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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: PP#7F3560/7H5543, PP#1F3992 -- Lambda-cyhalothrin for Use in/on Wheat, Sweet Corn, Sunflowers, Grain Sorghum. Responses to CBTS 12/26/91 and 1/22/92 memos.

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8/24/92

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By letter dated 1/28/92, ICI Agricultural Products has responded to our reviews dated 1/22/92 (PP#7F3560/7H5543, wheat, sunflowers, sweet corn) and 12/26/91 (PP#1F3992, grain sorghum). ICI's response includes a revised Section F in which the following tolerances are proposed for wheat, sunflowers, sweet corn and grain sorghum

Raw Agricultural Commodity	Proposed Tolerance (ppm)
Corn, sweet, forage	5.0
Corn, sweet (K+CWHR)	0.05
Fat of cattle, goats, hogs, horses, and sheep	3.0
Meat and mbyp of cattle, goats, hogs, horses and sheep	0.2
Meat, fat, mbyp and eggs of poultry	0.01
Milk, fat (reflecting 0.1 ppm in whole milk)	3.0

Sorghum grain	0.2
Sorghum, grain dust	1.5
Sunflower, seed	0.05
Wheat, forage, grain dust, and straw	2.0
Wheat, grain	0.05

In addition food/feed additive tolerances are proposed for sunflower hulls (0.07 ppm) and wheat bran (0.2 ppm). The previously proposed tolerance of 0.05 ppm for lambda-cyhalothrin in sunflower oil has been deleted. (See discussion below.)

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED

---- Storage stability data for metabolites needed.

---- Revised Section F needed.

Conclusions

1. The IUPAC name for lambda-cyhalothrin should appear in the tolerance expression. See our memos for FAP#0H5599 dated 3/23/92 and 4/7/92.

2. The nature of the residue in plants and animals is understood. The residue to be regulated is lambda-cyhalothrin, per se, and its epimer. The nomenclature for both species is given in our above-cited memos for FAP#0H5599.

   In a concurrent memo, CBTS has concluded that the ruminant and poultry metabolite 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methylcyclopropanecarboxylic acid (OH-CPA) need not appear in the tolerance expression. A ruminant feeding study indicates that levels of this metabolite in ruminant tissue will not exceed 0.01 ppm. Levels in poultry tissue will be even lower.

3a. The analytical methods for lambda-cyhalothrin in plant and animal matrices have successfully undergone EPA method validation.

3b. Recoveries for lambda-cyhalothrin have been obtained under FDA's multiresidue protocols and have been submitted to FDA for evaluation.

4. Storage stability data support the residue analyses for

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metabolites for one year only. Additional data -- up to 29 months in the case of sorghum -- are required. Studies are being continued.

5. Adequate residue data are available for the RACS in these petitions.

6. 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).

Recommendation

CBTS continues to recommend against the proposed tolerances for reasons given in Conclusions 4 (storage stability) and 6 (Section F).

Detailed Considerations

CBTS deficiencies from our 1/22/92 and 12/26/91 memos are listed along with ICI's response and CBTS' comments.

PP#7F3560/7H5543

CBTS Deficiency #2 (Conclusion #2 from our 1/22/92 memo)

Residue data from 15 states support the proposed tolerance of 0.03 ppm for residues of lambda-cyhalothrin in/on wheat grain and 2.0 ppm for residues on wheat forage and wheat straw. ICI should propose a tolerance of 0.05 ppm for wheat grain due to analytical uncertainties at low levels.

CBTS Deficiency #3

As a result of the wheat processing study, ICI should propose food/feed additive tolerances (revised Section F) for residues of lambda-cyhalothrin in/on wheat bran (0.3 ppm) and wheat shorts (0.1 ppm). The company should also propose a **408** tolerance of 2.0 ppm for lambda-cyhalothrin in/on grain dust.

ICI Response

A revised Section F has been submitted in which tolerances of 0.05 and 0.2 ppm are proposed for residues of lambda-cyhalothrin in/on wheat grain and wheat bran, respectively; and a tolerance of 2.0 ppm is proposed for grain dust. Although not requested by CBTS, the tolerance for sunflower seed has also been changed to 0.05 ppm and the proposed section 409 tolerance of 0.05 ppm for sunflower oil has been deleted.

