UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 19 1991

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EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **PP#7F3560/7H5543.** Lambda-cyhalothrin in/on Wheat, Sweet Corn and Sunflowers. Amendment Dated 1/28/91. Revision of Proposed Sweet Corn Tolerance. Residue Data and Processing Study.

MRID #'s 417711-01, -02. DEB # 7656. DP Barcode 161281.

PP#1F3952/1H5607. Lambda-cyhalothrin in/on Broccoli, Cabbage and Tomatoes. Evaluation of Analytical Method and Residue Data. Submission Dated 12/26/90.

MRID #'s 417370-01 through 417370-08, 417935-01. DEB #'s 7729, 7730. DP Barcode D162001.

FAP#0H5599. Lambda-cyhalothrin in/on Imported Dried Hops. Evaluation of Analytical Method and Residue Data. Submission dated 8/21/90.

MRID #'s 416146-02 through 416146-07. DEB # 7098. DP Barcode D156500.

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In PP#7F3560/7H5543, ICI Americas Inc. originally proposed tolerances for lambda-cyhalothrin in/on sweet corn grown in Florida for the fresh market only. The company now is proposing

to amend its petition to:

(1) include residues in/on sweet corn grown throughout the U.S.;

(2) include residues in processed sweet corn;

(3) remove the feeding restriction;

(4) increase the maximum single application rate from 0.03 lb ai/A to 0.04 lb ai/A; and

(5) decrease the maximum seasonal application rate from 0.6 lb ai/A/season to 0.48 lb ai/A/season.

In PP#1F3952/1H5607, ICI proposes tolerances for lambda-cyhalothrin in/on broccoli, cabbage, tomatoes, meat, milk, poultry and eggs; and in FAP#0H5599 ICI proposes tolerances for lambda-cyhalothrin in dried hops, meat, milk, poultry and eggs.

The following tolerances (for parent only) are proposed in PP#7F3560/7H5543:

Raw Agricultural Commodity	Proposed Tolerance (ppm)
Sweet corn	
Ears	0.02
Forage	6.0
Milk	0.03
Cattle, goats, hogs, horses and sheep	
Meat	0.03
Fat	2
Liver	0.1
Kidney	0.05
Poultry	
Meat, fat, liver, eggs	0.01

Not explicitly listed in the present submission but proposed earlier are tolerances for wheat grain (0.01 ppm), sunflower seeds (0.03 ppm), sunflower hulls (0.07 ppm) and sunflower oil (0.05 ppm). Although sunflower residue data and processing study were deemed adequate in F. Boyd's review of 2/3/88, final conclusions with respect to the proposed tolerance were deferred

pending satisfactory resolution of metabolism issues. An amendment to change the directions for use on wheat and new magnitude of residue and processing studies on wheat were submitted 5/9/91 and will be reviewed in a separate memo. The submission also contains a response to CBTS' review of the registrant's wheat metabolism study.

The following tolerances are proposed in PP#1F3952/1H5607:

Raw Agricultural Commodity	Proposed Tolerance (ppm)
Broccoli	0.4
Cabbage	
With wrapper leaves	0.4
Without wrapper leaves	0.02
Tomatoes	0.06
Milk	0.03
Cattle, goats, hogs, horses and sheep	
Meat	0.02
Fat	0.5
Liver	0.04
Kidney	0.03

The following tolerances for lambda-cyhalothrin are proposed in FAP#0H5599:

Raw Agricultural Commodity or Food/Feed Additive	Proposed Tolerance (ppm)
Dried Hops	12
Milk	0.01
Cattle, goats, hogs, horses, poultry and sheep	
Meat	0.01
Fat	0.10
Meat byproducts	0.01

Proposed meat, milk, poultry and egg tolerances in the petitions differ. Tolerances of 0.01 ppm are proposed for the meat, fat, liver and eggs of poultry in the first two petitions. Food/Feed Additive tolerances of 4 and 0.6 ppm are proposed for

parent residues in/on dry and wet tomato pomace, respectively.

Tolerances with an expiration date of August 30, 1991 have been established under 40 CFR 180.438 for the fat, meat and mbyp of cattle, goats, hogs, horses and sheep -- 0.01 ppm; milk -- 0.01 ppm; and cottonseed -- 0.05 ppm.

Conclusions

1. The registrant should obtain written confirmation from Chemical Abstracts Service that the proposed CAS name, [1α(S*),3α(Z)]-(+)-cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, is the correct Chemical Abstracts name.

2. (FAP#0H5599) The use label from West Germany is for a KARATE 2.5 EC. A Confidential Statement of Formula should be submitted for this particular product.

3a. The nature of the residue in plants is not adequately understood. Results from a metabolism study in which wheat straw was treated with ^{14}C-lambda-cyhalothrin and harvested 85 days after the last application should be submitted. (See our memo of 4/16/91.) When this study has been determined to be adequate, CB and TOX will issue a memo stating what residue should be regulated.

3b. The nature of the residue in ruminants and poultry is adequately understood. Parent lambda-cyhalothrin is the major component of the residue, except for kidney and liver of ruminants and liver of poultry. CPA, HO-CPA, 3-PBAcid and 4'-OH-3-PBAcid are the major metabolites. [Chemical names are given in Figure 2 (Attachment 1).] CB and TOX will determine which metabolites should appear in the tolerance expression. A separate memo will be forthcoming.

4a. ICI Method 81 for lambda-cyhalothrin, per se, in plant matrices has undergone successful EPA Method Validation.

4b. The analytical methods for metabolites in plant matrices (submitted in FAP#0H5599) has produced acceptable recoveries from the racs of the three petitions. Should it be determined that CPA and 3-PBAcid appear in the tolerance expression, the method must undergo independent laboratory validation prior to EPA Method Validation.

4c. ICI Method 86 for lambda-cyhalothrin, per se, in animal matrices has undergone successful EPA Method Validation.

4d. ICI Method 96 for metabolites in animal matrices (submitted in PP#0H5599) has produced acceptable recoveries. Should it be determined that CPA, 3-PBAcid and/or 4'-OH-3-PBAcid appear in the tolerance expression, the method must undergo independent laboratory validation prior to EPA Method Validation.

4e. At present, no residue analytical method is available for metabolite HO-CPA. If this metabolite is to appear in the tolerance expression or if residue data are necessary, such a method must be developed.

4f. Recoveries have been previously determined for cyhalothrin (and therefore lambda-cyhalothrin) under FDA's multiresidue protocols. A report of recoveries of CPA and 3-PBAcid under these protocols has been submitted and is being forwarded to FDA. (These metabolites are reportedly not recovered under the protocols.) Depending on the regulatory status of 4'-OH-3-PBAcid and HO-CPA, multiresidue testing of these compounds may be necessary.

5a. Lambda-cyhalothrin is stable in various plant matrices under frozen storage for up to 26 months and in 1:1 acetone:hexane extracts (<4°C) for up to 42 days. The same compound was shown to be stable in bovine liver, kidney, muscle and bodyfat under frozen storage from 96 days (fat) to 251 days (liver) in a study done to permit dermal use of lambda-cyhalothrin (PP#9F3770). Lambda-cyhalothrin is stable in eggs and poultry tissue for two years in frozen storage.

5b. CPA, 3-PBAcid and 3-PBAlcohol in various racs are stable for 3 months under frozen storage. This time period is insufficient to support the residue analyses; but, presumably, additional data will be reported at a later date.

5c. CPA, 3-PBAcid and 4'-OH-3-PBAcid are reportedly stable in cow and chicken matrices for 35-42 months under frozen storage conditions. Matrices spiked included muscle, milk, kidney, liver, egg and fat. Except for milk and egg, it is not clear whether cow or poultry tissues were fortified. The registrant should clarify this relatively minor issue.

5d. If residue data for HO-CPA are necessary, storage stability data for this metabolite in animal matrices

should be provided.

6a. (PP#7F3560/7H5543) Based on submitted data, proposed lambda-cyhalothrin tolerances of 0.02 ppm for sweet corn ears (i.e., sweet K + CWHR) and 6.0 ppm for sweet corn forage are adequate. However, because of analytical uncertainties at low levels, a tolerance of 0.05 ppm would be more appropriate for sweet corn (K + CWHR). (The tolerance should not be expressed as sweet corn ears.) The petitioner should submit a revised Section F in which this tolerance is proposed. CB and TOX will decide whether tolerances are necessary for metabolites and the epimer of lambda-cyhalothrin.

6b. No new data are reviewed in this memo for wheat or sunflowers. Sunflower residue data and a processing study have been deemed adequate pending resolution of certain metabolism issues (F. Boyd, memo of 2/3/88). CBTS will make a recommendation as to the adequacy of these data when the nature of the residue in plants is understood. New data on wheat, including a response to our review of the wheat metabolism study, will be reviewed in a separate memo.

7a. (PP#1F3952/1H5607) The proposed tolerance of 0.4 ppm for residues of lambda-cyhalothrin in/on broccoli is appropriate. Because no data reflecting aerial application have been submitted, the petitioner must either revise the use label or submit additional residue data from aerial application.

7b. The proposed tolerance of 0.4 ppm for residues of lambda-cyhalothrin in/on cabbage is appropriate. The rac is cabbage <u>with</u> wrapper leaves. Residue data for the same compound in cabbage <u>without</u> wrapper leaves showed residue levels of lambda-cyhalothrin not exceeding 0.02 ppm. This latter data set should be used in calculations of <u>anticipated residues</u>.

A revised Section F should be submitted for "cabbage" at 0.4 ppm. Any reference to wrapper leaves should be deleted.

Because no data reflecting aerial application have been submitted, the petitioner must either revise the use label or submit additional residue data from aerial application.

7c. The proposed tolerance of 0.06 ppm for residues of parent in/on tomatoes is adequate, but to allow for analytical uncertainties at low levels we consider a tolerance of 0.1 ppm to be more appropriate. A revised

Section F should be submitted in which this tolerance is proposed.

Because no data reflecting aerial application have been submitted, the petitioner must either revise the use label or submit additional residue data from aerial application.

7d. CB and TOX will decide whether or not metabolites and/or the epimer should be included in the tolerance expression. A separate memo will be forthcoming.

