8/22/94

MEMORANDUM

SUBJECT: PP#4G04323 (CBTS #'s 13217 and 13218; Barcode #'s D199464 and D199471). Thiazopyr (MON 13200) in/on Peanuts and Tree Nuts. Evaluation of Analytical Method and Residue Data (MRID #'s 431019-00, 431019-01, 431019-02, 431019-03, 431019-04, 431019-05, 430877-01).

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and

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Monsanto Company has proposed temporary tolerances for residues of the herbicide thiazopyr [3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester] and its metabolites determined as 3-pyridinecarboxylic acid, 5-(aminocarbonyl)-2-(difluoromethyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester and 3-

pyridinecarboxylic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-5-{[(2-sulfoethyl)amino]carbonyl}-6-(trifluoromethyl)-], expressed as parent equivalents, as follows:

Tree Nuts (group tolerance)

nutmeat	0.05 ppm
almond hulls	0.15 ppm

Peanuts

nutmeat	0.05 ppm
forage	0.3 ppm
hay	0.5 ppm
hulls	0.25 ppm

Under the EUP, Monsanto will ship 5964 pounds of formulated product (1330 lbs ai) for use on 1900 acres in 1994-1995.

For tree crops, a total of 950 lbs ai will be shipped for use on a total of 950 acres in the states of AL, AZ, CA, GA, and HI. Up to 4 quarts MON 13211 (up to 2.0 lbs ai) will be applied per acre per use season. (The "use season" for tree crops is defined by the petitioner as typically from August of one calendar year through July of the next year.)

For peanuts, a total of 380 lbs ai will be shipped for use on a total of 950 acres in the states of AL, GA, FL, VA, NC, SC, TX, OK, and NM. Up to 32 fluid oz MON 13211 (up to 0.5 lbs ai) will be applied per acre per use season. (The "use season" for peanuts is defined by the petitioner as typically from March of the calendar year through July of the same year.)

Temporary tolerances for thiazopyr and its metabolites have been established on citrus, whole fruit at 0.05 ppm; cotton seed at 0.05 ppm; and cotton forage at 0.2 ppm (PP#2G4122, Joel Garbus, Ph.D., 8/25/93; Federal Register Notice, Vol. 58, No. 182, 9/22/93). A petition for permanent tolerances for thiazopyr on citrus and cottonseed is concurrently under review (PP#3F4187, J. Stokes, 1994).

CONCLUSIONS

1. For a permanent tolerance, additional product chemistry data are required as discussed in the review of PP#3F4187 (J. Stokes, 1994). Refer to that concurrent review for details.

2. For a permanent tolerance, additional data regarding the manufacturing process are required as discussed in the review of PP#3F4187 (J. Stokes, 1994). Refer to that concurrent review for details.

3. A revised Section B/label for tree nuts must be submitted. The formulation contains 2 lb ai/gallon. The label indicates that the maximum application rate is 2 lbs ai/A/yr. This would be 4 quarts product, not 8 quarts as stated on page 3 of the label.

4. A revised Section B/label for tree nuts must be submitted. A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. (For example, simazine is registered for use on individual tree nuts but not on the crop group.) A note to this effect must be added to the proposed label.

5. A revised Section B/label for peanuts must be submitted. A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. A note to this effect must be added to the proposed label.

6. The proposed label statements regarding rotational crops are acceptable for this EUP. For a future permanent tolerance, the 18-month plant-back interval is not practical and not acceptable. Some rotational field trial residue data are under concurrent review in connection with PP#3F4187 on citrus and cotton.

7a. The peanut metabolism study is adequate. Extensive metabolism of thiazopyr occurs in peanuts. Over 40 metabolites were quantified, ranging from <0.01 to 13.71% of the total radioactive residue (TRR). Only one metabolite (the amide ester) accounted for >10% of the TRR, and this level was found only in one substrate (ie. in vines 56 days after treatment.) Major routes of metabolism include sulfur oxidation, thiazoline ring opening and methyl ester hydrolysis. Uptake from the soil into peanut plants was slight.

7b. In the table on page 9, residues for the hulls (189 days, SI/THI) were 0.1999 ppm on combustion and corresponding residues in the table on page 10 were 0.241 ppm on extraction. The petitioner must verify and explain how residues on extraction could be higher than on combustion.

8. For a future permanent tolerance, the HED Metabolism Committee will determine the residues of concern for thiazopyr in peanuts based on the peanut, lemon, and cotton metabolism studies.

9. The residues of concern in animal commodities have not been determined. The petitioner has proposed that tolerances be established for thiazopyr and those metabolites that can be converted to the sulfonic diacid (SAA) and the amide acid (AA). For future permanent tolerances, the residues of concern will be determined by the HED Metabolism Committee.

10. Method RES-017-91 is adequate for residue data collection to support the temporary tolerances on peanuts and tree nuts.

11. For future permanent tolerances, method RES-017-91 is not acceptable as an enforcement method because it is too complex and lengthy. Therefore, another enforcement method for thiazopyr and its metabolites of concern in peanuts and tree nuts would be needed. An independent laboratory validation and then an EPA method validation would also be needed for the enforcement method.

12. For future permanent tolerances, method RES-017-91 would be acceptable as a residue data collection method provided either the method is radiovalidated on peanuts and tree nuts using metabolism samples or method RES-017-91 is checked against a new validated enforcement method (for which radiovalidation has been conducted) using comparative analyses of the same residue samples. CBTS does not require but recommends that a protocol for any such comparative study be submitted.

13. No analytical methods for animal commodities have been submitted or referenced. However, since tolerances are not presently needed on animal commodities, an enforcement method for animal commodities is not needed at this time. (See Conclusion #26.)

14. For a permanent tolerance, the company must submit copies of the multiresidue testing results using the prescribed protocols without the company confidential or business security stamp on the submitted pages.

15. Adequate storage stability data are not available. For a permanent tolerance, storage stability data will be needed to

reflect storage intervals of the residue samples. In one study (MRID #431019-02), vines were stored up to 923 days; nutmeats up to 1008 days; hay up to 1034 days; and hulls up to 1050 days. In another study (MRID #430877-01), vines were stored up to 968 days; nutmeats up to 953 days (GA); hay up to 1029 days (AL); and hulls up to 1072 days (AL).

16. Residues in nutmeats of almonds, walnuts, and pecans will not exceed 0.05 ppm resulting from the proposed use. The representative crops for the tree nuts crop group [40 CFR 180.34(f)(9)(xiv)] are almonds, pecans, and English walnut. Therefore, the proposed temporary tolerance of 0.05 ppm on nutmeats of the tree nuts crop group will not be exceeded.

17. Residues in almond hulls resulting from the proposed use will not exceed the proposed temporary tolerance of 0.15 ppm.

18. Residues in peanut nutmeats resulting from the proposed use will not exceed the proposed temporary tolerance of 0.05 ppm.