"In the wheat processing study wheat was treated at five times the maximum use rate on the proposed label. The wheat received an application of 0.15 lb ai/A at tillering and a second application of 0.15 lb ai/A 30 days before harvest.....Since the

residues in midlings, shorts, germ and four resulting from treatment at 1X the proposed label rate are no greater than the proposed tolerance on whole grain, no food/feed additive tolerance is required for these processed commodities."

CBTS Comment

Treatment of the rac at exaggerated rates for processing studies is designed to obtain reliable concentration factors. The concentration factors are properly applied to the tolerance for the rac. The appropriate food additive tolerance would logically be 0.1 ppm. However, in this particular instance we agree that a food additive tolerance should not be necessary for shorts & germs. Although the highest level of lambda-cyhalothrin found in wheat grain was 0.03 ppm, we recommended that a tolerance of 0.05 ppm be proposed "due to analytical uncertainties at low levels". The slightly higher level would also encompass residues expected from processing grain into shorts.

The concentration factor for processing grain into bran as calculated in our 1/22/92 memo was based on lambda-cyhalothrin plus metabolites. CBTS and TB1 have decided not to include the metabolites in the tolerance expression, and if the calculation is solely based on lambda-cyhalothrin and its epimer, the concentration factor becomes 4 instead of 5. The appropriate food/feed additive tolerance is therefore 0.2 ppm, which ICI has proposed.

The same considerations apply to sunflower seeds and oil.

This deficiency is resolved.

PP#1F3992

CBTS Deficiency #1 (Conclusion #1 from our 12/26/91 memo)

The registrant should obtain written confirmation from Chemical Abstracts Service that the proposed CAS name for lambda-cyhalothrin.....is the correct Chemical Abstracts name.

ICI Response

ICI responded in its 1/15/92 submission.

CBTS Comment

This submission was reviewed in our 3/23/92 memo for FAP#0H5599. The CAS name for lambda-cyhalothrin is correct, but we have recommended that the IUPAC nomenclature appear in the tolerance expression.

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This deficiency is resolved.

CBTS Deficiency #3

.....The issue of HO-CPA remains outstanding (see our memo of 9/19/91).

ICI Response

Preliminary results of a residue transfer study in ruminants have been submitted. These results show very low levels of OH-CPA.

CBTS Comment

The complete study has been reviewed in a concurrent memo, which should be referred to. We have concluded that residue analyses of poultry tissue for OH-CPA are not necessary and have recommended that this metabolite not appear in any tolerance expression.

This deficiency is resolved.

CBTS Deficiency # 5b (Conclusion #5b from our 12/26/91 memo)

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.

ICI Response

Data to support 12-month storage stability of the crop metabolites in RACs were submitted February 13, 1992 with ICI's petition for use on onions....[MRID No. 42206801]. It is anticipated that the data to support storage stability for 24 months will be submitted soon.

For all lambda-cyhalothrin and metabolite analyses, there were concurrent analyses of at least one fortified sample. The storage stability of the extracts was assessed by the measured residues of the fortified samples. If the analytes were unstable in the extracts, a decrease in the measured residue in the fortified sample outside of the normal method variability would have been observed. Low recoveries were not observed. Therefore, lambda-cyhalothrin and its metabolites are stable in extracts for the period from extraction to analysis.

CBTS Comment

The submitted one year storage stability study on the metabolites PP890 (CPA), 3-PBAcid and 3-PBAlcohol were reviewed in conjunction with FAP#0H5599 (imported dried hops) (M. Flood, memo of 3/23/92). The data are adequate to support stability in sorghum grain for one year. The study is being extended to a

total of three years.

Concurrent analyses of fortified samples is sufficient to guarantee stability in extracts.

This deficiency remains, pending submission of adequate storage stability data.

CBTS Deficiency #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.

ICI Response

A revised Section F has been submitted which proposes a tolerance of 1.5 ppm for residues of lambda-cyhalothrin in/on grain dust.

