PP# 4F04407
7-1-96

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

JUL 1 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 4F04407. Sulfentrazone (Authority Herbicide) for Use on Soybeans. Amendments of 2/8/96, 3/15/96 and 5/6/96. MRID#s 439268-01 thru -13, 439538-01, 440056-01 and 440056-02. Chemical# 129081. Barcodes D223627, D226457 & D224687. CBTS#s 16977, 17224 & 17176.

FROM: G.F. Kramer, Ph.D., Chemist
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THRU: E. Zager, Acting Branch Chief
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TO: Steve Robbins/Debbie McCall
Registration Section, RCAB
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FMC has submitted an petition for permanent tolerances for the combined residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its major metabolite 3-hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl] methanesulfonamide) on soybeans and rotational crops. For residues on the primary crop, the petitioner has proposed the following tolerance (expressed as the combined residues parent plus the metabolite 3-hydroxymethyl sulfentrazone):

Soybean Seed	--	0.05 ppm

For residues in rotational crops (inadvertent residues), the petitioner has proposed the following tolerances (expressed as the combined residues of parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone [N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide]):

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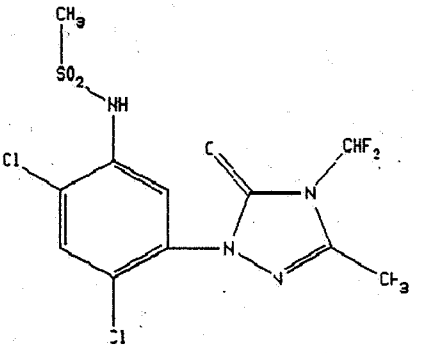
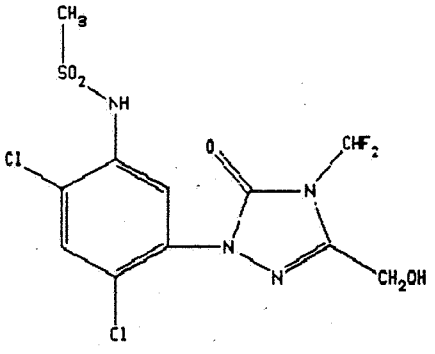
Wheat Forage	--	0.1 ppm
Wheat Straw	--	0.2 ppm
Wheat Hay	--	0.2 ppm
Wheat Grain	--	0.1 ppm
Corn Fodder	--	0.1 ppm
Corn Forage	--	0.1 ppm
Corn Grain	--	0.1 ppm
Rice Straw	--	0.2 ppm
Rice Grain	--	0.1 ppm
Rice Hulls	--	0.5 ppm
Rice Bran	--	0.2 ppm
Sorghum Fodder	--	0.1 ppm
Sorghum Forage	--	0.1 ppm
Sorghum Grain	--	0.1 ppm

The current amendments address deficiencies 1b, 1c, 2b, 2c, 3c, 4b, 5b, 5d, 5f, and 5g identified in CBTS's review of 9/19/95 (Memo, G. Kramer; CBTS# 15851) and deficiencies 2, 4, 5, 6, 7, 8b, 8c, 10, and 11b identified in CBTS's review of 3/21/96 (Memo, G. Kramer; CBTS# 16159).

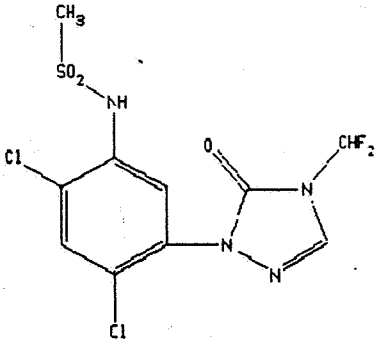
The structures of sulfentrazone and its metabolites are shown below:



Sulfentrazone



3-Hydroxymethyl Sulfentrazone



3-Desmethyl Sulfentrazone

Executive Summary of Chemistry Deficiencies

- Revised Section B and labels.
- Need new enforcement method for soybeans and rotational crops.
- Analysis of selected field residue samples with new method.
- Radiovalidation of new analytical method for plants.
- Revised Section F.
- Wheat processing study.
- Additional rice and sorghum residue data or withdrawal of tolerances.