8. (FAP#0H5599) Based on submitted residue data, a tolerance of 10 ppm for residues of lambda-cyhalothrin, per se, in/on dried hops appears to be adequate. However, before a revised Section F is submitted proposing this tolerance, the registrant must submit validation data from the 1985 field trials (at least the 1985 trial held in Germany -- the trial in Czechoslovakia employed much lower use levels, so residue levels were much lower). If validation data are unavailable, additional field trials will be necessary. The dates of analysis should also be submitted.

As in previous conclusions, CB and TOX will decide whether or not the epimer and metabolites should be included in the tolerance expression.

9. A processing study on tomatoes indicates concentration in wet and dry pomace. Based on the concentration factors and a tolerance of 0.1 ppm for tomatoes, the registrant should submit a revised Section F in which a feed additive tolerance of 6.0 ppm is proposed for residues of lambda-cyhalothrin in/on tomato pomace, wet or dry. As noted above, metabolites may have to be included in the tolerance expression.

10a. Based on results from ruminant and poultry feeding studies, ICI should submit a revised Section F in which the following tolerances for lambda-cyhalothrin are proposed:

Milk, meat and mbyp of cattle, goats, hogs, horses and sheep	0.2 ppm
Fat of cattle, goats, hogs, horses and sheep	4.0 ppm
Meat, fat, mbyp and eggs of poultry	0.01 ppm

Tolerances for ruminants have been calculated assuming a contribution due to dermal application to beef cattle. However tolerances for ruminants other than cattle would not differ significantly from the above tolerances except for fat, for which a tolerance of 3.0 ppm would be more appropriate. For simplicity we recommend that the same tolerances be established for all ruminants. However, should anticipated residues (AR's) be calculated, AR's for cattle should be determined separately from AR's for other ruminants.

10b. Because lambda-cyhalothrin -- as other pyrethroids -- concentrates in fat, data are necessary to show concentration of residues in the fat of milk. This can be done by analyzing milk fat from samples of the original feeding study or by spiking milk with lambda-cyhalothrin and analyzing the milk fat. Based on the concentration factor, an appropriate tolerance for lambda-cyhalothrin in milk fat should be proposed.

10c. CB and TOX will decide whether or not the epimer and metabolites should also be included in the tolerance expression for ruminants and poultry. Similarly, CB and TOX will determine whether or not residue data on HO-CPA will be necessary.

11. An International Residue Limit (IRL) Status sheet is appended to this review. A Codex IRL for cabbage, head has been set at 0.2 ppm. There is an incompatibility here that might be removed if a uniform label (directions for use) were adopted.

Recommendation

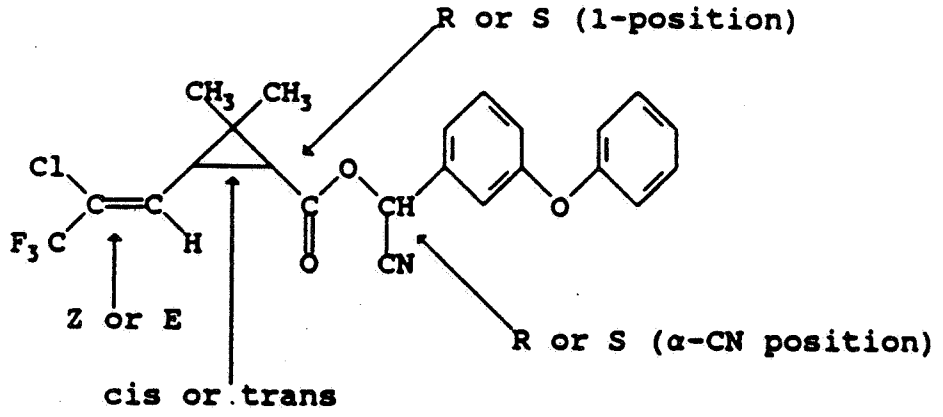
CBTS recommends against the proposed tolerances for reasons given in Conclusions 1 (CAS name); 2 (CSF for KARATE 2.5 EC); 3a (wheat metabolism); 5b (storage stability for metabolites in plant matrices); 5c (identification of animal matrices for metabolite storage stability); 6, 7 (lack of aerial data); 6, 7, 8, 9, 10a (revised Section F's); 10b (milk fat concentration).

Note to PM: As stated in the above conclusions, CB and TOX will jointly determine whether or not metabolites should appear in the tolerance expression and whether residue data will be necessary for the metabolite HO-CPA. A separate memo will be forthcoming.

Detailed Considerations

The detailed manufacturing process for lambda-cyhalothrin was submitted in PP#6F3318 (MRID # 401820-01) and discussed in S. Brooks' (now S. Willett's) memo of 9/29/87.

The structure of lambda-cyhalothrin is shown in Figure 1. The molecule contains three asymmetric carbon atoms and a center for geometrical isomerism. There are thus 16 (2^4) possible isomers comprising 8 pairs of enantiomers. These 8 pairs can be separated on an HPLC column. Lambda-cyhalothrin consists of 1 pair of these enantiomers (the "B" pair) in equal amounts. Cyhalothrin, which is less active, contains the B pair but also another pair (the "A" pair).



A pair of isomers Z (1R) cis (R) alpha-CN and Z (1S) cis (S) alpha-CN

B pair of isomers Z (1R) cis (S) alpha-CN and Z (1S) cis (R) alpha-CN

The IUPAC chemical name for lambda-cyhalothrin is --

A 1:1 mixture of

(S)-α-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)2,2-dimethylcyclopropane-carboxylate

and

(R)-α-cyano-3-phenoxybenzyl- (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)2,2-dimethylcyclopropane-carboxylate

The CAS chemical name is --

[1α(S*),3α(Z)]-(+)-cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclo-propanecarboxylate

The CAS Number is 91465-08-6

The CAS name appears in the CFR regulation. ICI should obtain written confirmation from Chemical Abstracts Service that the CAS name is the correct one. We note that the name differs slightly from that given on the proposed label.

Lambda-cyhalothrin has the ICI code number PP321. Technical PP321 (aka ICIA 0321 Technical), EPA Reg. No. 10182-131, contains 80% active ingredient, according to the Confidential Statement of Formula (CSF) submitted in PP#9F3770 (M. Flood, memo of 1/25/90). The registered formulation, heretofore known as KARATE®, EPA Reg. No. 10182-96, contains 13.1% ai, or 1 pound ai/gal. This formulation will now be sold under the trade name TROPHY® Another formulation, SABER® Pour-On Insecticide, which is used for dermal applications to beef cattle, is the subject of PP#9F3770.

The formulation to be applied to hops (to be exported to the U.S.) is KARATE 5%EC. According to the enclosed CSF for KARATE 5% EC, ICIA 0321 Technical contains nominally 85.1% lambda-cyhalothrin. The 5% EC formulation contains a nominal 6.46% of the technical product, or 5.5% ai. However, the proposed use label for West Germany lists a KARATE 2.5EC. The 5% EC formulation appears on the Czechoslovakia label. A CSF for the 2.5% EC formulation should be submitted.

Proposed Use

Sweet Corn. Apply 0.02-0.04 lb ai./A as required by scouting, usually at intervals of 3 or more days. Application may be by air or ground. Do not apply within 1 day of harvest. Do not apply more than 0.48 lb ai/A per season.

Broccoli. Apply 0.015-0.040 lb ai/A as required by scouting, usually at intervals of 5 or more days. Application may be by air or ground. Do not apply within 1 day of harvest. Do not apply more than 0.24 lb ai/A per season.

Cabbage. Label is identical to that for broccoli.

Tomatoes. Apply 0.015-0.040 lb ai/A as required by scouting, usually at intervals of 5 or more days. Application may be by air or ground. Do not apply within 5 days of harvest. Do not apply more than 0.36 lb ai/A per season.

Hops. West German label. KARATE may be applied to hops up to five times per year using a tractor sprayer or a mist blower. A "typical" worst case application rate would start at 57.5 g ai/ha and end at 142.5 g ai/ha. The total application per season would be 520 g ai/ha. The PHI is 14 days.

Czechosovakian label. The maximum single application rate is 10 g ai/ha. A maximum of three applications are permitted per season, so the maximum rate per season is 30 g ai/ha. The PHI is 14 days.

Nature of the Residue

Plants. Plant metabolism of lambda-cyhalothrin has been extensively discussed in F. Boyd's 2/3/88 memo (PP#7F3560/7H5543). Plant metabolism studies have been carried out on cotton plants and cottonseed, soybean plants and cabbage. The last study utilized cyhalothrin, not lambda-cyhalothrin. Studies were conducted using ^{14}C-cyclopropane labeled and ^{14}C-benzyl labeled compounds.

The studies show that the metabolism of lambda-cyhalothrin generally follows that of other pyrethroids. The ester linkage is cleaved to form cyclopropane carboxylic acids and the corresponding phenoxybenzyl alcohol. Structures of metabolites are given in Figure 2, attached. The cotton and soybean studies showed that the parent compound was the principal constituent of the residue. However, the cabbage plant study indicated that the cis- and trans- cyclopropane carboxylic acids were the major constituents.

At our request, the petitioner carried out a metabolism study on wheat. The study has been reviewed by L. Cheng (8/15/90) and M. Flood (4/16/91). Parent was found to be the principal constituent of the residue in both wheat grain and straw when these commodities were harvested at PHI's up to 30 days. Grain harvested 85 days after treatment showed much lower levels of parent, with the major constituents being the cyclopropane carboxylic acids. Less than half of the residue in grain could be identified (total activity in grain was less than 0.02 ppm). Corresponding data from wheat straw have not as yet been submitted. Therefore, the nature of the residue in wheat is not as yet adequately understood (M. Flood, memo of 4/16/91).

Animals. Sweet corn forage and cannery waste, tomato pomace, sunflower meal and hulls, and spent hops are beef and dairy cattle feed items; tomato pomace and sunflower meal are poultry feed items; so animal metabolism is relevant to these petitions.

