceptable (ranging from 73-123%). The existing storage stability database for lambda-cyhalothrin is considered adequate to support the crop residue data for the numerous crops presented in this petition.

OPPTS GLN 860.1380: Storage Stability Data - Animal Commodities

9. No new studies were submitted with this application. The existing animal commodity storage stability data is considered adequate for the purposes of this petition.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

10a. The poultry feed items associated with this petition are peanut meal, dried seeds of the cowpea and field pea, and sorghum grain. The maximum theoretical dietary burden from the combined residues of lambda-cyhalothrin and its epimer R157836 in poultry from use of these feedstuffs is 0.18 ppm. An earlier memorandum calculated an average dietary burden from lambda-cyhalothrin in poultry of 0.247 ppm. It was based on average residues from field trials at the proposed use pattern instead of on tolerance levels. Because that calculation was made before the August 1996 EPA Residue Chemistry Test Guidelines (OPPTS 860.1480 Meat/milk/poultry/eggs) existed, each feedstuff was corrected for percent dry matter when estimating the average dietary burden. Those guidelines indicate that there should be no such correction for poultry and swine. As a result, the average dietary burden of 0.247 ppm reported in that memorandum was recalculated by the reviewer according to the current guidelines, and it was found to be 0.224 ppm. The finding of an average dietary burden of 0.247 ppm did not lead to a raising of the tolerances for poultry commodities. Accordingly, because the maximum theoretical dietary burden of 0.18 for the commodities associated with the current petition is less than 0.247 ppm (and, indeed, less than 0.224 ppm), there is clearly no need to reconsider the tolerances for eggs, and the fat, meat, and meat byproducts of poultry.

10b. The feed items associated with this petition that apply to ruminants are peanut meal, peanut hay, dried seeds of the cowpea and field pea, sorghum grain, sorghum forage, sorghum fodder, and sugarcane molasses. The maximum theoretical dietary burdens from the combined residues of lambda-cyhalothrin and its epimer R157836 in beef cattle and dairy cattle from use of these feedstuffs are 1.38 and 2.15 ppm, respectively. An earlier memorandum calculated the average dietary burdens from lambda-cyhalothrin in beef and dairy cattle to be 2.873 and 2.867 ppm, respectively. Those dietary burdens were based on average residues from field trials at the proposed use pattern instead of on tolerance levels. The finding of average dietary burdens of 2.873 and 2.867 ppm did not lead to a raising of the tolerances for ruminant commodities. Accordingly, because the maximum theoretical dietary burdens of the commodities associated with the current petition in beef and dairy cattle of 1.38 and 2.15 ppm, respectively, are less that 2.873 ppm, there is clearly no need to reconsider the tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

10c. The swine feed items associated with this petition are peanut meal, dried seeds of the cowpea and field pea, and sorghum grain. The maximum theoretical dietary burden from the combined residues of lambda-cyhalothrin and its epimer R157836 in swine from use of these feedstuffs is 0.19 ppm. An earlier memorandum calculated an average dietary burden from lambda-cyhalothrin in swine of 1.299 ppm. It was based on average residues from field trials at the proposed use pattern instead of on tolerance levels. Because that calculation was made before the August 1996 EPA Residue Chemistry Test Guidelines (OPPTS 860.1480 Meat/milk/poultry/eggs) existed, each feedstuff was corrected for percent dry matter when estimating the average dietary burden. Those guidelines indicate that there should be no such correction for swine and poultry. As a result, the average of 1.299 ppm reported in that memorandum was recalculated by the reviewer according to the current guidelines, and it was found to be 0.760 ppm. The finding of the average dietary burden of 1.299 ppm did not lead to a raising of the tolerances for swine commodities. Accordingly, because the maximum theoretical dietary burden of 0.19 ppm for the commodities associated with the current petition is less than 1.299 ppm (and, indeed, less than 0.760 ppm), there is clearly no need to reconsider the tolerances for fat, meat, and meat byproducts of swine.

OPPTS GLN 860.1500: Crop Field Trials

11a. The petitioner, Zeneca Ag Products, submitted data from 6 field trials on avocados conducted in 1994 in Mexico to support its proposed permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as KARATE® Insecticide on imported avocados. Lambda-cyhalothrin as a KARATE® EC formulation prepared in Mexico was applied as a foliar spray in 4 applications at the nominal rate of 0.03 lb ai/A for a total of 0.12 lb ai/A/season, with an interval of 26–34 days between applications. The PHI was 7 days. Residue levels of lambda-cyhalothrin in/on avocados were 0.03–0.11 ppm. The highest average field trial (HAFT) was 0.085 ppm, and the mean ± standard deviation (SD) of the residue of lambda-cyhalothrin was 0.072 ± 0.026 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® Insecticide on imported avocados provided the label is modified as stated in Conclusion 2b. Tolerances established for lambda-cyhalothrin are for the combined

residues of lambda-cyhalothrin and its epimer R157836. Although the residue R157836 was not quantified in this study, information on the other crops discussed in this report provides ample evidence that expected residues of R157836 would be so much smaller than those for lambda-cyhalothrin that the lack of data on R157836 is not considered to be a serious limitation of the study.

11b(1). Zeneca Ag Products provided no new data from crop field trials on wheat and other small grain crops (which Zeneca lists as including barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, and triticale). Nonetheless, Zeneca submitted a proposed label that includes a proposed use for this group of crops (taken as a whole), and it has proposed permanent tolerances in Section F of the petition for the cereal grain crop group (except rice and wild rice) for grain, forage (except sorghum), hay, straw, aspirated grain dust, bran, and flour. Currently there are established tolerances for aspirated grain fractions, corn (grain of field corn and popcorn, fodder, forage, and flour), sweet corn, rice (grain, hulls, and straw), sorghum grain, and wheat (grain, forage, hay, straw, and bran). The petitioner argues in Section D of the petition that this group of tolerances can be broadened to the entire crop group 15 (excluding rice and wild rice, but including the wide array of small grains) because the existing tolerances for all of the representative crops (except for rice) of the cereal grain crop group meet the Agency's 'factor of 5' rule. According to that rule, the maximum residues of the representative crops must be within a factor of 5 to share the same tolerance, and the tolerances of these crops differ by 4-fold at most when the established tolerance levels for each grain are taken to reflect the maximum residues. The specific established tolerances are as follows for each type of grain: 0.05 ppm for sweet corn, 0.05 for field corn, 0.2 ppm for sorghum, and 0.05 ppm for wheat.

11b(2). **The petitioner's argument regarding the Agency's 'factor of 5' rule does not justify a tolerance for all members of the cereal grains, crop group 15 (except rice and wild rice) because the use patterns of the representative crops that were compared (namely sweet corn, field corn, sorghum, and wheat) are substantially different.** The establishment of tolerances for entire crop groups or crop subgroups assumes that the use patterns are reasonably similar. When they are not, similarities in residue levels do not confer confidence that the different crops respond rather similarly (or at least differ by no more than a factor of 5). To illustrate the differences in use patterns for crops that the petitioner wants to include in one group, the maximum application rates per season for sweet corn and wheat are 0.48 lb ai/A and 0.06 lb ai/A, respectively. Furthermore, the PHIs for sweet corn, field corn, sorghum, and wheat are 1, 21, 30, and 30 days, respectively.

11b(3). The proposed new label for KARATE® Insecticide 1EC maintains the same (and distinct) use patterns as in the present label for (1) field corn, popcorn, seed corn, (2) sweet corn, (3) sorghum, and (4) wheat, wheat hay, and triticale (taken as a group). The tolerances requested by Zeneca for the small grains cannot be established in the absence of additional data. The following instructions from paragraph (e) (2) (vii) (F) of Guidelines OPPTS 860.1500 Crop Field Trials show precisely what the petitioner must do to obtain the desired tolerances on small grains: "(F) Although there is no crop group for 'small grains' in CFR 180.41, for data generation purposes wheat, barley, oats, and rye may be treated as a group. Provided use patterns and resulting residues are similar, the numbers

of trials for wheat, barley, and oats may be reduced to 15, 9, and 12, respectively. Five trials are still needed for rye. The tolerances will be established on the individual crops due to the lack of an official small grain crop group." Since the publication of the guidelines, the Chemistry Science Advisory Council (ChemSAC) concluded that data would not be needed on rye (memo dated 1/9/98). There is no indication that the petitioner has conducted any crop field trials on barley and oats to support use on all the small grains.

11c(1). The petitioner, Zeneca Ag Products, submitted data from 8 field trials on bell peppers and 3 field trials on non-bell peppers conducted in 1996 to support its proposed permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on fruiting vegetables (except cucurbits), i.e.,crop group 8. There is already an established tolerance for tomatoes, which is the only other representative commodity in this crop group. KARATE® was applied in 12 applications of 0.03 lb ai/A as a broadcast foliar spray for a total of 0.36 lb ai/A/season, with intervals of 5–10 days between treatments and a PHI of 5 days. This reflects the maximum residue use pattern on the proposed label. Residue levels of lambda-cyhalothrin in/on bell peppers were 0.01–0.15 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 2 of 15 samples being 0.01 ppm. For the combined residues on bell peppers, the HAFT was 0.16 ppm, and the mean ± SD was 0.070 ± 0.048 ppm. Residue levels of lambda-cyhalothrin in/on non-bell peppers were 0.02–0.12 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 2 of 6 samples being 0.01 ppm. For the combined residues on non-bell peppers, the HAFT was 0.13 ppm, and the mean ± SD was 0.087 ± 0.043 ppm.

11c(2). The petitioner requested a permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on crop group 8: Fruiting Vegetables (Except Cucurbits). In addition to bell and non-bell peppers, tomatoes are representative commodities in this crop group. The application rate in the earlier field trials on tomatoes is similar to that in the field trials on peppers. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on crop group 8: fruiting vegetables (except cucurbits). The existing tomato and tomatillo tolerance of 0.1 ppm should be deleted when the crop group tolerance is established.

11d. The petitioner, Zeneca Ag Products, submitted data from 11 field trials on peanut hay conducted in 1995 to support its proposed permanent tolerance of 3.0 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on peanuts, with no restriction (as there is presently) on the use of peanut vines for hay or forage. There is already an established tolerance for peanuts. Lambda-cyhalothrin as the formulation KARATE® was applied in 4 applications of 0.03 lb ai/A as a broadcast foliar spray for a total of 0.12 lb ai/A/season, with an interval of 7–10 days between applications and a PHI of 12–21 days. (The interval from last treatment until digging of the peanuts was 12–21 days, and the peanuts were allowed to dry in the field for an additional 3–7 days before sample collection.) Residue levels of lambda-cyhalothrin in/on peanut hay were 0.34–2.2 ppm, and residue levels of R157836 were 0.06–0.41 ppm. For the combined residues, the HAFT was 2.36 ppm and the mean ± SD was 1.22 ± 0.67 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested

permanent tolerance of 3.0 ppm on peanut hay for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on peanuts.

11e. The petitioner, Zeneca Ag Products, submitted data from 3 field trials on edible-podded peas and 6 field trials on edible-podded beans conducted in 1996 to support its proposed permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the edible-podded legume vegetables subgroup (crop subgroup 6A). KARATE® was applied in 4 or 5 applications of 0.03 lb ai/A for a total of 0.12 lb ai/A/season (i.e., 1x application rate) to 0.15 lb ai/A/season (i.e., 1.25x application rate), with an interval of 5–7 days between applications and a PHI of 7 days. Residue levels of lambda-cyhalothrin in/on edible-podded peas at the 1x application rate were 0.01–0.12 ppm and residue levels of R157836 were <0.01–0.02 ppm, with 2 of 6 samples being 0.01 ppm or higher. For edible-podded peas at the 1x application rate and for the combined residues, the HAFT was 0.12 ppm and the mean ± SD was 0.066 ± 0.047 ppm. Residue levels of lambda-cyhalothrin in/on edible-podded beans at the 1.0–1.25x application rates were 0.01–0.03 ppm, and residue levels of R157836 were all <0.01 ppm. For the combined residues on edible-podded beans, the HAFT was 0.03 ppm and the mean ± SD was 0.031 ± 0.005. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the edible-podded legume vegetables subgroup (crop subgroup 6A).

11f. The petitioner, Zeneca Ag Products, submitted data from 6 field trials on succulent shelled peas and 6 field trials on succulent shelled beans conducted in 1996 to support its proposed permanent tolerance of 0.01 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the succulent shelled pea and bean subgroup (crop subgroup 6B). Lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 4 or 5 applications of 0.03 lb ai/A as a broadcast foliar spray for a total of 0.12 lb ai/A/season (i.e., 1x application rate) to 0.15 lb ai/A/season (i.e., 1.25x application rate), with an interval of 4–7 days between applications and a PHI of 6–7 days. Although it was not stated, it seems likely that the samples were seeds without pods because the RAC is defined in that way and residues were very low in concentration. All residue levels of both lambda-cyhalothrin and R157836 in/on succulent shelled peas at the 1.00–1.06x application rates were below 0.01 ppm. Residue levels of both lambda-cyhalothrin and R157836 in/on succulent shelled beans at the 1.00–1.25x application rates were also all below 0.01 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.01 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the succulent shelled pea and bean subgroup (crop subgroup 6B). The concentration of 0.01 ppm is the LOQ for lambda-cyhalothrin alone (as well as for R157836 alone), but it seems reasonable to use this concentration as the tolerance level for both lambda-cyhalothrin and R157836 because (1) every sample for lambda-cyhalothrin was below the LOQ and (2) because for all of the several crops considered in this petition that have much higher residue levels, the residue levels for lambda-cyhalothrin are always much higher than those for R157836. Since there are animal feed items of regulatory interest for croup group 6B, notably cowpea hay and forage, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit**

new labels specifying for succulent shelled pea and bean subgroup, crop subgroup 6B: "Do not graze livestock in treated areas or harvest vines for forage or hay.

11g. The petitioner, Zeneca Ag Products, submitted data from 5 field trials on dried shelled peas and 9 field trials on dried shelled beans conducted in 1996 to support its proposed permanent tolerance of 0.1 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the dried shelled pea and bean (except soybean) subgroup (crop subgroup 6C). Lambda-cyhalothrin as the formulation KARATE® 1E was applied in 4 applications of 0.03 lb ai/A as a broadcast foliar spray for a total of 0.12 lb ai/A/season, with an interval of 5–10 days between applications and a PHI of 19–21 days except at one site, where it was 24 days. Residue levels of lambda-cyhalothrin in/on dried shelled peas at the 1x application rate were <0.01–0.05 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 1 of 10 independent samples being 0.01 ppm. For the combined residues on dried shelled peas, the HAFT was 0.050 ppm and the mean ± SD was 0.026 ± 0.013 ppm. Residue levels of lambda-cyhalothrin and R157836 in/on dried shelled beans were all below the LOQ of 0.01 ppm except for in one sample, where the level was exactly 0.01 ppm. For the combined residues on dried shelled beans, the HAFT was 0.02 ppm and the mean ± SD was 0.02 ± 0 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.1 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the dried shelled pea and bean (except soybean) subgroup (crop subgroup 6C). Since there are animal feed items of regulatory interest for croup group 6C, notably cowpea hay and forage and field pea vines and hay, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for dried shelled pea and bean subgroup, crop subgroup 6C: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

11h(1). The petitioner, Zeneca Ag Products, submitted data from 13 field trials on grain sorghum conducted in 1995 to support its proposed permanent tolerances on sorghum forage and fodder for use of lambda-cyhalothrin as KARATE® 1E Insecticide on grain sorghum. The petitioner wishes to remove the restriction on use of sorghum forage and fodder from the existing label for grain sorghum. The proposed tolerances on sorghum forage and fodder are 0.3 and 0.5 ppm, respectively. There is an established tolerance of 0.2 ppm for sorghum grain. Samples were collected from 13 trials for forage and 12 trials for fodder. For sorghum that was to be used as forage, lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 2 applications at the nominal rate of 0.03 lb ai/A, for a total application of 0.06 lb ai/A/season. The first application was preemergence, and the second application was broadcast foliar between early and late bloom. The PHI for forage was between 16 and 31 days (mean = 23.8 days). For sorghum that was to be used as fodder, lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 3 applications at the nominal rate of 0.03 lb ai/A for the first two applications and 0.02 lb ai/A for the third application, for a total application of 0.08 lb ai/A/season. The first two broadcast applications were made identically to those for sorghum destined for forage, and the third application, by broadcast foliar, was made 30 days prior to the collection of the fodder. The re-treatment interval between the first two applications was 49–105 days, and it was 21–34 days between the second and third applications. Residue levels of lambda-cyhalothrin in/on sorghum forage were <0.01–0.27 ppm, and residue levels of

R157836 were <0.01–0.02 ppm. For the combined residues on sorghum forage, the HAFT was 0.245 ppm and the mean ± SD was 0.127 ± 0.070 ppm. Residue levels of lambda-cyhalothrin in/on sorghum fodder were 0.07–0.38 ppm, and residue levels of R157836 were <0.01–0.04 ppm. For the combined residues on sorghum fodder, the HAFT was 0.355 ppm, and the mean ± SD was 0.171 ± 0.091 ppm.

