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

DEC 26 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: PP#1F03992. Lambda-cyhalothrin in/on Sorghum Grain. Evaluation of Analytical Methods and Residue Data. Submission dated 4/12/91.

DP Barcode: D165006. MRID #'s 418924-00 through 418924-03. CB # 8099.

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ICI Americas Inc. is proposing the following tolerances for lambda-cyhalothrin {[1alpha-(S),3alpha-(Z)]-(±)-cyano-(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate}:

Sorghum grain	0.2 ppm
Milk	0.1
Cattle, goats, hogs, horses and sheep	
Meat	0.04
Fat	2.0
Liver	0.1
Kidney	0.1

Poultry	
Meat	0.01
Fat	0.01
Liver	0.01
Eggs	0.01

Temporary tolerances with an expiration date of August 30, 1991 were 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. Raw agricultural commodities (racs) for which tolerances are pending include soybeans (PP#7F3488), wheat, sweet corn and sunflowers (PP#7F3560/7H5543); broccoli, cabbage and tomatoes (PP#1F3952/1H5607); imported dried hops (FAP#0H5599); and head lettuce (PP#1F03985). The petition for use in/on soybeans was reviewed by S. Willett in memos of 8/13/87 and 10/27/89. The last of these petitions was reviewed by J. Morales in his memo dated 10/22/91. The remaining petitions have been most recently reviewed by M. Flood in his memo dated 9/19/91. We note that tolerances for lambda-cyhalothrin in animal products have also been proposed in these petitions.

Conclusions

1. The registrant should obtain written confirmation from Chemical Abstracts Service that the proposed CAS name for lambda-cyhalothrin, [1α(S),3α(Z)]-(+)-cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecamboxylate, is the correct Chemical Abstracts name. (Conclusion #1 from our 9/19/91 memo for PP#7F3560.)

2. 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. (These data were requested in our 4/16/91 memo for PP#7F3560. ICI's response to this memo is under review.)

   CB-1 and TB-1 have determined that the plant metabolites of lambda-cyhalothrin -- CPA (PP890), 3-PBAcid and 3-PBalcohol -- need not appear in the tolerance expression.

3. The nature of the residue in ruminants and poultry is adequately understood. Lambda-cyhalotrhin, per se, 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. (The names and structures are given in Attachment 2 to this memo.)

CB-1 and TB-1 have determined that the animal metabolites CPA, 3-PBAcid and 4'-OH-3-PBAcid need not appear in the tolerance expression. The issue of HO-CPA remains outstanding (see our memo of 9/19/91).

4a. ICI Method 81 for parent lambda-cyhalothrin and its epimer in plant matrices has undergone successful EPA method validation. The analytical method for metabolites produced acceptable recoveries from sorghum grain in the petitioner's hands. Because the metabolites need not appear in the tolerance expression at this time, independent laboratory validation and EPA method validation are not necessary.

4b. ICI Method 86 for parent lambda-cyhalothrin and its epimer in animal matrices has undergone successful EPA method validation. The analytical method for metabolites CPA, 3-PBAcid and 4'-OH-3-PBAcid produced acceptable recoveries (PP#0H5599) in the petitioner's hands. Because these metabolites need not appear in the tolerance expression at this time, independent laboratory validation and EPA method validation are not necessary. However, pending resolution the question concerning the metabolite HO-CPA, an analytical method may have to be developed and animal residue data generated (PP#7F3560, memo of 9/19/91).

4c. Recoveries have been determined under FDA's multiresidue protocols for cyhalothrin, CPA and 3-PBAcid. (Recoveries were not listed in FDA's 11/2/90 summary.)

5a. Storage stability data for lambda-cyhalothrin in plant matrices and in extracts are sufficient to support the submitted residue data.

5b. CPA, 3-PBAcid and 3-PBAlcohol have been shown to be stable in plant matrices under frozen storage for three months. An interim report demonstrating stability for twelve months will shortly be submitted. The sorghum grain samples were held for up to 29 months before analysis, and extracts were held for up to 27 days. Storage stability data must be generated to cover these time periods.

5c. Storage stability data for lambda-cyhalothrin and the animal metabolites PP890 (CPA), 3-PBAcid and 4'-OH-3-PBAcid support the residue analyses on meat, milk,

poultry and eggs. Depending on resolution of the question of HO-CPA, storage stability data on this species may have to be generated.