RECOMMENDATIONS

CBTS recommends against the proposed tolerances for residues of sulfentrazone and 3-hydroxymethyl sulfentrazone on soybeans and the inadvertent residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone on corn, rice, sorghum, and wheat RACs for reasons detailed in conclusions 1b, 1c, 3b, 5, 6, 7, 8a, 8b, 9, 10a, 10b, and 11 below.

CONCLUSIONS

1a. The petitioner previously submitted the results of nine rotational wheat trials (Memo, G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 23 wheat trials. The regional distribution of these trials does not correspond to that required for wheat as a primary crop, but does correlate well with the areas where soybeans are grown. CBTS thus concludes that the number and location of trials are adequate to set tolerances on wheat RACs when planted in rotation with the primary crop soybeans.

1b. The total of sulfentrazone and its metabolites in/on wheat was a maximum of 0.088 ppm in forage, 0.055 ppm in hay, 0.012 ppm in grain, and 0.115 ppm in straw. Based on these results, the appropriate tolerances for sulfentrazone and its metabolites are 0.10 ppm in wheat forage, 0.10 ppm in hay, 0.05 ppm in grain, and 0.15 ppm in straw. However, a final conclusion on the appropriate tolerance levels will be withheld pending reanalysis of field residue samples with the new enforcement method (see conclusion 8a).

1c. The petitioner previously requested a data waiver for the wheat processing study. As residues of sulfentrazone and its metabolites were nondetectable in grain samples from the first five limited field trials, CBTS conditionally recommended in favor of

this data waiver request pending resolution of all deficiencies related to the proposed wheat tolerances (Memo, G. Kramer 7/26/95). However, in the residue data submitted with this amendment, detectable residues were found in grain in over one half of the trials. CBTS thus concludes that a wheat processing study will be required for this petition. If concentration of residues is observed in bran, then residue data should also be provided for wheat aspirated grain fractions.

2. The petitioner has demonstrated that residues of sulfentrazone and its metabolites are stable during frozen storage in wheat RACs and rice grain for up to 14 months. The maximum storage intervals for samples from the wheat residue trials was 20 months for forage, 14 months for grain, 10 months for hay and 13 months for straw. CBTS is willing to extrapolate the results of this storage stability study from 14 to 20 months for forage and concludes that storage stability in wheat RAC samples is not an issue for this petition.

3a. The petitioner previously submitted the results of 13 rotational field corn trials (Memo, G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 22 field corn trials. The regional distribution of these trials does not correspond to that required for field corn as a primary crop, but does correlate well with the areas where soybeans are grown. CBTS thus concludes that the number and location of trials are adequate to set tolerances on field corn RACs <u>when planted in rotation with the primary crop soybeans</u>.

3b. The total of sulfentrazone and its metabolites in/on corn was a maximum of 0.060 ppm in forage, 0.015 ppm in grain and 0.028 ppm in fodder. Based on these results, the appropriate tolerances for sulfentrazone and its metabolites are 0.10 ppm in field corn forage, 0.05 ppm in grain, and 0.05 ppm in stover. However, a final conclusion on the appropriate tolerance levels will be withheld pending reanalysis of field residue samples with the new enforcement method (see conclusion 8a).

4. The petitioner has demonstrated that residues of sulfentrazone and its metabolites are stable during frozen storage in corn RACs for up to 11 months. As the maximum storage intervals for samples from the field corn residue trials was 10 months, CBTS concludes that storage stability in field corn RAC samples is not an issue for this petition.

