8-17-84

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

AUG 17 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP 3E2938/FAP 4H5433. BAYLETON on Coffee Beans, Refined Sugar, Molasses, Cottonseed Meal, Cottonseed Cake, and Cottonseed Oil. Amended Section F and new Food Additive Petition. No EPA Accession No.

FROM: R. W. Cook, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Branch Chief
Residue Chemistry Branch (TS-769)
Hazard Evaluation Division (TS-769)

TO: H. Jacoby, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

In our review of this petition, a number of deficiencies were noted (R. Cook, 1/27/84). To refresh our memory, we shall repeat the deficiency, the petitioner's response, and finally our comments or conclusions. In this review, we shall refer to Bayleton® by its ISO name triadimefon and to metabolite KWG 0519 as triadimenol (ISO).

Deficiency #1: An amended Section F specifying the tolerable residue in terms of parent compound and its chlorophenoxy and triazole moieties is needed.

Our Comments: The petitioner refers to the FR Notice of 11/30/83 which expresses the tolerance in terms of the parent compound and its metabolites containing the chlorophenoxy moiety in crop substrates and for animal commodities, the tolerance includes the parent and its metabolites containing the chlorophenoxy and triazole moities. Subsequently, however, the FR Notice of 3/21/84 (p. 10547) revised the expression of tolerance under 40 CFR 180.410 to reflect more recent data showing the presence of triazole moiety residues in sugar beet tops. The revised expression includes combined residues of parent and its metabolites containing chlorophenoxy and triazole moieties in both plant and animal derived commodities. We reiterate that an amended Section F specifying the residue in terms of parent compound and its chlorophenoxy and triazole moieties is needed. This deficiency is not resolved.

 INERT INGREDIENT INFORMATION IS NOT INCLUDED

Deficiency #2: The inert ingredient [redacted] must be cleared under 40 CFR 180.1001, or removed from the formulation.

Our Comments: The petitioner provides information which indicates that this inert ingredient is cleared. This deficiency is resolved.

Deficiency #3: Evidence should be provided showing that countries in which the subject commodities are grown have regulatory controls and further, that registration in those countries has been granted or application for registration has been made.

Our Comments: The petitioner has provided references to previously submitted information for Mexico (triadimefon on cucumbers and tomatoes, PP0E2393, 9/24/80) and for Costa Rica and Honduras (Baycor® on bananas, PP 2E2750, 8/10/83). While this information indicates that these countries have regulatory controls, no information is provided as to the countries where use is intended on the subject crops and as to whether these countries have registration acts. This subject was discussed in conference with the petitioner's representative (G. Brussels, 7/12/84). He said the parent company, Bayer, handles all pesticide matters outside the U.S. and it was difficult to obtain this information from the parent company. This deficiency is not resolved.

Deficiency #4: The petitioner should provide information regarding importation of raw sugarcane and unginned cotton into the U.S. We are not aware that these materials are international trade items. If in fact it is ginned baled cotton imported to the U.S., there should be no cottonseed available within the U.S. and therefore no need to establish any rac tolerances. If the imported material is sugar, in any form other than raw cane, then there may be no need to establish any rac commodity tolerance. Depending upon the nature of the commodity actually imported to the U.S., it may be appropriate to propose food additive tolerances for residues of BAYLETON® in or on sugar and molasses, or cottonseed oil and soapstock.

Our Comments: Along with the change from "F" to "E" petition, the petitioner now proposes tolerances of 0.05 ppm in or on coffeebeans, cottonseed meal, cottonseed cake, cottonseed oil, and refined sugar, and 0.1 ppm in molasses. Cottonseed and sugarcane are not imported; the above processed products derived from these crops are imported. This deficiency is resolved.

Deficiency #5: When the questions raised in question 4 above are resolved and sufficient numbers of residue studies are submitted from those countries, we will be able to draw conclusions on the adequacy of the proposed tolerances.

Our Comments: The petitioner combined the responses to #4 and #5, and the first part of this deficiency is resolved by the response to #4. However, no response is provided to the second part of #5. In the above mentioned conference, the petitioner stated that all the available residue data for these uses had been submitted. This deficiency is not resolved.