6. Residue data from twelve field trials support the proposed tolerance of 0.2 ppm for residues of lambda-cyhalothrin in/on sorghum grain.

7. No concentration of residues was observed when sorghum grain was processed into starch and flour. Grain dust showed a level of lambda-cyhalothrin 7x that in grain. The petitioner should propose a **408** tolerance of 1.5 ppm for residues of lambda-cyhalothrin in/on grain dust.

8a. As concluded in our 9/19/91 memo for PP#7F3560, the petitioner should propose lambda-cyhalothrin tolerances of 0.2 ppm for milk, meat and meat byproducts of cattle, goats, hogs, horses and sheep and a tolerance of 4.0 ppm for the fat from these animals.

8b. Inclusion of sorghum grain dust in the diet of poultry, could result in lambda-cyhalothrin residues exceeding the proposed tolerance of 0.01 ppm in fat. The registrant should submit a revised Section F in which a tolerance of 0.02 ppm is proposed for this commodity.

9. An International Residue Limit (IRL) Status sheet is appended to this review. There are no IRL's for lambda-cyhalothrin in/on any of the racs of this petition.

Recommendation

CBTS recommends against the proposed tolerances for reasons given in Conclusions 1 (CAS name); 2 (wheat metabolism); 3 (animal metabolism -- issue of HO-CPA); 5b (storage stability for metabolites in plant matrices); 5c (possible storage stability data on HO-CPA); 7 (grain dust tolerance); 8a and 8b (revised tolerances for ruminants and poultry tissues).

Detailed Considerations

Manufacturing Process and Formulation

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. Impurities in lambda-cyhalothrin do not pose residue chemistry problems. Lambda-cyhalothrin consists of one pair of enantiomers out of a total 16 possible isomers. Cyhalothrin, which is less active, also contains this pair, denoted the "B" pair, but also contains

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another pair, the "A" pair. The "A" pair is the epimer of the B pair and is always found at lower levels in residue studies using lambda-cyhalothrin. In a meeting held on 10/31/91 between CB1 and TB1, it was decided that the tolerance expression include the epimer (ICI # R157836).

The structure has been discussed in some detail in M. Flood's 9/19/91 memo (PP#7F3560). (The structures of lambda-cyhalothrin and metabolites appear as Attachment 1 to this memo.) ICI has been asked to provide written confirmation from Chemical Abstracts Service that the CAS name is the correct one.

Lambda-cyhalothrin has the ICI code numbers PP321, ICIA0321 and R119321. The formulation used in the sorghum field trials was GFU383C or Karate® Insecticide, EPA Reg. No. 10182-96. Karate® contains 1 pound active ingredient (ai) per gallon (13.1% by weight) and is an emulsifiable concentrate.

Proposed Use

Karate® may be applied with ground or air equipment. Do not apply within 30 days of harvest. Do not apply more than 0.08 lbs ai/A/season. Do not apply more than 0.06 lb ai/A/season after crop emergence. Do not apply more than 0.02 lb ai/A/season once crop is in soft dough stage. Do not graze livestock in treated areas or harvest for fodder, silage or hay.

Nature of the Residue

Metabolism of lambda-cyhalothrin in plants and animals has been summarized and reviewed in M. Flood's 9/19/91 memo, which should be consulted for a more complete discussion. Metabolism appears to be qualitatively similar to that of other pyrethroids. The ester linkage is cleaved to form cyclopropane carboxylic acids [cis-1-RS-3-(ZE-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylic acid (cis-PP890 or CPA) with the trans-acid present in much lower concentrations] and the corresponding 3-phenoxy-benzoic acid and/or 3-phenoxybenzyl alcohol (3-PBA). Complete data have not as yet been submitted concerning wheat metabolism -- there remains a question concerning metabolism of wheat in straw. ICI states that this question is addressed in a concurrent submission for PP#7F3560.

The nature of the residue in ruminants and poultry is adequately understood. In addition to the plant metabolites, lambda-cyhalothrin animal metabolites include 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-3-PBAcid). As a result of a meeting with TB1 held on 4/11/91 (concerning the proposed dermal use of lambda-cyhalothrin, PP#9F3770), the registrant was asked to provide evidence that OH-CPA was a rat metabolite. Otherwise residue data on this

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metabolite will be necessary.

The issue of which metabolites should appear in the tolerance expression has been reviewed by CB-1 and TB-1. It was decided that CPA, 3-PBAcid, 3-PBAlcohol and 4'-OH-3-PBAcid need not appear in the tolerance expression at this time.