11h(2). The petitioner deviated substantially from the recommended geographical distribution of grain sorghum crop trials. For example, there were no crop trials instead of the 3 recommended in region 8, where 29% of sorghum is produced. There are important differences between the proposed use described on the proposed label for grain sorghum and the application protocols used in the crop field trials for grain sorghum forage and fodder. For example, according to the proposed label, repeated treatments can be made as little as three days apart, but intervals between treatments in the field trials ranged from 21–105 days. Also, the crop field trials had a total application rate of only 0.06 lb ai/A applied to sorghum used as forage, with only half of that applied after crop emergence, but the proposed label allows a higher treatment rate. However, since the residues found in the forage studies were highest at 16 days after treatment, it is unlikely that the residues of lambda-cyhalothrin would exceed the proposed tolerance when used following the label directions with a 30-day PHI. Considering these commodities are only livestock feed items, the numbers of submitted field trials and samples, the storage stability data, and the geographic diversity are adequate, to support the proposed tolerances. The numbers of submitted field trials, the storage stability data, and the geographic diversity of the field trials are adequate to support the requested permanent tolerances.

11i. The petitioner, Zeneca Ag Products, submitted data from 9 field trials on sugarcane conducted in 1995 and 1996 to support its proposed permanent tolerance of 0.05 ppm for use of lambda-cyhalothrin as KARATE® 1E Insecticide on sugarcane. Lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 4 applications at the nominal rate of 0.04 lb ai/A, for a total application of 0.16 lb ai/A/season (maximum proposed rate), with an interval of 5–8 days between applications and a PHI of 20–26 days (versus the proposed 21-day PHI). Residue levels of lambda-cyhalothrin in/on sugarcane at the 1.0x application rate at a PHI of 21–26 days were <0.01–0.03 ppm and all residue levels of R157836 were <0.01 ppm. For the combined residues, the HAFT was 0.03 ppm (found at 4 of the sites) and the mean ± SD was 0.026 ± 0.006 ppm. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support the requested permanent tolerance of 0.05 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on sugarcane.

OPPTS GLN 860.1520: Processed Food/Feed

12a. The processed commodities of regulatory interest for this petition are tomato paste, tomato puree, peanut meal, refined peanut oil, sorghum flour, sugarcane molasses, and refined sugarcane sugar. There is also an existing tolerance for tomato pomace (dry or wet).

12b. The petitioner, Zeneca Ag Products, submitted data from a processing study conducted in 1995 in LA on sugarcane. Two plots were established, with one being untreated and the

other treated with KARATE® 1EC, which was applied in 4 broadcast foliar applications at the rate of 0.2 lb ai/A, for a total application of 0.8 lb ai/A/season or 5x the recommended application rate. The first application was 42 days prior to harvest, with subsequent treatments at 7 days intervals. The last application was made 21 days prior to harvest. The processing laboratory, which was Wm. J. Englar & Associates, Inc. (Moses Lake, WA), simulates commercial operations as closely as possible to generate the required fractions of unwashed cane, bagasse, molasses, and refined sugar. Following processing, the processing samples were stored frozen until they were shipped to the analytical laboratory at Zeneca, Inc. (Richmond, CA). Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. The processing study provided no evidence of concentration of lambda-cyhalothrin or its epimer R157836 in either molasses or refined sugar; indeed, there appears to be a large reduction in these residues. There is clearly no need for any tolerances for these two commodities.

12c. Regarding other crops considered in this petition, the new information provides no reason to add or change any tolerances on processed commodities made from tomatoes, cereal grains, or peanuts. For example, the raising of the tolerance on tomatoes from its current value of 0.1 ppm to that of 0.2 ppm as part of the fruiting vegetables crop (except cucurbits) group has no influence on the tolerances of processed commodities of tomatoes because they are based on the HAFT found for tomatoes and the concentration factors found on tomatoes.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

13. No studies of this type were submitted with this petition. Previous studies showed that significant residues (exceeding the LOQ of 0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. According to the EFED review of 4/6/88, no additional rotational crop data were needed to support registered application rates at that time. The current and proposed labels mention no restriction on replanting of crops for which lambda-cyhalothrin as the formulation KARATE® 1EC is used.

Other Considerations:

14. Current status sheets available to HED indicate that there are no Codex, Canadian, or Mexican maximum residue levels (MRLs) established for lambda-cyhalothrin on crops for which tolerances are being recommended: avocados, the fruiting vegetables (except cucurbits) crop group (crop group 8), peanut hay, the edible podded pea and bean subgroup (subgroup 6A), the succulent shelled pea and bean subgroup (subgroup 6B), the dried shelled pea and bean subgroup (subgroup 6c), sorghum fodder, sorghum forage, and sugarcane. Harmonization is thus not an issue.

RECOMMENDATIONS

Pending the resolution of deficiencies noted below and the forthcoming human health risk assessment, the following permanent tolerances expressed as residues of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3- (2-chloro-3,3,3- trifluoroprop-1-

enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3- trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate, should be established:

Avocados	0.2 ppm
Fruiting Vegetables (except cucurbits) group	0.2 ppm
Peanut hay	3.0 ppm
Pea and bean, edible podded, subgroup	0.2 ppm
Pea and bean, succulent shelled, subgroup	0.01 ppm
Pea and bean, dried shelled, subgroup	0.1 ppm
Sorghum, fodder	0.5 ppm
Sorghum, forage	0.3 ppm
Sugarcane	0.05 ppm

The proposed use directions for the KARATE® EC Insecticide formulation of lambda-cyhalothrin for use on avocados to be imported from Mexico do not match the submitted label. The petitioner should submit a revised label that shows the PHI of 7 days, an interval between applications of approximately 30 days, and a maximum total application rate per season of 0.12 lb ai/A. (The avocado tolerance should be footnoted in the CFR to indicate that there are no U.S. registration.)

The petitioner should submit a revised proposed label with the following restriction for succulent and dried shelled pea and bean subgroups, crop subgroups 6B and 6C: "Do not graze livestock in treated areas or harvest vines for forage or hay."

Regarding the small grains, the petitioner's argument regarding the Agency's 'factor of 5' rule does not justify a tolerance for all members of the cereal grains, crop group 15 (except rice and wild rice) because the use patterns of the representative crops that were compared (namely sweet corn, field corn, sorghum, and wheat) are substantially different. The Guidelines OPPTS 860.1500 Crop Field Trials state precisely what the petitioner must do to obtain the desired tolerances, as follows: "Although there is no crop group for 'small grains' in CFR 180.41, for data generation purposes wheat, barley, oats, and rye may be treated as a group. Provided use patterns and resulting residues are similar, the numbers of trials for wheat, barley, and oats may be reduced to 15, 9, and 12, respectively. Five trials are still needed for rye. The tolerances will be established on the individual crops due to the lack of an official small grain crop group." Since the publication of the guidelines, the Chemistry Science Advisory Council (ChemSAC) concluded that data would not be needed on rye (memo dated 1/9/98). There is no indication that the petitioner has conducted any crop field trials on barley and oats. The requested cereal grain crop group tolerance should be removed from Section F.

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

Product chemistry data for lambda-cyhalothrin were reviewed earlier and are summarized as follows (PP#7F3488, DP Barcode: D177185, J. J. Morales, 11/12/92). The manufacturing process for lambda-cyhalothrin was submitted in support of PP#6F3318 (MRID# 401820-01) and discussed in S. Willett's memo of 9/29/87. There are no toxicological concerns for any lambda-cyhalothrin impurities. Discussion about structure and isomers appears in M. Flood's memo of 9/19/91 (PP#7F3560/7H5543). CBTS concluded that the manufacturing process of technical grade lambda-cyhalothrin has been adequately described and did not foresee any residue problems from impurities in the technical grade product. Although deficiencies pertaining to the written confirmation from the Chemical Abstract Service were resolved, CBTS recommended that the IUPAC names for lambda-cyhalothrin and its epimer (rather than the Chemical Abstract names) appear in the regulation, since in their opinion, a practicing chemist can more readily relate the IUPAC names to the structure (refer to M. Flood's memo of 9/19/91, PP#7F3560/7H5543 and 3/23/92, FAP#OH5599 for more details). KARATE® 1E Insecticide (EPA Reg. No. 10182-96), which is the formulation used in all proposed uses besides that on avocados, contains 13.1% ai. It is an emulsifiable concentrate that contains 1 pound ai per gallon, or 0.0078 lb ai/ fl oz. Also available in the U.S. is WARRIOR® T (formulation number WF2616; EPA Reg No. 10182-434) a capsule suspension that contains 1 lb ai per gallon. ICIA0321 (lambda-cyhalothrin) Technical (EPA Reg. No. 10182-131) contains a minimum 81% ai. A CSF dated 1/28/92 was provided earlier (PP#2F4109 & PP#2F4114 and others, DP Barcodes: D176545 & D177078 and others, M.T. Flood, 11/18/92).

OPPTS GLN 860.1200: Proposed Uses

General Use Instructions

U.S. registered lambda-cyhalothrin is formulated as KARATE® 1E Insecticide (EPA Reg. No. 10182-96) an emulsifiable concentrate that contains 1 pound ai per gallon and WARRIOR® T (formulation number WF2616; EPA Reg No. 10182-434) a capsule suspension that also contains 1 pound ai per gallon. Proposed uses are described below for individual crops and crop subgroups. General instructions and precautions are as follows. Lambda-cyhalothrin is a combustible liquid that is corrosive, causes skin damage, and may be fatal if swallowed or inhaled. It causes eye injury, is harmful if absorbed through the skin, and may cause allergic skin reactions. Detailed spray drift precautions are presented on the label, as well as detailed instructions and precautions for applications by chemigation.

Avocados (imported from Mexico)

A KARATE® Insecticide formulation of lambda-cyhalothrin is proposed for foliar application (mixed with water) to avocados in Mexico to control or suppress the following insects: the leaf miner, whitefly, leaf hopper, and thrips. The petitioner has submitted a draft label translated into English for the end use product to be used in Mexico. This emulsifiable concentrate contains 0.584 lb ai/gal. The maximum application rate per treatment is 0.031 lb ai/A. The provided proposed use directions do not specify a maximum application rate per season, a recommended interval between applications, or a PHI. For ground application, KARATE® is to be applied at 21.4–64.2 gpa. For aerial application, it should be applied at 4.3–6.4 gpa unless Micronaire equipment is used, in which case it should be applied at 3.2–4.3 gpa. The choice of application rate must be based on the level of pest infestation, method of application, and crop developmental stage, with the maximum recommended rate being used when conditions are

extreme. KARATE® should be applied early in the morning or in the evening when temperatures are not high. **The petitioner should submit a revised label with translation that reflects the conditions used in the residue field trials showing the PHI of 7 days, an interval between applications of approximately 30 days, and a maximum total application rate per season of 0.12 lb ai/A.**

Cereal Grains, Crop Group 15 (excluding field corn, sweet corn, popcorn, rice, wild rice, and sorghum)

The use of lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on wheat, barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, and triticale. The maximum application rate per treatment is 0.03 lb ai/A, and the maximum application rate per season is 0.06 lb ai/A, with a PHI of 30 days. The product should be applied as required by scouting, usually at intervals of 5 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of foliage, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, lambda-cyhalothrin may be applied before, during, or after planting. For chinch bug control, applications should be repeated at intervals of 3–5 days if needed.

Fruiting Vegetables (except cucurbits), Crop Group 8

Lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on fruiting vegetables (except cucurbits), crop group 8, which were listed individually. The maximum application rate per treatment is 0.03 lb ai/A (3.84 fl oz of formulation per A), and the maximum application rate per season is 0.36 lb ai/A (2.88 pints of formulation per A), with a PHI of 5 days. The product should be applied as required by scouting, usually at intervals of 5 or more days. Timing and frequency of applications should be based upon insect populations reaching locally determined economic thresholds. The spray should be applied with ground or air equipment using enough water to obtain full coverage of the foliage, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, lambda-cyhalothrin may be applied before, during, or after planting. The present label (in its section for tomatoes and tomatilloes) includes the following restriction: "Do not use on varieties in which the mature tomatoes will be less than one inch in diameter (such as cherry tomatoes)." The proposed label includes a notation indicating the removal of that restriction.

Peanuts

Lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on peanuts. The maximum application rate per treatment is 0.03 lb ai/A (3.84 fl oz of formulation per A), and the maximum application rate per season is 0.12 lb ai/A (0.96 pint of formulation per A), with a PHI of 14 days. The product should be applied as required by scouting, usually at intervals of 7 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of the foliage, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, lambda-cyhalothrin may be applied before, during, or after planting. The proposed KARATE® 1E label removes the current restriction on grazing and on using treated vines or hay for animal feed. The restriction is still listed on the WARRIOR® T label but may be removed if the registrant wishes.

Edible-podded Legume Vegetables, Crop Subgroup 6A, and Succulent Shelled Pea and Bean Subgroup, Crop Subgroup 6B

The KARATE® 1E Insecticide formulation of lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on all varieties of edible-podded legume vegetables (i.e., crop subgroup 6A) and all varieties of the succulent shelled pea and bean subgroup (i.e., crop subgroup 6B). The maximum application rate per treatment is 0.03 lb ai/A (3.84 fl oz of formulation per A), and the maximum application rate per season is 0.12 lb ai/A (0.96 pint of formulation per A), with a PHI of 7 days. The product should be applied as required by scouting, usually at intervals of 5 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of the foliage, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, KARATE® 1E may be applied before, during, or after planting. Cowpea hay is a significant feedstuff for cattle, and cowpea forage is a significant feedstuff for cattle and swine. Since there are animal feed items of regulatory interest for croup group 6B, notably cowpea hay and forage, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for succulent shelled pea and bean subgroup, crop subgroup 6B: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

Dried Shelled Pea and Bean (Except Soybean) Subgroup, Crop Subgroup 6C

The KARATE® 1E Insecticide formulation of lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on all varieties of the Dried Shelled Pea and Bean (Except Soybean) Subgroup, Crop Subgroup 6C. The maximum application rate per treatment is 0.03 lb ai/A (3.84 fl oz of formulation per A), and the maximum application rate per season is 0.12 lb ai/A (0.96 pint of formulation per A), with a PHI of 21 days. The product should be applied as required by scouting, usually at intervals of 5 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of the foliage, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, KARATE® 1E may be applied before, during, or after planting. Both the cowpea (when dried) and the field pea are classified in Crop Subgroup 6C. The field pea as listed here includes cultivars grown for livestock feeding only such as the Austrian winter pea, but it does not include the canning field pea cultivars used for human food. Cowpea hay is a significant feedstuff for cattle, cowpea forage is a significant feedstuff for cattle and swine, and cowpea seeds are a significant feedstuff for cattle, poultry, and swine. Field pea seeds are a significant feedstuff for cattle, poultry, and swine, and field pea vines, hay, and silage are significant feedstuffs for cattle. Since there are animal feed items of regulatory interest for croup group 6C and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for dried shelled pea and bean subgroup, crop subgroup 6C: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

Sorghum

The KARATE® 1E and WARRIOR® T Insecticide formulations of lambda-cyhalothrin is proposed for foliar application to control or suppress the listed insects on grain sorghum. The maximum application rate per treatment is 0.03 lb ai/A (3.84 fl oz of formulation per A), and the maximum application rate per season is 0.08 lb ai/A (0.64 pint of formulation per A), with a PHI of 30 days. No more than 0.06 lb ai/A (0.48 pint of formulation per A) may be applied after crop

emergence. No more than 0.02 lb ai/A (0.16 pint of formulation per A) may be applied once the crop has reached the soft dough stage. The lambda-cyhalothrin products should be applied as required by scouting, usually at intervals of 5 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of target location, in a minimum of 2 gpa by air or 10 gpa by ground. For cutworm control, lambda-cyhalothrin may be applied before, during, or after planting. For sorghum midge control, applications should begin when 25% of the sorghum heads have emerged and are in tip bloom, and applications may be repeated at 5-day intervals if needed. For chinch bug control, applications should begin when the bugs migrate from grass weeds (or small grains) to the small sorghum. The spray should be directed to the base of sorghum plants, and applications should be repeated at intervals of 3–5 days if needed. The WARRIOR® T label has a restriction both on the grazing of livestock in treated areas and the harvesting for fodder, silage or hay. Those restrictions may be removed from the label.