CBTS Comment

This deficiency is resolved.

CBTS Deficiency #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.

ICI Response

ICI has proposed a tolerance of 0.2 ppm for the meat and mbyp of cattle, goats, hogs, horses and sheep; a tolerance of 3.0 for milk, fat (reflecting 0.1 ppm in whole milk); and a tolerance of 3.0 ppm for the fat of cattle, goats, hogs, horses and sheep. The rationale for these tolerances is given in the submission. In a 1/15/92 submission [not yet in review], ICI has amended the proposed tolerance for sweet corn forage from 6.0 ppm to 5.0 ppm.

CBTS Comment

A diet for beef cattle which would contain maximum levels of lambda-cyhalothrin was given in our 9/19/91 memo: sweet corn forage (25%), tomato pomace dry (25%), brewers grains (5%), cottonseed (20%) and wheat grain/soybean seed (25%). Using that hypothetical diet and the proposed tolerances, the maximum concentration of lambda-cyhalothrin residues in the diet of beef cattle was calculated to be 7.6 ppm. Since that memo was written, TB1 and CB1 have decided that only lambda-cyhalothrin per se and its epimer should appear in the tolerance expression. Therefore, ICI has proposed a tolerance of 5.0 ppm for sweet corn forage instead of 6.0 ppm, which corresponded to lambda-

cyhalothrin plus metabolites. Using the 5.0 ppm tolerance in the calculation of the residue in fat leads us to estimate a maximum fat residue of 2.8 ppm (which includes a contribution of 0.77 ppm from possible dermal application). The appropriate fat tolerance is therefore 3.0 ppm.

The proposed tolerance of 0.2 ppm for residues of lambda-cyhalthrin in/on meat and mbyp remains unchanged.

In our 1/22/92 memo for PP#7F3560, the maximum concentration of lambda-cyhalothrin in the diet of dairy cattle was calculated as 5.6 ppm. The major component of the diet -- 70% -- was wheat forage; the proposed tolerance for wheat forage was 2.0 ppm. A concentration in the diet of 5.6 ppm would yield a potential lambda-cyhalothrin concentration in milk of 0.2 ppm. A review of the residue data reported in our 1/22/92 memo shows that if metabolites are not included in the tolerance expression, the tolerance for wheat forage would still remain at 2.0 ppm. Therefore, a tolerance of 0.2 ppm for lambda-cyhalothrin in milk remains appropriate, and the tolerance expression should read "Milkfat (reflecting 0.2 ppm in whole milk) -- 5.0 ppm". We note that ICI's calculation of maximum residues in milk utilized the maximum residue found in wheat forage -- 1.2 ppm -- rather than the tolerance. CBTS routinely uses tolerances, not maximum residues, in its determination of meat and milk tolerances. For purposes of risk assessment, the anticipated residue for wheat forage -- in this case the average of the residue values found -- would be used to estimate a level in milk.

Tolerances in poultry muscle, liver and eggs remain unchanged at 0.01 ppm; tolerances in poultry fat remain at 0.02 ppm (see below).

CBTS Deficiency #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.

ICI Response

....Please note that Dick Schmitt (CB) advised Cynthia Smith (ICI) on January 30, 1990 that the Agency does not consider grain dust to be a significant poultry feed because it is too low in protein and too low in fiber to be part of a healthy poultry diet. Accordingly, grain dust is omitted from the above table of poultry feeds.....ICI therefore concludes that the currently proposed tolerance of 0.01 ppm in poultry fat is adequate.

CBTS Comment

Table II of our Residue Chemistry Guidelines, as updated in 1989, indicates that sorghum grain dust can constitute up to 20%

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of the diet of poultry. The table will be updated when information from one of our contracts becomes available. In the meantime CBTS will continue to use the 20% value, and the appropriate tolerance for poultry fat is 0.02 ppm.

cc: RF, SF, Circu., Mike Flood, E.Haeberer, PP#7F3560/7H5543, PP#1F3992.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):8/21/92.
RDI:SectionHead:ETHaeberer:BranchSeniorScientist:RALoranger: 8/20/92.