Analytical Method

Plants

The analytical method for parent and its epimer, R157836, in plant matrices is ICI Method 81, which was first described in MRID # 400540-01. Modifications by Huntingdon Analytical Services to this basic method are given in Appendix IV, MRID #418924-02.

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 lipids. The purified extracts are redissolved in 1 mL hexanes (saturated with acetonitrile) 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 the metabolites PP890 (CPA) and 3-PBA has not yet been formally issued by the ICI Report Center but is identical to that submitted for previous petitions. The method was submitted in FAP#0H5599 under the name "Method for Analysis of Lambda-Cyhalothrin Metabolites in Hops" and was discussed in our 9/19/91 memo.

Samples are extracted with acetonitrile and then acetonitrile:water. After filtration, parent and epimer are removed from the extracts by C18 solid phase extraction. The acetonitrile is removed by rotary evaporation, and sufficient 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 the extract is diluted with water and partitioned with dichloromethane. The dichlormethane extract is acid washed and then partitioned with pH 9.18 tetraborate buffer. The aqueous layer is retained, then 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.

The analytical procedure will not distinguish between cis-PP890 and trans-PP890 or between 3-PBAcid and 3-PBAlcohol. Metabolism studies have shown that most of PP890 is in the cis configuration. The trans configuration may be formed from the cis form by photoisomerization on plant surfaces. (Metabolism studies with animals have also shown that the cis configuration predominates.)

Recoveries from sorghum grain are given in the following table.

Table 1

Recoveries of Lambda-Cyhalothrin and Metabolites from Sorghum Grain

Compound	ICIA0321		R157836		PP890	3-PBAcid	3-PBAlcohol
Fortification Level (mg/kg)	0.021	0.21	0.021	0.28	0.05	0.05	0.0535
Percent Recovery	95.8±13.5 (n=11)	99.1±21.3 (n=11)	85.6±9.0 (n=11)	93.0±18.6 (n=11)	87.0±4.6 (n=6)	106.1±9.5 (n=3)	86.3±21.6 (n=3)

At fortification levels of 0.039 and 0.052 µg/g, percent recoveries of PP321 and R157836 varied from 71.1% to 118.5% from sorghum grain, starch and flour. At fortification levels of 0.05 and 0.1 µg/g, percent recoveries of PP890 varied from 87.4% to 107.1% from grain, starch and flour. Finally, at fortification levels of 0.05 µg/g in grain and flour and 0.10 µg/g in starch, recoveries of 3-PBAcid and 3-PBAlcohol varied from 96.1% to 118.3%.

Sample chromatograms from sorghum grain and processed commodities show well resolved peaks when PP321 and metabolites are spiked into controls.

Animals

No animal residue data are reviewed in this memo. Sorghum grain is an animal feed item, so potential residues in animal products are possible (see section on Meat, Milk, Poultry and Eggs). As noted in our memo of 9/19/91, page 17 (PP#7F3560/7H5543, PP#1F3952/1H5607, FAP#0H5599), 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). The method successfully underwent EPA method

validation (PP#6F3318/7F3488, E. Greer, memo of 9/30/87, S. Brooks, memo of 10/30/87).

The analytical method for metabolites CPA, 3-PBA and 4'-OH-3-PBA is ICI Method 96, submitted in FAP#0H5599 and discussed in our 9/19/91 memo for that petition. Because CB-1 and TB-1 have determined that these metabolites not be regulated at this time, it is not necessary that this method undergo independent laboratory validation and EPA method validation.

As noted in the Nature of the Residue section of this memo, there is still a question concerning the animal metabolite HO-CPA. If this issue cannot be satisfactorily resolved, residue data -- and an analytical method -- for this metabolite may be necessary.

The petitioner has determined recoveries of cyhalothrin, PP890 and 3-PBAcid under FDA's multiresidue protocols (PP#7F3488, S. Willett, memo of 3/15/88; PP#7F3560, et. al., M. Flood, memo of 9/19/91). As of 11/2/90, results had not been listed in FDA's summary. FDA's 6/89 summary reports that recoveries of 3-PBAcid and 3-PBAlcohol under protocols 1 through 5 are not likely.