Sugarcane

The KARATE® 1E Insecticide formulation of lambda-cyhalothrin is proposed for foliar application to sugarcane to control or suppress the sugarcane borer, rice borer, sugarcane beetle (adult), and yellow sugarcane aphid. The maximum application rate per treatment is 0.04 lb ai/A (5.12 fl oz of formulation per A), and the maximum application rate per season is 0.16 lb ai/A (1.28 pints of formulation per A), with a PHI of 21 days. The product should be applied as required by scouting, usually at intervals of 7 or more days. The spray should be applied with ground or air equipment using enough water to obtain full coverage of the foliage, in a minimum of 2 gpa by air or 10 gpa by ground.

OPPTS GLN 860.1300: Nature of the Residue - Plants

No new studies were submitted with this application. Based on metabolism studies conducted on cotton, cabbage, soybeans and wheat, the nature of the residue in plants is adequately understood (PP#7F3560/7H5543, M. Flood, 1/22/92). Lambda-cyhalothrin is metabolized by cleavage of the ester linkage to form cyclopropanecarboxylic acids and the corresponding phenoxybenzoic acids or alcohols. In most cases the parent compound is the principal constituent of the residue. However, in the cabbage metabolism study the cis- and trans- cyclopropanecarboxylic acids were the major constituents. HED has decided that the plant metabolites need not appear in the tolerance expression at this time due to lack of toxicological concern and low concentrations found from residue studies (Lambda-cyhalothrin SF, Memo from P. Hurley to M. Flood, 1/3/92). The residue to be regulated is lambda-cyhalothrin and its epimer R157836 (Lambda-cyhalothrin SF, G. Kramer, 2/9/96). The above details are summarized in PP#5F04588, DP Barcode: D219683, Linda L. Kutney, 8/26/96.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

No new studies were submitted with this application. Studies of lambda-cyhalothrin metabolism in ruminants and poultry have been reviewed. Lambda-cyhalothrin is the major component of the residue in them, except for kidney and liver of ruminants and liver of poultry, where, in addition to the plant metabolites, 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBAcid) may be present in significant quantities. A residue transfer study in which cows were

fed dietary levels of 8, 25 or 80 ppm lambda-cyhalothrin demonstrated that, at ≤ 8 ppm, OH-CPA levels in tissue would not exceed 0.01 ppm (See Reference in PP#2F4109, 2F4114, 7F3560, and 1F3992, M. Flood, 8/31/92). As with plants, the residue to be regulated is lambda-cyhalothrin and its epimer R157836. HED has determined that animal metabolites do not need to appear in the tolerance expression at this time (PP#1F3992, M. Flood, 12/26/91 and FAP#OH5599, M. Flood, 8/31/92). CBTS decided earlier not to require further animal metabolism data to support uses for lambda-cyhalothrin on alfalfa, lettuce or the Brassica crop group. The above details are summarized in PP#5F04588, DP Barcode: D219683, Linda L. Kutney, 8/26/96.

OPPTS GLN 860.1340: Analytical Methods - Plants

General Analytical Method - Description

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in plant commodities. ICI Method 81 (MRID#40054001) is used to determine the residues of lambda-cyhalothrin and its epimer in plant matrices. ICI Method 81, which is also called PPRAM 81, has undergone an EPA method validation for soybeans (PP#6F3318, PP#7F3488, E. Greer, 9/30/87) and was found to be adequate for enforcement purposes (PP#6F3318, S. Brooks, 10/30/87). This method involves acetone:hexane 1:1 (v/v) extraction, followed by liquid-liquid chromatography to remove lipids and florisil column cleanup. Quantification uses capillary GC with electron capture detection (GC/ECD). The limits of detection and quantification were 0.01 ppm for both lambda-cyhalothrin and its enantiomer (PP#7F3488, J. Morales, 11/17/92). ICI Method 81 (MRID#40054001) has been validated as an adequate enforcement method by EPA for determination of parent lambda-cyhalothrin and its epimer in/on plants. The above details are summarized in PP#5F04588, DP Barcode: D219683, Linda L. Kutney, 8/26/96.

In analytical studies of all crops besides avocados, and in the processing study on sugarcane, the procedure used was based on methods PPRAM 81 and PPRAM 70. PPRAM 81 and PPRAM 70 are identification symbols of two ICI Plant Protection Division Reports, published in 1984 and 1983, respectively, that describe these methods. This procedure identified both lambda-cyhalothrin and its epimer R157836, and the limit of quantitation was 0.01 ppm for both residues. In the PPRAM 81/PPRAM 70 method, lambda-cyhalothrin and R157836 are extracted from the sample with a 1:1 (v/v) acetone:hexane mixture. The acetone is removed by partitioning with deionized water. An acetonitrile liquid-liquid column cleanup is used to remove extracted lipids, and Florisil adsorption chromatography is used to remove interfering endogenous materials. Quantification by capillary GC/ECD uses an external standardization technique. The reference standard used for cyhalothrin (also called ICIA0321) had reference number ASY/Cyhalothrin/No242 and purity of 91.1% (containing 57.7% w/w R157836 & 33.4% w/w ICIA0321).

In the analytical studies on avocados, the method of analysis was Analytical Method 081/03, and the only residue detected was lambda-cyhalothrin. Analytical Method 081/03 appears to be a modification of EPA-validated method PPRAM 81, and it is a standard operating procedure published in 1995. In Method 081/03, following extraction in acetone:hexane, an aliquot is sampled and evaporated to dryness. The aliquot is then redissolved in hexane and cleaned up by absorption chromatography on a Silica Bond Elut chromatography column. Quantitative

determination is by capillary gas-liquid chromatography with ECD or by mass-spectrometric detection. The LOQ is 0.01 ppm.

Method Validation/Concurrent Recoveries

The petitioner submitted concurrent recovery studies for all crops (in MRIDs 44325701, 44325702, 44325703, 44325704, 44325705, 44325706, 44325707, 44325708, 44325709, 44325710, and 44924312), with the results being shown in Table 1. For most matrices, a detailed listing of results from simultaneous runs of procedural recoveries, controls, and treated samples was provided. The recovery values (both corrected and uncorrected for control values) shown in Table 1 were calculated by the reviewer using the formula provided by the authors. The reports provided only corrected values. Sometimes those values differed from those calculated by the reviewer, usually because of differences in rounding. The 46 uncorrected recoveries of lambda-cyhalothrin had a mean of 95.2% with a SD of 26.1%. The 3 samples with recoveries outside the acceptable range of 70–120% had uncorrected recoveries of 120.6, 182.9, and 228.0%. The 45 uncorrected recoveries of R157836 (all within the acceptable range) had a mean of 87.6% with a SD of 9.8%. The 57 corrected recoveries of lambda-cyhalothrin had a mean of 89.1% with a SD of 12.4%. The 5 samples with corrected recoveries outside the acceptable range had recoveries of 51.8, 59.0, 69.3, 69.8, and 120.6%. The 45 corrected recoveries of R157836 (all within the acceptable range) had a mean of 86.3% with a SD of 9.8%. For lambda-cyhalothrin, fortification levels for 8 of 15 crops/commodities failed to bracket the residues found in the magnitude of the residue testing. Usually this was because the maximum residue found exceeded the maximum fortification level (by from 1.3– 4.3x). For the epimer R157836, fortification levels for 13 of 14 crops/commodities failed to bracket the residues found in the magnitude of the residue testing. In all but one case, this was because the lowest fortification level tested exceeded 0.01, usually only slightly. The definition (and application) of the LOQ as being 0.01 ppm for R157836 was apparently based on earlier work Most of the lowest fortification levels for R157836 were close to 0.01 ppm, e.g. frequently they were 0.013. Similarly, the LOQ of 0.01 ppm that was applied for lambda-cyhalothrin is higher than the common lowest fortification level of 0.007 ppm.

The validation results show that adequate recoveries of residues of lambda-cyhalothrin may be expected on the crops evaluated in this review. Limited but adequate sample chromatograms were provided for the concurrent method recoveries by the analytical laboratory (Zeneca Ag Products at Richmond, CA). However, no lambda-cyhalothrin calibration curves were presented, and there was no mention of the LOD in the reports submitted with this petition. A substantial fraction of the control samples yielded positive responses for (1) the dried shelled pea and bean (except soybean) subgroup, (2) peanut hay, (3) sorghum forage and fodder, and (4) bell peppers. However, those interferences, which were found for both lambda-cyhalothrin and R157836, were usually less than the LOQ of 0.01 ppm. The five exceptions, which were all for lambda-cyhalothrin, were 0.05 and 0.01 ppm in sorghum forage, 0.06 ppm in sorghum fodder, and 0.03 and 0.04 ppm in bell peppers. The samples with residues of 0.03 and 0.04 ppm were duplicates of the control sample for which a fortified sample yielded an uncorrected recovery of 228%. The fortified sample of the control yielding 0.05 ppm exhibited 182.9% recovery. No explanation was given for these high control values and associated corresponding excessive recoveries, but one possibility would be contamination of a small fraction of the control samples.

TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.

Matrix	Compound	Fortification Level (ppm)	# of samples	Recovery (%) as the range, mean, and SD[1,2]	
				Uncorrected	Corrected[3]
Bell peppers	lambda-cyhalothrin	0.007	1	**82.9**	**82.9**
		0.037	2	70.7–228.0; **149.4** (111.2)	70.7–114.0; **92.4** (30.6)
		0.367	1	**86.9**	**86.8**
	R157836	0.013	1	**75.6**	**75.6**
		0.063	2	72.8–102.3; **87.6** (20.9)	72.8–97.1; **85.0** (17.2)
		0.63	1	**82.8**	**82.7**
Non-bell peppers	lambda-cyhalothrin	0.007	1	**77.5**	**77.5**
		0.073	1	**87.8**	**87.8**
	R157836	0.013	1	**75.7**	**72.0**
		0.127	1	**81.1**	**80.7**
Edible-podded peas and beans	lambda-cyhalothrin	0.007	1	**91.5**	**91.5**
		0.037	2	94.6-100.3; **97.4** (4.0)	94.6-100.3; **97.4** (4.0)
		0.073	2	86.5–92.5; **89.5** (4.2)	86.5–92.5; **89.5** (4.2)
	R157836	0.013	1	**84.7**	**84.7**
		0.063	2	90.1–97.2; **93.6** (5.0)	90.1–97.2; **93.6** (5.0)
		0.130	2	78.2–83.1; **80.6** (3.5)	77.4–83.1; **80.2** (4.0)
Succulent shelled peas and beans	lambda-cyhalothrin	0.007	5	73.7–98.0; **84.1** (9.2)	73.7–98.0; **84.1** (9.2)
		0.018	1	**89.8**	**89.8**
	R157836	0.013	5	73.5–81.2; **77.0** (3.4)	71.3–81.2; **75.8** (4.2)
		0.032	1	**78.9**	**78.9**
Dried shelled peas and beans	lambda-cyhalothrin	0.00734	3	92.6–108.7; **99.2** (8.4)	69.3–92.6; **81.9** (11.8)
		0.01835	2	83.3–91.6; **87.4** (5.9)	81.5–83.3; **82.4** (1.3)
	R157836	0.01266	3	78.4–95.3; **86.4** (8.5)	74.6–95.3; **85.1** (10.4)
		0.03165	2	77.9–85.6; **81.8** (5.4)	77.9–85.6; **81.8** (5.4)
Peanut hay	lambda-cyhalothrin	0.01	1	**71.4**	**51.8**
		0.07	1	**97.8**	**89.8**
		2.57	1	**82.5**	**82.4**
	R157836	0.013	1	**79.2**	**71.4**
		0.13	1	**84.0**	**82.0**
		4.4	1	**81.1**	**81.1**
Sorghum forage	lambda-cyhalothrin	0.007	1	**120.6**	**120.6**
		0.037	1	**86.4**	**86.4**
		0.07	1	**182.9**	**110.6**
		0.37	1	**84.3**	**84.3**

TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.

Matrix	Compound	Fortification Level (ppm)	# of samples	Recovery (%) as the range, mean, and SD[1,2]	
				Uncorrected	Corrected[3]
	R157836	0.013	1	**93.1**	**93.1**
		0.063	1	**87.7**	**87.7**
		0.13	1	**90.7**	**86.2**
		0.63	1	**84.6**	**84.6**
Sorghum fodder	lambda-cyhalothrin	0.007	1	**86.8**	**86.8**
		0.04	1	**94.0**	**87.6**
		0.11	1	**88.9**	**88.9**
		0.18	1	**95.9**	**95.9**
		0.64	1	**71.0**	**69.8**
	R157836	0.013	1	**101.7**	**92.3**
		0.06	1	**100.8**	**97.7**
		0.19	1	**94.8**	**94.8**
		0.32	1	**95.1**	**95.1**
		0.63	1	**109.6**	**109.0**
Sugarcane (1995 series)	lambda-cyhalothrin	0.007	1	**103.7**	**103.7**
	R157836	.013	1	**113.8**	**113.8**
Sugarcane (1996 series)	lambda-cyhalothrin	0.00734	1	**86.9**	**86.9**
		0.01835	2	85.6–90.6; **88.1** (3.5)	85.6–90.6; **88.1** (3.5)
		0.0367	2	91.6–95.2; **93.4** (2.5)	91.6–95.2; **93.4** (2.5)
		0.0734	1	**96.7**	**96.7**
	R157836	0.01266	1	**90.2**	**90.2**
		0.03165	2	85.3–88.7; **87.0** (2.4)	85.3–88.7; **87.0** (2.4)
		0.0633	2	86.1–88.6; **87.4** (1.8)	86.1–88.6; **87.4** (1.8)
		0.1266	1	**91.9**	**91.9**
Sugarcane (Processing study)	lambda-cyhalothrin	0.184	1	**107.4**	**107.4**
	R157836	0.317	1	**106.2**	**106.2**
Molasses (from sugarcane)	lambda-cyhalothrin	0.037	1	**95.3**	**95.3**
	R157836	0.063	1	**96.2**	**89.0**
Refined sugar (from sugarcane)	lambda-cyhalothrin	0.007	1	**90.7**	**90.7**
	R157836	0.013	1	**92.5**	**88.4**

TABLE 1: Validation recoveries of lambda-cyhalothrin and R157836 from samples of various matrices fortified with lambda-cyhalothrin.

Matrix	Compound	Fortification Level (ppm)	# of samples	Recovery (%) as the range, mean, and SD[1,2]	
				Uncorrected	Corrected[3]
Bagasse (from sugarcane)	lambda-cyhalothrin	0.037	1	**88.3**	**88.3**
	R157836	0.063	1	**91.9**	**91.9**
Avocado	lambda-cyhalothrin	0.02	6	-[4]	78–110; **95.5** (13.3)
		0.05	6	-[4]	59–96; **85.5** (14.0)

Data from pp. 45–46 of MRID 44325703, p. 26 of MRID 44325702, pp. 38–39 of MRID 44325704, pp. 39–40 of MRID 44325705, pp. 42–45 of MRID 44325706, pp. 43–44 of MRID 44325707, pp. 45–48 of MRID 44325708, p. 27 of MRID 44325709, p. 36–37 of MRID 44325712, p. 36–37 of MRID 44325712, pp. 18 and 45 of MRID 44325710, and pp. 65 and 69 of MRID 44325701.

[1]The mean value is in bold-face type and the SD is in parentheses.

[2]Recoveries were calculated by the reviewer based on data presented in the reports; the petitioner presented mostly corrected recoveries, and those sometimes differ from those presented here, primarily because of rounding differences.

[3]Corrected for control interferences by subtracting the concurrent control.

[4]The information on individual samples needed to determine the uncorrected recoveries was provided for only one sample of avocados and that was at the 0.05 ppm fortification level; for that sample the uncorrected and corrected recoveries were 102% and 91%, respectively.

OPPTS GLN 860.1340: Analytical Methods - Animals

Adequate enforcement methods are available for determination of lambda-cyhalothrin residues in animal commodities. ICI Method 86 is used to determine residues of lambda-cyhalothrin in animal matrices (PP#6F3318, M. Firestone, 1/22/86). Parent lambda-cyhalothrin is extracted from milk or animal tissues with 50% acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate. Clean-up is accomplished using Florisil column chromatography. Determination is accomplished using packed column gas chromatography and a ^{63}Ni electron capture detector. The LOQ is 0.01 ppm (PP#7F3488, J. Morales, 11/17/92). ICI Method 86 has been validated by EPA as an adequate enforcement method for determination of parent lambda-cyhalothrin and its epimer in/on animal tissues and milk (PP#6F3318, PP#7F3488, E. Greer, 9/30/87 and PP#6F3318, S. Brooks, 10/30/87).