19. Residues in peanut hay resulting from the proposed use will not exceed the proposed temporary tolerance of 0.5 ppm.

20. Residues in peanut hulls (shells) resulting from the proposed use will not exceed the proposed temporary tolerance of 0.25 ppm.

21. As indicated in the revised Table II (6/7/94) of the "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry", a tolerance on peanut forage is no longer required. Therefore, a revised Section F should be submitted with the proposed temporary tolerance for forage deleted.

22. The peanut processing study in MRID #431019-03 is adequate to support the temporary tolerances on peanuts and tree nuts. Residues are not expected to concentrate upon processing of the peanut nutmeat to meal, crude oil, and refined oil. Food additive tolerances for meal and oil are not needed.

23. For a future permanent tolerance, storage stability data for peanut nutmeats for a storage period of 3 years will be needed.

24. The proposed label statements regarding rotational crops are acceptable for this EUP.

25. For a future permanent tolerance, the 18-month plant-back interval is not practical and not acceptable unless it can be documented that phytotoxicity precludes planting for that amount of time. Therefore, rotational field trial residue data will be required for a future permanent tolerance. Some rotational field trial residue data are under concurrent review in connection with PP#3F4187 on citrus and cotton.

26. No animal feeding studies or tolerances on animal commodities are needed for this proposed use on peanuts and tree nuts. This conclusion is based on the low residues expected in the dairy cattle, beef cattle, and poultry diets as a result of the proposed temporary tolerances/tolerances on peanuts, tree nuts, citrus, and cotton and metabolism studies, which indicated that residues in animal commodities resulting from such low residue levels in the diet would be <0.007 ppm.

RECOMMENDATIONS

CBTS recommends against the proposed temporary tolerances for thiazopyr on peanuts and tree nuts for the reasons given in Conclusions #'s 3, 4, 5, 7b, and 21 above.

For a future permanent tolerance, Conclusions #'s 1, 2, 6, 8, 9, 11, 12, 14, 15, 23, and 25 must also be addressed.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY

Product Chemistry data have been discussed in the concurrent review of thiazopyr on citrus and cotton (PP#3F4187, J. Stokes, 1994). Additional product chemistry data are required as discussed in that review.

Conclusion

For a permanent tolerance, additional product chemistry data are required as discussed in the review of PP#3F4187 (J. Stokes, 1994). Refer to that concurrent review for details.

RESIDUE CHEMISTRY

Manufacture

The manufacturing process was discussed in PP#3F4187 (J. Stokes, 1994). Additional data were required.

Conclusion

For a permanent tolerance, additional data regarding the manufacturing process are required as discussed in the review of PP#3F4187 (J. Stokes, 1994). Refer to that concurrent review for details.

Formulation

MON 13211 Herbicide contains 22.3% active ingredient and 76.7% inerts. MON 13211 contains 2 lbs ai/gal. Registration Division determines whether the inerts in the formulation are cleared under 40 CFR 180.1001.

Note: The labels refer to MON 13211-C for use on tree nuts and to MON 13211-D for use in peanuts. However, these are both MON 13211.

Note: MON 13200 is the active ingredient thiazopyr.

Proposed Use

Tree Nuts:

Apply to soil with ground equipment before weed/grass emergence. Apply at the rate of 1/4- 4 quarts (0.125 - 2.0 lb ai/A), either as a single application or as 2-3 sequential applications, with the yearly total not to exceed 2.0 lb ai/A/year. Apply in 20 or more gallons of water or liquid fertilizer per acre.

Do not apply within 90 days of nut harvest.

Do not apply through any type of irrigation system.

Do not apply as an over-the-top spray to desirable flowers, vegetables, shrubs, or trees.

MON 13211 can be tank mixed with KARMEX™, PRINCEP™, CALIBER™90, PRINCEP™4L, SOLICAM™, diuron-based products, simazine-based products, Roundup®, or GRAMOXONE EXTRA™ and others.

Conclusions

A revised Section B/label for tree nuts must be submitted for the following reasons:

a) The formulation contains 2 lb ai/gallon. The label indicates that the maximum application rate is 2 lbs ai/A/yr. This would be 4 quarts product, not 8 quarts as stated on page 3 of the label.

b) A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. (For example, simazine is registered for use on individual tree nuts but not on the crop group.) A note to this effect must be added to the proposed label.

Peanuts:

Apply in one or two sequential applications at the rate of 8-32 fluid ounces product/A (0.125 - 0.5 lb ai/A), not exceeding 32 fluid ounces per acre per year (0.5 lb ai/A/yr). Apply broadcast or band with ground equipment in at least 20 gallons of water or fluid fertilizer per acre. Apply as a surface application prior to or immediately after planting and before crop or weed emergence, or shallowly incorporate prior to planting or bedding to blend the herbicide into the upper 1-2 inches of soil. An early postemergence application may be made no later than 30 days after planting. This product can be tank mixed with Lasso®, Dual™, Vernam™, Pursuit™, Starfire™, Butyrac™175, Butoxone™175, Butoxone™200, Balan™, Prowl™, Sonalan™, and others.

Do not apply as an over-the-top spray to desirable flowers, vegetables, shrubs, or trees.

Do not allow domestic animals to feed or forage on treated peanuts.

Do not apply through any type of irrigation system.

The following statements concern rotational crops:

"Except as otherwise noted below, land treated with this product can be planted to other crops the following season. The crop treated with this product must be grown to maturity and harvested before planting any rotational crops. Do not plant crops other than cotton or peanuts on the treated land for 9 months after application of this product.

Do not plant grain sorghum, corn, wheat, barley, or sugar beets within 18 months after application of this product except in GA, AL, and FL on coastal plains soils where these crops may be planted 12 months or more after application."

Conclusions

A revised Section B/label for peanuts must be submitted. A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. A note to this effect must be added to the proposed label.

The proposed label statements regarding rotational crops are acceptable for this EUP. For a future permanent tolerance, the 18-month plant-back interval is not practical and not acceptable unless it can be documented that phytotoxicity precludes planting for that amount of time. Some rotational field trial residue data are under concurrent review in connection with PP#3F4187 on citrus and cotton (conversation with J. Stokes, CBTS, on 7/27/94).

Metabolism

Plants:

Metabolism studies on citrus (MRID #422755-05) and cotton (MRID #422755-06) were previously reviewed (PP#2G4122, J. Garbus, 6/2/93; PP#3F4187, J. Stokes, 1994). CBTS determined that thiazopyr is extensively and rapidly degraded to a large number of polar metabolites, each comprising <10% of the total radioactive residue. The major routes of metabolism include sulfur oxidation, thiazoline ring opening and methyl ester hydrolysis, and transformation of the isobutyl side chain. The parent and most of the identified metabolites share a common moiety, 2-difluoromethyl-4-(2-methylpropyl)-6-trifluoromethyl-3-pyridinecarboxylate. The petitioner has proposed that the regulated residues be thiazopyr and its metabolites that can be converted to the sulfonic diacid (SAA), 2-difluoromethyl-4-(2-methylpropyl)-5-[(2-sulfoethyl)aminocarbonyl]-6-trifluoromethyl-3-pyridinecarboxylic acid and the amide acid (AA), 2-difluoromethyl-4-(2-methylpropyl)-5-aminocarbonyl-6-trifluoromethyl-3-pyridinecarboxylic acid. The HED Metabolism Committee will determine the residues of concern.