Storage Stability

Storage stability data for lambda-cyhalothrin in peach, pea, oil seed rape, wheat grain, sugarbeet root, cottonseed, apple, cabbage and potato were reported in PP#0H5599 (MRID # 416146-02) and reviewed in our memo of 9/19/91. Lambda-cyhalothrin is stable in these matrices at -18°C for up to 26 months. To assess stability in extracts, 1:1 acetone:hexane extracts from the treated racs were held at <4°C for 33-42 days after the 26 months analyses. No significant degradation was seen in these extracts.

Storage stability of PP890, 3-PBAcid and 3-PBAlcohol in 13 racs has been reported in PP#1F3952/1H5607, MRID # 417370-03. Residues were stable at -20°C±10°C for 3 months. The petitioner states that an interim report with data to document 12-month storage stability is in preparation and will be submitted.

Storage stability of lambda-cyhalothrin in meat, milk, poultry and eggs was submitted under PP#7F3488. Lambda-cyhalothrin was stable in cow tissues under frozen storage for nine weeks and 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 two years (N. Dodd, memo of 3/15/88).

Storage stability data for the animal metabolites PP890 (CPA), 3-PBAcid and 4'OH-3-PBAcid in cow and chicken matrices were reported in PP#1F3952, MRID # 417935-01 and reviewed in our

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9/19/91 memo. Metabolites were found to be stable in muscle, milk, kidney, liver, egg and fat for 35-42 months at <0°C. However the petitioner was asked to identify the matrices as cow or chicken.

Additional storage stability data were submitted in PP#9F3770 (for dermal applications to beef cattle) by Coopers Animal Health, Ltd. Samples of bovine liver, kidney, muscle and bodyfat were fortified with 0.05 ppm lambda-cyhalothrin, PP890, 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 three metabolites in muscle). Residues were found to be stable under these conditions, but as noted in M. Flood's memo of 1/25/90, zero time recoveries on the bovine matrices were not obtained. Recoveries after the allotted storage time varied from 57.4 to 103.9%.

Samples were frozen within 24 hours after sampling, with the exception of the samples from the Colorado trial, which were frozen five days after harvest. (The Colorado residues reflected only three applications of lambda-cyhalothrin.) Sampling, extraction and analysis dates for parent, epimer, PP890 and 3-PBA are given in Tables 5 and 6 of ICI, Volume 1, Report No. RR 90-417B (MRID # 418924-02) [discussed in the next section]. Lambda-cyhalothrin and its epimer were analyzed within 20 months of harvest. The extraction to analysis interval was 1-4 days. PP890 and 3-PBA (acid + alcohol) were analyzed within 29 months of harvest. Extraction to analysis intervals ranged from 10 to 27 days.

Storage stability data are sufficient to support the residue analyses for parent and epimer but not the metabolites. Additional storage stability data for metabolites should include stability in extracts at 0°C for periods up to 27 days in addition to stability in solid matrices for periods up to 29 months.

Residue Data

Residue data submitted in this petition appear in the following report:

> "ICIA0321 (Lambda-cyhalothrin): Magnitude of the Residue Study on Grain Sorghum;" P.D. Francis and P.S. Gillespie; 4/10/91; Laboratory Project ID's 6-321-87-04, -05 and -06; Report No. RR 90-417B. (MRID # 418924-02)

Analyses for residues of lambda-cyhalothrin and its epimer were performed at Huntingdon Analytical Services, Middleport, NY. Analyses for PP890 and 3-PBA were conducted at ICI Americas' Western Research Center, Richmond, CA. (As noted in the summary of the residue analytical methods, 3-PBAlcohol is converted to 3-

PBAcid by the procedure. "3-PBA" is therefore the sum of the concentrations of the acid and the alcohol.)

Field trials were held during 1987 in CO, KS(2), SD, NE, AZ(2), CA, GA, AR(2), NC(2), TX, and IL(2). According to Agricultural Statistics, 1986 these states accounted for about 78% of the U.S. sorghum production in 1984.

With certain exceptions (as noted) four plots were included in each field trial. One served as a control. The other three received 2, 3 or 4 applications of lambda-cyhalothrin at a rate of 0.02 lb ai/A/application. Applications were timed so that the first application was made about 5 days prior to emergence, the second was made 14-21 days after emergence, the third was made at 10% bloom and the final was made about 30 days prior to harvest. The trial in Colorado did not receive a fourth application because a killing frost occurred. The Texas trial was not sampled from the plot treated with 4 applications due to applicator error on the fourth application. (Lambda-cyhalothrin was aerially applied in this trial.) In addition, two trials were conducted at exaggerated rates in North Carolina and Illinois. (The two trials held in NC should really be considered as one trial. Location and application dates were the same.) Aerial application was made for three trials. Furrow irrigation was used for four of the trials.

