5.16-94

Residue Chemistry Review

Comments:	
Subject:	**PP#'s 7F3488 (Lambda-Cyhalothrin in/on Soybeans); 7F3560/7H5543 (Wheat, Sweet Corn, Sunflowers); 1F3952/1H5607 (Broccoli, Cabbage, Tomatoes);1F3985 (Head Lettuce); 1F3992 (Grain Sorghum); 2F4100 (Dry Bulb Onions, Garlic); 2F4109 (Field, Pop, Seed Corn); 2F4114 (Peanuts). Responses to Various CBTS Reviews. Storage Stability in Raw and Processed Commodities. CBTS #'s: 12362, 12363, 12364, 12365, 12366, 12367, 12368, 12369, 12370, 12371, 12571, 12572, 12983, 12984, 12985, 12986, 12987, 12988, 12989, 12990, 13453, 13454.**
Document Class:	
Product Chem:	
Residue Chem:	**860.1200 Directions for use** **860.1380 Storage stability data** **860.1550 Proposed tolerances**
Biochemicals:	
DP Barcode:	**D193852, D193853, D193856, D193867, D193868, D193869, D193870, D193871, D193872, D193873, D195189, D195192, D197574, D197575, D197578, D197579, D197580, D197581, D197583, D197689, D200994, D200995, D200996**
MRIDs:	**42761201, 42761202, 42761203, 42761204, 42761205, 42761206, 43032001**
PC Codes:	**128897 lambda-Cyhalothrin**
Commodities:	**Soybean; Wheat; Corn, sweet; Sunflower; Broccoli; Cabbage; Tomato; Lettuce, Head; Sorghum, Grain; Onion, dry bulb; Garlic; Corn, Field; Corn, pop; Corn; Peanut**
Administrative #:	**1F03952; 1F03985; 1F03992; 1H05607; 2F04100; 2F04109; 2F04114; 7F03488; 7F03560; 7H05543**
Reviewers:	**Michael T. Flood**
Review Approver:	**Esther Saito** **Approved on: May 16, 1994**
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MEMORANDUM

SUBJECT: PP#'s 7F3488 (Lambda-Cyhalothrin in/on Soybeans); 7F3560/7H5543 (Wheat, Sweet Corn, Sunflowers); 1F3952/1H5607 (Broccoli, Cabbage, Tomatoes);1F3985 (Head Lettuce); 1F3992 (Grain Sorghum); 2F4100 (Dry Bulb Onions, Garlic); 2F4109 (Field, Pop, Seed Corn); 2F4114 (Peanuts). Responses to Various CBTS Reviews. Storage Stability in Raw and Processed Commodities.

DP Barcodes: D193852, D193853, D193856, D193867, D193872, D193868, D193869, D193870, D193871, D193873, D195192, D195189, D197574, D197575, D197578, D197579, D197580, D197581, D197583, D197689, D200994, D200995, D200996.

CBTS #'s: 12362, 12363, 12364, 12365, 12366, 12367, 12368, 12369, 12370, 12371, 12571, 12572, 12983, 12984, 12985, 12986, 12987, 12988, 12989, 12990, 13453, 13454.

MRID #'s: 427612-01, 427612-02, 427612-03, 427612-04, 427612-05, 427612-06, 430320-01.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
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THROUGH: Esther Saito, Ph.D., Chief
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TO: Adam Heyward/George LaRocca, PM 13
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and

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2

These submissions from Zeneca Ag Products (formerly ICI Ag Products), dated 4/29/93, 2/24/94 and 3/6/94, are responsive to CBTS' reviews of the various petitions. The following tolerances have been proposed:

RAC/Processed Commodity	Proposed Tolerance (ppm)	Petition No./Relevant CBTS Memo Dates
Broccoli	0.4	1F3952
Cabbage	0.4	4/9/92
Lettuce, head	2.0	1F3985 10/22/91
Onions/garlic	0.1	2F4100 10/20/92
Sweet corn (k+cwhr)	0.05	7F3560
Sweet corn, forage	6.0	9/19/91
Tomatoes	0.1	1F3952/1H5607
Tomato pomace, wet or dry	6.0	9/19/91 4/9/92
Soybeans, seed	0.01	7F3488 4/12/90 11/16/92
Corn, grain, field, pop & seed	0.05	2F4109
Corn grain, flour	0.15	9/19/91
Corn, forage	1.0	11/19/92
Corn, fodder	1.0	
Peanuts	0.05	2F4114
Peanuts, hulls	0.05	11/19/92
Wheat, grain	0.05	7F3560/7H5543 9/1/92
Wheat forage, straw, grain dust	2.0	
Wheat bran	0.2	
Sorghum, grain	0.2	1F3992
Sorghum, grain dust	1.5	9/1/92