5. The petitioner previously submitted the results of 4 rotational rice trials (Memo G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 9 rice trials. The number and regional distribution of these trials does not correspond to that required for rice as a primary crop. CBTS thus concludes that an additional 7 rice field

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trials are required. Conclusions on the adequacy of the proposed tolerances will be withheld pending submission and review of additional residue data.

6. Total residues of sulfentrazone and its metabolites were found to concentrate in rice hulls (3.9X) and bran (1.9X). The petitioner has proposed tolerances for these commodities. However, these feed items are not ready-to-eat. As the dilution factors used to calculate the residues in a ready-to-eat diet (5X for rice hulls and 4X for rice bran) exceed observed concentration factors, Section 701 MRLs will be required for rice bran and hulls. Once adequate residue data are available to set tolerances on rice RACs, a proposal for Section 701 MRLs should be submitted for rice bran and hulls. A conclusion on the appropriate levels for these MRLs will be withheld pending submission and review of the additional residue data.

7. The revised labels for Authority 4F and 75DF still contain crop rotation restrictions of 12 months or less for crops for which residue data has not been provided (10 months for sorghum and 12 months for alfalfa, barley, dry beans, peanuts, sunflowers, tobacco, and sugarcane). The petitioner has justified the barley restriction by stating that this crop will be covered by a crop group tolerance. However, neither a tolerance for the cereal grains group has been proposed nor has residue data been submitted for all of the representative commodities (sweet corn, field corn, rice, grain sorghum and wheat). Based on the residue data submitted, all plantback intervals of 1 year or less should be removed from the sulfentrazone label except for soybeans, wheat and field corn.

8a. The petitioner has developed a streamlined method (P-3063M, MRID# 440056-01) which simultaneously measures all three analytes in rotational crops. This method is also very similar to the analytical enforcement method for soybeans. However, in a recent meeting with representatives of FMC, CBTS was informed that the current methodology fails to release a significant portion of the conjugated 3-hydroxymethyl sulfentrazone. The petitioner is in the process of developing a new enforcement method for soybeans and rotational crops. The revised method will be submitted along with an ILV. CBTS will then initiate a PMV. The petitioner has also agreed to reanalyze selected field samples of every RAC associated with this petition using the new method. At least six samples of each RAC will be analyzed, including those which contained the greatest residues when analyzed with the previous methods. Supporting storage stability data will also be provided.

8b. Radiovalidation of the new enforcement method for soybeans and rotational crops will be required.

9. In the labels submitted with this amendment, the phrase "Do not graze treated fields or harvest for forage or hay" has been added

to the "Directions for Use" portion of the labels. As this restriction actually applies only to soybeans (both primary and rotational), it should be modified to "Do not feed treated soybean forage or soybean hay to livestock" and be included in both the "Directions for Use" and "Rotational Crop Guidelines" portions of the labels. **A revised Section B is required.**

10a. The proposed rice and sorghum tolerances should be withdrawn as there are insufficient residue data available for these crops. Also, the corn tolerances should be expressed as "corn, field, grain; corn, field, stover; and corn, field, forage." **A revised Section F is required.**

10b. If residue data are submitted for grain sorghum, then data should also be provided for sorghum aspirated grain fractions as concentration of residues has been observed in the bran of another cereal grain (rice).

11. CBTS will reevaluate the need for a cow feeding study once the appropriate tolerance levels are determined for soybeans and rotational crops by reanalysis of field residue samples with the new enforcement method.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1b (from Memo, G. Kramer 9/19/95)

1b. Rotational crop tolerances are required for wheat. The required number of field trials required to set rotational crop tolerances is the same as that required to establish primary crop tolerances (i.e., 20 for wheat- see *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94*).