A metabolism study on peanuts (MRID #431019-01) has now been submitted. Monsanto Agricultural Company was the performing lab. Separate tests were conducted with the active ingredient MON 13200 labeled with a mixture of ^{14}C and ^{13}C at the C-4 position of the pyridine ring (PYR MON 13200) and with MON 13200 labeled with a mixture of ^{14}C and ^{13}C at the C-4' and C-5' positions of the thiazoline ring (THI MON 13200). Pots in a greenhouse were treated by soil incorporation and preemergence. Actual doses applied (experimentally determined doses per pot) were 0.151 lb ai/A PYR MON 13200 and 0.141 lb ai/A THI MON 13200. These application rates correspond to 0.3 X and 0.1 X the proposed maximum application rates for peanuts and tree nuts, respectively. Peanut vines were sampled at 56 and 185 days after treatment. Peanuts were sampled 185 days after treatment and fractionated into hay, hulls, and nutmeat. Samples were stored frozen at -20°C immediately after collection. Total radioactive residues (TRR) were determined by combustion as follows:

Label*	PHI (days)	Crop Part	dpm/mg	ppm	ug per plant	% TRR	% of AA**
SI PYR	56	Vines	18.03	0.1657	3.53	100.00	0.34
	185	Hay	14.70	0.1351	24.60	90.46	2.38
	187	Hulls	27.19	0.2499	2.19	8.07	0.21
	187	Nut-meat	1.36	0.0126	0.40	1.47	0.04
PE PYR	56	Vines	17.51	0.1610	3.60	100.00	0.35

	185	Hay	14.07	0.1293	23.27	87.99	2.25
	187	Hulls	18.27	0.1679	2.66	10.04	0.26
	187	Nut-meat	1.40	0.0128	0.52	1.97	0.05
SI THI	56	Vines	10.99	0.1341	2.63	100.00	0.27
	185	Hay	9.62	0.1173	15.26	82.49	1.58
	189	Hulls	16.39	0.1999	1.64	8.85	0.17
	189	Nut-meat	4.85	0.0592	1.60	8.66	0.17
PE THI	56	Vines	12.98	0.1582	2.47	100.00	0.26
	185	Hay	10.94	0.1334	22.73	84.09	2.36
	189	Hulls	27.34	0.3334	2.69	9.94	0.28
	189	Nut-meat	5.18	0.0632	1.61	5.97	0.17

* SI = Soil Incorporation
PE = Preemergence
PYR= radiolabeled in the pyridine ring
THI= radiolabeled in the thiazoline ring

** uptake of AA (Applied Activity) in %

Peanut foliage and hulls were extracted with acetonitrile and then with acetonitrile/water. Nutmeats were extracted with chloroform/methanol/water. Acid hydrolysis in the presence of hydrogen peroxide, followed by base hydrolysis was used on the extraction filtercakes for all substrates. Extractabilities were reported as follows:

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Label	PHI in days	Crop Part	ppm in Extract	ppm in Filtercake Hydrolysis	ppm in Filtercake Residue
SI PYR	56	vines	0.154	0.008	0.004
	185	hay	0.076	0.016	0.006
	187	hulls	0.205	0.027	0.018
	187	nut-meat	0.013	0.000	0.000
PE PYR	185	hay	0.113	*	0.016
SI THI	56	vines	0.101	*	0.033
	185	hay	0.089	*	0.044
	189	hulls	0.241	*	0.092
	189	nut-meat	0.025	*	0.038

Residues were identified by HPLC, gas chromatography, high-voltage electrophoresis, and mass spectrometry [including liquid chromatography mass spectrometry (LC/MS), gas chromatography mass spectrometry (GC/MS), static fast-atom bombardment mass spectrometry (FAB/MS), and liquid chromatography fast-atom bombardment mass spectrometry (LC/FAB/MS)].

Structures and nomenclature of compounds in the MON 13200 peanut metabolism report are attached (Attachment 1). Metabolites identified in peanuts are attached (Attachment 2). The proposed routes of metabolism in peanuts, cotton, citrus, rotational crops, and rats are attached (Attachments 3, 4, 5, 6, and 7). A chart of peanut metabolites in other crops is also attached (Attachment 8).

Separation of residues into aqueous and organic fractions is shown in Attachment 9. Identified metabolites in ppb and as %

total radioactive residue (TRR) are listed in Attachments 10 and 11, respectively. Additional metabolites accounting for <3% of the TRR were listed by retention time (Attachment 12).

Conclusions

The peanut metabolism study is adequate. Extensive metabolism of thiazopyr occurs in peanuts. Over 40 metabolites were quantified, ranging from <0.01 to 13.71% of the total radioactive residue (TRR). Only one metabolite (the amide ester) accounted for >10% of the TRR, and this level was found only in one substrate (ie. in vines 56 days after treatment.) Major routes of metabolism include sulfur oxidation, thiazoline ring opening and methyl ester hydrolysis. Uptake from the soil into peanut plants was slight.

In the table on page 9, residues for the hulls (189 days, SI/THI) were 0.1999 ppm on combustion and corresponding residues in the table on page 10 were 0.241 ppm on extraction. The petitioner must verify and explain how residues on extraction could be higher than on combustion.

For a future permanent tolerance, the HED Metabolism Committee will determine the residues of concern for thiazopyr in peanuts based on the peanut, lemon, and cotton metabolism studies.

Animals:

Animal metabolism studies on goats (MRID #422755-07) and poultry (MRID #422755-08) have been reviewed (PP#2G4122, J. Garbus, 6/2/93 and PP#3F4187, J. Stokes, under concurrent review in 1994). See the referenced reviews for complete details. The following data have been excerpted from the review of PP#2G4122 (J. Garbus, 6/2/93):

In the goat metabolism study, residues in liver, kidney, fat, muscle, and milk reflecting 12 ppm (Goat #1) and 21 ppm (Goat #2) in the diet were as follows:

Matrix	Goat #	ppm
liver	1	0.193
	2	0.375

kidney	1	0.023
	2	0.112
renal fat	1	0.013
	2	0.034
omental fat	1	0.011
	2	0.026
muscle	1	0.006
	2	0.013

Matrix	Goat #	ppm
milk	1	0.020
	2	0.013

Residues in the milk during the 4-day study were as follows:

Time		Goat #1 (ppm)	Goat #2 (ppm)
Day 0		0.003	0.013
Day 1	AM	0.004	0.017
	PM	0.008	0.022
Day 2	AM	0.012	0.023
	PM	0.020	0.041
Day 3	AM	0.015	0.031
	PM	0.011	0.033
Day 4	AM	0.007	0.031

Residues in Goat #2 were identified as follows: (The chemical names and structures of the metabolites, identified by number in the tables below, are shown in Appendix 13.)