Sunflower, seed	0.05	7F3560/7H5543 2/3/88
Sunflower, seed, hulls	0.07	9/19/91 9/8/92
Fat of poultry	0.02	7F3560
Milkfat	5.0 (reflecting 0.2 ppm in whole milk)	9/1/92
Meat & mbyp of cattle, goats, hogs, horses and sheep	0.2	
Fat of cattle, goats, hogs, horses and sheep	3.0	
Meat, fat mbyp and eggs of poultry	0.01	

We assume that the final entry of the first column is in error and should read "Meat, mbyp and eggs of poultry".

Summary of Deficiencies Remaining to Be Resolved

All data deficiencies have been resolved for PP#'s 1F3952/1H5607, 1F3985, 2F4100, and 2F4109.

Additional residue data must be generated in support of PP#'s 7F3488, 1F3992, and 2F4114.

Additional information on the storage stability in soapstock should be provided.

A revised Section B must be submitted for PP#7F3560/7H5543.

A complete Section F with revised tolerances for certain corn commodities and with the appropriate chemical names for lambda-cyhalothrin and its epimer should be submitted.

Conclusions (pertaining to this memo only)

1a. Lambda-cyhalothrin metabolites (PP890, 3-PBAcid, 3-PBAlcohol) have been shown to be stable in plant matrices under frozen storage for periods up to 36-months.

1b. Lambda-cyhalothrin and its epimer have been shown to be stable in processed commodities under frozen storage for periods up to 34 months. The petitioner should

explain the discrepancy between the 18-month levels for soapstock reported in the interim and the final reports. Chromatograms from the storage stability study on soapstock should be submitted. (This information should preferably be submitted as a part of PP#7F3488. Because the updated Table II of our Residue chemistry guidelines no longer lists "soapstock" as a significant feed item, storage stability in soapstock is not an issue. However, since these data have already been generated, they remain useful in determining the overall stability profile of the pesticide.)

1c. The interim storage stability study for lambda-cyhalothrin metabolites in processed commodities shows that these metabolites are stable in frozen storage for periods up to 21 months.

2a. Proposed tolerances for field corn grain, forage, fodder and corn flour (11/19/92 memo); poultry fat, milkfat (9/1/92 memo); tomato pomace (4/9/92 memo); head lettuce (10/22/91 memo) -- as requested in the cited CBTS memos have been submitted. All tolerance values are now appropriate, with one exception. The corn forage tolerance should be proposed at 6.0 ppm, and the sweet corn forage tolerance in PP#7F3560 should be deleted. Also, a tolerance on seed corn grain is not necessary, for it is covered by the field corn grain tolerance. We also note that tolerances for meat and milk may have to be revised in the future depending on the residue levels found in certain animal feed items. (See Conclusion 2b.)

2b. Our Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines (April 1994) no longer lists soybean forage, soybean hay, grain sorghum forage, grain sorghum fodder, and peanut hay as being under grower control. Feeding restrictions are not considered practical, and hence, residue data must be generated before permanent tolerances can be established on any of the RACS associated with soybeans, grain sorghum or peanuts. The residue data should be collected from the same number of field trials with the same geographic distribution as were the residue data on the other RACs of these crops. In the meantime, tolerances with expiration dates can be established on soybeans, peanuts, peanut hulls, sorghum grain, and sorghum grain dust based on the residue data already submitted. Also, the feeding restrictions on forages, hays and fodders of these crops should remain on the label while data are being generated.

Wheat hay is now considered to be a RAC. However, because tolerances for wheat forage and wheat straw are the same and lambda-cyhalothrin is not a systemic pesticide -- concentration of residues in the seed head does not occur -- the tolerance for wheat hay can be set at 2.0 ppm without submission of residue data. However, the petitioner should submit a revised Section B in which use directions for lambda-cyhalothrin in/on hay are proposed. In the meantime, tolerances can be established on the other wheat RACs (and the other RACs of PP#7F3560 -- sweet corn, sunflower with the exception of the sweet corn forage tolerances, which should be deleted from the Section F). The tolerance for hay should appear in the revised Section F (see next conclusion).