A study in which ^{14}C-cyclopropane lambda-cyhalothrin was fed to a single lactating goat for 7 days was reviewed in PP#6F3318 (M. Firestone, memo of 1/22/86). In an earlier study ^{14}C-cyclopropane labeled cyhalothrin and ^{14}C-benzyl labeled cyhalothrin were fed to dairy cattle (PP#5G3204, memo of J. Worthington, 5/6/85). Both studies showed that parent compound was the only major component of the residue in milk, muscle and fat. The principal component of the ^{14}C-cyclopropane labeled

residue in liver and kidney was 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylic acid (CPA, or CTFPA). Also present in significant concentrations was 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropane-carboxylic acid (OH-CPA, or OHMe-CTFPA), in which one of the cyclopropane ring methyl groups is replaced with an hydroxyl group. Liver and kidney metabolites found from the ^{14}C-benzyl labeled study were 3-phenoxybenzoic acid (3-PBAcid) and 4-hydroxy-3-phenoxybenzoic acid (4'-OH-3PBAcid).

Poultry metabolism was first reviewed in PP#7F3488 (S. Willett, ne' S. Brooks, memo of 8/13/87; memo of 10/27/89) and later in PP#7F3560/7H5543 (L. Cheng, memo of 8/15/90). Two laying hens were dosed with daily with ^{14}C-cyclopropane labeled lambda-cyhalothrin at 10.8 ppm over 14 days. Total residue levels in egg albumin, breast muscle and leg muscle were 0.01 ppm. The principal constituent of the residue in egg yolk and fat was parent. In liver the major constituent was CPA with lower but significant levels of OH-CPA. No corresponding ^{14}C-benzyl labeled study was submitted, but from a study conducted using ^{14}C-benzyl labeled cypermethrin, in which the alcohol side of the molecule is identical to that of lambda-cyhalothrin, it could be concluded that 3-PBAcid and 4'-OH-3-PBAcid are significant components of the residue in liver. The principal constituent of liver in that study was parent, but one would not expect similar concentrations of constituents from two different pyrethroids. The <u>qualitative</u> nature of the phenoxybenzyl residue should be the same. CBTS has concluded that the primary terminal residues of concern in poultry are the same as those in ruminants (L. Cheng, PP#7F3560/7H5543, memo of 8/15/90).

ICI has submitted an edited version of the original hen metabolism study (PP#7F3488, MRID # 400279-06). The date of this edited version is 4/18/90; the new MRID # is 417370-02. Pages 13, 14 and 15 of the original report have been modified. These are summary tables for residues in yolk, liver and fat. Changes made are minor and do not affect our earlier conclusions.

Dermal metabolism studies conducted on lactating cows were submitted in PP#9F3770 and reviewed in M. Flood's memos of 1/25/90 and 4/17/91. Results were qualitatively similar to the oral ruminant studies summarized above. Parent constituted the only significant component of the residue in milk, muscle and fat. CPA and OH-CPA and conjugates were the major components found in liver and kidney after treatment with ^{14}C-cyclopropane labeled lambda-cyhalothrin. 3-PBAcid and conjugates were the major components of the ^{14}C-benzyl labeled residue. 4'-OH-3-PBAcid was not found in the metabolism study but was observed in the residue studies.

The nature of the residue in ruminants and poultry is adequately understood. Parent lambda-cyhalothrin is the major

component of the residue, except for kidney and liver of ruminants and liver of poultry. CPA, OH-CPA, 3-PBAcid and 4'-OH-3-PBAcid are the major metabolites. A meeting with TB1 was held on 4/11/91 concerning regulation of these metabolites as a result of dermal use. It was noted that CPA, 3PBA and 4-OH-3-PBAcid were products of rat metabolism and were found in tissue at only low levels. Hence, it was decided that these metabolites need not appear in the tolerance expression. However, OH-CPA was not identified as a rat metabolite, and no residue data reflecting dermal application were available. Therefore, CBTS and TB1 (R. Gardner, P. Hurley) decided that unless the registrant could show that OH-CPA was a rat metabolite, residue data on this metabolite and a validated analytical method would be needed before a final decision whether or not it should appear in the tolerance expression could be made (PP#9F3770, M. Flood, memo of 4/17/91). This issue was addressed earlier in the case of Karate® by S. Willett in her memo of 10/27/89 (PP#7F3560, PP#7F3488). In that memo CBTS stated that poultry residue levels of OH-CPA could not be derived from observed residue levels of CPA by using the ratio of levels found in the poultry metabolism study. The conclusion in our memo for PP#9F3770 applies to the present petition. Unless TB is able to say that the hydroxylated metabolite is not of concern (i.e., unless it is a rat metabolite), residue data must be generated for this metabolite.

Analytical Method

Plants

The analytical method for parent and its epimer, R157836 [a 1:1 mixture of the enantiomers (R)-α-cyano-3-phenoxybenzyl (1R)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl-cyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1S)-cis-3-(Z-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylate] in plant matrices is ICI Method 81, which was first described in MRID # 400540-01. The actual analysis of sweet corn commodities was performed at Huntingdon Analytical Services in Middleport, NY.

Ground samples are extracted with acetone:hexane (1:1 v/v). The extracts are washed with water and the aqueous acetone layers discarded. The hexane extracts are evaporated to dryness and the residuum redissolved in a specified amount of hexane. Aliquots of the extracts are subjected to liquid partition chromatography to remove liquids. (The liquid partition column is prepared by adding Florisil to a column containing acetonitrile saturated with hexane. The acetonitrile solution is allowed to drain through the column followed by hexane saturated with acetonitrile. The hexane extract is then passed through the column which is then washed with hexane saturated with acetonitrile, "hexanes". The compounds of interest are then eluted with ether/hexanes (25%, v/v).) The evaporated extract is

redissolved in 1 mL hexanes and purified on a Florisil column. Final analysis is by capillary GC.

The method has successfully undergone EPA Method Validation for soybeans (PP#6F3318/PP#7F3488, E. Greer, memo of 9/30/87).

The analytical method for metabolites (used in all three petitions) was submitted in FAP#0H5599:

> "Method for Analysis of Lambda-Cyhalothrin Metabolites in Hops," D.M. Clarke and A. Sapieto, 6/1990, Laboratory Project ID M54114B. (MRID # 416146-03)

The method was developed at ICI Agrochemicals laboratory in Bracknell, Berkshire, UK. Metabolite analyses for PP#7F3560/7H5543 and PP#1F3952/1H5607 were performed by Pharmacology and Toxicology Research Laboratory West, Inc. in Richmond, CA.

Samples were analyzed for CPA (PP890) and 3-PBAcid. Lambda-cyhalothrin includes the cis isomer only. Some of the CPA formed in the metabolism of lambda-cyhalothrin is in the trans form. The method provides for the co-analysis of the two isomers. The method converts any 3-phenoxybenzyl alcohol to 3-PBAcid. Hence, concentrations reported as 3-PBAcid are really the sum of the concentrations of the two metabolites.

Samples are extracted with acetonitrile and then acetonitrile: pH 9 water 1:1 v/v. After filtration, lambda-cyhalothrin and its epimer are removed from the extracts by C18 solid phase extraction. The acetonitrile is removed by rotary evaporation, and sufficient concentrated HCl is added to the extract to produce a 2N solution. The extract is then refluxed for two hours to hydrolyze any conjugates. After cooling, the extract is partitioned with dichloromethane and the aqueous layer discarded. The dichloromethane is evaporated and the residuum taken up in acetone. Jones Reagent, prepared by dissolving chromium (VI) oxide in aqueous sulfuric acid, is added to oxidize 3-phenoxybenzyl alcohol to the acid. After the reaction (3 min.) the extract is diluted with water and partitioned with dichloromethane. The dichloromethane extract is acid washed and then partitioned with pH 9.18 tetraborate buffer. The aqueous layer is retained, acidified, and partitioned with dichloromethane. The extract is evaporated to dryness and derivatised with trifluoroacetic anhydride and trifluoroethanol at 100°C for 5 minutes. The derivatised extract is analyzed by capillary GC using a mass selective detector.

Should it be determined that CPA and 3-PBAcid appear in the tolerance expression, the method must undergo independent laboratory validation prior to EPA Method Validation.

Recoveries for lambda-cyhalothrin (PP321) and its epimer (R157836) from sweet corn on the cob and sweet corn forage are given in Table 1a, recoveries from broccoli are given in Table 1b, recoveries from cabbage are given in Table 1c.

Table 1a

Recoveries of PP321 and R157836 from Sweet Corn on the Cob and Sweet Corn Forage

		Sweet Corn on the Cobb	Sweet Corn Forage
	Fortification Levels (ppm)	Mean Percent Recovery	Mean Percent Recovery
PP321	0.013, 0.021, 0.025, 0.064, 0.13, 0.21, 2.1	92.7±9.7 (n=16) [92.6±15.5 (n=3) at lowest fortification level]	90.4±13.4 (n=26) [92.8±13.1 (N=3) at lowest fortification level]
R157836	0.017, 0.028, 0.033, 0.084, 0.17, 0.28, 2.8	90.7±10.0 (n=16) [86.8±16.6 (n=3) at lowest fortification level]	84.8±9.2 (n=27) [80.7±9.9 (n=4) at lowest fortification level]

Sweet corn samples were separately fortified with CPA (PP890), 3-PBAcid, and 3-PBAlcohol at 0.05 ppm. Percent recoveries of CPA averaged 103.9±6.3 (n=9); percent recoveries of 3-PBAcid averaged 87.0±5.6 (n=5); and percent recoveries of 3-PBAlcohol averaged 89.2±10.8.

Submitted chromatograms show well resolved peaks at a fortification level of 0.05 ppm for the metabolites. Chromatograms for PP321 and R157836 show well resolved peaks at a number of fortification levels, including the minimum levels.

Table 1b

Recoveries of PP321 and R157836 from Broccoli

	Fortification Levels (ppm)	Mean Percent Recovery
PP321	0.013, 0.025, 0.064, 0.11, 0.13, 0.53, 1.3, 12.7	91.7±12.8 (n=20)
R157836	0.017, 0.033, 0.084, 0.14, 0.17, 0.70, 1.7, 16.7	89.2±13.4 (n=20)

Broccoli samples were separately fortified with CPA, 3-PBAcid and 3-PBAlcohol at levels of 0.05 and 0.10 µg/g. Percent recoveries of CPA averaged 81±10%. Recoveries of 3-PBAcid and 3-PBAlcohol averaged 88±6% and 80±5%, respectively. Sample chromatograms show well resolved peaks.