ICI Method 96, (MRID# 41793501) is used to determine lambda-cyhalothrin metabolites in meat, milk, poultry and eggs. Samples are extracted with acetonitrile:hydrochloric acid or methanol, the extract is diluted with water, and parent lambda-cyhalothrin is removed on a C_{18}-bonded silica cartridge. The eluate is evaporated and refluxed for 4 hours with concentrated hydrochloric acid. The hydrolysate is then partitioned into dichloromethane. For 3-PBAcid and/or 4'-OH-3-PBAcid analyses, the extracts are evaporated, reconstituted in 50% methanol and passed through a C_{18} column. The eluate is evaporated and redissolved in dichloromethane. 3-PBAcid is methylated with diazomethane prior to GCMS with selected ion monitoring (SIM). CPA is benzylated with benzyl bromide and purified on a Florisil column prior to GC with an electron capture detector. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The LOQ is 0.01 ppm (PP#7F3488, J. Morales, 11/17/92). The above details are summarized in PP#5F04588, DP Barcode: D219683, Linda L. Kutney, 8/26/96.

OPPTS GLN 860.1360: Multiresidue Method

The petitioner has determined recoveries of cyhalothrin and its metabolites PP890 and 3-PBAcid under FDA's multiresidue protocols (PP#7F3488, S. Willett's memo of 3/15/88; PP#7F3560/7H5543, M. Flood's memo of 9/19/91). As of 11/2/90, the results had not been listed in FDA's summary (PP#6F4769 & PP#6H4775, DP Barcodes: D228792 & D228931, J. J. Morales, 5/28/97). On the basis of the recoveries made, the multiresidue requirement was considered to have been met in PP#5E4431, 43421701, S. Willett, 6/3/96.

OPPTS GLN 860.1380: Storage Stability Data - Plants

No new studies were submitted with this application. Storage stability data for lambda-cyhalothrin have been previously reviewed. Storage stability data for lambda-cyhalothrin and its epimer indicate that residues are stable in peach, pea, oilseed rape, wheat grain, sugar beet roots, cottonseed, apple, cabbage and potato when stored at -18° C for periods up to 26 months (PP#1F3952/1H5607, M. Flood, 9/19/91). Storage stability data were also reviewed earlier and found to be adequate for alfalfa and lettuce, as summarized below (PP#5F04588; DP code: D219683, Linda L. Kutney, 8/26/96). Alfalfa forage and hay samples were stored frozen at <-15° C for 126-956 days from sampling to extraction and an additional 2-22 days from extraction to analysis. Recoveries reported for alfalfa samples were acceptable (90-123% for lambda-cyhalothrin and 82-129% for its enantiomer). Leaf lettuce samples were stored frozen at <-15° C for 503-720 days from sampling to extraction and an additional 1-7 days from extraction to analysis. The sample storage conditions and timeframes were similar to the concurrent fortified samples. Recoveries reported for leaf lettuce were acceptable (ranging from 73-123%).

OPPTS GLN 860.1380: Storage Stability Data - Animals

No new studies were submitted with this application. The existing animal commodity storage stability data is considered adequate for the purposes of this petition.

OPPTS GLN 860.1500: Crop Field Trials

Avocados (imported)

Zeneca Ag Products has submitted data from 6 field trials on avocados conducted in 1994 in Mexico to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® Insecticide on imported avocados. The KARATE® Insecticide was formulated in Mexico at 7% w/v as an emulsifiable concentrate (EC). Field trials on avocados were conducted at six different sites found at three general locations in Mexico. The results are reported in:

> MRID 44325701. Jones, S.D. (1995) Lambda-cyhalothrin: residue levels in avocados from trials carried out in Mexico during 1994. ZENECA Agrochemicals, Jealott's Hill Research Station, Bracknell Berkshire, UK.; United States address: Zeneca Ag Products, Wilmington, DE 19850-5458. Report No. RJ1997B. November 23, 1995. Unpublished.

All of the magnitude of the residue field trials included two treated plots and one untreated control plot. Each plot was sufficiently large (consisting of 4 avocado trees) to obtain a representative sample without sampling the plot boundaries. Each plot was surrounded by 1–2 "guard" rows of trees to prevent contamination of other plots with the spray. The avocados were grown under typical Mexican climatic conditions and agricultural practices. The Hass variety

was used because it is commonly grown in this geographical area. The spray was applied using a motorized sprayer with 1 nozzle that produced a spray of fine quality. Lambda-cyhalothrin of a KARATE® EC formulation prepared in Mexico was applied in 4 applications at the nominal rate of 0.03 lb ai/A (35 g ai/ha), for a seasonal total application of 0.12 lb ai/A. The first application was 97 days prior to harvest, with subsequent treatments at intervals of 26–34 (usually 30) days. The PHI was 7 days. Spray made by diluting the formulated product with water was applied using 85.5–132.6 gpa (800–1240 L/ha). One sample was collected from each treated plot (2 samples per trial) and each untreated control plot (1 sample per trial). Samples were collected by hand, picking 12 avocados systematically from the central areas of each plot. Samples were frozen within 12 hr of collection and were held at -18° to -21° C until they were shipped frozen to the Jealotts Hill Research Station (Bracknell, Berks, United Kingdom). From then until analysis, samples were stored frozen at below -15° C. Samples were prepared by removing the seeds (which are single and large) and grinding the pulp and skin in a Tecator homogenizer, and they were analyzed for lambda-cyhalothrin alone (and not its epimer R157836) using Analytical Method 081/03 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to analysis was 7 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on avocados are summarized in Table 2.

Residue levels of lambda-cyhalothrin in/on avocados were 0.03–0.11 ppm. The HAFT for lambda-cyhalothrin of 0.085 ppm was found both at Huerta Jaramillo and Huerta El Lloron. The mean ± SD of the residue of lambda-cyhalothrin in/on avocados was 0.072 ± 0.026 ppm. All 6 untreated control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin. Fortification levels bracketed the residue levels for lambda-cyhalothrin at only the lower end. The highest fortification level of 0.05 ppm is 45% of the highest concentration of residue found.

TABLE 2: Residues of lambda-cyhalothrin in/on avocados following 4 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A for a seasonal total of 0.12 lb ai/A, with re-treatment intervals of approximately 30 days and a pre-harvest interval (PHI) of 7 days.

Test location in Mexico	Variety of crop	Residue levels of lambda-cyhalothrin (ppm)[1]
Huerta Jaramillo	Hass	0.10; 0.07
Huerta Tanazuro	Hass	0.03; 0.03
Rancho San Jose	Hass	0.09; 0.1
Huerta La Joya	Hass	0.06; 0.07
Huerta El Monje	Hass	0.08; 0.07
Huerta El Lloron	Hass	0.06; 0.11

Data from pp. 14, 18, 25, 32, 39, 48, and 55 of MRID 44325701.

[1]Values are not corrected for procedural recoveries or control values; no measurement was made of the epimer R157836. The limit of quantitation (LOQ) was 0.01 ppm for lambda-cyhalothrin.

Conclusions: The petitioner has requested a permanent tolerance of 0.2 ppm on imported avocados for use of lambda-cyhalothrin as the formulation KARATE® Insecticide. The recommended minimum numbers of field trials and samples to support a tolerance on avocados grown in the United States are 5 and 10, respectively. The petitioner reported results from 6 field trials and 12 treated samples of avocados raised according to typical Mexican agricultural practices. Tolerances established for lambda-cyhalothrin are for the combined residues of lambda-cyhalothrin and its epimer R157836; however, the residue of R157836 was not quantified in this study. Nonetheless, information on the other crops discussed in this report provides ample evidence that the expected residues of R157836 would be so much smaller than those for lambda-cyhalothrin that the lack of data on R157836 is not considered to be a serious limitation of the study. Indeed, for the only 4 crops in this petition for which residues of R157836 exceeded its LOQ of 0.01 in at least one sample, residues of lambda-cyhalothrin exceeded those of R157836 by at least 5 fold even when the values < 0.01 ppm were considered to be 0.01 ppm when computing mean values for each residue. The ratios of the means (i.e., mean ppm of lambda-cyhalothrin divided by mean ppm of R157836) for these four crops were as follows: 6.1 for peanut hay, 5.0 for edible-podded peas, 8.8 for sorghum forage, and 9.1 for sorghum fodder. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® Insecticide on imported avocados. Method-validation data support the reliability of the residue data. The failure to provide any residue decline studies is not considered a serious limitation because lambda-cyhalothrin is known to be non-systemic, and it has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

Cereal Grains, Crop Group 15 (except rice and wild rice)

Although Zeneca Ag Products has provided no new data from crop field trials on wheat and other small grain crops (said, on their proposed label, to include barley, buckwheat, pearl millet, proso millet, oats, rye, teosinte, and triticale), it has submitted a proposed label that includes a use for this group of crops (taken as a whole), and it has proposed permanent tolerances in Section F of the petition for the cereal grain crop group (except rice and wild rice) for grain, forage (except sorghum), hay, straw, aspirated grain dust, bran, and flour. Currently, there are established tolerances for aspirated grain fractions, corn (grain of field corn and popcorn, fodder, forage, and flour), sweet corn, rice (grain, hulls, and straw), sorghum grain, and wheat (grain, forage, hay, straw, and bran). The petitioner argues in Section D of the petition that this group of tolerances can be broadened to the entire crop group 15 (excluding rice and wild rice, but including the wide array of small grains) because the existing tolerances for all of the representative crops (except for rice) of the cereal grain crop group meet the Agency's 'factor of 5' rule. According to that rule, the maximum residues of the representative crops must be within a factor of 5 to share the same tolerance, and the tolerances of these crops differ by 4-fold at most when the established tolerance levels for each grain are taken to reflect the maximum residues. The specific tolerances are as follows for each representative type of grain: 0.05 ppm for sweet corn, 0.05 for field corn, 0.2 ppm for sorghum, and 0.05 ppm for wheat.

Conclusions:

The petitioner's argument regarding the Agency's 'factor of 5' rule does not justify a tolerance for all members of the cereal grains, crop group 15 (except rice and wild rice) because the use patterns of the representative crops that were compared (namely sweet

corn, field corn, sorghum, and wheat) are substantially different. The establishment of tolerances for entire crop groups or crop subgroups assumes that the use patterns are reasonably similar. When they are not, similarities in residue levels do not confer confidence that the different crops respond rather similarly (or at least differ by no more than a factor of 5). To illustrate the differences in use patterns for crops that the petitioner wants to include in one group, the maximum application rates per season for sweet corn and wheat are 0.48 lb ai/A and 0.06 lb ai/A, respectively. Furthermore, the PHIs for sweet corn, field corn, sorghum, and wheat are 1, 21, 30, and 30 days, respectively. The proposed new label for KARATE® Insecticide 1EC maintains the same (and distinct) use patterns as in the present label for (1) field corn, popcorn, seed corn, (2) sweet corn, (3) and sorghum. The presently used label also has a separate use for wheat, wheat hay, and triticale (taken as a group). The petitioner indicated that that use should be deleted as part of its request to have tolerances for all of the small grains. Because their request is being denied, the separate proposed use for wheat, wheat hay, and triticale (taken as a group) on the present label should be retained. **The following instructions from paragraph (e) (2) (vii) (F) of Guidelines OPPTS 860.1500 Crop Field Trials state precisely what the petitioner must do to obtain the desired tolerances: "Although there is no crop group for 'small grains' in CFR 180.41, for data generation purposes wheat, barley, oats, and rye may be treated as a group. Provided use patterns and resulting residues are similar, the numbers of trials for wheat, barley, and oats may be reduced to 15, 9, and 12, respectively. Five trials are still needed for rye. The tolerances will be established on the individual crops due to the lack of an official small grain crop group." Since the publication of the guidelines, the Chemistry Science Advisory Council (ChemSAC) concluded that data would not be needed on rye (memo dated 1/9/98). There is no indication that the petitioner has conducted any crop field trials on barley and oats.**

Crop Group 8: Fruiting Vegetables (Except Cucurbits)

Zeneca Ag Products has submitted data from 8 field trials on bell peppers and 3 field trials on non-bell peppers conducted in 1996 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on fruiting vegetables (except cucurbits), i.e., crop group 8. There is already an established tolerance for tomatoes, which is the only other representative commodity in this crop group. Field trials on bell peppers were conducted in EPA crop regions 2 (1 in NC and 1 in NJ), 3 (2 in FL), 5 (IL), 6 (TX), and 10 (1 in AZ and 1 in CA), and field trials on non-bell peppers were conducted in EPA crop regions 8 (NM), 9 (AZ), and 10 (CA). The results are reported in:

MRID 44325702. Markle, J.C., P.D. Francis, M.T. Kepler, and E.M. Roper (1997) Lambda-cyhalothrin (ICIA0321): residue levels on peppers (non-bell) from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-105B. January 23, 1997. Unpublished.

and

MRID 44325703. Markle, J.C., P.D. Francis, M.T. Kepler, and E.M. Roper (1997) Lambda-cyhalothrin (ICIA0321): residue levels on bell peppers from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-103B. February 26, 1997. Unpublished.

All magnitude of the residue field trials included one treated plot and one untreated control plot. Lambda-cyhalothrin as the formulation KARATE® was applied in 12 applications as a broadcast foliar spray using either a CO_2 pressurized backpack sprayer or a tractor-mounted sprayer at the rate of 0.03 lb ai/A, for a seasonal total application of 0.36 lb ai/A, with re-treatment intervals of 5–10 days and a PHI of 5 days. This use pattern reflects the worst case permitted by the label with respect to residue levels. The first applications were made 60–110 days and 74–93 days prior to harvesting the peppers and non-bell peppers, respectively. Spray made by diluting the formulated product with water was applied using 8–30 and 8.6–33 gpa on peppers and non-bell peppers, respectively. With one exception, two samples were collected from treated plots and one sample from untreated control plots. The exception had a single sample from the treated plot. Samples for bell peppers and non-bell peppers weighed at least 4 and 4.5 lb, respectively, and they were harvested from at least 12 separate plants, avoiding plants near plot boundaries. Samples were frozen within 2.5 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Hobart VCM-40 or VCM-25 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. For bell peppers and non-bell peppers, the periods of frozen storage prior to extraction and analysis were less than 3 and 2–5 months, respectively. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on bell peppers and and non-bell peppers are summarized in Table 3.

Results from each test of each sample were reported, and residue data were not corrected for procedural recoveries or for control interferences. Residue levels of lambda-cyhalothrin in/on bell peppers were 0.01–0.15 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 2 of 15 samples being 0.01 ppm. The HAFT for bell peppers for the combined residues was 0.16 ppm at St. Paul, TX, and the mean ± SD of the combined residues in/on bell peppers was 0.070 ± 0.048 ppm. (In this calculation, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) There were no residue decline trials for bell or non-bell peppers. Control samples from 7 of the 8 trials were below the LOQ of 0.01 ppm for lambda-cyhalothrin. Duplicate control samples from the other trial, at Ft. Pierce, FL, were 0.03 and 0.04 ppm, and residue levels from that trial were among the highest levels found. All control samples were below the LOQ of 0.01 ppm for R157836. Fortification levels bracketed the residue levels found for lambda-cyhalothrin, but not for R-157836, for which the lowest fortification level slightly exceeded the LOQ that was applied.

Residue levels of lambda-cyhalothrin in/on non-bell peppers were 0.02–0.12 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 2 of 6 samples being 0.01 ppm. The HAFT for non-bell peppers for the combined residues was 0.13 ppm at Safford, AZ, and the mean ± SD of the combined residues was 0.087 ± 0.043 ppm. (In this calculation, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) For each type of residue, none of the 3 control samples exceeded the LOQ of 0.01 ppm. Fortification levels did not bracket the residue levels found for either residue.