2c. CBTS has not reviewed a complete proposed Section F, since only a table of numerical tolerances has been submitted. All conclusions relating to these tolerances are therefore provisional. To be acceptable, the tolerance expression should include lambda-cyhalothrin and its epimer, and the nomenclature used should be the IUPAC names for these compounds. (The IUPAC names were given in our 3/23/92 memo for FAP#0H5599.) The petitioner should submit a complete Section F for our review that includes appropriate chemical names, a revised tolerance level for corn forage (see Conclusion 2a), and deletion of tolerances for sweet corn forage and seed corn grain. Although this Section F needs to address numerous petitions, it can be submitted as one document so long as the appropriate petition number is provided for each tolerance.

3. Proposed tolerances for meat, milk, poultry and eggs are appropriate, and permanent tolerances can be established (TOX considerations permitting). As noted, additional residue data on animal feeds may result in higher future tolerances for meat and milk.

4. An International Residue Limits Status sheet is attached to this review. There is a CODEX maximum residue limit (MRL) of 0.2 ppm for residues of cyhalothrin in/on head cabbage. Because lambda-cyhalothrin contains two of the four isomers in cyhalothrin and these two isomers are the insecticidally active isomers, an equivalent MRL for lambda-cyhalothrin would be lower than 0.2 ppm, and if such an MRL were ever established it would not be in harmony with the proposed tolerance of 0.4 ppm.

Recommendations

TOX considerations permitting and provided that a revised Section B (to address wheat hay) and a complete Section F are submitted, as noted below, CBTS recommends that the proposed tolerances for residues of lambda-cyhalothrin and its epimer in/on broccoli; cabbage; tomatoes; head lettuce; onion/garlic; field and pop corn grain, corn fodder; sweet corn (k + cwhr); sunflowers, seed and hulls; wheat grain, forage, straw and grain dust; and meat, milk, poultry and eggs be established. The corn forage tolerance should be increased to 6 ppm.

TOX considerations permitting, CBTS recommends that the proposed tolerances for residues of lambda-cyhalothrin and its epimer in/on soybeans, peanuts and peanut hulls, and sorghum grain and grain dust be established with an expiration date. During the time period of the tolerance, the petitioner will need to generate residue data on various animal feed items. A question concerning storage stability of the pesticide in soapstock needs to be answered.

A complete Section F, including the requested (IUPAC) chemical names should be submitted. We note that "fat" should be deleted from the "meat, fat mbyp and eggs of poultry" tolerance in the submitted table of numerical tolerances. Tolerances for certain corn commodities need to be revised or deleted, as noted in Conclusion 2a.

A DRES analysis can now be carried out using the proposed tolerances in the above table.

Detailed Considerations

NOTE: Any recommendations for tolerances are contingent upon a revised Section F being submitted as stated above in Conclusion 2c.

Deficiencies noted in various CBTS reviews are stated, followed by ICI/Zeneca's response and CBTS' comments:

PP#2F4100 -- for use in/on dry bulb onions and garlic.

CBTS Deficiency #5 (Conclusion #5 from our 10/13/92 memo)

The storage stability data of lambda-cyhalothrin on dry onion bulbs are adequate to support the residue analyses for parent and epimer but not the metabolites. The petitioner needs to submit storage stability data of metabolites CPA, 3-PBAcid and 3-PBAlcohol [3-phenoxybenzyl alcohol] for periods up to 26 months and in extracts for up to 42 days (the conclusion that the residue to be regulated consists only of parent and epimer was made under the assumption that the residue data on metabolites of concern were accurate).

Petitioner Response

The petitioner refers to our review of 11/19/92 for PP#'s 2F4109 (field, pop, and seed corn), 2F4114 (peanuts), and 7F3560 (wheat, sweet corn and sunflower) which concluded that storage stability data for metabolites in a number of plant matrices support analyses for periods up to two years.

CBTS Comment

Our 11/19/92 memo has concluded that metabolite storage stability in plant matrices is not a problem for up to two years.

As reported in J. Morales' 10/13/92 memo for PP#2F4100, the maximum interval between extraction and analyses of dry bulb onions was 11 days. Stability of lambda-cyhalothrin metabolites in extracts from various plant compounds has been demonstrated over this time period. For example, in the interim report on storage stability of metabolites in processed commodities, submitted as Volume 6 (MRID # 427612-06) and reviewed later in this memo, intervals between extraction and storage varied from two to twenty-two days. In the 36-month storage stability study of metabolites in various raw agricultural commodities, reviewed in this memo, intervals between extraction and chromatography varied from one to 45 days.