Table 1c

Recoveries of PP321 and R157836 from Cabbage

	Fortification Levels (ppm)	Mean Percent Recovery
PP321	0.013, 0.021, 0.025, 0.064, 0.13, 2.1	101±13.4 (n=32)
R157836	0.017, 0.028, 0.033, 0.084, 0.17, 2.8	95.6±13.0 (n=32)

Cabbage samples were separately fortified with CPA, 3PBAcid and 3PBAlcohol at levels of 0.05 and 0.1 μg/g. Percent recoveries of CPA averaged 78±9%. Recoveries of PBAcid and PBAlcohol averaged 108±23% and 99±14%, respectively. Submitted chromatograms show acceptable resolution.

Table 1d

Recoveries of PP321 and R157836 from Tomatoes

	Fortification Levels (ppm)	Mean Percent Recovery
PP321	0.013, 0.021, 0.025, 0.064, 0.13, 2.12	99.5±14.0 (n=19)
R157836	0.017, 0.028, 0.033, 0.084, 0.17, 2.79	96.6±16.1 (n=19)

Tomato samples were separately fortified with CPA, 3-PBAcid and 3-PBAlcohol at 0.05 ppm. Percent recoveries of CPA averaged 84.2±11.6%. Recoveries of 3-PBAcid and 3-PBAlcohol averaged 92.0±10.1% and 87.6±3.2%.

Percent recoveries were obtained for PP321, R-157836, PP890, 3-PBAcid and 3-PBAlcohol from wet pomace, dry pomace, puree, ketchup, paste and juice. (Samples were not fortified with PP321 but with cyhalothrin -- 43.2% PP321, 56.8% R-157836. Recoveries were obtained for both species.) Average percent recoveries varied from 75% to 112%. High recoveries (130%) were obtained when puree was fortified with cyhalothrin. The corresponding chromatograms show no major interference.

Lambda-cyhalothrin residues in dried hops were determined using ICI Method 81. The analytical method for analysis of lambda-cyhalothrin metabolites in hops (MRID # 416146-03) has been discussed above. Recovery data from dried hops and brewers grains, as reported with results from the 1989 field trials, are given in the following table:

Table 1e

Recoveries of PP321 and R157836 from Dried Hops and Brewers Grains

	Dried Hops		Brewers Grains	
	Fortification Levels (ppm)	Mean Percent Recovery	Fortification Levels (ppm)	Mean Percent Recovery
PP321	2.0	98±6 (n=2)	0.1, 0.24	100.4±0.8 (n=4)
R157836	------	------	0.1, 0.26	97.4±3.1 (n=4)

These latter recoveries were corrected for an internal standard. Recoveries of 0.1 ppm CPA from dried hops and brewers grains averaged 98.9±25.2% (n=9). There were two high recoveries of 132 and 150%. Recoveries of 0.1 ppm 3-PBAcid averaged 113.8±23.6%. These included high values of 134, 142 and 145%. Residue levels were not corrected for recoveries higher than 100%. Sample chromatograms of control and fortified samples show that interferences could account at least in part for the high recoveries.

As noted in the magnitude of residue section of this memo, there are no validation data accompanying the 1985 hop field trials. The data cannot be accepted until such information is provided.

Animals

The analytical method used to determine residues of PP321 in meat, milk, poultry and eggs is ICI Method 86, reviewed in M. Firestone's memo of 1/22/86 (PP#6F3318). PP321 is extracted from milk or animal tissue with 50 percent acetone:hexane. The aqueous fraction is removed and the organic layer dried with sodium sulfate. The organic fraction is cleaned up by Florisil column chromatography prior to determination by packed column gas chromatography using a ^{63}Ni electron capture detector.

ICI Method 81 (for residues of PP321 on crops) and Method 86 (for these residues in animal products) were successfully validated by EPA (PP#6F3318/7F3488, E. Greer, memo of 9/30/87, S. Brooks, memo of 10/30/87).

The analytical method used to determine metabolites of PP321 in meat, milk, poultry and eggs is ICI Method 96. The method (dated October, 1988) is given in PP#1F3952, MRID # 417935-01, which is a report of a residue transfer study with laying hens. Samples fortified with an internal standard are extracted with acetonitrile, 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 to aqueous, adjusted to 4 molar with HCl, and refluxed

for 4 hours. 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 GC-MS with selected ion monitoring (SIM). CPA is benzylated with benzyl bromide and purified on a Florisil column prior to GC with electron capture detection. 4'-OH-3-PBAcid is quantitated using HPLC with electrochemical detection. The internal standards used are 4-phenoxybenzoic acid and CPA in which the chlorine has been replaced with a bromine.

An updated Method 96 (March, 1990) was submitted as part of FAP#0H5599 (MRID # 416146-04). In the revised method, after extraction of the hydrolysate by dichloromethane, the dichloromethane solutions are divided into two equal portions. One half is used for 4'-OH-3-PBAcid analysis and the other half for CPA and 3-PBAcid analyses. The hydroxylated metabolite in solution is passed through an aminopropyl bonded silica column. The other two metabolites are purified on a C_{18} bonded silica column. This latter cleanup procedure may also be used for 4'-OH-3-PBAcid if the samples have not been sufficiently cleaned up on the aminopropyl column. Both CPA and 3-PBAcid are benzylated using benzyl bromide, and the benzyl esters are subsequently purified on a Florisil column. Both esters are quantitated by GC-MS-SIM. The revised method does not utilize internal standards.

Percent recovery data for metabolite analyses in cow and poultry tissue are given in PP#0H5599, MRID # 416146-08 (residue levels of metabolites in dairy cows). Fortifications were generally made at 0.05, 0.10 and 0.20 ppm. Percent recoveries for 4'-OH-3-PBAcid averaged 77±18% in all tissues and milk/eggs; percent recoveries for 3-PBAcid averaged 68±18%; and percent recoveries for CPA averaged 82±17%. Additional recovery data are given in PP#1F3952/1H5607, MRID # 417935-01 (residue levels of metabolites in laying hens). These recoveries, as well as the residue analyses were obtained using the earlier version of Method 96.

Recoveries using revised Method 96 were better than those using the earlier version, and acceptable recoveries were obtained at lower concentrations. Percent recoveries for 3-PBAcid in milk, meat, fat, kidney, liver and egg averaged 96±21% at the 0.01 ppm fortification level, 94±21% at 0.02 ppm, 81±16% at 0.05 ppm and 77±15% at 0.1 ppm. Percent recoveries for CPA in milk, meat and egg averaged 88±17% at the 0.01 ppm and 86±16% at 0.02 ppm. Recoveries from milk, egg, fat, kidney and liver averaged 87±16% at the 0.05 ppm level; recoveries from milk, meat, fat, kidney and liver averaged 82±7%; and recoveries from fat, kidney and liver averaged 93±13% at the 0.2 ppm level. Percent recoveries for 4'-OH-3-PBAcid in milk, meat, fat, kidney

and egg averaged 87±10% at the 0.02 ppm fortification level. Recoveries from meat, fat, kidney, liver and egg averaged 72±17% at 0.05 ppm and 80±17% at 0.1 ppm; and recoveries from milk, meat, fat, kidney, liver and egg averaged 90±15% at 0.2 ppm.

Should it be necessary to regulate these metabolites in animal products, the latest version of Method 96 must undergo independent laboratory validation before it can be validated at EPA.

No residue analytical method has been submitted for the animal metabolite HO-CPA. Because it will be necessary to know levels of this metabolite in animals before CB/TOX can determine whether or not this metabolite should appear in the tolerance expression, an appropriate method may have to be developed.

Multiresidue Testing. The petitioner has determined recoveries of cyhalothrin under FDA's multiresidue protocols (PP#7F3488, S. Willett, memo of 3/15/88).

Included in this petition is the following report:

"Analysis of Pyrethroid Metabolites R173204, 3-Phenoxybenzoic Acid and PP890 by Analytical Methods in the FDA Manual Volume 1;" R.K. Malhotra and T.Formella; 4/19/89; ICI Report No. RR 90-358B, Huntingdon Study No. A030.002. (MRID # 417370-05.

R173204 is a Tefluthrin metabolite. The remaining two are lambda cyhalothrin metabolites. This volume is being forwarded to FDA for review.

Storage Stability

Storage stability data have been submitted on a number of crops in the following report (PP#0H5599):

"PP321: 26-Month Storage Stability in Frozen Crop Samples (Final Report)," O.J. Tummon and A. Sapiets, 12/14/88, Lab. Project ID # M4845B. (MRID # 416146-02)

Analyses were carried out in ICI Agrochemicals Jealott's Hill Research Station in the UK.

Samples of peach, pea, oil seed rape, wheat grain, sugarbeet root, cottonseed, apple, cabbage and potato were fortified with lambda-cyhalothrin at 0.5 mg/kg and held at -18°C for periods up to 26 months. No significant degradation of lambda-cyhalothrin occurred over this time period. Percent recoveries at 26 months varied from 103 to 122%. Submitted chromatograms show well resolved peaks. Samples were analyzed by Analytical Method No. 81. To assess stability in extracts, 1:1 acetone:hexane extracts

of the treated racs were held at <4°C for 33-42 days after the 26 months analyses. No significant degradation was seen in extracts under these conditions.

Storage stability of CPA, 3-PBAcid and 3-PBAlcohol on 13 racs has been reported in PP#1F3952/1H5607, MRID # 417370-03. Racs studied included tomatoes, cabbage, lettuce, sugarbeets, corn forage, corn fodder, peanut meats, peanut hulls, sorghum grain, apples, soybeans, cottonseed and tobacco. Residues were stable at -20°C±10°C for 3 months. Presumably, this is an ongoing study.

In an earlier study, storage stability of Tefluthrin metabolites under frozen storage conditions was assessed. CPA is one of this pesticide's metabolites. The study was submitted 3/13/87 under an EUP and assigned MRID # 401413-27. In this study CPA as a percent of the total radioactive residue was found to be stable under frozen storage conditions for 11-22 months. Absolute concentrations are not reported, however, so real storage stability cannot be determined from this report.

Storage stability of lambda-cyhalothrin in meat, milk, poultry and eggs was submitted under PP#7F3488. Lambda-cyhalothrin was stable in animal tissues from a cow residue transfer study under frozen storage for nine weeks. The same compound was shown to be stable in milk, eggs and various poultry tissues for periods up to three months (S. Willett, memo of 8/13/87). In a subsequent report, lambda-cyhalothrin was shown to be stable in poultry tissues and eggs stored at -18°C for 2 years (PP#7F3488, N. Dodd, memo of 3/15/88).