Petitioner's Response: Submission of:

Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Winter Wheat as a Rotated Crop Following Soybeans Treated with Authority 4F at 0.375 Pounds Active per Acre. MRID# 439268-04

Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Winter Wheat as a Rotated Crop Following Soybeans Treated with Authority 80WP at 0.375 Pounds Active per Acre. MRID# 439268-03

Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Winter

Wheat as a Rotated Crop Following Soybeans Treated with Authority (F6285) 75DF at 0.375 Pounds Active per Acre. MRID# 439268-05

A total of 14 rotational field trials were conducted in the states of AR, LA, MS, GA, TX (2), NE, KS, SD, MN, IL, VA and IA in 1994/95. Sulfentrazone 75DF, 80WP or 4F was applied at a rate of 0.375 lbs. ai/A (1X). Preplant soil incorporation (PPI) was employed in 11 trials and preemergence application was used in three trials. Soybeans were planted, grown and harvested. Rotational winter wheat was planted 83-133 days after sulfentrazone application. Wheat forage was harvested 78-231 days after planting; wheat hay, 160-285 days after planting; and wheat grain and straw, 197-308 days after planting. After harvest, samples were stored frozen until analysis. The maximum storage interval was 10 months. The proposed enforcement method was used for residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (see Memo, G. Kramer 4/3/95 for review). Forage samples were also analyzed for residues of desmethyl des(difluoromethyl) sulfentrazone using the method reviewed previously (Memo, G. Kramer 4/3/95). The methods were validated in wheat forage, straw and grain over a range of 0.025-0.20 ppm. The average recovery for sulfentrazone was 89 ± 15% (n=44); for 3-desmethyl sulfentrazone, 95 ± 14% (n=44); for 3-hydroxymethyl sulfentrazone, 78 ± 13% (n=44); and for desmethyl desdifluoromethyl sulfentrazone, 101 ± 13% (n=16). Analysis of the treated samples showed that the total of sulfentrazone and its metabolites was a maximum of 0.083 ppm in forage, 0.055 ppm in hay, 0.012 ppm in grain, and 0.115 ppm in straw (Table 1).

CBTS's Conclusion: The petitioner previously submitted the results of nine rotational wheat trials (Memo G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 23 wheat trials, conducted in Regions 2 (5 trials), 4 (5 trials), 5 (11 trials), 6 (1 trial) and 8 (1 trial). This regional distribution does not correspond to that required for wheat as a primary crop (i.e., a total of 12 trials are required in Regions 7, 8 and 11), but does correlate well with the areas where soybeans are grown. CBTS thus concludes that the number and location of trials are adequate to set tolerances on wheat RACs <u>when planted in rotation with the primary crop soybeans</u>. The total of sulfentrazone and its metabolites was a maximum of 0.088 ppm in forage, 0.055 ppm in hay, 0.012 ppm in grain, and 0.115 ppm in straw. Based on these results, the appropriate tolerances for sulfentrazone and its metabolites are 0.10 ppm in forage, 0.10 ppm in hay, 0.05 ppm in grain, and 0.15 ppm in straw. However, a final conclusion on the appropriate tolerance levels will be withheld pending reanalysis of field residue samples with the new enforcement method (see below).

The petitioner previously requested a data waiver for the wheat processing study. As residues of sulfentrazone and its metabolites

were nondetectable in grain samples from the first five limited field trials, CBTS conditionally recommended in favor of this data waiver request pending resolution of all deficiencies related to the proposed wheat tolerances (Memo, G. Kramer 7/26/95). However, in the residue data submitted with this amendment, detectable residues were found in grain in over one half of the trials. CBTS thus concludes that a wheat processing study will be required for this petition. If concentration of residues is observed in bran, then residue data should also be provided for wheat aspirated grain fractions.

Table 1- Results of limited field trials for winter wheat in which Sulfentrazone 75DF was applied to the primary crop at a rate of 0.375 lbs. ai/A. Values of 0.005-0.025 ppm are above the LOD, but below the LOQ.