This deficiency is resolved. **TOX considerations permitting, CBTS recommends that a tolerance of 0.1 ppm be established for residues of lambda-cyhalothrin and its epimer in/on dried bulb onions and garlic.**

PP#'s 2F4109, 2F4114,7F3560 - for use on field, pop and seed corn; peanuts; wheat, sweet corn and sunflowers.

CBTS Deficiency #3c (Conclusion #3c from our 11/19/92 memo)

> Storage stability data are adequate to support the residue analyses for parent in peanut meat and hulls; however storage stability data on metabolites for periods up to 31 months are necessary....

CBTS Deficiency #3d (Conclusion #3d from our 11/19/92 memo)

> Storage stability data are lacking in support of the analyses for parent and metabolites in the processed commodities of corn, peanuts and soybeans (PP#7F3488). Stability of parent and metabolites in three processed commodities must be demonstrated for periods up to 17 months. Because available storage stability data on racs indicate a potential problem with peanuts, two of these processed commodities should be peanut meal and peanut oil. If parent or a metabolite is not stable in these matrices, stability data in other processed commodities may also be required.

Petitioner Response (MRID # 427612-05)

Storage stability of the metabolites cis-1-RS-3-(ZE-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-

carboxylic acid (PP890), 3-phenoxybenzoic acid (3-PBAcid) and 3-phenoxybenzyl alcohol (3-PB Alcohol) in peanut meats and hulls have now been completed up to 36 months...The data demonstrates that the metabolites are stable when stored for up to 36 months at -20°±5°C.

Storage stability of lambda cyhalothrin (ICIA0321) and epimer (R157836) has been conducted on the processed commodities dry pomace (apple), flour (sorghum), juice (tomato), soapstock (corn), refined oil (soybean) and starch (sorghum) when stored at -20°±10°C.....Lambda cyhalothrin and epimer residues appear to be stable for up to 18 months in dry pomace (apple), flour (sorghum), juice (tomato), refined oil (soybean) and starch (sorghum)...Residues however decline in soapstock and tomato juice with a half-life of about 13 months. Degradation is due to the high alkaline pH of soapstock and acidic pH of tomato juice. The pH extremes of these commodities probably result in hydrolysis of the ester to give the metabolites PP890 and 3-phenoxybenzyl alcohol.

CBTS Comment

The results of the storage stability study of metabolites in peanut meats and hulls are given in Tables 1 and 2 of MRID # 427612-05. 3-PBAlcohol levels showed no decline in either matrix over the 36 month period. PP890 and 3-PBAcid levels declined to about two-thirds of the 0 day values. In both cases the decline occurred during the first 12 months; levels then remained constant for the remainder of the period. These data were only summarized in MRID #427612-05. The complete report was submitted subsequently:

> "Part III: Final Report on Storage Stability of Pyrethroid Metabolites (PP890, 3-PB acid, 3-PB alcohol, and DCVA) in Raw Agricultural Commodities (36-Month Interval);" C.L. Eckstein; 8/17/93; Zeneca Ag Products, Richmond, CA; Study No. PYRE-89-SS-01; Report No. RR 92-101B. (MRID # 429192-01).

The interim, 24-month, report was reviewed in our 11/19/92 memo. Samples were analyzed by the GC/MS method described in our 9/19/91 memo. Observed values were corrected for recoveries of fortifications done on the day of analysis. Chromatograms have been submitted.

Stability of PP890, 3-PBAcid, 3-PBAlcohol and the permethrin metabolite DCVA (dichlorovinyl acid) was determined in the following frozen matrices: apples, cabbage, corn fodder, corn forage, cottonseed, lettuce, peanut hulls, peanut meats, sorghum grain, soybeans, sugar beets, tobacco and tomatoes. After fortification at 0.10 µg/g with each metabolite, samples were analyzed after 0-day, 3-months, 12-months, 24-months and 36-

months of storage at -20±5°C. In general, the metabolites were stable during the 36 month period. In no case was a final metabolite level found to be less than 60% of the 0-day level. Those matrices in which the final level was lower than 80% of the 0-day level are given in the following table:

Table 1

Matrices in which 36-Month Metabolite Levels Were Lower than 80% of 0-Day Levels

Sample Matrix	PP890	3-PBAcid	3-PBAlcohol
Apples	66.7%	72.6%	
Corn Forage			77.9%
Corn Fodder			76.5%
Peanut Hulls			74.3%
Peanut Meats	64.6%	70.6%	
Sorghum Grain	66.1%	79.8%	73.9%
Soybeans			76.4%
Tomatoes	66.7%		

The data for peanut nutmeat confirm that the observed residue decline occurs during the first 12 months. CBTS concludes that the three metabolites of lambda-cyhalothrin are stable in RACS under frozen storage conditions for periods up to 36 months.