MILK

Metabolite #	% of Tissue Radioactivity	ppm

12	43.90	0.015
9 & 10	18.38	0.006

LIVER

Metabolite #	% of Tissue Radioactivity	ppm
11	3.68	0.014
10	4.08	0.015
5	12.05	0.045
4	18.90	0.071
3	6.04	0.023
2	5.92	0.022
1	1.90	0.007

KIDNEY

Metabolite #	% of Tissue Radioactivity	ppm
12	31.46	0.035
5	21.34	0.024

RENAL FAT

Metabolite #	% of Tissue Radioactivity	ppm
7	6.23	0.002
6	9.19	0.003
4	7.79	0.003
2	8.53	0.003
1	18.45	0.006

OMENTAL FAT

Metabolite #	% of Tissue Radioactivity	ppm
7	13.11	0.003
6	20.71	0.005
4	10.53	0.003
2	12.37	0.003
1	23.33	0.006

MUSCLE

Metabolite #	% of Tissue Radioactivity	ppm
12	24.15	0.003
9	9.84	0.001
8	10.23	0.001
5	7.81	0.001
1	8.93	0.001

In the poultry metabolism study, residues in liver, kidney, fat, muscle, and eggs reflecting 12 ppm (Groups #1 and #2) and 78 ppm (Group #3) in the diet were as follows:

Matrix	Hen Group #	ppm
liver	1	0.222
	2	0.298
	3	1.112
kidney	1	0.047
	2	0.052
	3	0.501
abdominal fat	1	0.123
	2	0.173
	3	1.417
skin with fat	1	0.049
	2	0.097
	3	0.488

Matrix	Hen Group #	ppm
muscle, thigh	1	0.010
	2	0.008
	3	0.086
muscle, breast	1	0.004
	2	0.005
	3	0.033
egg white	1	0.008*

	2	0.008
	3	0.052
egg yolk	1	0.077*
	2	0.075
	3	0.626

* data for eggs of day 4

Residues in the eggs during the 4-day study were as follows:

WHITES

Time	Hen Groups #1 and #2 (mean ppm)	Hen Group #3 (ppm)
Day 1	0.005	0.003
Day 2	0.007	0.048
Day 3	0.008	0.060
Day 4	0.008	0.052

YOLKS

Time	Hen Groups #1 and #2 (ppm)	Hen Group #3 (ppm)
Day 1	ND	ND
Day 2	0.014	0.104
Day 3	0.038	0.326
Day 4	0.077	0.626

Residues in Group #3 hens were identified as follows: (The chemical names and structures of the metabolites, identified by number in the tables below, are shown in Appendix 13.)

YOLK

Metabolite #	% of Tissue Radioactivity	ppm
8	7.69	0.006
5	10.61	0.008
3	2.78	0.002
1	2.05	0.002
2	24.49	0.018
unextracted	30.53	0.023

LIVER

Metabolite #	% of Tissue Radioactivity	ppm
7	2.52	0.008
5	40.84	0.122
3	6.68	0.020
1	0.51	0.002
2	1.42	0.004
unextracted	22.98	0.068

KIDNEY

Metabolite #	% of Tissue Radioactivity	ppm
7	4.24	0.002
5	56.76	0.029
2	2.26	0.001
unknown	9.04	0.005
unextracted	29.88	0.015

ABDOMINAL FAT

Metabolite #	% of Tissue Radioactivity	ppm
6	7.03	0.012
3	7.94	0.014
1	2.69	0.005
2	68.73	0.119
unextracted	8.60	0.015

SKIN WITH FAT

Metabolite #	% of Tissue Radioactivity	ppm

6	3.39	0.003
5	4.22	0.004
3	7.65	0.007
1	2.47	0.003
2	59.19	0.057
unextracted	7.23	0.007

MUSCLE

Metabolite #	% of Tissue Radioactivity	ppm
7	1.41	0.0001
6	3.16	0.0002
5	9.89	0.0007
3	1.88	0.0001
1	1.52	0.0001
2	16.15	0.0011
unknown	10.36	0.0007
unextracted	19.47	0.0013

Conclusion

The residues of concern in animal commodities have not been determined. The petitioner has proposed that tolerances be established for thiazopyr and those metabolites that can be converted to the sulfonic diacid (SAA) and the amide acid (AA). For future permanent tolerances, the residues of concern will be determined by the HED Metabolism Committee.

Analytical Method

Plants:

The analytical method is "Analytical Method for the Determination of Thiazopyr and its Major Metabolites in Raw Agricultural Commodities", Document #RES-017-91. Version 6 (MSL 13022) is in MRID #430877-01. The analytical method converts the metabolites to the sulfonic diacid (SAA) or to the amide acid (AA) as shown in Attachment 14. Peanut hay and vines are extracted with 70% methanol/30% 0.2N hydrochloric acid. Sodium bicarbonate is added to the peanut nutmeats, almond nutmeats, and peanut hulls before extraction with 70% methanol/30% deionized water. Pecan and walnut nutmeats are extracted with methanol. Acid (6N HCL) and 30%

hydrogen peroxide are added for acid hydrolysis. Three percent of the sample is taken for amide acid (AA) analysis, leaving 97% for the SAA analysis. The sample for AA analysis is microwaved. Sodium hydroxide is added for base hydrolysis. The sample is microwaved, evaporated, resuspended in dilute hydrochloric acid/methanol, partitioned with ethyl acetate/isooctane, derivatized with trimethylsilyldiazomethane to the methyl ester, optionally cleaned up on an SPE column, and quantitated by gas chromatography/mass spectroscopy. The sample for SAA analysis is refluxed for 3 hours. Sodium hydroxide is added for base hydrolysis. The sample is refluxed for 2.5 hours. The methanol is distilled off. The sample is acidified with glacial acetic acid. Oily crops are partitioned with methylene chloride. The sample is cleaned up on an AG 1-X8 acetate ion exchange column and quantitated by HPLC with UV detection. Recoveries were determined from fortifications with thiazopyr (to represent the sulfonic diacid class of metabolites) and the nitrile ester (to represent the amide class of metabolites). A schematic diagram of the analytical method is attached (Attachment 15). The limit of method validation is 0.025 ppm for SAA and 0.025 ppm for AA. The time for taking 12 samples from extraction to chromatography is 3-4 days. GC/MS analysis takes 23 minutes per injection. Chromatography of the SAA takes 80-95 minutes per injection.

There is no confirmatory technique for the SAA. The AE samples are analyzed by mass spectroscopy.