Site	Form.	DAT[1]	RAC	Crop Age (Days)	Maximum Residue (ppm)				
					Sulfen.	DMS	HMS	DDS	Total
AR[2]	75DF	99	Forage	168	ND	ND	0.005	0.012	0.017
			Hay	203	ND	ND	ND	NA	ND
			Straw	248	ND	0.016	ND	NA	0.016
			Grain	248	ND	0.009	ND	NA	0.009
LA[2]	75DF	118	Forage	78	ND	0.008	0.022	0.022	0.052
			Hay	160	ND	0.026	0.010	NA	0.036
			Straw	202	ND	0.081	0.034	NA	**0.115**
			Grain	202	ND	0.010	ND	NA	0.010
MS[2]	75DF	98	Forage	170	ND	0.009	0.031	ND	0.040
			Hay	226	ND	0.013	ND	NA	0.013
			Straw	238	ND	0.029	0.012	NA	0.041
			Grain	238	ND	ND	ND	NA	ND
TX[2]	75DF	112	Forage	140	ND	0.022	0.014	ND	0.036
			Hay	161	ND	0.015	ND	NA	0.015
			Straw	197	ND	0.044	ND	NA	0.044
			Grain	197	ND	0.011	ND	NA	0.011
TX[2]	75DF	126	Forage	185	ND	0.007	0.034	0.042	**0.083**
			Hay	224	ND	0.043	0.012	NA	**0.055**
			Straw	247	ND	0.077	0.043	NA	0.120
			Grain	247	ND	0.008	ND	NA	0.008
NE[2]	75DF	86	Forage	231	ND	0.005	0.012	0.011	0.028
			Hay	283	ND	0.024	ND	NA	0.024
			Straw	308	ND	0.038	ND	NA	0.038
			Grain	308	ND	ND	ND	NA	ND
KS[2]	75DF	97	Forage	204	0.006	0.009	0.026	ND	0.041
			Hay	241	ND	0.032	ND	NA	0.032
			Straw	278	ND	0.069	ND	NA	0.069
			Grain	278	ND	0.005	ND	NA	0.005
SD[2]	75DF	101	Forage	258	ND	0.022	0.024	0.023	0.069
			Hay	285	ND	0.024	ND	NA	0.024
			Straw	NS	NS	NS	NS	NS	NS
			Grain	NS	NS	NS	NS	NS	NS

Site	Form.	DAT[1]	RAC	Crop Age (Days)	Maximum Residue (ppm)				
					Sulfen.	DMS	HMS	DDS	Total
MN[2]	75DF	122	Forage	229	ND	0.011	0.019	ND	0.030
			Hay	255	ND	0.014	ND	NA	0.014
			Straw	284	ND	0.032	0.012	NA	0.044
			Grain	284	ND	0.009	ND	NA	0.009
IN[2]	75DF	83	Forage	204	ND	0.008	0.015	ND	0.023
			Hay	253	ND	0.044	ND	NA	0.044
			Straw	276	ND	0.015	ND	NA	0.015
			Grain	276	ND	ND	ND	NA	ND
IL[3]	80WP	105	Forage	188	ND	0.010	0.028	0.024	0.062
			Hay	233	ND	0.021	0.027	NA	0.048
			Straw	256	ND	0.027	0.032	NA	0.059
			Grain	256	ND	ND	ND	NA	ND
GA[3]	80WP	169	Forage	141	ND	ND	0.006	ND	0.006
			Hay	181	ND	ND	0.010	NA	0.010
			Straw	219	ND	ND	0.010	NA	0.010
			Grain	219	ND	0.012	ND	NA	**0.012**
VA[3]	80WP	133	Forage	101	0.005	0.017	0.023	0.010	0.055
			Hay	212	ND	0.031	0.016	NA	0.047
			Straw	243	ND	0.043	0.030	NA	0.073
			Grain	243	ND	ND	ND	NA	ND
IA[2]	4F	99	Forage	231	ND	ND	0.008	ND	0.008
			Hay	274	ND	ND	ND	NA	ND
			Straw	293	ND	ND	ND	NA	ND
			Grain	293	ND	ND	ND	NA	ND