In the storage stability study, intervals between extraction and chromatography varied from 1 to 45 days. We conclude from this that stability of metabolites in extracts is not a problem.

The final report of storage stability in <u>processed</u> commodities over a 34-month period has now been submitted:

> "Lambda-cyhalothrin (ICIA0321): Stability of Residues of Lambda-cyhalothrin and its Epimer (R157836) in Stored Processed Commodity Analytical Samples (Final Report 34-Month Interval)"; C.F. Eckstein; 11/17/93; Zeneca Ag. Products, Richmond, CA; Study Number 0321-90-SS-01; Report Number RR 93-080B. (MRID # 430320-01)

The processed commodities listed in the previous section of this memo were fortified at 0.091 µg/g cyhalothrin, which consisted of 43.2% ICIA0321 and 56.8% R157836, resulting in fortification levels of 0.039 µg/g ICIA0321 and 0.052 µg/g

R157836. Samples were analyzed at O-day, 4 months, 18 months and 34 months by ICI Method 81, which was summarized in our 9/19/91 memo. Soapstock samples were extracted by homogenization with 1:1 (v/v) acetone water under acidic (pH <2) conditions. The extract was partitioned into dichloromethane. The solvent was removed by evaporation and the sample brought up in hexane. The remainder of the procedure is identical to that in Method 81.

No decline in either ICIA0321 nor the epimer was observed in flour, starch, dry pomace, or refined oil. Levels in juice at 34 months were 63% of the 0-day level for ICIA0321 and 73% for epimer. No significant decline was observed in soapstock, in contrast to the interim results reported in MRID # 427612-05. Chromatograms are given for all matrices except soapstock. The petitioner should explain the discrepancy between the 18-month levels for soapstock reported in the interim and final reports. Chromatograms from the storage stability study on soapstock should be submitted, preferably as a part of PP#7F3488. Because the updated Table II of our Residue Chemistry Guidelines no longer lists "soapstock", as a significant feed item, storage stability in soapstock, per se, is not an issue. However, since these data have already been generated, they remain useful in determining the overall stability profile of the pesticide.

The corresponding storage stability study on metabolites has been submitted:

> "Part II: Interim Report on Storage Stability of Pyrethroid Metabolites in Processed Commodities (21 Month Interval);" C.L. Eckstein; 11/11/92; ICI Americas, Richmond, CA; Study No. PYRE-90-SS-01; Report No. RR 92-071B. (MRID # 427612-06)

The storage stability of the three lambda-cyhalothrin metabolites plus dichlorovinyl acid (DCVA), a permethrin metabolite, was studied in the same processed matrices, except corn soapstock. Samples were fortified at 0.1 ppm and analyzed at 0-day, 4-months and 21-months by the GC/MS procedure described in our 9/19/91 memo. The only significant decline was observed in tomato juice. In that matrix, residues of PP890 declined to 66% of the initial value by 21 months. Residues of 3-PBAcid declined to 80% over the same time period. No significant decline was observed with 3-PBAlcohol. We can conclude that in general, frozen storage stability of metabolites is not a problem for time periods up to 21 months. The study will be continued to 36 months.

We had originally requested storage stability data for peanut oil and flour. The submitted processing study was probably begun before receipt of our 11/19/92 memo. At this time we will not pursue this issue further. Stability has been demonstrated in sorghum flour and soybean oil. The 36 month

11

storage stability study on peanuts now shows that metabolite residues are generally stable in nutmeat, although there was a decline during the first 12 months. Moreover, because lambda-cyhalothrin is non-systemic, detectable residues are not expected in nutmeat to begin with. (see our memo dated 11/19/42 for PP#2F4114).

Deficiencies #3c and #3d are resolved.

CBTS Deficiency #4a (Conclusion #4a from our 11/19/92 memo)

Based on submitted residue data, appropriate tolerances for corn grain, forage and fodder are 0.05, 1.0 and 1.0 ppm, respectively. At this time, we do not consider results which include the fonofos/lambda-cyhalothrin premix applications as relevant to the present submission. However, registration of this latter formulation may require additional residue data. ICI Americas should submit a revised Section F in which the above tolerances are proposed.

Because lambda-cyhalothrin residues in corn grain were non-detected, we do not consider a tolerance for these residues in/on grain dust to be necessary. The petitioner should submit a revised Section F in which the proposed tolerance on grain dust is omitted.