TABLE 3: **Residues of lambda-cyhalothrin and its epimer R157836 in/on bell peppers and non-bell peppers following 12 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A, for a seasonal total application of 0.36 lb ai/A, with re-treatment intervals of 5–10 days and a pre-harvest interval of 5 days.**

Test location: Nearest city, state (EPA crop region)	Variety of crop	Residue levels (ppm)[1]		
		lambda-cyhalothrin	epimer R157836	Sum of all residues
Bell peppers				
Whitakers, NC (2)	California Wonder	0.05; 0.04	< 0.01; < 0.01	< 0.06; < 0.05
Cornish Point, NJ (2)	Camelot	0.02	< 0.01	< 0.03
Oviedo, FL (3)	California Wonder	0.05; 0.05	< 0.01; < 0.01	< 0.06; < 0.06
Ft. Pierce, FL (3)	California Wonder	0.07; 0.12[2]	< 0.01; < 0.01	< 0.08; < 0.13
Champaign, IL (5)	Bell Captain	0.02; 0.01	< 0.01; < 0.01	< 0.03; < 0.02
St. Paul, TX (6)	860 Rogers NK	0.15; 0.15	0.01; 0.01	0.16; 0.16
Yuma, AZ (10)	Ivan	0.02; 0.02; 0.02[3]	< 0.01; < 0.01; < 0.01[3]	< 0.03; < 0.03; < 0.03[3]
Visalia, CA (10)	Jupiter	0.01; 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Non-bell peppers				
Portales, NM (8)	Big Jim	0.09; 0.08	< 0.01; < 0.01	< 0.10; < 0.09
Safford, AZ (9)	Navajaro	0.12; 0.12	0.01; 0.01	0.13; 0.13
Visalia, CA (10)	Fresno Chili Grande	0.03; 0.02; 0.02[3]	< 0.01; < 0.01; < 0.01[3]	< 0.04; < 0.03; < 0.03[3]

Data from pp. 9, 17, and 20 of MRID 44325703 and pp. 9, 16, and 19 of MRID 44325702.
[1]Values are not corrected for procedural recoveries and control values.
[2]Uncorrected for duplicate control values of 0.03 and 0.04 ppm, respectively; all other controls for peppers (bell and non-bell) were <0.01 ppm for both residues.
[3]Duplicate analysis of second sample.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on crop group 8: fruiting vegetables (except cucurbits). According to OPPTS Guideline 860.1500, a combination of 12 field trials on tomatoes, 6 field trials on bell peppers, and 3 field trials on non-bell peppers is adequate to support a tolerance on fruiting vegetables (except cucurbits). The petitioner reported results from 8 field trials on bell peppers and 3 on non-bell peppers. There is currently an established tolerance of 0.1 ppm on tomatoes and tomatilloes. The former proposed use for tomatoes and tomatilloes is identical to that proposed for the entire crop group 8, with the exception that on the proposed label there is a note to remove the following restriction: "Do not use on varieties in which the mature tomatoes will be less than one inch in diameter (such as cherry tomatoes)." Considering the higher residues found on peppers (relative to the existing tolerance), the change is acceptable. Method-validation data support the reliability of the residue data. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.2 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on crop group 8: fruiting vegetables (except cucurbits).

Peanut hay

Zeneca Ag Products has submitted data from 11 field trials on peanut hay conducted in 1995 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on peanuts, with there being no restriction (as there is presently) on the use of peanut vines for hay or forage. There is already an established tolerance for peanuts. Field trials on peanut hay were conducted in EPA crop regions 2 (2 in AL, 2 in GA, 2 in NC, and 1 in VA), 3 (FL), and 6 (1 in OK, 2 in TX). The results are reported in:

> MRID 44325707. Roper, E.M., P.D. Francis, M.T. Kepler, and J.C. Markle (1996) Lambda-cyhalothrin (ICIA0321): residue levels on peanut hay from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-073B. October 31, 1996. Unpublished.

All magnitude of the residue field trials included one treated plot and one untreated control plot. Lambda-cyhalothrin as the formulation KARATE® was applied in 4 applications as a broadcast foliar spray using either a CO_2 pressurized backpack sprayer or a tractor-mounted sprayer at the rate of 0.03 lb ai/A, for a seasonal total application of 0.12 lb ai/A, with re-treatment intervals of 7–10 days. The interval from last treatment until digging of the peanuts, which EPA defines as harvest, was 12–21 days, and the peanuts were allowed to dry in the field for 3–7 days before sample collection (total of 17-24 days from last application). The first applications were made 33–49 days prior to digging the peanuts. Spray made by diluting the formulated product with water was applied using 10–30 gpa. Two samples were collected from treated plots and one sample from untreated control plots. Samples of hay weighed at least 1.0 lb and were harvested by hand or by machine. The hay was harvested from at least 12 separate plants, avoiding plants near plot boundaries. Samples were frozen within 3 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Hobart VCM-40 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The periods of frozen storage prior to extraction and analysis were 6–9 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on peanut hay are summarized in Table 4.

Results from each test of each sample were reported, and residue data were not corrected for procedural recoveries or for control interferences. Residue levels of lambda-cyhalothrin in/on peanut hay were 0.34–2.2 ppm, and residue levels of R157836 were 0.06–0.41 ppm. The HAFT for peanut hay for the combined residues was 2.36 ppm at Malone, FL. The mean ± SD of the combined residues in/on peanut hay at a PHI of 17–24 days was 1.22 ± 0.67 ppm. (In this calculation, duplicates for individual samples were averaged.) There was no residue decline trial. All control samples were below the LOQ of 0.01 ppm for both lambda-cyhalothrin and R157836. Fortification levels bracketed the residue levels found for both lambda-cyhalothrin and R157836. Five of the trials, including the one with the HAFT, were affected by Hurricane Opal, which

produced 2.7–6.4 in of rain either immediately before the peanuts were dug or while they were drying.

TABLE 4: Residues of lambda-cyhalothrin and its epimer R157836 in/on peanut hay following 4 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A for a seasonal total of 0.12 lb ai/A, with re-treatment intervals of 6–10 days.

Test location: Nearest city, state (EPA crop region)	Variety of crop	PHI[1]	Residue levels (ppm)[2]		
			lambda-cyhalothrin	epimer R157836	Sum of all residues
Enterprise, AL (2)	Florunner	17	1.3; 0.99	0.25; 0.19	1.55; 1.18
Headland, AL (2)	Florunner	24	1.6; 0.91	0.23; 0.13	1.83; 1.04
Ivor, VA (2)	NC10	21	0.91; 1.4 1.3[3]	0.11; 0.14 0.13[3]	1.02; 1.54 1.43[3]
Statesboro, GA (2)	Georgia Runner	20	0.59; 0.34	0.12; 0.07	0.71; 0.41
Sunsweet, GA (2)	Georgia Runner	21	1.6; 1.3	0.32; 0.27	1.92; 1.57
Whitakers, NC (2)	VA92R	18	0.35; 0.35	0.06; 0.06	0.41; 0.41
Windsor, NC (2)	NC7	19	0.65; 0.46	0.11; 0.10	0.76; 0.56
Malone, FL (3)	Florunner	22	2.2; 1.8	0.41; 0.32	2.61; 2.12
Brookshire, TX (6)	Spanish	20	0.43; 0.54	0.09; 0.12	0.52; 0.66
Dill City, OK (6)	Spanco	19	1.3; 0.87	0.11; 0.11	1.41; 0.98
Yoakum, TX (6)	Florunner	19	1.1; 2.2	0.18; 0.29	1.28; 2.49

Data from pp. 10, 19, 23, and 44 of MRID 44325707.
[1]Pre-harvest interval plus drying interval.
[2]Values are not corrected for procedural recoveries or control values.
[3]Duplicate for sample immediately above it.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 3.0 ppm for peanut hay for use of lambda-cyhalothrin on peanuts. The recommended minimum numbers of field trials and samples to support a tolerance on peanuts are 12 and 24, respectively. A tolerance of 0.05 ppm was established earlier for peanuts themselves but not for the hay. The proposed use is identical to that currently in use on peanuts, except that it is proposed that the following restriction be removed: "Do not graze livestock in treated areas. Do not use treated vines or hay for animal feed." The petitioner deviated from the recommendation regarding geographical distribution in that there were 7 crop trials instead of 8 in region 1, 3 instead of 2 in region 6, and none when there should have been one in region 8. There was one as recommended in region 3. In total, there were 11 trials and 22 samples, which is slightly below the minimum recommended, and no explanation was given for the shortfall. Method-validation data support the reliability of the residue data. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 3.0 ppm on peanut hay for use of lambda-cyhalothrin on peanuts.

Edible-Podded Legume Vegetables Subgroup (Crop Subgroup 6A)

Zeneca Ag Products has submitted data from 3 field trials on edible-podded peas and 6 field trials on edible-podded beans conducted in 1996 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the edible-podded legume vegetables subgroup (crop subgroup 6A). Field trials on edible-podded peas were conducted in EPA crop regions 2 (MD), 5 (WI), and 11 (WA), and field trials on edible-podded beans were conducted in EPA crop regions 1 (NY), 2 (NC), 3 (FL), 5 (1 in MI and 1 in WI), and 11 (OR). The results are reported in:

> MRID 44325704. Markle, J.C., P.D. Francis, and M.T. Kepler (1997) Lambda-cyhalothrin (ICIA0321): residue levels on edible-podded peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-106B. April 9, 1997. Unpublished.

All field trials were magnitude of the residue trials. All trials included one treated plot and one untreated control plot. Lambda-cyhalothrin as the formulation KARATE® was applied in 4 or 5 applications as a broadcast foliar spray using either a CO_2 pressurized backpack sprayer or a tractor-mounted sprayer at the rate of 0.03 lb ai/A, for a seasonal total application of 0.12 lb ai/A (i.e., 1x application rate) or 0.15 lb ai/A (i.e., 1.25x application rate), with re-treatment intervals of 5–7 days and a PHI of 7 days, intervals consistent with the proposed label. The first applications were made 23–35 days prior to harvest. Spray made by diluting the formulated product with water was applied using 9–30 gpa. Two samples were collected from treated plots and one sample from untreated control plots. Samples were harvested by hand, and they weighed at least 2.0 lb (including pods). Samples were collected from at least 12 separate plants, avoiding plants near plot boundaries. Samples were frozen within 1 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Hobart VCM-40 or VCM-25 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was 1–5 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on edible-podded peas and edible-podded beans are summarized in Table 5.

Results from each test of each sample were reported, and residue data were not corrected for procedural recoveries or for control interferences. Residue levels of lambda-cyhalothrin in/on edible-podded peas at the 1x application rate were 0.01–0.12 ppm, and residue levels of R157836 were <0.01–0.02 ppm, with 2 of 6 samples being 0.01 ppm or higher. The HAFT for edible-podded peas at the 1x application rate for the combined residues was 0.12 ppm at Walla Walla, WA, and the mean ± SD was 0.066 ± 0.047 ppm. In this calculation, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm. There were no residue decline trials for edible-podded peas. Control samples from all trials were below the LOQs of 0.01 ppm for lambda-cyhalothrin and R157836. Fortification levels did not bracket the residue levels found for either residue. (For lambda-cyhalothrin the maximum fortification was 0.073 ppm and the maximum residue was 0.12 ppm.)

Residue levels of lambda-cyhalothrin in/on edible-podded beans at the 1.0–1.25x application rates were 0.01–0.03 ppm, and residue levels of R157836 were all <0.01 ppm. The HAFT for edible-podded beans for the combined residues was 0.035 ppm at both Williamson, NY, (which was the only trial with a 1.25 application rate) and Whitakers, NC. (In calculating the HAFT, samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) The mean ± SD of the combined residues in/on edible-podded beans (at the 1.0–1.25x application rates) was 0.031 ± 0.005 ppm. In this calculation, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm. Control samples from all trials were below the LOQs of 0.01 ppm for lambda-cyhalothrin and R157836. Fortification levels bracketed the residue levels for lambda-cyhalothrin and almost did so for R157836.

TABLE 5: Residues of lambda-cyhalothrin and its epimer R157836 in/on edible-podded peas and beans following 4 or 5 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A, with re-treatment intervals of 5–7 days and a pre-harvest interval of 7 days.

Test location: Nearest city, state (EPA crop region)	Variety of crop	Total application rate in lb ai/A/season	Residue levels (ppm)[1]		
			lambda-cyhalothrin	epimer R157836	Sum of all residues
Peas					
Sudlersville, MD (2)	Oregon Sugarpod #2	0.12	0.04; 0.05	< 0.01; <0.01	< 0.05; < 0.06
Baraboo, WI (5)	Sugar Snap	0.12	0.01; 0.01	< 0.01; <0.01	< 0.02; < 0.02
Walla Walla, WA (11)	Oregon Sugar Pod	0.12	0.11 0.12; 0.10[2]	0.01 0.02; 0.01[2]	0.12 0.14; 0.11[2]
Beans					
Williamson, NY (1)	Long Tendergreen	0.15 (1.25x)	0.02; 0.03	< 0.01; <0.01	< 0.03; <0.04
Whitakers, NC (2)	Contender	0.12	0.03; 0.02	< 0.01; <0.01	< 0.04; <0.03
Oviedo, FL (3)	Contender	0.12	0.01 0.02; 0.02[2]	< 0.01 < 0.01; <0.01[2]	< 0.02 < 0.03; <0.03[2]
Conklin, MI (5)	Spartan Arrow	0.12	0.02; 0.02	< 0.01; <0.01	< 0.03; <0.03
Baraboo, WI (5)	Early Contender	0.12	0.02; 0.02	< 0.01; <0.01	< 0.03; <0.03
Ontario, OR (11)	Gold Mine	0.15	0.02; 0.02	< 0.01; <0.01	< 0.03; <0.03

Data from pp. 9, 18, and 22 of MRID 44325704.
[1]Values are not corrected for procedural recoveries or control values.
[2]Duplicate analysis of second sample.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 0.2 ppm for use of lambda-cyhalothrin on the edible-podded legume vegetables subgroup (crop subgroup 6A). According to OPPTS Guideline 860.1500, a combination of 3 field trials on one succulent cultivar of edible podded pea and 6 field trials on one succulent cultivar of edible podded bean is adequate to support a tolerance on crop subgroup 6A. The petitioner reported results from 3 field trials on varieties of edible-podded peas and 6 field trials on varieties of edible-podded beans. The geographic diversity of the trials was compared to that recommended for snap beans and succulent garden peas. There was perfect agreement for beans and adequate agreement for peas. The recommendation for peas is given for 6 field trials, in which there should be 1 from either

Region 1 or 2, and from Regions 5, 11, and 12, there should be 3, 1, and 1 trials, respectively. There was one trial reported from each of Regions 2, 5, and 11. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.2 ppm for use of lambda-cyhalothrin on the edible-podded legume vegetables subgroup (crop subgroup 6A). Method-validation data support the reliability of the residue data. The failure to provide any residue decline studies is not considered a serious limitation because lambda-cyhalothrin is known to be non-systemic, and it has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

Succulent Shelled Pea and Bean Subgroup, Crop Subgroup 6B

Zeneca Ag Products has submitted data from 6 field trials on succulent shelled peas and 6 field trials on succulent shelled beans conducted in 1996 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the succulent shelled pea and bean subgroup (crop subgroup 6B). Field trials on succulent shelled peas were conducted in EPA crop regions 2 (MD), 5 (1 each in IL, MN, and WI), 11 (WA), and 12 (OR). Field trials on succulent shelled beans were conducted in EPA crop regions 2 (1 in MD and 1 in SC), 5 (IL), 10 (2 in CA), and 11 (WA). The results are reported in:

> MRID 44325705. Markle, J.C., P.D. Francis, and M.T. Kepler (1997) Lambda-cyhalothrin (ICIA0321): residue levels on succulent shelled peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 97-007B. May 28, 1997. Unpublished.

All magnitude of the residue field trials included one treated plot and one untreated control plot. Lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 4 or 5 applications as a broadcast foliar spray using either a CO_2 pressurized backpack sprayer or a tractor-mounted sprayer at the nominal rate of 0.03 lb ai/A, for a seasonal total application of from 0.12 lb ai/A (i.e., 1x application rate) to 0.15 lb ai/A (i.e., 1.25x application rate), with re-treatment intervals of 4–7 days and a PHI of 7 days (except for 1 trial with a PHI of 6 days), intervals consistant with the proposed label. The first applications were made 21–42 days prior to harvest. Spray made by diluting the formulated product with water was applied using 9–28 gpa. Two samples were collected from treated plots and one sample from untreated control plots. Samples were harvested by hand, and they weighed at least 2.0 lb, with the exception of the trial in WA for which the sample weighed 0.9 lb. Samples were collected from at least 12 separate plants, avoiding plants near plot boundaries. Although it was not stated, it seems likely that the samples were seeds without pods because the RAC is defined that way and residues were very low in concentration. Samples were frozen within 2 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Hobart VCM-40 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was 1–6 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period

of storage. The results from the field trials on succulent shelled peas and succulent shelled beans are summarized in Table 6.