Results for the four applications are given in the following table. Except for one trial in Georgia, where a residue of parent of 0.02 ppm was measured after three applications, only those plots which received four applications at the 0.02 lb ai/A level showed any residues above the limit of determination (<0.02 ppm or <0.01 ppm). With one exception, of the twelve trials in which 4 applications were made, residues of epimer (R157836), PP890 and 3-PBA were not detected at levels of 0.02 ppm, 0.01 ppm and 0.01 ppm, respectively. PP890 was found at a level of 0.02 ppm from the trial in South Dakota.

Table 2

Residues of Lambda-Cyhalothrin (ICIA0321) in Sorghum Grain after Four Applications at 0.02 lb ai/A

Location	PHI	Mode of Appl.	Residue (mg/kg)
Desoto, KS	40		0.02
Brookings, SD	30		0.18
Waverly, NE	36		0.05
Yuma, AZ	31	Furrow	0.04
Visalia, CA	28	Furrow	0.05
Statesboro, GA	30		0.06
Lewisville, AR	30		<0.02

Pikeville, NC	39		<0.02
Wathena, KS	30	Aerial	0.05
Proctor, AR	36	Aerial	0.02
Seymour, IL	29		0.02
Yuma, AZ	30	Furrow	0.16

Volumes of 3 to 4 gallons/A were used in the aerial applications. There is no apparent difference in residues resulting from ground, ground-furrow, or aerial application.

Results from the two trials in which exaggerated rates were employed are given in the next table. R157836, the epimer of lambda-cyhalothrin remained undetected (<0.02) in these trials.

Table 3

Residues of Lambda-cyhalothrin (ICIA0321), PP890 and 3-PBA in/on Sorghum Grain Treated with Lambda-cyhalothrin at Exaggerated Application Rates

Location	Appl. Rate (lb ai/A)	PHI	Residue (mg/kg)		
			ICIA0321	PP890	3-PBA
Pikeville, NC	0.02x3 + 0.2	39	0.04-0.08	0.01	<0.01
Seymour, IL	2 x 0.1	85	<0.02	<0.02	
	3 x 0.1	51	<0.02		
	4 x 0.1	29	0.14	0.02	0.01

Residue data support the proposed tolerance of 0.2 ppm for residues of lambda-cyhalothrin in/on sorghum grain. No tolerances are necessary for the metabolites at this time. Supporting chromatograms show well resolved peaks when extracts were fortified at this level. As noted above, existing storage stability data do not support the residue analyses for the metabolites.

Processing Study

Grain sorghum was processed into starch, flour and dust. Results and data appear in the following report:

"KARATE (Lambda-cyhalothrin) - Magnitude of the Residue Study on Processed Sorghum Products," J.C. McKay, 3/4/91, Laboratory Project IDs 6-321-87-06 and 0321-90-PR-01, Report No. RR 90-426B. (MRID # 418924-03)

Samples were processed at the Food Cereal Quality Laboratory, at Texas A & M University, College Station, Texas and analyzed at ICI Americas Inc.'s Western Research Center, Richmond, California.

Sorghum grain from the 1987 field trial held in Seymour, IL

(Table) was used in the study. In that trial, lambda-cyhalothrin was applied at 4 x 1 lb ai/A, a 5x application rate. Sufficient grain was collected to conduct both a wet-milling and a dry-milling processing study. Processing occurred during 1990. Samples were analyzed for residues of parent and metabolites within 2 months of processing.

Grain samples were cleaned. The light impurities fraction (grain dust), amounting to 2.2 grams out of an initial 14.4 lbs. dried grain, was collected and analyzed. The cleaned grain was wet milled into bran (flour), germ and starch or dried milled into flour. Refer to the report, pages 12-14, for a more complete description of the processing study. Results are given in Table 4. Concentration occurred in grain dust.

Table 4

Residues (mg/kg) of Lambda-cyhalothrin and Metabolites in Processed Sorghum Grain Samples

Commodity	ICIA0321	R157836	PP890	3-PBA	Total	Concentration Factor
Grain	0.06	<0.01	0.04	0.02	0.12	
Starch	<0.01	<0.01	<0.01	<0.01	<0.01	<0.3
Flour	0.06	<0.01	0.02	0.01	<0.10	<0.8
Dust	0.42	0.04	*	*	0.46	7

* Insufficient sample for analysis.