The method includes an internal standard, which was used for all of the hay and hull samples. The internal standard method was used for nutmeat samples from five locations. The older external standard method was used for nutmeat samples from the other five locations.

An independent method validation was not conducted for the method RES-017-91 but was conducted for the simplified method RES-041-92 (PP#3F4187, J. Stokes, 1994). (See the "Discussion" below.)

Analytical reference standards for thiazopyr, the nitrile ester metabolite, the sulfonic diacid metabolite/analyte, the amide ester metabolite/analyte, and the deuterated amide ester (an internal standard for GC/MS quantitation) were sent to EPA's Chemical Standard Repository on 6/10/93.

Discussion

In connection with PP#2G4122 (J. Garbus, 6/2/93) and PP#3F4187 (J. Stokes, concurrent review in 1994) on citrus and cotton, CBTS has indicated and EPA's Beltsville laboratory (ACL) has concurred that Method RES-017-91 is "too complex and lengthy for use as an enforcement method". CBTS and ACL also agreed that a simplified method (Method RES-041-92), which determines only those metabolites convertible to the AA chemophore, was not suitable as an enforcement method because it does not determine parent, which is converted to the SAA chemophore. As stated in the concurrent review of PP#3F4187 (J. Stokes, 1994), Monsanto will submit another proposed enforcement method which converts all residues to one chemophore, a triacid with a fluorinated pyridine ring still intact.

Conclusions

Method RES-017-91 is adequate for residue data collection to support the temporary tolerances on peanuts and tree nuts.

For future permanent tolerances, method RES-017-91 is not acceptable as an enforcement method because it is too complex and lengthy. Therefore, another enforcement method for thiazopyr and its metabolites of concern in peanuts and tree nuts would be needed. An independent laboratory validation and then an EPA method validation would also be needed for the enforcement method.

For future permanent tolerances, method RES-017-91 would be acceptable as a residue data collection method provided either the method is radiovalidated on peanuts and tree nuts using metabolism samples or method RES-017-91 is checked against a new validated enforcement method (for which radiovalidation has been conducted) using comparative analyses of the same residue samples. CBTS does not require but recommends that a protocol for any such comparative study be submitted.

Animals:

No analytical methods for animal commodities have been submitted or referenced.

Conclusion

No analytical methods for animal commodities have been submitted or referenced. However, since tolerances are not presently needed on animal commodities, an enforcement method for animal commodities is not needed at this time.

Multiresidue Methods

Multiresidue methods data have been submitted (PP#2G4122, J. Garbus, 6/2/93):

> "The parent compound was analyzed using Protocols C, D, and E. Tomatoes, analyzed using Protocol D, were fortified with 0.1 and 0.5 ppm parent. Tomatoes and peanuts fortified at 0.05 and 0.5 ppm with parent were analyzed using Protocol E."

However, as indicated in the review of PP#3F4187 (J. Stokes, concurrent review in 1994), "the company must submit copies of the multiresidue testing results using the prescribed protocols without the company confidential or business security stamp on the submitted pages. CBTS had forwarded this information to FDA (See memo of 3/1/94, J. Stokes) but it was returned (See memo of 3/25/94, M. Wirtz, FDA) because the multiresidue information cannot be accepted by FDA with a confidential stamp on the copy of the method description."

Conclusion

For a permanent tolerance, the company must submit copies of the multiresidue testing results using the prescribed protocols without the company confidential or business security stamp on the submitted pages.

Storage Stability

An interim storage stability study on peanut nutmeats and vines was submitted (MRID #431019-02, Appendix M). The final storage stability data were to be collected at the end of 1993. In the interim study, vines were stored frozen for 635 days and nutmeats were stored frozen for 642 days after spiking with 0.2 ppm nitrile ester (recovered as amide ester) or parent (recovered as sulfonic diacid). Results reported in the interim study in Appendix M were as follows:

NUTMEATS

PPM Applied	Days in Storage	PPM (uncorrected/corrected*) Amide Ester	Sulfonic Diacid
0.00	0	0.0/0.0	0.0/<0.025
0.20	0	0.149/0.202	0.14/0.205
0.20	426	0.142/0.192	0.14/0.206
0.20	488	0.158/0.214	0.13/0.185
0.20	642	0.135/0.183	0.14/0.193

*The amide ester values were corrected for a recovery of 73.91% at a fortification level of 0.20 ppm. The sulfonic diacid values were corrected for a recovery of 70.32% at a fortification level of 0.20 ppm.

VINES

PPM Applied	Days in Storage	PPM (uncorrected/corrected*) Amide Ester	Sulfonic Diacid
0.00	0	0.031/0.039	0.02/<0.026
0.20	0	0.158/0.200	0.185/0.226
0.20	419	0.150/0.189	0.185/0.229
0.20	481	0.128/0.162	0.185/0.232
0.20	635	0.124/0.156	0.195/0.238

*The amide ester values were corrected for a recovery of 79.09% at a fortification level of 0.20 ppm. The sulfonic diacid values were corrected for a recovery of 80.33% at a fortification level of 0.20 ppm.

The interim storage stability study indicates that the nitrile ester (recovered as the amide ester) decreases 9.4% (both uncorrected and corrected) in nutmeats while the parent (recovered as sulfonic diacid) decreases 0% (uncorrected) to 5.8% (corrected) in nutmeats over a period of 642 days. In vines, the nitrile ester (recovered as amide ester) decreases 22% (both uncorrected and corrected) while no decrease was observed for the parent (recovered as sulfonic diacid) over a period of 635 days.

In the peanut residue study in MRID #431019-02, vines were stored for up to 923 days prior to analysis (FL), nutmeats for up to 1008 days (FL), hay for up to 1034 days (TX(B)), and hulls for up to 1050 days (FL).

In the peanut residue study in MRID #430877-01, vines were stored for up to 968 days prior to analysis (AL), nutmeats for up to 953 days (GA), hay for up to 1029 days (AL), and hulls for up to 1072 days (AL).

In the tree nut residue study in MRID #431019-05, almonds were stored up to 956 days prior to analysis, walnuts up to 918 days, pecans up to 884 days, and almond hulls up to 975 days.

Conclusion

Adequate storage stability data are not available. For a permanent tolerance, storage stability data will be needed to reflect storage intervals of the residue samples. In one study (MRID #431019-02), vines were stored up to 923 days; nutmeats up to 1008 days; hay up to 1034 days; and hulls up to 1050 days. In another study (MRID #430877-01), vines were stored up to 968 days; nutmeats up to 953 days (GA); hay up to 1029 days (AL); and hulls up to 1072 days (AL).

Residue Data

Tree Nuts:

The petitioner requests a crop group tolerance for tree nuts and indicates that he has provided data on the representative crops for the tree nuts crop group as listed in 40 CFR 180.34(f)(9)(XIV)(B). The petitioner has submitted residue data on pecan nutmeat, walnut nutmeat, almond nutmeat, and almond hulls.