Deficiency #6: The petitioner should correct the proposed application rate for coffee to specify a maximum of 28.6 ounces or 2000 grams of formulated product per crop season.

Our Comments: The error is corrected and the deficiency resolved.

Deficiency #7: The petitioner should be aware that if and when use of BAYLETON® within the U.S. is proposed, additional residue data for principal U.S growing regions will be required. For sugarcane, residue data from Louisiana or Florida and Hawaii would be appropriate. Further, data on sugarcane forage and fodder may be required, and a tolerance may be needed. Alternatively, a practical label restriction against the use of sugarcane forage and fodder as animal feed should be proposed. Residue data for bagasse may also be needed. For cotton, major growing regions should be represented. If this data indicate that tolerances higher than those proposed herein are required, such higher tolerances should be proposed. Further, if higher tolerances are required, new sugarcane and cottonseed processing studies may be needed.

Our Comments: The petitioner acknowledges that additional residue data will be submitted when domestic uses are requested. This deficiency is resolved. We have recently recommended against 24(c) registration of the use of triadimefon on sugarcane grown for seed in Florida (FL-840013, S. Malak, 6/12/84). The adverse recommendation was based on a lack of data demonstrating no uptake into the aerial portion of the plant.

Deficiency #8: We note in Section G that the petitioner lists the tolerance on eggs as 0.002 ppm. Our records indicate the established tolerance is 0.04 ppm. We suggest the petitioner be advised of this error.

Our Comments: This petitioner is aware that the established tolerance is 0.04 ppm in eggs, not 0.002 ppm. This deficiency is resolved.

Conclusions:

1. We have previously concluded that the metabolism of triadimefon in plants and animals is adequately understood. The residue of concern in plants and animals is the parent compound and its free and conjugated metabolites KWG 0519 [beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol, KWG 1342 (triadimefon diol), and KWG 1323 (hydroxylated triadimefon). For the purposes of 40 CFR 180.410, the tolerance is expressed as combined residues of 1-(4-chlorophenoxy)-3,3-dimethyl-1(1H-1,2,4-triazol-1-yl)-2-butanone and its metabolites containing chlorophenoxy and triazole moieties (expressed as the parent compound).

2. An amended Section F expressing the tolerance in terms of combined residues of parent compound and its metabolites containing the chlorophenoxy and triazole moieties (expressed as parent compound) is required.

3. An adequate enforcement method is available.

4. Residues of triadimefon and its metabolites are not concentrated in cottonseed processing fractions or sugarcane processing fractions.

5. Submitted data on raw cottonseed are too sparse to estimate the residue levels to be expected on the raw commodity cottonseed, and we can draw no conclusions whether combined residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties are likely to exceed the proposed tolerance level of 0.05 ppm in the processed commodities cottonseed meal and cottonseed oil, even though we can conclude that residues do not concentrate in these processed products.

6. Submitted data on raw sugarcane are too sparse to estimate residue levels to be expected on the raw commodity sugarcane, and we can draw no conclusions whether combined residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties are likely to exceed the proposed 0.05 ppm tolerance level in sugar, and 0.1 ppm in sugarcane molasses, even though we can conclude that residues do not concentrate in these products.

7. Additional residue data are needed for coffeebeans grown in other primary producing areas, before we can conclude that residues are not likely to exceed the proposed 0.05 ppm tolerance level.

8. Maximum residues in beverage coffee would be much less than the proposed tolerance.

9. Secondary residues in meat, milk, poultry and eggs resulting from the feeding of the byproducts of sugarcane and cottonseed processing will be adequately covered by existing tolerances.

10. The petitioner should identify the countries where use is intended and provide information as to whether there are registration acts in those countries and whether registration has been granted or application for registration has been made in these countries.

11. An International Residue Limit Status sheet is attached. There are no Canadian, Mexican or Codex tolerances for cottonseed meal and oil, or sugar and sugarcane molasses and no problems of incompatibility are anticipated at this time.