Results from each test of each sample were reported, and residue data were not corrected for procedural recoveries or for control interferences. All residue levels of both lambda-cyhalothrin and R157836 in/on succulent shelled peas at the 1.00–1.06x application rates were below 0.01 ppm. Residue levels of both lambda-cyhalothrin and R157836 in/on succulent shelled beans at the 1.00–1.25x application rates were also all below 0.01 ppm. For both succulent shelled peas and succulent shelled beans, control samples from all trials were below the LOQs of 0.01 ppm for lambda-cyhalothrin and R157836. There were no residue decline trials. Fortification levels did not bracket the residue levels found for R157836, with the lowest fortification level being 0.013 ppm.

TABLE 6: Residues of lambda-cyhalothrin and its epimer R157836 in/on succulent shelled peas and beans following 4 or 5 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A, with re-treatment intervals of 4–7 days and a pre-harvest interval (PHI) of 7 days (unless noted) or 6 days.

Test location: Nearest city, state (EPA crop region)	Variety of crop	Total application rate in lb ai/A/season and (No. of applications)	Residue levels (ppm)[1]		
			lambda-cyhalothrin	epimer R157836	Sum of all residues
Peas					
Sudlersville, MD (2)	Early Freezer 680	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Champaign, IL (5)	Knight	0.122 (4)	< 0.01; < 0.01; < 0.01[2]	< 0.01; < 0.01; < 0.01[2]	< 0.02; < 0.02; < 0.02[2]
Cannon Falls, MN (5)	Freezer Packer	0.127 (4)[3]	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Delevan, WI (5)	Quad	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Moses Lake, WA (11)	June Lot #332272	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Hillsboro, OR (12)	Methow	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Beans					
Sudlersville, MD (2)	Fordhook 1072	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Elko, SC (2)	Cangreen	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Champaign, IL (5)	Fordhook 242	0.15 (5)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Visalia, CA (10)	Fordhook 242	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Live Oak, CA (10)	Henderson Baby Lima	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Moses Lake, WA (11)	Mendoza	0.12 (4)	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02

Data from pp. 9–10, 18, 22, 25–27 of MRID 44325705.
[1]Values are not corrected for procedural recoveries or control values.
[2]Duplicate analysis of second sample.
[3]PHI of 6 days.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 0.01 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the succulent shelled pea and bean subgroup, crop subgroup 6B. According to OPPTS Guideline 860.1500, a combination of 6 field trials on one garden pea variety and 6 field trials on one succulent shelled cultivar of bean is adequate to support a tolerance on crop subgroup 6B. The petitioner reported results from 6 field trials on varieties of succulent shelled peas and 6 field trials on varieties of succulent shelled beans. The geographic diversity of the trials was compared to the distribution recommended for green lima beans and garden peas. There was perfect agreement for succulent garden peas, for which the recommendation is that there should be 1 trial from either Region 1 or 2, as well as 3, 1, and 1 trials from Regions 5, 11, and 12, respectively. For succulent shelled beans, there should be 3 trials from Region 2, and 1 each from Regions 5, 10, and 11. The petitioner reported results for 2 trials instead of 3 in Region 2 and from 2 trials instead of 1 in Region 10. The other two regions had exactly the recommended number. The percentages of this crop grown in Regions 2, 5, 10, and 11 are 46%, 12%, 28%, and 11%, respectively. Especially in view of these percentages, the geographical distribution is adequate. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.01 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the succulent shelled pea and bean subgroup (crop subgroup 6B). The concentration of 0.01 ppm is the LOQ for lambda-cyhalothrin alone (as well as for R157836 alone), but it seems reasonable to use this concentration as the tolerance level for both lambda-cyhalothrin and R157836 because (1) every sample for lambda-cyhalothrin was below the LOQ and (2) because for all of the several crops considered in this petition that have much higher residue levels, the residue levels for lambda-cyhalothrin are always much higher than those for R157836. Method-validation data support the reliability of the residue data. The failure to provide any residue decline studies is not considered a serious limitation because all residue levels were below the LOQ of 0.01 ppm at the PHI of 6–7 days. Furthermore, lambda-cyhalothrin is known to be non-systemic, and it has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

Since there are animal feed items of regulatory interest for croup group 6B, notably cowpea hay and forage, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for succulent shelled pea and bean subgroup, crop subgroup 6B: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

Dried Shelled Pea and Bean (Except Soybean) Subgroup, Crop Subgroup 6C

Zeneca Ag Products has submitted data from 5 field trials on dried shelled peas and 9 field trials on dried shelled beans conducted in 1996 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on the dried shelled pea and bean (except soybean) subgroup (crop subgroup 6C). Field trials on dried shelled peas were all conducted in EPA crop region 11 (2 in ID, 1 in OR, and 2 in WA), and field trials on dried shelled beans were conducted in EPA crop regions 5 (2 in MI and 2 in ND), 7 (NE), 8 (CO), 9 (CO), 10 (CA), and 11 (ID). The results are reported in:

> MRID 44325706. Markle, J.C., P.D. Francis, C.J. Spillner, and S.G. Patterson (1997) Lambda-cyhalothrin (ICIA0321): residue levels on dried, shelled peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western

Research Center, 1200 South 47th Street, Richmond, CA 94804-4610. Report No. RR 97-016B. June 11, 1997. Unpublished.

All field trials were magnitude of the residue trials. All trials included one treated plot and one untreated control plot. Lambda-cyhalothrin as the formulation KARATE® was applied in 4 applications as a broadcast foliar spray using either a CO_2 pressurized backpack sprayer or a tractor-mounted sprayer at the rate of 0.03 lb ai/A, for a seasonal total application of 0.12 lb ai/A (i.e., 1x application rate), with re-treatment intervals of 5–8 days (excepted for an interval of 10 days between the last two treatments in the trial at Orchard City, CO). The PHI was 19–21 days except at Brampton, ND, where it was 24 days. The proposed PHI is 21 days. The first applications were made 37–43 days prior to harvest. Spray made by diluting the formulated product with water was applied using 8.62–22.5 gpa. Two samples were collected from treated plots and one sample from untreated control plots. Samples of dried, shelled, peas or beans were harvested by hand or with a mechanical harvester, and they weighed at least 2.0 lb except at Johnstown, CO, where the two samples weighed only 0.8 and 1.4 lb due to crop disease problems. Samples were collected from at least 12 separate plants, avoiding plants near plot boundaries. Samples were frozen within 2.5 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Brinkman Centrifugal Mill until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was from about 3 to 6 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on dried shelled peas and dried shelled beans are summarized in Table 7.

Results from each test of each sample were reported, and residue data were not corrected for procedural recoveries or for control interferences. Residue levels of lambda-cyhalothrin in/on dried shelled peas were <0.01–0.05 ppm, and residue levels of R157836 were <0.01–0.01 ppm, with only 1 of 10 independent samples being 0.01 ppm. The HAFT for dried shelled peas for the combined residues was 0.050 ppm at Hermiston, OR. (To estimate this, the one value of <0.01 ppm was considered to be 0.01 ppm.) The mean ± SD of the combined residues in/on dried shelled peas was 0.026 ± 0.013 ppm. (In this calculation, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) There were no residue decline trials for dried shelled peas. Control samples from all trials were below the LOQs of 0.01 ppm for lambda-cyhalothrin and R157836. Fortification levels did not bracket the residue levels found for either residue. (For lambda-cyhalothrin the maximum fortification was 0.01835 ppm and the maximum residue was 0.05 ppm.)

Residue levels of lambda-cyhalothrin and R157836 in/on dried shelled beans were all below the LOQ of 0.01 ppm except for in one sample, where the level was exactly 0.01 ppm for lambda-cyhalothrin. The HAFT for dried shelled beans for the combined residues was 0.02 ppm at all locations. (In calculating the HAFT, samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) The mean ± SD of the combined residues in/on dried shelled beans at a PHI of 19–24 days was 0.02 ± 0 ppm. (In this calculation, duplicates for individual samples were

averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) Control samples from all trials were below the LOQs of 0.01 ppm for lambda-cyhalothrin and R157836. Fortification levels bracketed the residue levels for lambda-cyhalothrin and almost did so for R157836.

TABLE 7: Residues of lambda-cyhalothrin and its epimer R157836 in/on dried shelled peas and beans following 4 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.03 lb ai/A for a seasonal total of 0.12 lb ai/A, with re-treatment intervals of 5–10 days.

Test location: Nearest city, state (EPA crop region)	Variety of crop	Pre-harvest interval (days)	Residue levels (ppm)[1]		
			lambda-cyhalothrin	epimer R157836	Sum of all residues
Peas					
Moscow, ID (11)	Columbia	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Genesee, ID (11)	Columbia	21	< 0.01; < 0.01; < 0.01[2]	< 0.01; < 0.01; < 0.01[2]	< 0.02; < 0.02; < 0.02[2]
Hermiston, OR (11)	Balero	21	0.05; 0.03	0.01; < 0.01	0.06; < 0.04
Moses Lake, WA (11)	Polar Lot# 657071	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Walla Walla, WA (11)	Columbia	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Beans					
Conklin, MI (site 1) (5)	Avanti	20	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Conklin, MI (site 2) (5)	Sierra	20	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Northwood, ND (5)	Norstar	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Brampton, ND (5)	Agri 1	24	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Madrid, NE (7)	Foxfire	20	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Johnstown, CO (8)	Bilz	19	0.01; < 0.01; < 0.01[2]	< 0.01; < 0.01; < 0.01[2]	< 0.02; < 0.02; < 0.02[2]
Orchard City, CO (9)	Bill Z	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Visalia, CA (10)	Greencrop	21	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02
Minidoka, ID (11)	Pink Rosa	20	< 0.01; < 0.01	< 0.01; < 0.01	< 0.02; < 0.02

Data from pp. 9, 20, 24, 42–45 of MRID 44325706.
[1]Values are not corrected for procedural recoveries or control values.
[2]Duplicate analysis of second sample.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 0.1 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the dried shelled pea and bean (except soybean) subgroup (crop subgroup 6C). According to OPPTS Guideline 860.1500, a combination of 5 field trials on one dried cultivar of pea (genus *Pisum*) and 9 field trials on one dried cultivar of bean (genus *Phaseolus*) is adequate to support a tolerance on crop subgroup 6C. The petitioner reported results from 5 field trials on varieties of dried peas and 9 field trials on varieties of dried beans. The geographic diversity of the bean trials was in perfect agreement with that recommended for dried beans. The 5 field trials for dried peas must be made on the *Pisum* spp. Accordingly, the recommended geographic distribution for trials on cowpeas is not

applicable because cowpeas are more closely related to the beans (*Phaseolus*) than to the peas (*Pisum*). No particular distribution per region is recommended in the guidelines for dried peas. All 5 crop field trials on dried peas were conducted in Crop Production Region 11, which is appropriate since 97% of the U.S. production of dried garden peas is in that region, according to the 2nd Edition Revised of *Food and Feed Crops of the United States*. The geographic diversity, number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.1 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on the dried shelled pea and bean (except soybean) subgroup (crop subgroup 6C). Method-validation data support the reliability of the residue data.

Since there are animal feed items of regulatory interest for croup group 6C, notably cowpea hay and forage and field pea vines and hay, and no data on these items or similar items have been submitted, a feeding restriction is required. **The petitioner should submit new labels specifying for dried shelled pea and bean subgroup, crop subgroup 6C: "Do not graze livestock in treated areas or harvest vines for forage or hay.**

Sorghum

Zeneca Ag Products has submitted data from 13 field trials on sorghum conducted in 1995 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on sorghum (grain) without any restriction on use of forage and fodder. There is already an established tolerance for sorghum grain. Field trials on grain sorghum for the RACs forage and fodder (with samples collected in 13 trials for forage and 12 trials for fodder) were conducted in EPA crop regions 2 (1 in GA and 1 in NC), 4 (2 for forage in AR, 1 for fodder in AR), 5 (1 in IL, 2 in KS, 1 in SD, and 1 in NE), 6 (TX), 9 (CO), and 10 (1 in AZ and 1 in CA). The results are reported in:

> MRID 44325708. Markle, J.C., E.M. Roper, P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sorghum forage and fodder from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-080B. November 11, 1996. Unpublished.

All field trials were magnitude of the residue trials. All trials included one treated plot and one untreated control plot. The broadcast spray was applied using either tractor mounted or backpack hand held boom sprayers. For sorghum that was to be used as forage, KARATE® 1EC was applied in 2 applications at the nominal rate of 0.03 lb ai/A, for a seasonal total application of 0.06 lb ai/A. The first application was preemergence, and the second application was broadcast foliar between early and late bloom. For sorghum that was to be used as fodder, KARATE® 1EC was applied in 3 applications at the nominal rate of 0.03 lb ai/A for the first two applications and 0.02 lb ai/A for the third application, for a seasonal total application of 0.08 lb ai/A. The first two broadcast applications were made identically to those for sorghum destined for use as forage, and the third application, by broadcast foliar, was made 30 days prior to the collection of the fodder. The PHI for forage was between 16 and 31 days (mean = 23.8 days). The proposed PHI is 30 days. The re-treatment interval between the first two applications was 49–105 days. Only sorghum to be used as fodder received the third application, and it was applied 21–34 days after the second application. The third application at the trial in GA was mistakenly made at a rate of 0.03 lb ai/A.

Spray made by diluting the formulated product with water was applied using 10–30.3 gpa. Two samples were collected from treated plots and one sample from untreated control plots. The weather was highly unusual in the GA trial because there was rain amounting to 9 inches 3 days prior to collection of forage samples. Samples were harvested by hand, and they weighed at least 2.0 lb for both forage and fodder. Samples were collected from at least 12 separate plants, avoiding plants near plot boundaries. There is no indication that either forage or fodder samples were dried in the field before sampling. Samples were frozen within 3 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C.

Samples were chopped in a Hobart VCM-40 or a Hobart VCM-25 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was 9–13 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on sorghum forage and fodder are summarized in Table 8.

Residue levels of lambda-cyhalothrin in/on sorghum forage were <0.01–0.27 ppm, and residue levels of R157836 in/on sorghum forage were <0.01–0.02 ppm. The HAFT for sorghum forage for the combined residues was 0.245 ppm at Statesboro, GA. This was at the site with excessive rainfall 3 days before collection of samples. The mean ± SD of the combined residues in/on sorghum forage was 0.127 ± 0.070 ppm. In this calculation, for both sorghum forage and fodder, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm. Residue levels of lambda-cyhalothrin in/on sorghum fodder were 0.07–0.38 ppm, and residue levels of R157836 were <0.01–0.04 ppm. The HAFT for sorghum fodder for the combined residues was 0.355 ppm at Scotland, SD. The mean ± SD of the combined residues in/on sorghum fodder was 0.171 ± 0.091 ppm. For sorghum forage, 11 of the 13 control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin, and the untreated controls at Statesboro, GA, and Shoffner, AR, were 0.01 and 0.05 ppm, respectively. For sorghum fodder, 11 of the 12 control samples were below the LOQ of 0.01 ppm for lambda-cyhalothrin, and the untreated control at West Sinton, TX, was 0.06 ppm. Untreated control samples for R157836 from all trials were below the LOQ of 0.01 ppm. For both sorghum forage and fodder, fortification levels bracketed the residue levels for lambda-cyhalothrin and almost did so for R157836.

TABLE 8: Residues of lambda-cyhalothrin and its epimer R157836 in/on sorghum forage and fodder following applications of lambda-cyhalothrin as the formulation KARATE® as a broadcast spray in 2 applications to forage (nominal seasonal total of 0.06 ai/A) or 3 applications to fodder (nominal seasonal total of 0.08 ai/A).