Storage stability of the metabolites CPA, 3-PBAcid and 4'OH-3-PBAcid in cow and chicken matrices are given in PP#1F3952, MRID # 417935-01. Muscle, milk, kidney, liver, egg and fat were fortified at 0.2 mg/kg and stored for 35-42 months. Residues were found to be stable under these conditions. Except for milk and eggs, it is not clear whether the matrices spiked were chicken or beef or both. For the record this information should be provided.

Additional storage stability data were submitted in support of PP#9F3770 (Lambda-cyhalothrin for dermal applications to beef cattle) by Coopers Animal Health, Ltd., a firm formed from the merger of the animal health interests of the Wellcome Foundation and ICI. Samples of bovine liver, kidney, muscle and bodyfat were fortified with 0.05 ppm lambda-cyhalothrin, CPA, 4'-OH-3-PBAcid and 3-PBAcid and stored at -15°C to -20°C for periods of 96 days (lambda cyhalothrin in bodyfat) to 267 days (each of the three metabolites in muscle). Residues were found to be stable under these conditions, but it should be noted that zero time recoveries on the bovine matrices were not obtained. Recoveries after the allotted storage time varied from 57.4 to 103.9%. (M.

Flood, memo of 1/25/90).

Also submitted as a part of PP#1F3952/FAP#1H5607 is a report of storage stability of metabolites in soil: "Tefluthrin: Storage Stability of the Metabolite Residues in Frozen Soil Samples. Interim Report," 5/22/89. (MRID # 417370-04) CPA and 2,3,5,6-tetrafluoro-4-methyl benzoic acid were found to be stable in soil at -18°C for up to 22 months. We are returning this volume to the PM, for it is not CB's responsibility to review stability in soil.

Residue Data

PP#7F3560/7H5543. Residue data reflecting the application of lambda-cyhalothrin to sweet corn appear in the following report:

> "ICIAO321 and Metabolites: Magnitude-of-the-Residue Study on Sweet Corn, Forage, Ears and Cannery Waste;" J.C. McKay; 1/16/91; Laboratory Project ID #'s 0321-89-PR-06, 0321-89-MR-10, 0321-89-MR-18. Performing laboratories were ICI Americas Inc., Western Research Center, Richmond, CA; Huntingdon Analytical Services, Middleport, NY; and Pharmacology and Toxicology Research Laboratory-West, Inc, Richmond, CA 94806. (MRID # 417711-02)

Fourteen trials were conducted during 1989 in CA, FL, ID, IL, IN, MD, MI, MN, NJ, NY, OR, PA, WA and WI. According to Agricultural Statistics, 1988, these states accounted for at least 74% of the sweet corn production for fresh market in the U.S. during the year 1986. Lambda-cyhalothrin was ground or air applied at a rate of 0.04 lb ai/A in a 12 application spray program. All but one of the field trials were conducted using an EC formulation in water. In the New Jersey trial a wettable granule formulation was used. Applications were made at about 2-8 day intervals with the last application 1 day before harvest (PHI=1day). Samples were frozen within a few hours of sampling and shipped directly to either the Eastern Research Center, Goldsboro, NC or to the Western Research Center, Richmond, CA.

The frozen forage and ear (kernels with cobs, husks removed) samples were ground in dry ice, subsampled and stored at -20°C±10°C prior to analysis. Corn ear samples from 5 trials were prepared with husks not removed and were not analyzed. Cannery waste samples -- the cob and plant parts remaining after the kernels are removed -- were obtained by following sweet corn processing procedures in the laboratory.

Samples were analyzed for parent and epimer up to almost one year after sampling. Maximum interval between extraction and analysis was 9 days. Analysis for metabolites occurred up to 14 months after sampling, and the maximum interval between

extraction and analysis was 8 days. The storage stability data are adequate to support the analyses of parent and epimer but are not adequate to support metabolite analysis.

Results (uncorrected for recoveries) for sweet corn forage are given in Table 2.

Table 2

Residues (ppm) of Lambda-cyhalothrin and Metabolites in Sweet Corn Forage

	PP321	R157836	CPA (PP890)	3-PBAcid
Jerome, ID	0.85,0.69	0.09,0.07	0.083,0.092	0.047,0.043
Geneseo, IL	0.42	0.05	0.061,0.069	0.032,0.030
Benton Harbor, MI	3.1	0.34	0.21,0.24	0.093,0.102
Delevan, WI	3.7	0.39	0.137	0.048
Rising Sun, MD	5.0	0.45	0.163	0.072
Woodruff, NJ	2.93	0.28	0.11,0.16	0.073,0.072
Thermal, CA*	3.1	0.44		
Ontario, OR	0.98	0.12		
Ephrata, WA	1.8	0.19		
Owatonna, MN	0.56	0.06		
Hebron, IN	2.7	0.33		
Phelps, NY	1.39	0.13		
Germansville, PA	1.95,2.08	0.19,0.20		
Belle Glade, FL*	0.53,0.50	0.06,0.07		

* Aerial Application

Sweet corn ears (cob with husk removed) were analyzed from the trials in ID, IL, WI, MD, NJ, OR, WA, IN, CA, and FL. Residue levels of lambda-cyhalothrin, the epimer and the two metabolites were nondetected (<0.01 ppm) except for the Florida trial, where a lambda-cyhalothrin level of 0.02 ppm was measured. Residue levels in kernels and cannery waste were nondetected (<0.01 ppm) in two additional trials (MD -- parent and epimer plus metabolites -- and ID -- metabolites only). Cannery waste is the cob and plant parts remaining after the kernels are removed. There are no application data sheets for the Idaho trial (16ID89-651), and kernels/cannery waste were apparently analyzed for metabolites only. For the Maryland trial (54MD89-652) Karate® was applied at a 4x application rate (12 x 0.15 lb ai/A). We conclude that no concentration of residues occurs in

these processed commodities.

Representative chromatograms are included in the submission. Relevant peaks are well resolved.

Based on these data, proposed tolerances of 0.02 ppm and 6.0 ppm for residues of parent in/on sweet corn ears and forage, respectively, are adequate. However, because of analytical uncertainties at low levels, a tolerance of 0.05 ppm would be more appropriate for sweet corn. The appropriate expression is not "sweet corn ears" but "sweet corn (K + CWHR)".

PP#1F3952/1H5607. Field trial data on broccoli, cabbage and tomatoes are included in this petition.

Broccoli. Residue data appear in the following report:

"ICIA0321 (Lambda Cyhalothrin)- Magnitude of the Residue Study on Broccoli;" P.D. Francis; 12/19/90; Laboratory Project ID #'s 0321-88-MR-03, 0321-89-MR-17; Report # RR 90-427B. (MRID # 417370-03)

Analyses for residues of lambda-cyhalothrin and the epimer R157846 were conducted at Huntingdon Analytical Services, Middleport, NY. Samples were analyzed 2-18 months after harvest. Chromatography was done 0-9 days after initial extraction. Analyses for PP890 and 3-PBAcid were conducted at ICI Americas, Inc, Western Research Center, Richmond, CA. Samples were analyzed 3-22 months after harvest. Chromatography was done 2-4 days after initial extraction.

Our comments regarding storage stability are identical to our comments for corn: storage stability data are adequate to support the analyses for parent and epimer but not analyses for metabolites.

Ten trials were conducted during 1988 and 1989 in CA, TX, AZ and OR. According to Agricultural Statistics, 1988, these states account for virtually 100% of the U.S. broccoli production. In 1988 the field trials were conducted using a water dispersable granular formulation (WDG). In 1989 an emulsifiable concentrate formulation was used. Applications were made using backpack sprayers with the sprays directed to the plants. A total of 8 applications were made at a rate of 0.03 lb ai/A/application. Applications were made at approximately 10 day intervals. The broccoli was harvested one or three days after the final application. Results are given in Table 3.

Table 3

Residues (ppm) of Lambda-cyhalothrin and Metabolites in/on Broccoli

Location	PHI (days)	PP321	R157836	PP890	3-PBAcid
Watsonville, CA	1	0.30	0.01	0.01	<0.01
	3	0.23	0.02	0.02	<0.01
Watsonville, CA	1	0.26	0.01		
	3	0.28	<0.01		
Mercedes, TX	1	0.20	<0.01	<0.01	<0.01
	3	0.08,0.12	<0.01,<0.01	<0.01,<0.01	<0.01,<0.01
Yuma, AZ	1	0.28	0.02		
	3	0.15	0.01		
Hillsboro, OR	1	0.21	0.01	<0.01	<0.01
	3	0.23	0.01	<0.01	<0.01
Oxnard, CA	1	0.28	0.02	<0.01	<0.01
	3	0.12,0.08	0.01,0.01	<0.01,<0.01	<0.01,<0.01
Mercedes, TX	1	0.09	<0.01	<0.01	<0.01
	3	0.05	<0.01	<0.01,0.01	<0.01,<0.01
Yuma, AZ	1	0.04	<0.01	<0.01	<0.01
	3	0.04	<0.01	<0.01	<0.01
Watsonville, CA	1	0.21,0.14	0.01,0.01	0.02	<0.01
	3	0.12	<0.01	0.02	<0.01
Watsonville, CA	1	0.03	<0.01	<0.01,<0.01	<0.01,<0.01
	3	0.05	<0.01		

Based on the residue data, the proposed tolerance of 0.4 ppm for residues of parent is appropriate. However, because no data reflecting aerial application have been submitted, the petitioner must either revise the use label or submit additional residue data.

Cabbage. Residue data appear in the following report:

"ICIA0321 (Lambda Cyhalothrin)- Magnitude of the Residue and Reduction of the Residue Study on Cabbages;" P.D. Francis; 12/18/90; Laboratory Project ID #'s 0321-88-MR-04, 0321-89-MR-15; Report No. RR 90-415B. (MRID # 417370-06)

As in previous residue studies, analyses for parent and epimer were performed at ICI's Western Research Center, Richmond, CA; analyses for metabolites were performed at Huntingdon Analytical Services, Middleport, NY.

During 1988 and 1989 eleven trials were conducted in NY, CA, Fl, TX, WI, NJ and NC. According to the Foods and Food Production Encyclopedia, 1982, these states account for about 75% of the U.S. cabbage production.