For coffee beans, interim Codex limits for the sum of triadimefon and its metabolite triadimenol are 0.1 mg/kg. However, the petitioner has requested a U.S. tolerance at 0.05 ppm for combined residues of triadimefon and triadimenol. Since the established U.S. tolerances include triadimefon metabolites (containing the triazole moiety) apparently not covered by Codex limits, there are problems of incompatibility regarding both the amount and the nature of the tolerable residue. Resolution of these incompatibility problems is not anticipated herein.

Recommendations:

We recommend against the proposed tolerances because of Conclusions 2, 5, 6, 7 and 10. For a favorable recommendation, the petitioner should be advised of the following:

1. An amended Section F expressing the tolerance in terms of combined residues of parent compound and its metabolites containing the chlorophenoxy and triazole moieties is required.

2. Additional residue data for cottonseed and sugarcane are needed, to provide a better estimate of levels expected in the raw commodities, from which the processed commodities to be regulated under food additive tolerances will be derived. Additional residue data for coffee beans grown in other primary producing areas are needed.

3. Information as to what countries use is intended in, whether these countires have a pesticide registration act and evidence showing that registration has been granted or that application for registration has been made in the countries of intended use should be presented.

DETAILED CONSIDERATIONS:

Residue Data: Coffee:

We have previously reviewed the coffee bean residue data from four Brazilian locations. Although limited data, including exaggerated tests, apparently indicate residues of triadimefon and its metabolites do not exceed the proposed 0.05 ppm tolerance level in coffee beans, we do not believe that the limited data are sufficient basis for establishing tolerances on an important commodity such as coffee. According to Agricultural Statistics, 1981, less than 20% of the coffee imported to the U.S. is grown in Brazil, and several other countries export similar amounts to the U.S. Additional residue data for coffee grown in other primary coffee producing areas are required.

Cottonseed:

No new residue studies are available. Previous data for 4 Mexican trials were reviewed. Cotton plants received 2 foliar treatments at 0.250 kg/ha and seeds sampled at 61 days PHI. Total combined residues were 0.03-0.09 ppm, with greater amounts of parent compound than KWG 0519. KWG 1342 residues were <0.01 ppm in all cases. Cottonseed containing 0.06 ppm parent and 0.05 ppm KWG 0519 were fractioned into hulls, meal, crude and refined oil, deodorized refined oil and soapstock. Except 0.01 ppm in crude oil, all fractions showed less than detectable residues (<0.01 ppm). We previously concluded that cottonseed processing fractions do not concentrate residues and that food additive tolerances are not required; i.e. we do not expect levels in processed fractions to be greater than the levels which may occur in the raw cottonseed.

With clarification from the petitioner that imported commodity items are cottonseed meal and oil, and not raw cottonseed, we now conclude that food additive tolerances are appropriate and that RAC tolerances under 40 CFR 180 are not required, even though residues may be present in raw agricultural commodity when it is processed outside of the U.S.

We find the submitted data on raw cottonseed are too sparse to make an adequate estimate of the level of residues to be expected on the raw commodity. Without adequate residue data for raw cottonseed, we cannot draw conclusions on the expected residues in cottonseed meal and oil, even though we can conclude that residues do not concentrate in processed products above the levels to be expected in the raw agricultural commodity cottonseed. Thus, we can draw no conclusions whether combined residues of triadimefon and its metabolite containing the chlorophenoxy and triazole moieties are likely to exceed the proposed tolerance level of 0.05 ppm in cottonseed meal and oil.

Sugarcane:

No new residue data are currently submitted. Previous data included 4 trials in 3 locations in Mexico for both at-planting (0.25 kg/ha, 5 inch bands) and 3 foliar treatments (0.5 kg/ha). In all sugarcane treated at-planting, residues of parent and KWG 1342 were <0.01 ppm, while KWG 0519 was 0.04-0.07 ppm. Foliarly treated sugarcane showed triadimefon at <0.01-0.02 ppm; KWG 1342, <0.01 ppm; and KWG 0519 was 0.03-0.06 ppm.