CBTS Deficiency #4b

Based on submitted residue data for residues of lambda-cyhalothrin in/on peanut meats and hulls, the proposed tolerances of 0.05 ppm for these commodities is appropriate. However, the tolerance for "peanuts, nutmeats" should be expressed simply as "peanuts". This conclusion is provisional, pending submission of adequate storage stability data.

CBTS Deficiency #5a

Lambda-cyhalothrin concentrates when corn grain is processed into flour. The petitioner should submit a revised Section F in which a food additive tolerance of 0.15 ppm is proposed for this commodity. This conclusion is provisional pending submission of adequate storage stability data.

Petitioner Response

A revised Section F has been submitted (4/29/93 letter) in which the requested tolerances or changes in the tolerance expressions have been incorporated.

CBTS Comment

These particular deficiencies are resolved, but see Conclusion 2c.

CBTS Deficiency #6 (Conclusion #6 from our 9/1/92 memo)

A revised Section F has been submitted. Most of the proposed tolerances are acceptable; however, ICI should submit a revised Section F in which a tolerance of 0.02 ppm is proposed for the fat of poultry and a tolerance of 5 ppm is proposed for milkfat (reflecting 0.2 ppm in whole milk).

Petitioner Response

The appropriate Section F has been submitted (4/29/93 letter).

CBTS Comment

This deficiency is resolved, but see Conclusion 2c.

CBTS Conclusion for PP#753560/7H5543 (Wheat, Sweet Corn, Sunflowers)

TOX considerations permitting, and provided that a revised Section B is submitted to address wheat hay, CBTS recommends that the following tolerances be established:

Wheat grain, 0.05 ppm; wheat forage, hay*, straw, grain dust, 2.0 ppm; sweet corn (k+cwhr), 0.05 ppm; sunflower seed, 0.05 ppm; sunflower seed hulls, 0.07 ppm. The sweet corn forage tolerance should be deleted and a 6.0 ppm corn forage tolerance proposed in PP#2F4109.

* Wheat hay is now considered to be a rac, according to our latest Table II update. Because residue levels in wheat forage and wheat straw were similar, similar levels are predicted in hay. Generation of additional residue data is not warranted, and the inclusion of hay in the tolerance expression can be handled administratively without submission of a new Section F. However, the petitioner must submit a revised Section B which gives the use directions for the pesticide on wheat hay. In the meantime, tolerances with an expiration date can be established.

CBTS Conclusion for PP#2F4109 (Corn, field, seed, pop)

TOX considerations permitting, CBTS recommends that the following permanent tolerances be established:

Corn, grain, field and pop, 0.05 ppm; corn grain, flour, 0.15 ppm; corn fodder, 1.0 ppm; corn forage 6.0 ppm (revised from 1.0 ppm). The seed corn grain tolerance can be deleted since this commodity is covered by the field corn grain tolerance.

Note that the different tolerances for sweet corn forage and field corn forage reflect different labels for these two racs. (See our memo of 11/19/92). We prefer that a "corn forage" tolerance be set at the higher residue level of the two forages. If for some reason, use in/on sweet corn is deleted, the corn forage tolerance can be reproposed at 1.0 ppm. Fodder is not a sweet corn rac.

CBTS Conclusion for PP#2F4114 (Peanuts)

According to our updated Table II, peanut hay is not under grower control. Hence residue data on this commodity are needed. Data should be obtained on hay from the same number of trials as were previously carried out for peanuts.

TOX considerations permitting, CBTS recommends that tolerances with an expiration date be established for peanuts and peanut hulls at 0.05 ppm.

PP#1F3952/1H5607 -- for use in/on broccoli, cabbage and tomatoes.

CBTS Deficiency #6b (Conclusion #6b from our 4/9/92 memo)

The proposed tolerance of 0.4 ppm for residues of lambda-cyhalothrin in/on broccoli is appropriate, but ICI should submit a revised Section F in which the epimer is included in the tolerance expression. The numerical value of the tolerance need not be changed.

CBTS Deficiency #6c

ICI has proposed a tolerance of 0.4 ppm for residues of lambda-cyhalothrin in/on cabbage. A revised Section F should be submitted in which the epimer is included in the tolerance expression. The numerical value of the tolerance need not be changed.

CBTS Deficiency #6d

ICI has proposed a tolerance of 0.1 ppm for residues of lambda-cyhalothrin in/on tomatoes. a revised Section F should be submitted in which the epimer is included in the tolerance expression. The numerical value of the tolerance need not be changed.