The concentration factor of 7 is clearly only an estimate because metabolites were not analyzed due to insufficient sample. At this time we do not consider further analyses of grain dust to be necessary.

Based on a concentration factor of 7, a 408 tolerance of 1.5 ppm should be proposed for residues of lambda-cyhalothrin in/on sorghum grain dust.

Meat, Milk, Poultry and Eggs

Sorghum grain can comprise up to 80% of the diet of beef cattle, 40% of the diet of dairy cattle, and 60% of the diet of turkey & broilers and laying hens. Sorghum grain commonly replaces corn grain in the diet of animals, according to Morrison's Feeds and Feeding.

In our 9/19/91 memo, residues for dairy and beef cattle and poultry were calculated from diets comprised of feeds which would give the maximum concentration of lambda-cyhalothrin in the diet. Maximum concentrations in the diet of 4.0 ppm and 7.6 ppm were predicted for dairy and beef cattle, respectively. The

registrant was requested to propose lambda-cyhalothrin tolerances of 0.2 ppm for milk and meat, 4.0 ppm for fat, 0.1 ppm for liver and 0.2 ppm for kidney. The principal source of lambda-cyhalothrin in the diet is corn forage in both cases. Since appearance of corn forage and sorghum grain in the same diet is unlikely, a diet consisting in part of sorghum grain would almost certainly yield a lower lambda-cyhalothrin concentration. Therefore, such a diet will not be devised in this memo. Corn forage does not comprise part of the diet of poultry. Inclusion of sorghum grain will cause an increase in lambda-cyhalothrin concentration in the diet from that previously considered.

Table 5

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

Commodity	Maximum Diet Percentage	Tolerance (ppm)	Contribution to Daily Diet (ppm)
Sorghum, Grain Dust	20	1.5	0.30
Sorghum, Grain	40	0.2	0.08
Tomato Pomace Wet	3	1.0 (6.0 ppm, dry weight basis)	0.18
Cottonseed Meal/Soapstock	15	0.05	0.008
Sunflower Meal	15	0.03	0.004
Soybean Seed, Wheat Grain	7 (balance)	0.01	0.0007
			Total = 0.6 ppm

Table 6

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

Commodity	Maximum Diet Percentage	Tolerance (ppm)	Contribution to Daily Diet (ppm)
Sorghum, Grain Dust	20	1.5	0.30
Sorghum, Grain	40	0.2	0.08
Tomato Pomace Wet	2	1.0 (6.0 ppm, dry weight basis)	0.12
Cottonseed Meal/Soapstock	8	0.05	0.004
Sunflower Meal	15	0.03	0.004
Soybean Seed, Wheat Grain	15 (balance)	0.01	0.0015
			Total = 0.5 ppm

In both of these tables we have assumed that the maximum sorghum grain + grain dust contribution is 60 %.

A poultry feeding study was reviewed by S. Willett (S. Brooks) in PP#7F3488 (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. At the 25 ppm feeding level mean plateau levels in eggs were 0.05 ppm; the maximum levels found in liver, fat and muscle were 0.006, 0.02 and 0.82 ppm, respectively. Using these levels and the diets above, we calculate that the maximum residue in fat of poultry should be 0.02 ppm (0.6 ppm x 0.82 ppm/25 ppm). Residues in eggs, liver and muscle are predicted to be <0.01 ppm.

In our previous memo we asked that tolerances of 0.01 ppm be proposed for residues of lambda-cyhalothrin in the above poultry commodities. We now ask that a tolerance of 0.02 ppm be proposed for residues of lambda-cyhalothrin in poultry fat.

Levels of metabolites are predicted to be ≤0.005 ppm. The highest metabolite concentration found from the 25 ppm feeding study was in liver, 0.22 ppm.

Other Considerations

An International Residue Limit (IRL) Status sheet is appended to this review. There is no IRL's for lambda-cyhalothrin in/on any of the commodities reviewed in the petition. Therefore, there is no problem with harmonization.

Attachment 1: International Residue Limit Status sheet.
Attachment 2: Chemical Names and structures of lambda-cyhalothrin and metabolites.

cc: SF, RF, Circu., C. Furlow (PIB/FOD), Mike Flood, E. Haeberer, PP#1F3992.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):12/23/91.
RDI:SectionHead:ETHaeberer:12/11/91:BranchSeniorScientist:RALoranger: 12/18/91.