Previous data for sugarcane and sugarbeet processing studies indicated triadimefon residues do not concentrate in refined sugar nor in byproducts of sugar refining; i.e. we do not expect levels in processed fractions to be greater than levels which may occur in the raw sugarcane. However, with petitioner's clarification that imported commodity items are refined sugar and sugarcane molasses, and not raw sugarcane, we now conclude food additive tolerances are appropriate and RAC tolerances under 40 CFR 180 are not required.

We find that the submitted data on raw sugarcane are too sparse to make an adequate estimate of the level of residues to be expected on the raw commodity. Without adequate residue data for raw sugarcane, we cannot draw conclusions on the expected residues in sugarcane molasses and refined sugar, even though we can conclude that residues do not concentrate in processed products above the levels to be expected in the raw agricultural commodity cottonseed. Thus, we can draw no conclusions whether combined residues of triadimefon and its metabolites containing the chlorophenoxy and triazole moieties are likely to exceed the proposed tolerance level of 0.05 ppm in sugar and 0.1 ppm in sugarcane molasses.

Residues in Eggs, Milk, Meat, and Poultry:

Animal feeding studies (cattle and poultry) have been reviewed and triadimefon tolerances in meat, milk, poultry, and eggs are established. Animal feed items of current concern are sugarcane molasses and cottonseed meal and soapstock. Since residue levels contemplated herein and animal dietary ingestion levels of the feed items of concern are considerably less than animal burdens resulting from other established tolerances, we conclude that secondary residues in meat, milk, poultry, and eggs are not likely to exceed established tolerances for these commodities.

OTHER CONSIDERATIONS:

International Tolerances:

There are no Codex, Mexican or Canadian tolerances for residues of BAYLETON® on cottonseed or sugarcane.

Interim Codex limits (below Step 6) for triadimefon residues (as the sum of parent and its metabolite KWG0519, triadimenol [ISO]) in or on coffee beans are established at 0.1 mg/kg. The petitioner has requested a U.S. tolerance at 0.05 ppm of combined residues of triadimefon and triadimenol. However, established U.S. tolerances for triadimefon include other metabolites containing chlorophenoxy and triazole moieties. Therefore, the proposed U.S. tolerance and the Codex limits are not compatible, both as to residue levels and the nature of the residue. Resolution of these problems is not anticipated herein.

cc:R.F., Circu, Reviewer, TOX, EAB, EEB, PP#3E2938/FAP#4H5433
FDA, Robert Thompson
RDI:R. Quick:8/16/84:R.D. Schmitt:8/16/84
TS-769:RCB:R. Cook:edited by:wh:8/17/84:CM#2:RM810:X7377

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone

[BAYLETON®] Triadimefon

CCPR NO. 133

PETITION NO. 3E2938/FAP 4H 5433
R. W. Cook
6/19/84

(Note: Previously considered under PP 3F 2938)

N. Dodd 6/19/84
F. Suss 6/27/84

Codex Status

☒ No Codex Proposal Step 6 or above

Residue (if Step 9): Sum of triadimefon and 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1,2,4-triazol-1-yl)butan-2-ol ("triadimenol").

Proposed U.S. Tolerances

Residue: 1-(4-chlorophenoxy)-3,3-dimethyl-1(1H-1,2,4-triazol-1--yl)-2-butanone and its metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazol-1-ethanol

Crop(s)	Limit (mg/kg)
Coffee beans	0.1 1/

Crop(s)	Tol. (ppm)	
Coffee beans*	0.05	
Cottonseed meal**	0.05	(FAT)
Cottonseed cake	0.05	(FAT)
Cottonseed oil	0.05	(FAT)
Refined Sugar**	0.05	(FAT)
Molasses	0.1	(FAT)

CANADIAN LIMIT

Residue: Crop	Limit (ppm)
None	

MEXICAN TOLERANCIA

Residue: Crop	Tolerancia (ppm)
None	

Comments: * Coffee imported from Brazil
** Cottonseed products and sugar products imported from Mexico, Costa Rica, and Honduras

1/ at or about limit of determination. Temporary limit pending establishment of full ADI. Numerical value unlikely to change.

Russ: Note "sum of" approach to expression