[1]Days after treatment of soil with sulfentrazone when wheat was planted
[2]Sulfentrazone applied by preplant incorporation, [3]Sulfentrazone applied preemergence
ND = Not Detected; i.e., below the LOD (0.005 ppm for sulfentrazone, HMS and DMS; 0.01 ppm for DDS).; NA = Not Analyzed, and NS = Not Sampled
HMS = Hydroxy Methyl Sulfentrazone
DMS = Des-Methyl Sulfentrazone
DDS = Desmethyl Des(difluoromethyl) Sulfentrazone

Deficiency - Conclusion 1c (from Memo, G. Kramer 9/19/95)

1c. CBTS is unable to comment on the adequacy of the proposed wheat tolerances until receipt and review of the requested residue data. If the wheat field residue data submitted with this petition are to be used for setting rotational crop tolerances, then the registrant must demonstrate the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in wheat RACs (conclusion 12c of Memo, G. Kramer 4/3/95).

Petitioner's Response: Submission of:

> Storage Stability of Sulfentrazone and its Metabolites in/on Laboratory-Fortified Winter Wheat and Rice Matrices. MRID# 439268-12

Samples of wheat forage were fortified with 0.25 ppm of sulfentrazone, 3-desmethyl sulfentrazone, 3-hydroxymethyl sulfentrazone and desmethyl des(difluoromethyl) sulfentrazone; wheat straw, with 0.25 ppm of sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone; wheat grain, with 0.25 ppm of sulfentrazone and 3-desmethyl sulfentrazone; and rice grain, with 0.25 ppm of sulfentrazone and 3-hydroxymethyl sulfentrazone and stored frozen at -18 °C. Samples were maintained frozen and three subsamples were removed and analyzed at various intervals (0, 6, 10 and 14 months) for residues using the methods described above. Each analysis included two freshly fortified controls. The results demonstrate that residues of sulfentrazone and its metabolites are stable during frozen storage in wheat RACs and rice grain for up to 14 months.

CBTS's Conclusion: The maximum storage intervals for samples from the wheat residue trials was 20 months for forage, 14 months for grain, 10 months for hay and 13 months for straw. CBTS is willing to extrapolate the results of this storage stability study from 14 to 20 months for forage and conclude that storage stability in wheat samples is not an issue for this petition. This deficiency is now resolved.

Deficiency - Conclusion 2b (from Memo, G. Kramer 9/19/95)

2b. Rotational crop tolerances are required for field corn. The required number of field trials required to set rotational crop tolerances is the same as that required to establish primary crop tolerances (i.e., 20 for field corn- see *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94).*

Petitioner's Response: Submission of:

> Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Field Corn as a Rotated Crop Following Soybeans Which Were Treated

with Authority 75DF or 4F at 0.375 Pounds Active per Acre. MRID# 439268-07

A total of nine rotational field trials were conducted in the states of MI, MO, OH, IA (2), NE, KS, MN, and IN in 1994/95. Sulfentrazone 75DF or 4F was applied at a rate of 0.375 lbs. ai/A (1X). Preemergence application was used in all trials. Soybeans were planted, grown and harvested. Rotational field corn was planted 9-12 months after sulfentrazone application. Corn forage was harvested 105-140 days after planting; and corn grain and fodder, 142-192 days after planting. After harvest, samples were stored frozen until analysis. The maximum storage interval was 2 months. The proposed enforcement method was used for residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (see Memo, G. Kramer 4/3/95 for review). The method was validated in corn forage, fodder and grain at 0.025 ppm. The average recovery for sulfentrazone was 86 ± 11% (n=27); for 3-desmethyl sulfentrazone, 101 ± 15% (n=27); and for 3-hydroxymethyl sulfentrazone, 88 ± 15% (n=27). Analysis of the treated samples showed that the total of sulfentrazone and its metabolites was a maximum of 0.015 ppm in grain, and 0.012 ppm in fodder (Table 2). Residues were nondetectable in all forage samples.