Lambda-cyhalothrin was applied eight times at a rate of 0.03 lb ai/A using either the WDG or EC formulation. Applications were made using either tractor mounted sprayers or backpack sprayers. The last application was made one day before harvest. Cabbage was sampled at one day and three days after the last application. A portion of the cabbages had the outer wrapper leaves removed.

Analysis of cabbage for parent and epimer occurred 6 to 18 months after harvest. Analysis for metabolites occurred 5 months to two years after harvest. Samples were extracted up to one month before analysis for parent and from five days to five months before analysis for metabolites (Volume 85, Table 5). As noted above, available storage stability data are adequate for parent and epimer analyses only. Additional data must be generated for metabolites, including data to demonstrate stability in extracts for periods up to five months.

Residue data are given in the following tables:

Table 4a

Residues (ppm) of Lambda-Cyhalothrin and Metabolites in/on Cabbage With Wrapper Leaves

Location	PHI (days)	PP321	R157836	PP890	3PBAcid
Phelps, NY	1	0.02	0.01		
	3	0.05	<0.01		
Watsonville, CA	1	0.10	0.01		
	3	0.07	0.01		
Groveland, FL	1	0.21	0.02		
	3	0.09	0.01		
Mercedes, TX	1	0.09	0.01		
	3	<0.01	<0.01		
Waterloo, WI	1	0.05	<0.01	<0.01,<0.01	<0.01,<0.01
	3	0.06	<0.01	<0.01	<0.01
Salem, NJ	1	0.24	0.01	0.02	<0.01
	3	0.20	0.01	<0.01	<0.01

Goldsboro, NC	1	0.13	0.01	0.01	<0.01
	3	0.12	0.01	0.01,0.01	<0.01,<0.01
Mercedes, TX	1	0.15	0.01	0.01	<0.01
	3	0.13	0.01	<0.01	<0.01
Watsonville, CA	1	0.24	0.02	0.04	0.02
	3	0.19,0.22	0.02,0.02	0.03	0.01
Groveland, FL	1	0.13	0.02	0.03	0.01
	3	0.20	0.03	0.03	0.01
Phelps, NY	1	0.21	0.02	0.07	0.04
	3	0.12	<0.01	0.06	0.04

Table 4b

Residue (ppm) of Lambda-Cyhalothrin
and Metabolites in/on Cabbage Without Wrapper Leaves

Location	PHI (days)	PP321	1R157836	PP890	3PBAcid
Phelps, NY	1	0.01	<0.01		
	3	0.01,0.02	<0.01,<0.01		
Watsonville, CA	1	<0.01	<0.01		
	3	<0.01	<0.01		
Groveland, FL	1	<0.01	<0.01		
	3	<0.01,<0.01	<0.01,<0.01		
Mercedes, TX	1	0.01	<0.01		
	3	<0.01,<0.01	<0.01,<0.01		
Waterloo, WI	1	0.02	<0.01	<0.01	<0.01
	3	0.02,0.01	<0.01,<0.01	<0.01	<0.01
Salem, NJ	1	0.02	<0.01	<0.01,<0.01	<0.01,<0.01
	3	0.01,0.01	<0.01,<0.01	<0.01	<0.01
Goldsboro, NC	1	0.02	<0.01	<0.01	<0.01
	3	0.01,0.01	<0.01,<0.01	<0.01	<0.01
Mercedes, TX	1	<0.01	<0.01	<0.01	<0.01
	3	<0.01,<0.01	<0.01,<0.01	<0.01	<0.01
Watsonville, CA	1	<0.01	<0.01	<0.01	<0.01
	3	<0.01	<0.01	<0.01	<0.01
Groveland, FL	1	0.01	<0.01	<0.01	<0.01
	4	<0.01	<0.01	<0.01	<0.01
Phelps, NY	1	0.02,0.02	<0.01,<0.01	<0.01	<0.01
	3	<0.01	<0.01	<0.01	<0.01

For purposes of this tolerance petition, the proposed tolerance of 0.4 ppm for residues of lambda-cyhalothrin, per se, in/on cabbage is appropriate. However, in the absence of data reflecting aerial application, the registrant must either revise the use label or submit additional data. We note that the rac is cabbage with all but decomposed/wilted wrapper leaves. Therefore, a tolerance for cabbage with wrapper leaves removed should not be proposed. However, for calculation of anticipated residues a more accurate consumption estimate will be obtained by using the residue data from cabbage without wrapper leaves.

Tomatoes. Residue data appear in the following report:

"ICIA0321 and Metabolites: Magnitude-of-the-Residue Study on Tomatoes," J.C. McKay, 12/19/90, Laboratory Project ID # 0321-89-MR-11, Report # RR-90-414B. (MRID # 417370-07)

Analyses for residues of lambda-cyhalothrin and its epimer were conducted at Huntingdon Analytical Services, Middleport, NY. Analyses for metabolites were conducted at Pharmacology and Toxicology Research Laboratory-West, Inc., Richmond, CA.

Thirteen field trials were conducted on tomatoes during 1988 and 1989 in CA, FL, MI, NJ, TX, SC and OH. According to Agricultural Statistics, 1988, these states accounted for over 95% of the production of tomatoes for processing and over 82% of the production of fresh tomatoes in 1986. Tomatoes received 12 applications of 0.03 lb ai/A lambda-cyhalothrin, with ground equipment, at approximately ten day intervals and were harvested 5 or 10 days after the last application. The WDG formulation was used in the 1988 trials; the EC formulation was used in the 1989 trials.

Samples were analyzed for parent and epimer 4-10 months after harvest. Chromatography was done 11-37 days after extraction. Samples were analyzed for CPA (PP890) and PBAcid 7-12 months after harvest. Chromatography was done one day after extraction. As for the other racs, stability of metabolites under frozen storage must be demonstrated.

In all samples analyzed, concentrations of epimer (R157836), PP890 and 3-PBAcid were <0.01. Concentrations of PP321 are given in the following table:

Table 5

Residues (ppm) of Lambda-Cyhalothrin in/on Tomatoes

Location	PHI (days)	PP321
Alachua, FL	5	<0.01
	10	<0.01
Groveland, FL	5	0.02
	10	0.02, 0.02
	10	<0.01
Oneco, FL	5	<0.01, <0.01
	10	<0.01
Brentwood, CA	5	0.01, <0.01
	10	<0.01
Sultana, CA	5	0.02
	10	0.01
Mercedes, TX	5	<0.01
	10	<0.01
Marcellus, MI	5	0.02
	10	0.02, 0.02
Penns Grove, NJ	5	0.04
	10	0.03
Clemson, SC	5	<0.01*
	10	<0.01*
Sultana, CA	5	0.04
Groveland, FL	5	0.05, 0.03
Columbus, OH	5	0.04
Oxford, FL	5	0.06

* Due to a mathematical error, only 12 x 0.0019 lb ai/A was applied in the SC trial.

Based on the residue data, the proposed tolerance of 0.06 ppm for residues of lambda-cyhalothrin in/on tomatoes is adequate, but to allow for analytical uncertainties, we consider a tolerance of 0.1 ppm to be more appropriate. The registrant should submit a revised Section F in which this tolerance is proposed. As in the cases of broccoli and cabbage, either the label must be revised to limit application to ground equipment or additional residue trials must be carried out in which the compound is aerial applied.

Hops. Residue data have been submitted in three reports:

"Lambda-cyhalothrin: Residue Levels of the Insecticide and Its Metabolites in Dried Hops and Brewers Grains from Trials Carried Out in the Federal Republic of Germany During 1989," D.M. Clarke and A. Sapiets, 6/29/90, Lab. Project ID 89JH152. (MRID # 416146-05) Analyses were carried out at ICI's Jealott's Hill Research Station, Bracknell, Berkshire, UK.

"PP321: Residue Levels on Hops from Trials Carried out in Germany During 1985;" S. Burk, D. Tyldesley, A. Sapiets; 9/29/86; Lab. Project ID M4315B. (MRID# 416146-06) Analyses were carried out at ICI Plant Protection Division, Fernhurst, UK.

"PP321: Residue Levels on Hops from a 1985 Trial in Czechoslovakia," D.Tyldesley and A. Sapiets, 5/12/86, Lab Project ID M4211B. (MRID # 416146-07) Analyses were carried out at Fernhurst, UK.

In the first report, data from field trials held in Germany in 1989, hops were treated in five trials. Dried hop samples containing the highest residue level of lambda-cyhalothrin (#4960) were further analyzed for metabolites. Beer was made from these same hop samples, and the resulting brewers grains were analyzed for lambda-cyhalothrin and metabolites.

Dried hop samples were received frozen during October, 1989 and brewers grains in December, 1989. Samples were analyzed for parent during October, 1989 and metabolites during February, 1990. Brewers grains were analyzed for both parent and metabolites during February-March, 1990. A storage stability study is reportedly in progress. Results are given in the following tables:

Table 6

Residues (ppm) of Lambda-cyhalothrin in/on Dried Hops (Germany, 1989)

Location	ICI Sample #	Application Rate (g ai/ha)	PHI (days)	Lambda-cyhalothrin Residue (ppm)
Haunsbachen	4954	1x91.0 + 4x141.5	14	4.4
Au-Haarhan	4956	1x18.5 + 1x50.0 + 3x150.0	14	3.8
Hedersdorf	4958	1x57.5 + 1x82.5 + 1x95.0 + 2x142.5	19	4.2
Hedersdorf	4960	1x57.5 + 1x82.5 + 1x95.0 + 2x142.5	8	9.6
Sillertshausen	4962	2x67.5 + 1x97.5 + 2x112.5	10	6.7

Metabolites residues from sample 4960 were 1.0 ppm for CPA

(PP890) and 1.0 ppm for 3-PBAcid, which would include residues from the alcohol. Hops from sample 4960 were used in brewing both in St. Lewis and West Germany. Residue levels in brewers grains are given in Table 9:

Table 7

Residue Levels of Lambda-cyhalothrin and Metabolites in Brewers Grains Prepared from Hops Sample 4960

Location	Lambda-cyhalothrin (ppm)	Isomer (R157836) (ppm)	CPA (ppm)	3-PBAcid (ppm)
St. Louis, USA	0.75	0.11	0.35	0.18
West Germany	0.62	0.09	0.03	<0.02

For the second report eight trials were carried out on hops in Germany during 1985. Metabolites were not analyzed. In addition to dried hops, fresh hops were analyzed at PHI's from 0 days to 14 days at 4 or 5 day intervals. Not surprisingly, residues concentrated in the dried hops.