A total of twenty studies were conducted on tree nuts: 10 on almonds, 5 on walnuts, and 5 on pecans (MRID #431019-04 and 431019-05). All the studies on almonds and walnuts were conducted in CA. The five studies on pecans were conducted in the four states of MN (1), TX (1), LA (1), and GA (2). Five varieties of each nut were used. The field work was supervised by a contractor, Pan-Agricultural Laboratories, Inc. The laboratory work was conducted by Monsanto Company. A 2 lb ai/gal emulsifiable concentrate was applied broadcast to the ground between the trunks. Each study consisted of a control plot, a plot treated at the rate of 1.0 lb ai/A, and a plot treated at the rate of 2.0 lb ai/A. The application was made approximately 3 months (82-96 days for almonds, 91-112 days for walnuts, and 82-97 days for pecans) before harvest. The applications were made with ground equipment (bicycle sprayers, tractor-mounted boom sprayers, backpack sprayers) in 13.6-41.2 gals spray/A. Samples were frozen after sampling or processing and transported frozen. Hulls, shells, and nutmeats were ground for storage. All samples were kept frozen from receipt until analysis. Temperatures during shipping and frozen storage were 22°F to -20°F. The analytical method was "Analytical Method for the Determination of Thiazopyr and its Major Metabolites in Raw Agricultural Commodities", RES-017-91, version 4 (MRID #431019-04) and version 5 (MRID #431019-05).

Residues in nutmeats (almonds, walnuts, and pecans) were all <0.025 ppm amide class and <0.025 ppm sulfonic diacid class. Residues in almond hulls were reported as follows:

Commodity	Treatment Rate (lb ai/A)	Amide Class (ppm)	Sulfonic Diacid Class (ppm)
almond hulls	0.0	<0.025	<0.025
	1.0	<0.025-0.034	<0.025-0.060
	2.0	<0.025-0.064	<0.025-0.076

Recoveries were determined by spiking nutmeats and almond hulls with parent and the nitrile ester metabolite.

Recoveries on almond nutmeats for the amide ester at fortifications of 0.025-0.2 ppm were 61.29-98.93% (average 78.55%). Recoveries on almond nutmeats for the sulfonic diacid at fortifications of 0.025-0.2 ppm were 62.79-116.72% (av. 87.41%).

Recoveries on almond hulls for the amide ester at fortifications of 0.025-0.15 ppm were 63.39-100.32% (av. 80.41%). Recoveries on almond hulls for the sulfonic diacid at fortifications of 0.025-0.15 ppm were 58.48-121.84% (av.79.63%).

Recoveries on walnut nutmeats for the amide ester at fortifications of 0.025-0.2 ppm were 65.91-122.77% (average

83.37%). Recoveries on walnut nutmeats for the sulfonic diacid at fortifications of 0.025-0.2 ppm were 57.29-124.30% (av. 83.79%).

Recoveries on pecan nutmeats for the amide ester at fortifications of 0.025-0.2 ppm were 69.73-128.56% (average 80.89%). Recoveries on pecan nutmeats for the sulfonic diacid at fortifications of 0.025-0.2 ppm were 52.00-119.69% (av. 83.41%).

Conclusion

Residues in nutmeats of almonds, walnuts, and pecans will not exceed 0.05 ppm resulting from the proposed use. The representative crops for the tree nuts crop group [40 CFR 180.34(f)(9)(xiv)] are almonds, pecans, and English walnut. Therefore, the proposed temporary tolerance of 0.05 ppm on nutmeats of the tree nuts crop group will not be exceeded.

Residues in almond hulls resulting from the proposed use will not exceed the proposed temporary tolerance of 0.15 ppm.

Peanuts:

Ten studies were conducted on peanuts in 1989 in the six states of NC (1), VA (1), AL (2), GA (3), FL (1), and TX (2) (MRID #431019-02). Residue levels in peanut forage (green immature plants, 6-8 weeks after planting), hay, nutmeat, and hulls were determined. Peanut varieties were Florunner in Al and GA, Sunrunner in FL, Florigiant in NC and VA, and Starr in TX. The field work was supervised by a contractor, American Agricultural Services, Inc. The laboratory work was conducted by Monsanto Company. A 2 lb ai/gal emulsifiable concentrate was applied preplant and incorporated to a depth of 3 inches. The applications were made with ground equipment (tractor or backpack) in 10-20 gals spray/A. At each location, five plots were treated as follows:

control
0.3 lb ai/A pre-plant incorporated (PPI)
0.6 lb ai/A PPI
0.2 lb ai/A PPI + 0.4 lb ai/A postemergence (POST)
0.4 lb ai/A PPI + 0.2 lb ai POST

For harvest of nuts in shells, the peanuts were dug up and allowed to dry in the field for 3- 9 days. Samples were frozen within 5 hours of sampling and transported frozen. Forage, hay, nutmeat, and hulls were ground for storage. All samples were kept frozen from receipt until analysis. Temperatures during shipping and storage were <0°F. The analytical method was "Analytical Method for the Determination of Thiazopyr and its Major Metabolites in Raw Agricultural Commodities", RES-017-91, version 3 (MSL 12508) in MRID #431019-02.

Residues in peanut nutmeat, forage, hay, and hulls are tabulated below:

Commodity	Treatment Rate (lb ai/A)	Amide Class (ppm)	Sulfonic Diacid Class (ppm)
nutmeat	0.0	<0.025	<0.025
	0.3	<0.025	<0.025
	0.6	<0.025	<0.025
	0.2 + 0.4	<0.025	<0.025
	0.4 + 0.2	<0.025	<0.025
forage	0.0	<0.025	<0.025
	0.3	<0.025-0.096	<0.025
	0.6	<0.025-0.204	<0.025

	0.2 + 0.4	<0.025-0.088	<0.025-0.082
	0.4 + 0.2	<0.025-0.106	<0.025-0.060
hay	0.0	<0.025	<0.025
	0.3	<0.025-0.048	<0.025-0.027
	0.6	<0.025-0.105	<0.025-0.037
	0.2 + 0.4	<0.025-0.077	<0.025-0.044
	0.4 + 0.2	0.025-0.090	<0.025-0.039
hulls	0.0	<0.025	<0.025
	0.3	<0.025-0.031	<0.025-0.027
	0.6	<0.025-0.053	<0.025-0.034
	0.2 + 0.4	<0.025-0.043	<0.025-0.055
	0.4 + 0.2	<0.025-0.046	<0.025-0.047

Recoveries were determined by spiking untreated forage, hay, nutmeat, and hulls with parent and the nitrile ester metabolite.

Recoveries on nutmeats for the amide ester at fortifications of 0.025-0.20 ppm were 52-141% (average 77%). Recoveries on nutmeats for the sulfonic diacid at fortifications of 0.025-0.02 ppm were 56-92% (av. 76%).