Based on the determined concentration factor, ICI should submit a revised Section F in which a feed additive tolerance of 6.0 ppm is proposed for residues of lambda-cyhalothrin and its epimer in/on tomato pomace, wet or dry.

Petitioner Response

The proposed tolerances have been revised as requested in the enclosed Section F.

CBTS Comment

Zeneca's letter of 4/29/93 includes a table of pending tolerances in which the numerical changes in the tolerances have been incorporated. We do not have an actual revised Section F in which the tolerance expression includes the epimer. The petitioner should submit a complete Section F for our review that includes appropriate chemical (IUPAC) names, a revised tolerance level for corn forage and deletion of the tolerances for sweet corn forage and seed corn grain.

PP#1F3985 -- for use in/on head lettuce.

CBTS' memo of 10/22/91 cited various deficiencies (nature of residue, ground versus aerial application) that have since been resolved. Other deficiencies from that memo are given with Zeneca's response and our comment.

CBTS Deficiency #5 (Conclusion #5 from our 10/22/91 memo)

.....The petitioner should note that the commodity definition for head lettuce is lettuce with wrapper leaves. Residue data for lettuce without wrapper leaves should be used in calculations of anticipated residues. a revised Section F is needed reflecting a tolerance proposal for the rac only.

Petitioner Response

The requested change in the tolerance proposal is reflected in the enclosed Section F.

CBTS Comment

The previous Section F had specified two tolerances -- one for lettuce with wrapper leaves, the other for lettuce without wrapper leaves. The new Section F, as it appears in Zeneca's 4/29/93 letter, has one tolerance for head lettuce -- the original tolerance proposed for lettuce with wrapper leaves. This deficiency is resolved, pending submission of the complete Section F (see Conclusion 2c).

CBTS Deficiency #6a (Conclusion #6a from our 10/22/91 memo)

....The ratio of lambda-cyhalothrin and its epimer is stable when stored for 16 months at <-18°C. Parent and its epimer analyses were conducted in a period of 13 to 24 months after harvest. Therefore, additional storage stability data for the ratio of parent and its epimer should be submitted for longer periods of time to support the subject petition.

Petitioner Response/CBTS Comment

In our 11/19/92 review, we concluded that available storage stability data for lambda-cyhalothrin would also cover the epimer. This deficiency is resolved.

CBTS Deficiency #6b (Conclusion #6b from our 10/22/91 memo)

Available storage stability data indicate that CPA [PP890], 3-PBAcid and 3-PBAlcohol are stable in various racs for 3 months under frozen storage. This period of time is inadequate to support the subject petition. Additional storage stability data are needed reflecting storage time and conditions used for the field residue samples in this submission.

CBTS Comment

As reported above, the petitioner has now shown that metabolites are stable under frozen storage in a number of racs for up to 36 months. This deficiency is resolved.

TOX considerations permitting, CBTS now recommends that a tolerance of 2.0 ppm be established for residues of lambda-cyhalothrin and its epimer in/on head lettuce.

PP#7F3488 -- for use in/on soybeans.

CBTS Deficiency #5 (Conclusion #5 from J. Morales' 11/16/92 memo)

> .....The petitioner needs to submit storage stability data of metabolites CPA [PP890], 3-PBAcid and 3-PBAlcohol for periods up to 26 months and in extracts for up to 42 days....

CBTS Comment

As noted above, acceptable storage stability data have been received. This deficiency is resolved.

CBTS Deficiency #6 (Conclusion #6 from our 11/16/92 memo)

> Residue data on soybean seed show that nondetectable (<0.01 ppm) residues were obtained after lambda-cyhalothrin treatment. No residue data were sent for soybean forage and hay. In the absence of residue data for these feed items, the registrant should impose a label restriction against feed use of forage and hay. A revised Section B is needed. Alternatively, the petitioner may submit residue data on soybean forage and hay in order to support the subject tolerance petition.

Petitioner Response

A revised Section B (use directions) for soybeans is included in this submission which imposes a label restriction against feed use of forage and hay.

CBTS Comment

Our revision of Table II to our Residue Chemistry Guidelines no longer lists soybean forage or hay as being under grower control. Hence, grazing restrictions on the label are not now considered to be practical, and residue data on hay and forage are required. Because the residue data on soybean seed were generated when the earlier version of the table was operative, CBTS recommends that a time-limited tolerance be established while residue data on forage and hay are generated.