It probably would be more accurate to say that six trials were carried out, for trial reference numbers 8512E2, 8513E2 and 8512E4, 8513E4 apparently refer to adjacent plots. Treatment dates, treatment levels, and varieties are identical for each pair. The final applications were made from June through August, 1985. Dates of analyses are not given, but the sample chromatograms are dated 12/4/85. Since the report is dated 9/29/86, analyses could have been done from about four months to 15 months. Dates of analyses for these and the Czechoslovakian trial should be submitted. No validation data were submitted with the residue analyses. Before we can accept the results given in the following table, such data are necessary. Results are given in Table 8.

Table 8

Residues of Lambda-cyhalothrin in/on
Dried Hops (Germany, 1985)

Location	Trial Ref. No.	Application Rate	PHI	Lambda-cyhalothrin Residue (ppm)
Sandhausen	8513E1	1x15 + 1x37.5 + 1x62.5 + 1x75 + 2x112.5	13	3.1
Tettnang-Holzhausern	8513E2	1x85 + 4x112.5	15	3.6
Biburg	8513E3	1x11.25 + 2x65 + 1x75 + 1x87.5 + 1x97.5	15	4.4
Pfaffenhofen	8513E4	1x12.5 + 2x37.5 + 2x50 + 1x62.5	15	3.3
Geisenhausen	8513E5	1x16.26 + 1x35 + 1x42.5 + 1x62.5 + 1x105 + 1x82.5	15	3.1
Kapellen-Drusweiler	8513E6	1x21.25 + 1x50 + 1x105 + 1x112.5 + 1x140 + 1x105	16	4.5
Tettnang-Holzhausern	8512E2	1x85 + 4x112.5	15	3.2
Pfaffenhofen	8512E4	1x12.5 + 2x37.5 + 2x50 + 1x62.5	15	2.9

One field trial was conducted in Czechoslovakia during 1985. Lambda-cyhalothrin was applied at a rate of 1 x 26 g ai/ha on 8/12/85. Dried hops were analyzed at 0, 4, 7, 14 and 17 days. Lambda-cyhalothrin levels declined from 0.64 ppm at day 0 to 0.22 ppm at day 14. Times of analyses have not been reported. A total of nine months elapsed from application to the final report.

Based on the submitted data, the registrant should propose a food additive tolerance of 10.0 ppm for lambda-cyhalothrin in/on dried hops. However, as noted, we consider the data set to be incomplete in the absence of suitable validation data.

Processed Commodities

Residues resulting from the processing of tomatoes has been submitted in the following report:

"ICIA0321 (Lambda-cyhalothrin)- Magnitude of the Residue Study in Processed Tomato Products," P.S. Gillespie, 12/18/90, Laboratory Project ID # 0321-89-PR-08, Report No. RR-90-419B. (MRID # 417370-08)

Tomatoes grown in a field near Oxford, FL were treated with twelve applications lambda-cyhalothrin using a backpack sprayer. The application rates were 10 x 0.03 lb ai/A followed by 2 x 0.15 lb ai/A. The first eleven applications were made at approximately 7 day intervals. The last application was made 5

days before harvest. The total application rate was 1.67x the proposed total maximum rate. Tomato samples were transported to the Institute of Food and Agricultural Sciences, University of Florida at Lake Alfred, where they were processed into wet and dry pomace, puree, paste, ketchup and juice. (The complete processing procedure is given on page 12 of the report.)

Samples were analyzed for metabolites within 2 months and for lambda cyhalothrin and its epimer within 10 months from sampling. Storage stability data indicate no significant decline in parent/epimer residue levels in wet or dry pomace and juice when stored at -18°C over a six month period. Metabolites were stable in tomatoes under frozen storage for three months.

Results are given in Table 9.

Table 9

Residues (ppm) of Lambda-Cyhalothrin and Metabolites in Processed Tomato Products

Commodity	PP321	R157836	PP890	3PBAcid
Whole tomatoes at harvest	0.23±0.02	0.02	<0.01	<0.01
Whole tomatoes prior to processing	0.32±0.05	0.03	<0.01, 0.14	<0.01, 0.05
Wet pomace	2.8±0.2	0.31±0.08	<0.01	<0.01
Dry pomace	17.6±1.8	2.0±0.2	0.03, 0.02	0.05, 0.02
Puree	0.08	0.02	<0.01	<0.01
Ketchup	0.07	0.01	<0.01	<0.01
Paste	0.1	0.02	<0.01	<0.01
Juice	0.02	<0.01	<0.01, 0.01	0.02

Based on the above residue data, feed additive tolerances should be proposed for wet and dry pomace. The PP321 concentration factors for wet pomace and dry pomace (relative to whole tomatoes prior to processing) are 8.8 and 55, respectively. Therefore, the appropriate feed additive tolerance for wet pomace is 1.0 ppm and that for dry pomace is 6.0 ppm (based on a tolerance of 0.1 ppm for PP321 in/on tomatoes).

Meat, Milk, Poultry and Eggs

A feeding study in which PP321 was fed to three groups of three cows at levels of 1.0, 5.0 and 25 ppm for 28-30 days was submitted for PP#6F3318 (Accession No. 073982) and reviewed by M. Firestone in his memo of 1/22/86. Maximum levels of parent lambda cyhalothrin in milk from cows fed at the three feeding levels were 0.03, 0.08 and 0.85 ppm. Maximum levels in tissue at

the three feeding levels were: muscle -- 0.01, 0.07, 0.41 ppm; fat -- 0.50, 1.8, 7.9 ppm; liver -- 0.03, 0.01 and 0.10 ppm; and kidney -- 0.02, 0.07 and 0.36 ppm.

Analysis for ruminant metabolites CPA (PP890), 3-PBAcid (R41207) and 4'-OH-3-PBAcid (R175447) have been submitted under PP#0H5599 in the following report:

> "Lambda-Cyhalothrin (PP321): Residue Levels of the Major Metabolites in Dairy Cows Fed on a Diet Containing the Insecticide," O.J. Tummon and A. Sapiets, 10/88, Laboratory Project ID # RJ0655B. (MRID # 416146-08)

Analyses were performed at ICI Agrochemicals' Jealott's Hill Research Station in the UK. The residue analytical method was ICI Agrochemical Residue Analytical Method No. 96. Samples were received during October, 1984-January, 1985 and were stored at <-18°C until analysis. Bulked 24 hour milk samples from individual cows were analyzed during August, 1985 - January, 1986. The majority of muscle and kidney samples were analyzed during September, 1985 - April, 1986. Fat and liver samples were analyzed during July - October, 1987. The report is not more specific as to times of analyses. Storage stability data are adequate to support these analyses.

None of the three metabolites were found in milk (<0.005 ppm) at any of the three feeding levels.

Of the three metabolites, 4'-OH-3-PBAcid could not be detected in tissue from cows fed at 1.0 or 5.0 ppm. At the 25 ppm feeding level, residues remained nondetected in muscle (<0.005 ppm) and fat (<0.01 ppm) and were only detected in one kidney sample (0.01 ppm). Residues in liver at the 25 ppm level averaged 0.03 ppm, with a maximum observed level of 0.05 ppm.

3-PBAcid was nondetected in all tissues from cows fed at 1.0 ppm and was not detected (<0.005 ppm) in muscle at each feeding level. At the 25 ppm level, detectable residues (0.01 ppm) in fat were observed in one of three animals. Residues in liver averaged 0.01 ppm at the 5.0 ppm feeding level, with a high value of 0.02 ppm. At the 25 ppm level, the average residue level was 0.18 ppm, with a high value of 0.36 ppm. Residues in kidney averaged 0.02 ppm at the 5.0 ppm feeding level, with a high value of 0.02 ppm. At the 25 ppm level, the average residue level was 0.07 ppm, with a high value of 0.11 ppm.

CPA was nondetected (<0.005 ppm) in muscle from cows fed at the 1.0 or 5.0 ppm level. Residues in fat, liver and kidney at the 1.0 ppm feeding level varied from <0.01-0.01 ppm. The following residue levels were found at the 25 ppm feeding level: adductor muscle, <0.005 ppm; pectoral muscle, 0.01 ppm average, 0.03 ppm high; subcutaneous fat, 0.02 ppm average, 0.04 ppm,

high; peritoneal fat, 0.04 ppm average, 0.06 ppm high; liver, 0.06 ppm average, 0.07 ppm high; kidney, 0.07 ppm average, 0.08 ppm high.

A poultry feeding study was reviewed by S. Willett (S. Brooks) in PP#7F3488 [MRID # 400279-14] (memo of 8/13/87). Seven groups of 10 laying hens were fed diets containing 1.0, 5.0, and 25 ppm lambda-cyhalothrin for up to 28 consecutive days. Residues did not accumulate and declined when feeding of the treated diet ceased. Residues in tissues and eggs are given in the following table. The residue levels for eggs are the mean plateau residues.

Table 10

Residue Levels (ppm) of Lambda-cyhalothrin in Egg and Tissue of Hens Fed at Three Levels

	1.0 ppm	5.0 ppm	25.0 ppm
Eggs	<0.005	0.01	0.05
Liver	<0.005	<0.005	<0.005-0.006
Muscle	<0.005	<0.005	0.005-0.02
Fat (abdominal)*	0.02-0.03	0.06-0.09	0.025-0.82

* Residue levels in subcutaneous fat were lower than corresponding levels in abdominal fat.

Analyses for poultry <u>metabolites</u> were done at a later date and have been submitted in PP#1F3952/1H5607 as the following report:

> "LAMBDA-CYHALOTHRIN: Residue Transfer Study with Laying Hens Fed on a Diet Containing the Insecticide. Part 2 - Metabolite Analyses", A. Sapiets and O.J. Tummon, 10/11/90, Laboratory Project ID # PP321BB01. (MRID # 417935-01)

The analyses were carried out at ICI Agrochemicals' Jealott's Hill Research Station in the UK. The feeding study was conducted during 1985. Samples were stored at <18°C until analyses, which occurred at periods up to 910 days after sampling. Storage stability data support the analyses. Samples were analyzed using ICI Agrochemicals Residue Analytical Method No. 96.