Recoveries on peanut vines (forage) for the amide ester at fortifications of 0.025-0.20 ppm were 56-132% (av. 91%). Recoveries on peanut vines for the sulfonic diacid at fortifications of 0.025-0.20 ppm were 66-106% (av. 85%).

Recoveries on peanut hay for the amide ester at fortifications of 0.025-0.25 ppm were 52-132% (av. 68%). Recoveries on peanut hay for the sulfonic diacid at fortifications of 0.025-0.25 ppm were 56-118% (av. 84%).

Recoveries on peanut hulls for the amide ester at fortifications of 0.025-1.00 ppm were 55-96% (av. 74%). Recoveries on peanut hulls for the sulfonic diacid at fortifications of 0.025-1.00 ppm were 63-101% (av. 79%).

Ten studies were conducted in 1990 on peanuts in the six states of GA(3), TX(2), AL(2), NC(1), VA(1), and FL(1) (MRID #430877-01). Residue levels in peanut forage (green immature plants, 6-8 weeks after planting), hay, nutmeat, and hulls were determined. Six peanut varieties (Florunner, GK-7, Florigiant, Spanish, Tamrun 88, and NC-7) were used. The field work was supervised by a contractor, American Agricultural Services, Inc. The laboratory work was conducted by Monsanto Company. A 2 lb ai/gal emulsifiable concentrate was applied preplant and incorporated to a depth of 2-4 inches. The applications were made with ground equipment (tractor or backpack) in 16-22 gals spray/A. At each location, four plots were treated as follows:

control
0.3 lb ai/A pre-plant incorporated (PPI)
0.6 lb ai/A PPI
0.4 lb ai/A PPI + 0.2 lb ai/A early postemergent (PE) when peanuts are 3-5 inches in diameter

At five of the locations, an additional plot was also treated as follows:

0.6 lb ai/A preemergent (PRE)

For harvest of nuts in shells, the peanuts were dug up and allowed to dry in the field for 4-11 days. Samples were frozen within 4 hours of sampling and transported frozen. Forage, hay, nutmeat, and hulls were ground for storage. All samples were kept frozen from receipt until analysis. Temperatures during shipping and storage were <0°F. The analytical method was "Analytical Method for the Determination of Thiazopyr and its Major Metabolites in Raw Agricultural Commodities", RES-017-91, version 6 (MSL 13022) in

MRID #430877-01. This revision involves use of a trideuterated amide ester as an internal reference standard.

Residues in peanut nutmeat, forage, hay, and hulls are tabulated below:

Commodity	Treatment Rate (lb ai/A)	Amide Class (ppm)	Sulfonic Diacid Class (ppm)
nutmeat	0.0	<0.025	<0.025
	0.3 PPI	<0.025	<0.025
	0.6 PPI	<0.025	<0.025
	0.6 PRE	<0.025	<0.025
	0.4 PPI + 0.2 PE	<0.025	<0.025
forage	0.0	<0.025	<0.025
	0.3 PPI	<0.025-0.072	<0.025
	0.6 PPI	<0.025-0.140	<0.025-0.034
	0.6 PRE	0.026-0.099	<0.025-0.028
	0.4 PPI + 0.2 PE	<0.025-0.152	<0.025-0.036
hay	0.0	<0.025	<0.025
	0.3 PPI	<0.025-0.113	<0.025-0.043
	0.6 PPI	0.030-0.193	<0.025-0.079
	0.6 PRE	0.025-0.064	<0.025-0.028
	0.4 PPI + 0.2 PE	<0.025-0.180	<0.025-0.076

hulls	0.0	<0.025	<0.025
	0.3 PPI	<0.025-0.048	<0.025-0.039
	0.6 PPI	<0.025-0.083	<0.025-0.074
	0.6 PRE	<0.025-0.048	<0.025-0.058
	0.4 PPI + 0.2 PE	<0.025-0.070	<0.025-0.054

Recoveries were determined by spiking untreated forage, hay, nutmeat, and hulls with parent and the nitrile ester metabolite.

Recoveries on nutmeats for the amide ester at fortifications of 0.025-0.118 ppm were 61-89% (average 73%). Recoveries on nutmeats for the sulfonic diacid at fortifications of 0.025-0.10 ppm were 57-107% (av. 84%).

Recoveries on peanut vines (forage) for the amide ester at fortifications of 0.02-0.25 ppm were 52-99% (av. 74%). Recoveries on peanut vines for the sulfonic diacid at fortifications of 0.02-0.50 ppm were 52-100% (av. 79%).

Recoveries on peanut hay for the amide ester at fortifications of 0.025-0.25 ppm were 64-106% (av. 81%). Recoveries on peanut hay for the sulfonic diacid at fortifications of 0.025-0.25 ppm were 64-111% (av. 84%).

Recoveries on peanut hulls for the amide ester at fortifications of 0.025-0.25 ppm were 54-107% (av. 82%). Recoveries on peanut hulls for the sulfonic diacid at fortifications of 0.025-0.25 ppm were 56-131% (av. 82%).

Conclusions

Residues in peanut nutmeats resulting from the proposed use will not exceed the proposed temporary tolerance of 0.05 ppm.

Residues in peanut hay resulting from the proposed use will not exceed the proposed temporary tolerance of 0.5 ppm.

Residues in peanut hulls (shells) resulting from the proposed use will not exceed the proposed temporary tolerance of 0.25 ppm.

As indicated in the revised Table II (6/7/94) of the "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry", a tolerance on peanut forage is no longer required. Therefore, a revised Section F should be submitted with the proposed temporary tolerance for forage deleted.

Processing Study

There are no processed commodities associated with tree nuts.

The processed commodities for peanuts are meal, crude oil, and refined oil. A peanut processing study has been submitted (MRID #431019-03). The performing laboratories were Monsanto Agricultural Company and American Agricultural Services. Thiazopyr formulated as a 2 lb ai/gal emulsifiable concentrate was applied preplant incorporated to peanuts in GA and TX. The application rates were 0.3 (0.6X), 0.6 (1.2X), or 1.5 (3X) lb ai/A in 11 or 20 gals/acre. One application was made. Peanuts were dug up and air dried in the field for 3 days in GA and for 9 days in TX. Peanuts and processed samples were shipped and stored frozen. Processed fractions included meal, crude oil, refined oil, and soapstock. The processing simulated industrial procedures. Processing occurred within 2 months after harvest. Storage intervals between sampling and analysis were approximately 3 years (1111 days in GA and 1092 days in TX). The analytical method was "Analytical Method for the Determination of Thiazopyr and its Major Metabolites in Raw Agricultural Commodities, Version 3, Document #RES-017-91 (MRID #431019-03). Recoveries at fortifications of 0.025-0.25 ppm were 87-99% for the sulfonic diacid and 66-105% for the amide ester. No detectable residues (<0.025 ppm amide ester and <0.025 ppm sulfonic diacid) were found in peanut nutmeats.