CBTS Deficiency #7 (Conclusion #7 from our 11/16/92 memo)

> No data were sent on the storage stability of the processed commodities. The petitioner may either; submit storage stability data for lambda-cyhalothrin, its epimer, and metabolites for periods up to 10 months in soybean refined oil and meal; or resolve this deficiency as part of a concurrent CBTS review for PP#2F4109 (field corn) and PP#2F4114 (peanuts) by M. Flood.

CBTS Comment

Storage stability data on processed commodities have been submitted and are discussed earlier in this memo. This deficiency is resolved.

TOX considerations permitting, CBTS recommends in favor of a time-limited tolerance of 0.01 ppm for residues of lambda-cyhalothrin and its epimer in/on soybean seed. Residue data must be generated for soybean hay and forage. The number of field trials as well as the geographic representation should match that used to generate the data for seed.

PP#1F3992 -- for use in/on grain sorghum.

CBTS Deficiency #4 (Conclusion #4 from our 9/1/92 memo)

> Storage stability data support the residue analyses for metabolites for one year only. Additional data -- up to 29 months in the case of sorghum -- are required...

CBTS Comment

As noted above, adequate storage stability data now exist. This deficiency is resolved. However, our updated Table II no longer lists forage, fodder or silage as being under grower control. Therefore, residue data should be generated on these commodities. Silage samples should include the whole aerial portion and be harvested at late dough/early dent stage. Silage may be analyzed immediately after collection, or after ensiling for 3-weeks maximum and reaching a pH of 4.2 or less. However, residue data on forage would cover silage. Hay is no longer considered to be a RAC.

As in the case of soybeans, **CBTS recommends that -- TOX considerations permitting -- tolerances with expiration date be established for residues of lambda-cyhalothrin and its epimer in/on sorghum grain, at 0.2 ppm, and sorghum grain dust, at 1.5 ppm.**

Meat, Milk, Poultry and Egg Tolerances (PP#7F3560/7H5543)

Deficiencies relating to meat and milk tolerances have been resolved previously. (See discussion under CBTS Conclusion #6 from our 9/1/92 memo.)

TOX considerations permitting, CBTS recommends that permanent tolerances be established for residues of lambda-cyhalothrin and its epimer in milkfat at 5.0 ppm (reflecting 0.2 ppm in whole milk); meat and mbyp of cattle, goats, hogs, horses and sheep at 0.2 ppm; fat of cattle, goats, hogs, horses and sheep at 3.0 ppm; and the meat, fat, mbyp and eggs of poultry at 0.01 ppm. We note, however, that the tolerances on meat and milk may have to be raised in the future when residue data on additional ruminant feed items are submitted.

Other Considerations

Revised Labels

Submissions dated 2/24/94 and 4/29/94 contain several label revisions, none of which affect our previous conclusions. The following changes have been made:

1. Application interval for field, seed or popcorn is 7

days, formerly 3-7 days. New complete proposed label was not submitted.

2. The maximum single application use rate on sorghum grain is now 0.03 lb ai/A, formerly 0.04 lb ai/A. New complete label was not submitted.

3. The maximum single application use rate on broccoli, cabbage, or tomatoes is now 0.03 lb ai/A, formerly 0.04 lb ai/A. Suggested application interval is now 5 days, the interval specified in the label reviewed in our 9/19/91 memo.

4. "Tomatillos" has been added to the label for tomatoes. The restriction has been added: Do not use on varieties in which mature tomatoes will be less than 1 inch in diameter (such as cherry tomatoes).

Nomenclature and Residue to Be Regulated

We reiterate the conclusion originally made in our 3/23/92 memo for FAP#0H5599: The IUPAC names for lambda-cyhalothrin and its epimer -- rather than the Chemical Abstract names -- should appear in any regulation for lambda-cyhalothrin.

The residue to be regulated is both lambda-cyhalothrin and its epimer.

International Harmonization

An International Residue Limits Status sheet is appended to this review. There are no Codex, Mexican or Canadian maximum residue limits (MRLs) for lambda-cyhalothrin; however there is a Codex MRL of 0.2 ppm for residues of cyhalothrin in/on head cabbage. Cyhalothrin consists of two pairs of enantiomers; lambda-cyhalothrin consists of one of these pairs and is more insecticidally active. It is our understanding that eventually all cyhalothrin will be replaced with lambda-cyhalothrin. However, the equivalent MRL for lambda-cyhalothrin would be about 0.1 ppm, so there is a potential incompatibility.

Attachment: International Residue Limits Status sheet.

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5/13/94:BranchChief:ECSaito:5/16/94.