Results from feeding lambda-cyhalothrin at the maximum level (25 ppm) are given in the following table.

Table 11

Maximum and Mean Residue Levels (ppm) of Metabolites
in Chicken Tissue and Egg from Feeding Lambda-cyhalothrin at 25 ppm in the Diet

Substrate	CPA Maximum Residue	CPA Mean Residue	3-PBAcid Maximum Residue	3-PBAcid Mean Residue	4'OH-3-PBAcid Maximum Residue	4'OH-3PBAcid Mean Residue
Muscle	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Subcutaneous Fat and Skin	0.05	0.04±0.01	<0.01	<0.01	<0.01	<0.01
Abdominal Fat	0.03	0.025±0.005	<0.01	<0.01	<0.01	<0.01
Liver	0.22	0.18±0.03	<0.01	<0.01	0.03	0.02±0.01
Egg	0.03	0.025	<0.01	<0.01	0.01	0.01

With the exception of liver, metabolites were not detected in tissue or eggs at the 1 or 5 ppm feeding level. The maximum CPA residues found in liver from hens fed at 5 ppm and 1 ppm were 0.13 ppm (0.11 ppm, mean) and 0.03 (0.025 ppm, mean), respectively. Other metabolites were not detected.

Diets for cattle and poultry containing the maximum levels of lambda-cyhalothrin are given in the following tables:

Table 12

Diet for Dairy Cattle Producing the Maximum Residues of Lambda-Cyhalothrin

Commodity	Maximum Diet Percentage	Tolerance	Contribution to Daily Diet
Sweet Corn Forage	10%	6.0 ppm (24.0 ppm, dry weight basis)	2.4 ppm
Tomato Pomace Dry	25%	6.0 ppm	1.5 ppm
Brewers Grains (Spent Hops)	5%	1.0 ppm	0.05 ppm
Cottonseed	20%	0.05 ppm	0.01 ppm
Wheat Grain/Soybean Seed	50% (balance)	0.01 ppm	0.005 ppm
			Total = 4.0 ppm

Table 13

Diet for Beef Cattle Producing the Maximum Residues of Lambda-Cyhalothrin

Commodity	Maximum Diet Percentage	Tolerance	Contribution to Daily Diet
Sweet Corn Forage	25%	6.0 ppm (24.0 ppm, dry weight basis)	6.0 ppm
Tomato Pomace Dry	25%	6.0 ppm	1.5 ppm

Brewers Grains	5%	1.0 ppm	0.05 ppm
Cottonseed	20%	0.05 ppm	0.01 ppm
Wheat Grain/Soybean Seed	25% (balance)	0.01 ppm	0.0025 ppm
			Total = 7.6 ppm

Table 14

Diet for Turkeys/Broilers Producing the Maximum Residues of Lambda-Cyhalothrin

Commodity	Maximum Diet Percentage	Tolerance	Contribution to Daily Diet
Tomato Pomace Wet	3%	1.0 ppm (6.0 ppm, dry weight basis*)	0.18 ppm
Cottonseed Meal/Soapstock	15%	0.05 ppm	0.008 ppm
Sunflower Meal	15%	0.03 ppm	0.004 ppm
Soybean Seed, Wheat Grain	67% (balance)	0.01 ppm	0.007 ppm
			Total = 0.2 ppm

* To convert wet tomato pomace to dry weight basis, the value for dry tomato pomace is used.

Table 15

Diet for Laying Hens Producing the Maximum Residues of Lambda-Cyhalothrin

Commodity	Maximum Diet Percentage	Tolerance	Contribution to Daily Diet
Tomato Pomace Wet	2%	1.0 ppm (6.0 ppm, dry weight basis)	0.12 ppm
Cottonseed Meal/Soapstock	8%	0.05 ppm	0.004 ppm
Sunflower Meal	15%	0.03 ppm	0.004 ppm
Soybean Seed, Wheat Grain	74% (balance)	0.01 ppm	0.007 ppm
			Total = 0.14 ppm

Predicted Maximum Residues -- Dairy and Beef Cattle

Based on the cattle feeding study and scaling from the highest feeding level (25 ppm), predicted maximum levels of lambda-cyhalothrin and metabolites in milk and tissue are given in the following table:

Table 16

Predicted Maximum Residue Levels in Milk and Tissue of Cattle

Commodity	Lambda-Cyhalothrin	CPA	3-PBAcid	4'-OH-3-PBAcid
Milk	0.14 ppm	<0.005 ppm	<0.005 ppm	<0.005 ppm
Meat (muscle)	0.12 ppm	<0.01 ppm	<0.005 ppm	<0.005 ppm
Fat	2.4 ppm	0.01 ppm	<0.01 ppm	<0.01 ppm
Liver	0.03 ppm	0.02 ppm	0.11 ppm	0.02 ppm
Kidney	0.11 ppm	0.02 ppm	0.03 ppm	<0.01 ppm

Because lambda-cyhalothrin may also be applied dermally to beef cattle -- PP#9F3770 is still active -- residues resulting from dermal application must be added to those resulting from oral ingestion. As noted in our 1/25/90 memo for PP#9F3770, the maximum level of lambda-cyhalothrin observed in fat from a dermally treated animal was 0.77 ppm; the maximum level in muscle was 0.04 ppm; the maximum level in kidney was 0.06 ppm; and the maximum level in liver was 0.03 ppm. For metabolites, CPA was found in fat at a maximum 0.009 ppm, 4'OH-3PBAcid and 3PBAcid were not found in fat (<0.005 ppm). No metabolite was found in muscle (<0.005 ppm). In kidney CPA was found at a maximum 0.007 ppm; 4'-OH-3PBacid was found at 0.008 ppm in animals treated at an exaggerated dose, but was otherwise not detected (<0.005 ppm); and 3PBAcid was found at a maximum 0.008 ppm. In liver CPA was found at a maximum 0.007 ppm, 4'OH-3PBAcid was found at a maximum 0.018 ppm and 3PBAcid was not detected (<0.005 ppm).

Combining maximum residues from oral and dermal administration, we conclude that the following tolerances are most appropriate for parent lambda-cyhalothrin:

Milk	0.2 ppm
Meat (muscle)	0.2 ppm
Fat	4.0 ppm
Liver	0.1 ppm
Kidney	0.2 ppm

CBTS recommends that tolerances of 0.2 ppm be proposed for residues of parent in/on milk, meat and meat byproducts and 4.0 ppm for parent in/on fat. We note, however, that the appropriate tolerances for ruminants other than cattle are those derived from the feeding study alone. The only significant difference would be fat -- 3.0 ppm instead of 4.0 ppm. For simplicity we recommend that the tolerance expression be the same for all ruminants. Corrections can be made in any calculation of anticipated residues.

Data are necessary to show concentration of residues of parent in the fat of milk. This can be done by either analyzing

milk fat obtained from samples from the feeding study or analyzing milk fat from milk fortified with lambda-cyhalothrin. Based on the determined concentration factor, an appropriate milk fat tolerance should be proposed.

For metabolites, maximum total residues (dermal + oral) are the following:

Table 17

Maximum Total Residues (ppm) (Dermal + Oral)
Predicted in Milk and Tissue of Cattle

	CPA	3PBAcid	4'OH-3PBAcid
Milk	<0.005	<0.005	<0.005
Muscle	<0.01	<0.01	<0.01
Fat	0.02	<0.01	<0.01
Liver	0.03	0.11	0.04
Kidney	0.12	0.04	<0.01

As noted in our memo of 4/17/91 for PP#9F3770, TB1 and CBTS in a joint meeting decided that for dermal applications, CPA, 3-PBAcid and 4'-OH-3PBAcid need not appear in the tolerance expression because these metabolites are products of rat metabolism and are found in tissues only at low levels. As in the case of dermal residues, we are unable to predict residues of HO-CPA from the information currently available to us.

Predicted Maximum Residues -- Poultry

Based on the poultry feeding study and scaling from the highest feeding level (25 ppm), predicted maximum levels of lambda-cyhalothrin and metabolites in eggs and tissue of poultry are the following:

Table 18

Maximum Total Residues (ppm) (Dermal + Oral)
Predicted in Egg and Tissue of Poultry

	Lambda-Cyhalothrin	CPA	3-PBAcid	4'OH-3PBAcid
Egg	<0.005	<0.005	<0.005	<0.005
Liver	<0.005	<0.005	<0.005	<0.005
Muscle	<0.005	<0.005	<0.005	<0.005
Fat	0.01	<0.005	<0.005	<0.005

Tolerances of 0.01 ppm should be proposed for residues of lambda-cyhalothrin in each of the above poultry commodities.

Regarding levels of HO-CPA in poultry, because the other metabolite levels in poultry are <0.005 ppm, it would not be advisable that poultry tissue be analyzed for this metabolite unless residue analysis of beef liver and kidney show significant levels.

Other Considerations

An International Residue Limit (IRL) Status sheet is appended to this review. A Codex IRL of 0.2 ppm has been established for head cabbage. There is an incompatibility with the proposed tolerance in PP#1F3952/1H5607 that might be removed if a uniform use label could be adopted.

Attachment: International Residue Limit status sheet.

cc: SF, RF, Circu., C.Furlow(PIB/FOD), MikeFlood, E.Haeberer, PP#7F3560/7H5543, PP#1F3952/1H5607, FAP#0H5599.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:557-4362:typist(mtf):9/17/91.
RDI:SectionHead:ETHaeberer:9/16/91:BranchSeniorScientist:RALoranger: 9/17/91.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Lambda-Cyhalothrin

CODEX NO. 146

CODEX STATUS:

☐ No Codex Proposal Step 6 or above

Residue(if Step 8): _____

cyhalothrin (sum of all isomers)

Crop(s)	Limit (mg/kg)
cabbage, head	0.2

PROPOSED U.S. TOLERANCES:

Petition No. PP# 7F3560/7H5543
PP# 1F3952/1H5607
FAP# 0H5599

RCB Reviewer FLOOD

Residue: Lambda-Cyhalothrin

Crop(s)	Limit (mg/kg)
Sweet Corn Ears	0.02
" " Forage	6.0
Milk	0.03
Broccoli	0.4
Cabbage	0.4
Tomatoes	0.06
Dried Hops (FAT)	12.
Cattle etc (other side) →	

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

Form revised 1986