Test location: Nearest city, state (EPA crop region)	Variety of crop	Interval(s) between treatments (days)	PHI[1] (days)	Residue levels (ppm)[2]		
				lambda-cyhalothrin	epimer R157836	Sum of all residues
Forage						
Statesboro, GA (2)	NK2600	61	16	0.27; 0.18	0.02; 0.02	0.29; 0.20
Whitakers, NC (2)	Hyperformer 1289	62	33	0.07; 0.09	< 0.01; 0.01	< 0.08; 0.10
Scott, AR (4)	Pioneer 3305	81	28	0.14; 0.12	0.02; 0.01	0.16; 0.13
Shoffner, AR (4)	Cherokee	86	24	0.11; 0.16	0.01; 0.02	0.12; 0.18
Carlyle, IL (5)	Northrup King 1210	50	24	0.20; 0.07 0.23; 0.08[3]	0.02; < 0.01 0.01; 0.02[3]	0.22; < 0.08 0.24; 0.10[3]
De Soto, KS (5)	Cargill 837 CS	49	31	0.06; 0.05	0.01; < 0.01	0.07; < 0.06
La Cygne, KS (5)	Ciba 1655	63	23	0.06; 0.09	< 0.01; < 0.01	< 0.07; < 0.10
Scotland, SD (5)	Dekalb 28E	56	25	0.06; 0.10	< 0.01; < 0.01	< 0.07; < 0.11
Waverly, NE (5)	Dekalb 56	58	21	0.18; 0.15	0.02; 0.01	0.20; 0.16
West Sinton, TX (6)	Chaparral-Asgrow	57	18	< 0.01; < 0.01 < 0.01[4]	< 0.01; < 0.01 < 0.01[4]	< 0.02; < 0.02 < 0.02[4]
Fort Collins, CO (9)	Pioneer 8500	105	24	0.09; 0.11	< 0.01; 0.01	< 0.10; 0.12
Visalia, CA (10)	NK Hybrid 1580	52	24	0.08; 0.07	0.01; < 0.01	0.09; < 0.08
Yuma, AZ (10)	Cargill Hybrid 577	70	18	0.21; 0.21	0.02; 0.02	0.23; 0.23
Fodder						
Statesboro, GA (2)	NK2600	61, 25	30	0.14; 0.21	0.01; 0.02	0.15; 0.23
Whitakers, NC (2)	Hyperformer 1289	62, 34	30	0.11; 0.08	0.01; 0.01	0.12; 0.09
Scott, AR (4)	Pioneer 3305	81, 31	No samples were collected.			
Shoffner, AR (4)	Cherokee	86, 25	30	0.12; 0.10	0.02; 0.02	0.14; 0.12
Carlyle, IL (5)	Northrup King 1210	50, 26	30	0.24; 0.25	0.02; 0.02	0.26; 0.27
De Soto, KS (5)	Cargill 837 CS	49, 31	30	0.15; 0.09	0.01; < 0.01	0.16; < 0.10
La Cygne, KS (5)	Ciba 1655	63, 23	30	0.07; 0.12	< 0.01; < 0.01	< 0.08; < 0.13
Scotland, SD (5)	Dekalb 28E	56, 25	30	0.38; 0.27	0.03; 0.03	0.41; 0.30
Waverly, NE (5)	Dekalb 56	58, 31	30	0.33; 0.17	0.04; 0.02	0.37; 0.19
West Sinton, TX (6)	Chaparral-Asgrow	57, 21	30	0.16; 0.17	0.02; 0.02	0.18; 0.19

TABLE 8: Residues of lambda-cyhalothrin and its epimer R157836 in/on sorghum forage and fodder following applications of lambda-cyhalothrin as the formulation KARATE® as a broadcast spray in 2 applications to forage (nominal seasonal total of 0.06 ai/A) or 3 applications to fodder (nominal seasonal total of 0.08 ai/A).

Test location: Nearest city, state (EPA crop region)	Variety of crop	Interval(s) between treatments (days)	PHI[1] (days)	Residue levels (ppm)[2]		
				lambda-cyhalothrin	epimer R157836	Sum of all residues
Fort Collins, CO (9)	Pioneer 8500	105, 24	30	0.08; 0.11	< 0.01; 0.01	< 0.09; 0.12
Visalia, CA (10)	NK Hybrid 1580	52, 34	30	0.08; 0.08	0.01; 0.01	0.09; 0.09
Yuma, AZ (10)	Cargill Hybrid 577	70, 21	30	0.10; 0.10 0.09[4]	0.02; 0.01 0.02[4]	0.12; 0.11 0.11[4]

Data from pp. 10–11, 25, 28–30, 37, and 45–48 of MRID 44325708.
[1]Pre-harvest interval
[2]Values are not corrected for procedural recoveries or control values.
[3]The two values in this row are from different samples, and they are duplicates of the two samples in the row above them.
[4]Duplicate for sample immediately above it.

Conclusions: The petitioner has requested permanent tolerances of 0.3 and 0.5 ppm on sorghum forage and fodder, respectively, for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on grain sorghum. The recommended minimum numbers of field trials and samples to support a tolerance on grain sorghum are 12 and 24, respectively. A tolerance of 0.2 ppm was established earlier for grain sorghum grain but not for its forage or fodder. The proposed new use is identical to that currently in use on sorghum (grain), except that it is proposed that the following restriction be removed: "Do not graze livestock in treated areas or harvest for fodder, silage or hay." Without providing any explanation, the petitioner deviated substantially from the recommendation regarding geographical distribution of crop trials in that (for forage) there were 2 crop trials instead of 1 in region 1, 2 instead of 1 in region 4, 5 instead of 4 in region 5 (where 34% of sorghum is produced), 1 instead of 2 in region 6, none instead of 1 in region 7, none instead of 3 in region 8 (where 29% of sorghum is produced), 1 instead of none in region 9, and 2 instead of none in region 10. There is little sorghum raised in crop regions 9 and 10 compared to the regions in which trials are recommended. The distribution was the same for sorghum fodder except for there being one fewer trial in region 4; thus in that region the number done was the number recommended. Method-validation data support the reliability of the residue data. The failure to provide any residue decline studies is not considered a serious limitation because lambda-cyhalothrin is known to be non-systemic, and it has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

There are important differences between the proposed use (described on the current and proposed label) and the application protocols used in the crop field trials. For example, according to the proposed label, repeated treatments can be made as little as three days apart, whereas intervals between treatments in the field trials ranged from 21–105 days. Also, the crop field trials had a total application rate of only 0.06 lb ai/A applied to sorghum used as forage, with only half of that applied after crop emergence, but the proposed label allows a higher treatment rate. However, since the residues found in the forage studies were highest at 16 days after treatment, it is unlikely that the residues of lambda-cyhalothrin would exceed the proposed tolerance when used following the label directions with a 30-day PHI. Considering these commodities are only

livestock feed items, the numbers of submitted field trials and samples, the storage stability data, and the geographic diversity are adequate, to support the proposed tolerances.

The WARRIOR® T label has the restriction both on the grazing of livestock in treated areas and the harvesting for fodder, silage or hay. Those restrictions may be removed from the label.

Sugarcane

Zeneca Ag Products has submitted data from 9 field trials on sugarcane conducted in 1995 and 1996 to support the proposed permanent tolerance for use of lambda-cyhalothrin as KARATE® 1E Insecticide on sugarcane. Field trials on sugarcane were conducted in EPA crop regions 3 (3 in FL), 4 (4 in LA), 6 (TX), and 13 (HI). The results are reported in:

> MRID 44325709. Roper, E.M., P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sugarcane from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-017B. April 23, 1996. Unpublished.
>
> MRID 44325712. Markle, J.C., P.D. Francis, C.J. Spillner, and S.G. Patterson (1997) Lambda-cyhalothrin (ICIA0321): residue levels on sugar cane from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Richmond, CA 94804-4610. Report No. RR 97-017B. June 24, 1997. Unpublished.

All field trials were magnitude of the residue trials. All trials included one treated plot and one untreated control plot. The broadcast foliar spray was applied using either tractor mounted or CO_2 pressurized backpack sprayers. Lambda-cyhalothrin as the formulation KARATE® 1EC was applied in 4 applications at the nominal rate of 0.04 lb ai/A, for a seasonal total application of 0.16 lb ai/A (maximum proposed rate). The first application was 38–42 days prior to harvest, with subsequent treatments at intervals of 5–8 days. The PHI was 20–26 days. (For all but one trial, the PHI was 20–21 days). The proposed PHI is 21 days. Spray made by diluting the formulated product with water was applied using 8.3–30.0 gpa. Two samples were collected from treated plots and one sample from untreated control plots. Samples were harvested by hand, and they weighed at least 10.0 lb. Samples were collected from at least 12 separate plants, avoiding plants near plot boundaries. Samples were frozen within 3.5 hr after collection and were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). From then until analysis, samples were stored frozen at -18 ± 5 °C. Samples were chopped in a Hobart VCM-40 or a Hobart VCM-25 with dry ice until completely homogeneous, and they were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was 1.9–7 months. Earlier storage stability studies on numerous other crops for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the field trials on sugarcane are summarized in Table 9.

Residue levels of lambda-cyhalothrin in/on sugarcane were <0.01–0.03 ppm, and all residue levels of R157836 were <0.01 ppm. The HAFT for sugarcane of 0.03 ppm for the combined residues was found at 4 of the sites. (In this calculation, as well as in calculation of the mean and SD below, duplicates for individual samples were averaged, and samples less than the LOQ of 0.01 ppm were considered to be 0.01 ppm.) The mean ± SD of the combined residues in/on sugarcane was 0.026 ± 0.006 ppm. All 8 untreated control samples for both lambda-cyhalothrin and R157836 were below the LOQ of 0.01 ppm. Fortification levels bracketed the residue levels for lambda-cyhalothrin and almost did so for R157836.

TABLE 9: Residues of lambda-cyhalothrin and its epimer R157836 in/on sugarcane following 4 broadcast foliar applications of lambda-cyhalothrin as the formulation KARATE® at the rate of 0.04 lb ai/A for a seasonal total of 0.16 lb ai/A, with re-treatment intervals of 5–8 days.

Test location: Nearest city, state (EPA crop region)	Variety of crop	PHI[1]	Residue levels (ppm)[2]		
			lambda-cyhalothrin	epimer R157836	Sum of all residues
Crop trials in 1995					
Rosa, LA (4)	321	21	0.02; 0.02	<0.01; < 0.01	<0.03; < 0.03
Washington, LA (4)	357	26	0.03; 0.01 0.01[3]	<0.01; < 0.01 <0.01[3]	<0.04; < 0.02 <0.02[3]
Crop trials in 1996					
Belle Glade, FL (3)	1827	21	0.02; 0.01	< 0.01; < 0.01	< 0.03; < 0.02
Clewiston, FL (site 1) (3)	CL77-797	20	< 0.01; <0.01	< 0.01; < 0.01	< 0.02; < 0.02
Clewiston, FL (site 2) (3)	CL73-239	20	0.03; < 0.01 < 0.01[4] < 0.01[4] < 0.01[4] < 0.01[4]	< 0.01; < 0.01 < 0.01[4] < 0.01[4] < 0.01[4] < 0.01[4]	< 0.04; < 0.02 < 0.02[4] < 0.02[4] < 0.02[4] < 0.02[4]
Washington, LA (4)	321	20	0.02; 0.02	< 0.01; < 0.01	< 0.03; < 0.03
Big Cane, LA (4)	CP 321	21	0.02; 0.02	< 0.01; < 0.01	< 0.03; < 0.03
Raymondville, TX (6)	321	21	<0.01; < 0.01 <0.01[3]	<0.01; < 0.01 <0.01[3]	<0.02; < 0.02 <0.02[3]
Haleiwa, HI (13)	74-4527	21	0.01; 0.02	< 0.01; < 0.01	< 0.02; < 0.03

Data from pp. 9, 15, and 19 of MRID 44325709 and pp. 9, 18, and 22 of MRID 44325712.
[1]Pre-harvest interval.
[2]Values are not corrected for procedural recoveries or control values.
[3]Duplicate for sample immediately above it.
[4]One of 4 (additional) duplicates for first sample in first row of this cell of the table.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The petitioner has requested a permanent tolerance of 0.05 ppm on sugarcane for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide. The recommended minimum number of field trials and samples to support a tolerance on sugarcane are 8 and 16, respectively. The petitioner reported results from 9 field trials (and 18 samples) on sugarcane. Regarding geographic diversity of the trials, it is recommended that there be 3, 3, 1, and 1 trials from Regions 3, 4, 6, and 13, respectively. The results reported by the petitioner fit this recommendation with one extra trial being conducted in region 4. The geographic diversity,

number of submitted field trials, and storage stability data are adequate and support a tolerance of 0.05 ppm for use of lambda-cyhalothrin as the formulation KARATE® 1E Insecticide on sugarcane. Method-validation data support the reliability of the residue data. The failure to provide any residue decline studies is not considered a serious limitation because lambda-cyhalothrin is known to be non-systemic, and it has a rather short half-life of 10–14 days (NV920006, DP Barcode: D185478, G. Jeffrey Herndon, 10/8/92).

OPPTS GLN 860.1520: Processed Food/Feed

The processed commodities of regulatory interest for this petition are as follows: for the fruiting vegetables crop (except cucurbits) group there are tomato paste and tomato puree, for the cereal grain crop group there are numerous commodities that will not be listed here (except grain sorghum), for peanuts there are peanut meal and refined oil, for grain sorghum there is flour, and for sugarcane there are molasses and refined sugar. Tolerances presently exist for several commodities produced from the cereal grain crop group and for tomato pomace (dry or wet), and peanuts.

Sugarcane

The only crop for which new data were presented on processed commodities was sugarcane. Zeneca Ag Products has submitted data from a processing study on sugarcane conducted in the United States in 1995. The results are reported in:

> MRID 44325710. Roper, E.M., P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sugarcane and processing fractions from a trial conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-024B. April 23, 1996. Unpublished.

One crop of sugarcane was raised in Rosa, LA, in 1995 to support the processing study. Two plots were established, with one being untreated and the other treated with KARATE® 1EC, which was applied in 4 broadcast foliar applications at the rate of 0.2 lb ai/A, for a total application of 0.8 lb ai/A/season or 5x the recommended application rate. The first application was 42 days prior to harvest, with subsequent treatments at 7-day intervals. The last application was made 21 days prior to harvest. Spray volumes (diluted in water) for the trial were 18–20 gpa. In order to estimate the level of residue on the RAC, at least 7 lb of sugarcane were harvested by hand from both the treated and untreated plots, with samples being collected from 12 separate areas, avoiding plot boundaries. These samples were frozen within 3 hr of harvest. Additional samples of at least 300 lb were harvested from both the treated and untreated plots for processing. The samples to be used to determine the magnitude of the residue on the RAC were shipped frozen to the analytical laboratory at Zeneca, Inc. (Richmond, CA). The much larger samples to be processed were shipped directly from the field at ambient temperature, and by overnight delivery, to the processing laboratory, which was Wm. J. Englar & Associates, Inc. (Moses Lake, WA). Upon receipt, these large samples were placed in storage at -22 ± 8 °C until processing. Wm. J. Englar & Associates, Inc.'s laboratory simulates commercial operations as closely as possible to generate the required fractions of unwashed cane, bagasse, molasses, and refined sugar. Cleaned sugarcane was reduced to chips and shreds using a chipper shredder. Sugar was extracted from chips and shreds in a series of steam-heated Ball canning kettles with a

mixture of fresh water and exhausted bagasse press juice at temperatures of approximately 70–75° C. Extracted bagasse was pressed using a Suntech Fruit Press to recover sugar solution. Pressed bagasse was dried to < 50% moisture. Diffusion juice was clarified by heating with phosphoric acid and a lime slurry. The clarified juice was concentrated in a Groen Vacuum evaporator, filtered using Buchner funnels, and then the massecuite (i.e., the concentrated juice) was fed to a laboratory vacuum pan and granulator. Sugar was removed by centrifugation. The initial spin-off syrup (molasses) was collected for analysis. The washed sugar was removed and dried with hot air to obtain the refined sugar. Following processing, the processing samples were stored frozen until they were shipped to the analytical laboratory at Zeneca, Inc. (Richmond, CA). All samples at Zeneca, Inc. were stored at -18 ± 5 °C.

Samples of sugarcane and bagasse were chopped in a Hobart VCM-40 with dry ice until completely homogeneous. Samples of sugar and molasses were analyzed as received without any additional preparation. Samples were analyzed for lambda-cyhalothrin and its epimer R157836 using methods PPRAM81/PPRAM70 described in Section OPPTS GLN 860.1340: Analytical Methods - Plants. Limited but sufficient sample chromatograms were provided. Calibration information was not provided, but the method is considered well enough established to make the procedure acceptable. The period of frozen storage prior to extraction and analysis was 28–65 days for the RAC and 30 days or less for the processed commodities. Earlier storage stability studies on numerous other crops (and including some of their processed commodities) for various intervals up to almost 32 months show that lambda-cyhalothrin is sufficiently stable during such a period of storage. The results from the processing study on sugarcane are summarized in Table 10.

TABLE 10: Residues of lambda-cyhalothrin and its epimer R157836 in the processed commodities of sugarcane harvested 21 days following 4 broadcast foliar applications, at 7 day intervals, of the lambda-cyhalothrin formulation KARATE® at 0.2 lb ai/A/application (0.8 lb ai/A/season; 5x the maximum proposed seasonal rate).