Discussion

The processing study in MRID #431019-03 was conducted at 0.6X, 1.2X, and 3X the maximum proposed use rate for peanuts of 0.5 lb ai/A. The theoretical concentration factors for peanut nutmeats processed to meal and oil are 2.2X for meal and 2.8X for oil ("Pesticide Reregistration Rejection Rate Analysis, Residue

Chemistry, Follow-up Guidance for Maximum Theoretical Concentration Factors", EPA 737-R-93-001, February 1993). The application rate of 3X in the processing study exceeds the maximum theoretical concentration factors of 2.2X for meal and 2.8X for oil. CBTS requires no food additive tolerance in cases where no residues are found in the raw agricultural commodity treated at an exaggerated rate provided that 1) the application rate was exaggerated by at least the theoretical concentration factor; 2) the data are sufficiently representative of important growing regions; and 3) the exaggerated rate was not unrealistically high ("Clarification of the Requirement for Processing Studies when the RAC Contains No Detectable Residues", C. Trichilo, 11/17/88). These conditions are met.

Conclusion

The peanut processing study in MRID #431019-03 is adequate to support the temporary tolerances on peanuts and tree nuts. Residues are not expected to concentrate upon processing of the peanut nutmeat to meal, crude oil, and refined oil. Food additive tolerances for meal and oil are not needed.

For a future permanent tolerance, storage stability data for peanut nutmeats for a storage period of 3 years will be needed.

Rotational Crops

A confined rotational crop study (MRID #42275515) was reviewed by EFGWB. Some rotational field trial residue data are under concurrent review in connection with the citrus and cotton petition, PP#3F4187 (conversation with J. Stokes, CBTS, on 7/27/94). Cotton was treated as the primary crop and the rotational crops were grain sorghum, wheat, lettuce, sugar beets, spinach, radish, and turnips.

Conclusion

The proposed label statements regarding rotational crops are acceptable for this EUP.

For a future permanent tolerance, the 18-month plant-back interval is not practical and not acceptable unless it can be documented that phytotoxicity precludes planting for that amount of time. Therefore, rotational field trial residue data will be required for a future permanent tolerance. Some rotational field trial residue data are under concurrent review in connection with PP#3F4187 on citrus and cotton (conversation with J. Stokes, CBTS, on 7/27/94).

Meat, Milk, Poultry, and Eggs

No animal feeding studies have been submitted or referenced. In connection with PP#2G4122 on citrus and cotton, CBTS (J. Garbus, 6/2/93) concluded for purposes of the temporary tolerance that "the proposed uses would result in sufficiently low potential residues of thiazopyr and its metabolites of concern that feeding studies or temporary tolerances for meat, milk, poultry, and eggs would not be required. The petition for the permanent tolerance on citrus and cotton is under concurrent review (PP#3F4187, J. Stokes, 1994).

Almond hulls are an animal feed item. There are no other animal feed items from use on tree nuts.

The animal feed items from use on peanuts are meal, hay, and hulls (shells) (Table II Update, June 1994).

The residues in the diet of dairy cattle resulting from the proposed uses on peanuts, tree nuts, citrus, and cotton can be calculated as follows:

Commodity	% Dry Matter	% in Diet	Proposed Tolerance	Dietary Contribution
peanut meal	85	20	0.05	0.01
peanut hay	85	60	0.5	0.35
almond hulls	90	15	0.15	0.02
citrus pulp, wet	21	5	0.05	0.01
		100		0.39

The residues in the diet of beef cattle resulting from the proposed uses on peanuts, tree nuts, citrus, and cotton can be calculated as follows:

Commodity	% Dry Matter	% in Diet	Proposed Tolerance	Dietary Contribution
peanut meal	85	15	0.05	0.01
peanut hay	85	25	0.5	0.15
peanut hulls	95	15	0.25	0.04
almond hulls	90	25	0.15	0.04
citrus pulp, wet	21	20	0.05	0.05
		100		0.29

The residues in the diet of poultry resulting from the proposed uses on peanuts, tree nuts, citrus, and cotton can be calculated as follows:

Commodity	% Dry Matter	% in Diet	Proposed Tolerance	Dietary Contribution
peanut meal	85	25	0.05	0.015
cotton meal	89	20	0.05	0.01
				0.025

In the goat metabolism study, the animals fed 12 and 21 ppm in the diet had residues in the liver of 0.193 ppm and 0.375 ppm, respectively. Corresponding residues in the goat from a feeding level of 0.39 ppm can be calculated as follows:

$$\frac{0.193}{12} = \frac{X}{0.39} \qquad X = 0.006 \text{ ppm}$$

$$\frac{0.375}{21} = \frac{X}{0.39} \qquad X = 0.007 \text{ ppm}$$

In the hen metabolism study, the animals fed 12 ppm had residues in the liver of 0.298 ppm. Residues in the fat were 1.417 ppm from the 78 ppm feeding level. Corresponding residues in the poultry from a feeding level of 0.025 ppm can be calculated as follows:

$$\frac{0.298}{12} = \frac{X}{0.025} \qquad X = 0.0006$$

$$1.417 = X \qquad X = 0.0004$$

78 0.025

Conclusion

No animal feeding studies or tolerances on animal commodities are needed for this proposed use on peanuts and tree nuts. This conclusion is based on the low residues expected in the dairy cattle, beef cattle, and poultry diets as a result of the proposed temporary tolerances/tolerances on peanuts, tree nuts, citrus, and cotton and metabolism studies, which indicated that residues in animal commodities resulting from such low residue levels in the diet would be <0.007 ppm.

Attachment 1: Structures and Nomenclature of the Compounds in the Peanut Metabolism Report
Attachment 2: Metabolites Identified in Peanuts
Attachment 3: Pathways of Metabolism in Peanuts
Attachment 4: Pathways of Metabolism in Cotton
Attachment 5: Pathways of Metabolism in Citrus
Attachment 6: Pathways of Metabolism in Rotational Crops
Attachment 7: Pathways of Metabolism in Rats
Attachment 8: Chart of Peanut Metabolites in Other Crops
Attachment 9: Aqueous/Organic Partitioning of Peanut Extracts
Attachment 10: Quantification of Identified Metabolites (ppb)
Attachment 11: Quantification of Identified Metabolites (%TRR)
Attachment 12: Quantification of Characterized Metabolites (%TRR)
Attachment 13: Structures and Nomenclature of the Compounds in the Goat and Poultry Metabolism Studies
Attachment 14: Final Analytes of the Analytical Method
Attachment 15: Schematic Diagram of the Analytical Method

cc with all attachments: RF, N. Dodd (CBTS), PM#23, PP#4G04323, A. Kocialski (CCB)
cc with no Attachments: Circu., E. Haeberer (CBTS)

RDI:E. Haeberer:8/9/94:M. Flood:8/12/94
7509C:CBTS:CM#2:Rm 804F:305-5681:N. Dodd:nd:8/22/94