Substrate	Residues, ppm[1]		Concentration/Reduction Factor	
	lambda-cyhalothrin	epimer R157836	lambda-cyhalothrin	epimer R157836
Sugarcane before processing	0.24; 0.18	0.02; 0.02	–	–
-Molasses	< 0.01	< 0.01	< 0.05x	< 0.5x
-Refined sugar	< 0.01	< 0.01	< 0.05x	< 0.5x
-Bagasse	0.46	0.05	2.2x	2.5x

Data from p. 8 and Table 1, p. 18, MRID 44325710.
[1]Values are not corrected for procedural recoveries or control values.
The limit of quantitation (LOQ) was 0.01 ppm for both lambda-cyhalothrin and the epimer R157836.

Conclusions: The processing study provides no evidence of concentration of lambda-cyhalothrin or its epimer R157836 in either molasses or refined sugar; indeed, there appears to be a large reduction in these residues. Clearly, there is no need for any tolerances for these two commodities. There is evidence of concentration of both residues in bagasse, with both residues showing approximately a doubling in value. According to the guidelines, sugarcane bagasse is mainly used for fuel, and residue data are not needed presently. As a result, there is no need for a tolerance for sugarcane bagasse. The processing study was adequate, and the results indicate that the tolerance for sugarcane is adequate for the processed commodities of sugarcane.

Processed commodities from crops other than sugarcane

The petitioner presented no new data on the processed commodities of tomatoes. The raising of the tolerance on tomatoes from its current value of 0.1 ppm to that of 0.2 ppm as part of the fruiting vegetables crop (except cucurbits) group has no influence on the tolerances of processed commodities of tomatoes (paste and puree) because they are based on the HAFT found for tomatoes and the concentration factors found on tomatoes. The petitioner's request for tolerances for RACs and processed foods and feedstuffs on numerous additional small grains cannot be granted because of the lack of necessary data (as discussed in Section OPPTS GLN 860.1500: Crop Field Trials). Hence, that request has no relevance to this guideline. The only new data presented by the petitioner for peanuts are for peanut hay. Because the processed commodities from peanuts (peanut meal and refined oil) are made from the peanuts themselves, which were considered at an earlier time to derive their established tolerances, the new data on peanut hay have no relevance to a tolerance for commodities made from peanuts. Similarly, the new data presented by the petitioner for grain sorghum forage and grain sorghum fodder are not relevant for the processed commodity sorghum flour, which is made from grain sorghum grain and which was considered at an earlier time to derive its established tolerance.

OPPTS GLN 860.1480: Meat/Milk/Poultry/Eggs

Eggs and the Fat, Meat, and Meat Byproducts of Poultry

The poultry feed items associated with this petition are peanut meal, dried seeds of the cowpea and field pea, and sorghum grain. Since the petitioner's request for numerous tolerances on additional small grain RACs and commodities made from them is not justified, cereal grains for which tolerances already exist are not considered here. However, sorghum grain has been considered so that it is possible to get a 100% poultry diet related to this petition, and since new data were presented for this crop, albeit for forage and fodder. The tolerance for the RAC peanuts is applied to peanut meal. The calculation of the maximum theoretical dietary burden is presented in Table 11.

TABLE 11. Calculation of the maximum theoretical dietary burden of residues of lambda-cyhalothrin and its epimer R157836 to poultry for commodities associated with this petition.

Feed Commodity	Estimated tolerance, ppm (lambda-cyhalothrin and R157836)	Poultry	
		% of diet	Burden (ppm)
Sorghum grain	0.2	80	.16
Cowpea seed, dried	0.1	10	.01
Field pea seed	0.1	10	.01
Total		100	.18

Burden in poultry = (Residue in ppm x Fraction of diet)

Field peas can constitute up to 20% of the poultry diet, and peanut meal (with its tolerance of 0.05 ppm) can constitute up to 25% of the diet. It is apparent that replacement of sorghum grain

with either one of them would reduce the maximum theoretical dietary burden of combined residues of lambda-cyhalothrin and R157836 from that shown in Table 11. An earlier memorandum (PP#9F3770 & PP#7F3560, DP Barcodes: D206401 & D208492, J. Morales, 12/14/94) calculated an average dietary burden from lambda-cyhalothrin in poultry of 0.247 ppm. It was based on average residues from field trials at the proposed use pattern instead of on tolerance levels. Because that calculation was made before the August 1996 EPA Residue Chemistry Test Guidelines (OPPTS 860.1480 Meat/milk/poultry/eggs) existed, each feedstuff was corrected for percent dry matter when estimating the average dietary burden. Those guidelines indicate that there should be no such correction for poultry and swine. As a result, the average dietary burden of 0.247 ppm reported in that memorandum was recalculated by the reviewer according to the current guidelines, and it was found to be 0.224 ppm. The finding of an average dietary burden of 0.247 ppm did not lead to a raising of the tolerances for poultry commodities. Accordingly, because the maximum theoretical dietary burden of 0.18 for the commodities associated with the current petition is less than 0.247 ppm (and, indeed, less than 0.224 ppm), there is clearly no need to reconsider the tolerances for eggs, and the fat, meat, and meat byproducts of poultry.

Milk, and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep

The feed items associated with this petition that apply to ruminants are peanut meal, peanut hay, dried seeds of the cowpea and field pea, sorghum grain, sorghum forage, sorghum fodder, and sugarcane molasses. Since the petitioner's request for numerous tolerances on additional small grain RACs and commodities made from them is not justified, cereal grains for which tolerances already exist are not considered here. However, sorghum grain has been considered since new data were presented for this crop, albeit for forage and fodder. The tolerance for the RAC peanuts is applied to peanut meal. The calculation of the maximum theoretical dietary burden is presented in Table 12.

TABLE 12. Calculation of the maximum theoretical dietary burdens of residues of lambda-cyhalothrin and its epimer R157836 to cattle for commodities associated with this petition.

Commodity	Dry matter (%)	Proposed tolerance (ppm)	Beef cattle		Dairy cattle	
			% in diet	Burden (ppm)	% in diet	Burden (ppm)
Peanut meal	85	0.05	0	0	0	0
Peanut hay	85	3	25	0.88	50	1.76
Cowpea seeds, dried	88	0.1	0	0	0	0
Field pea seeds	90	0.1	0	0	0	0
Sorghum grain	86	0.2	10	0.02	0	0
Sorghum forage	35	0.3	40	0.34	35	0.30
Sorghum fodder	88	0.5	25	0.14	15	0.09
Sugarcane molasses	75	0.05	0	0	0	0
Total			100	1.38	100	2.15

Burden = (Residue (ppm) x % Diet)/% dry matter

In beef cattle, peanut meal, cowpeas, field peas, sorghum grain, and sugarcane molasses can constitute up to 15, 20, 20, 40, and 10% of the diet, respectively. In dairy cattle, peanut meal, cowpeas, field peas, sorghum grain, sorghum forage, and sugarcane molasses can constitute up to 15, 20, 20, 40, 50, and 10% of the diet, respectively. In view of this information, it is apparent that replacement of peanut hay with any of these other feedstuffs would substantially reduce the maximum theoretical dietary burden of combined residues of lambda-cyhalothrin and R157836 from that shown in Table 12. An earlier memorandum (PP#9F3770 & PP#7F3560, DP Barcodes: D206401 & D208492, J. Morales, 12/14/94) calculated the average dietary burdens from lambda-cyhalothrin in beef and dairy cattle to be 2.873 and 2.867 ppm, respectively. Those dietary burdens were based on average residues from field trials at the proposed use pattern instead of on tolerance levels. The finding of average dietary burdens of 2.873 and 2.867 ppm did not lead to a raising of the tolerances for ruminant commodities. Accordingly, because the maximum theoretical dietary burdens of the commodities associated with the current petition in beef and dairy cattle of 1.38 and 2.15 ppm, respectively, are less that 2.873 ppm, there is clearly no need to reconsider the tolerances for milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

Fat, Meat, and Meat Byproducts of Swine

The swine feed items associated with this petition are peanut meal, dried seeds of the cowpea and field pea, and sorghum grain. Since the petitioner's request for numerous tolerances on additional small grain RACs and commodities made from them is not justified, cereal grains for which tolerances already exist are not considered here. However, sorghum grain has been considered so that it is possible to get a 100% swine diet related to this petition, and because new data were presented for this crop, albeit for forage and fodder. The tolerance for the RAC peanuts is applied to peanut meal. The calculation of the maximum theoretical dietary burden is presented in Table 13.

TABLE 13. Calculation of the maximum theoretical dietary burden of residues of lambda-cyhalothrin and its epimer R157836 to swine for commodities associated with this petition.

Feed Commodity	Estimated tolerance, ppm (lambda-cyhalothrin and R157836)	Swine	
		% of diet	Burden (ppm)
Peanut meal	0.05	0	0
Cowpea seed, dried	0.1	10	.01
Field pea seed	0.1	0	0
Sorghum grain	0.2	90	0.18
Total		100	0.19

Burden in swine = (Residue in ppm x Fraction of diet)

Cowpeas, field peas, and peanut meal can constitute up to 50, 20, and 15% of the swine diet, respectively. It is apparent that replacement of sorghum grain with any one of those other feedstuffs would reduce the maximum theoretical dietary burden of combined residues of lambda-cyhalothrin and R157836 from that shown in Table 13. An earlier memorandum (PP#9F3770 & PP#7F3560, DP Barcodes: D206401 & D208492, J. Morales, 12/14/94)

calculated an average dietary burden from lambda-cyhalothrin in swine of 1.299 ppm. It was based on average residues from field trials at the proposed use pattern instead of on tolerance levels. Because that calculation was made before the August 1996 EPA Residue Chemistry Test Guidelines (OPPTS 860.1480 Meat/milk/poultry/eggs) existed, each feedstuff was corrected for percent dry matter when estimating the average dietary burden. Those guidelines indicate that there should be no such correction for swine and poultry. As a result, the average of 1.299 ppm reported in that memorandum was recalculated by the reviewer according to the current guidelines, and it was found to be 0.760 ppm. The finding of the average dietary burden of 1.299 ppm did not lead to a raising of the tolerances for swine commodities. Accordingly, because the maximum theoretical dietary burden of 0.19 ppm for the commodities associated with the current petition is less than 1.299 ppm (and, indeed, less than 0.760 ppm), there is clearly no need to reconsider the tolerances for fat, meat, and meat byproducts of swine.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

No new studies were submitted with this petition. Previous studies showed that significant residues (exceeding the LOQ of 0.01 ppm) will not be present in crops rotated 30 days after application of parent lambda-cyhalothrin. According to the EFED review of 4/6/88, no additional rotational crop data were needed to support registered application rates at that time (PP#6F4769 & PP#6H4775, DP Barcodes: D228792 & D228931, J.J. Morales et al., 5/28/97). The current and proposed labels mention no restriction on replanting of crops for which lambda-cyhalothrin as the formulation KARATE® 1EC is used.

International Residue

Current status sheets available to HED indicate that there are no Codex, Canadian, or Mexican maximum residue levels (MRLs) established for lambda-cyhalothrin on the crops for which tolerances are being recommended, namely: avocados, the fruiting vegetables (except cucurbits) crop group (crop group 8), peanut hay, the edible podded pea and bean subgroup (subgroup 6A), the succulent shelled pea and bean subgroup (subgroup 6B), the dried shelled pea and bean subgroup (subgroup 6C), sorghum fodder, sorghum forage, and sugarcane. Harmonization is thus not an issue.

Attachment 1: Citations of studies reviewed by ORNL for DP Barcode D238603.
Attachment 2: International Residue Status Sheet

Attachment 1.

CITATIONS

The following reports were reviewed by ORNL as part of the data package on lambda-Cyhalothrin (DP Barcode: D238603):

1) MRID 44325701. Jones, S.D. (1995) Lambda-cyhalothrin: residue levels in avocados from trials carried out in Mexico during 1994. ZENECA Agrochemicals, Jealott's Hill Research Station, Bracknell Berkshire, UK.; United States address: Zeneca Ag Products, Wilmington, DE 19850-5458. Report No. RJ1997B. November 23, 1995. Unpublished.

2) MRID 44325702. Markle, J.C., P.D. Francis, M.T. Kepler, and E.M. Roper (1997) Lambda-cyhalothrin (ICIA0321): residue levels on peppers (non-bell) from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-105B. January 23, 1997. Unpublished.

3) MRID 44325703. Markle, J.C., P.D. Francis, M.T. Kepler, and E.M. Roper (1997) Lambda-cyhalothrin (ICIA0321): residue levels on bell peppers from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-103B. February 26, 1997. Unpublished.

4) MRID 44325704. Markle, J.C., P.D. Francis, and M.T. Kepler (1997) Lambda-cyhalothrin (ICIA0321): residue levels on edible-podded peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-106B. April 9, 1997. Unpublished.

5) MRID 44325705. Markle, J.C., P.D. Francis, and M.T. Kepler (1997) Lambda-cyhalothrin (ICIA0321): residue levels on succulent shelled peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 97-007B. May 28, 1997. Unpublished.

6) MRID 44325706. Markle, J.C., P.D. Francis, C.J. Spillner, and S.G. Patterson (1997) Lambda-cyhalothrin (ICIA0321): residue levels on dried, shelled peas and beans from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Richmond, CA 94804-4610. Report No. RR 97-016B. June 11, 1997. Unpublished.

7) MRID 44325707. Roper, E.M., P.D. Francis, M.T. Kepler, and J.C. Markle (1996) Lambda-cyhalothrin (ICIA0321): residue levels on peanut hay from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-073B. October 31, 1996. Unpublished.

8) MRID 44325708. Markle, J.C., E.M. Roper, P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sorghum forage and fodder from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-080B. November 11, 1996. Unpublished.

9) MRID 44325709. Roper, E.M., P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sugarcane from trials conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-017B. April 23, 1996. Unpublished.

10) MRID 44325710. Roper, E.M., P.D. Francis, and M.T. Kepler (1996) Lambda-cyhalothrin (ICIA0321): residue levels on sugarcane and processing fractions from a trial conducted in the United States during 1995. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Box Number 4023, Richmond, CA 94804-0023. Report No. RR 96-024B. April 23, 1996. Unpublished.

11) MRID 44325711. Sargent, D.E. (1997) Lambda-cyhalothrin: dietary exposure and risk assessment update. Zeneca Agricultural Products, P.O. Box 15458, Wilmington, DE 19850-5458. Report No. DES0697. June 24, 1997. Unpublished.

12) MRID 44325712. Markle, J.C., P.D. Francis, C.J. Spillner, and S.G. Patterson (1997) Lambda-cyhalothrin (ICIA0321): residue levels on sugar cane from trials conducted in the United States during 1996. Zeneca Ag Products, Western Research Center, 1200 South 47th Street, Richmond, CA 94804-4610. Report No. RR 97-017B. June 24, 1997. Unpublished.

Attachment 2.

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name:	Common Name:	x Proposed tolerance □ Reevaluated tolerance □ Other	Date:
lambda-cyhalothrin [1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate]	lambda-cyhalothrin		August 24, 2000

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested	Petition Number: 7F04875 DP Barcode: D238603 Other Identifier: Chemical 128897 (formerly Chemical 128867)
Residue definition (step 8/CXL): MRLs exist for cyhalothrin, but not for lambda-cyhalothrin. For cyhalothrin, there are no MRLs for the commodities of interest. Residue definition is sum of all isomers.	Reviewer/Branch: Bill Cutchin/RAB2
	Residue definition: residues of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl- (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2- dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm) **PROPOSED**
		Avocados	0.2
		Fruiting Vegetables (except cucurbits) group	0.2
		Peanut hay	3
		Pea and bean, dried shelled, subgroup	0.1
		Pea and bean, edible podded, subgroup	0.2
		Pea and bean, succulent shelled, subgroup	0.01
		Sorghum, fodder	0.5
		Sorghum, forage	0.3
		Sugarcane	0.05

Limits for Canada	Limits for Mexico
□ No Limits X No Limits for the crops requested	X No Limits □ No Limits for the crops requested
Residue definition:(S)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S, 3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate	Residue definition:

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions:
S. Funk, 08/29/00

Rev. 1998

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Chemical:	**ALPHA-CYANO-3-PHENOXYBENZYL-3-(2-CHLORO-**
PC Code:	**128897**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**06/27/2001**
File ID:	**DPD238603**
Accession Number:	**412-03-0018**

HED Records Reference Center
11/12/2002