CBTS's Conclusion: The petitioner previously submitted the results of 13 rotational field corn trials (Memo G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 22 field corn trials, conducted in Regions 2 (2 trials), 4 (3 trials) and 5 (17 trials). This regional distribution does not correspond to that required for field corn as a primary crop (i.e., 2 trials are required in Regions 1 and 6), but does correlate well with the areas where soybeans are grown. CBTS thus concludes that the number and location of trials are adequate to set tolerances on field corn RACs <u>when planted in rotation with the primary crop soybeans</u>. The total of sulfentrazone and its metabolites was a maximum of 0.060 ppm in forage, 0.015 ppm in grain and 0.028 ppm in fodder. Based on these results, the appropriate tolerances for sulfentrazone and its metabolites are 0.10 ppm in forage, 0.05 ppm in grain, and 0.05 ppm in stover. However, a final conclusion on the appropriate tolerance levels will be withheld pending reanalysis of field residue samples with the new enforcement method (see below).

Table 2- Results of limited field trials for field corn in which Sulfentrazone 75DF or 4F was applied to the primary crop at a rate of 0.375 lbs. ai/A. Values of 0.005-0.025 ppm are above the LOD, but below the LOQ.

Location	MAT[1]	RAC	Crop Age (Days)	Maximum Residue (ppm)			
				Sulfent.	DMS	HMS	Total
MI[2]	12	Forage	109	ND	ND	ND	ND
		Grain	142	ND	ND	ND	ND
		Fodder	142	ND	ND	ND	ND
IA[2]	11	Forage	110	ND	ND	ND	ND
		Grain	165	ND	ND	ND	ND
		Fodder	165	ND	ND	0.009	0.009
MO[3]	9	Forage	140	ND	ND	ND	ND
		Grain	186	ND	ND	ND	ND
		Fodder	186	ND	ND	ND	ND
NE[3]	10	Forage	123	ND	ND	ND	ND
		Grain	161	ND	ND	ND	ND
		Fodder	161	ND	ND	ND	ND
KS[3]	9	Forage	131	ND	ND	ND	ND
		Grain	192	0.006	ND	0.009	**0.015**
		Fodder	192	ND	ND	ND	ND
MN[3]	11	Forage	105	ND	ND	ND	ND
		Grain	142	ND	ND	ND	ND
		Fodder	142	ND	0.006	0.006	**0.012**
IN[3]	10	Forage	116	ND	ND	ND	ND
		Grain	143	ND	ND	ND	ND
		Fodder	143	ND	ND	ND	ND
OH[3]	9	Forage	124	ND	ND	ND	ND
		Grain	173	ND	ND	ND	ND
		Fodder	173	ND	ND	ND	ND
IA[3]	9	Forage	110	ND	ND	ND	ND
		Grain	165	ND	ND	ND	ND
		Fodder	165	ND	ND	0.008	0.008

[1]Months after treatment of soil with sulfentrazone when corn was planted
[2]4F Formulation, [3]75DF Formulation
ND = Not Detected; i.e., below the LOD (0.005 ppm).

HMS = Hydroxy Methyl Sulfentrazone
DMS = Des-Methyl Sulfentrazone

Deficiency - Conclusion 2c (from Memo, G. Kramer 9/19/95)

2c. CBTS is unable to comment on the adequacy of the proposed corn tolerances until receipt and review of the requested residue data. If the field corn residue data submitted with this petition are to be used for setting rotational crop tolerances, then the registrant must demonstrate the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in corn RACs (conclusion 12c of Memo, G. Kramer 4/3/95).

Petitioner's Response: Submission of:

Storage Stability of Sulfentrazone and its Metabolites in/on Laboratory-Fortified Field Corn Matrices. MRID# 439268-11

Samples of corn forage, grain and fodder were spiked with 0.25 ppm of sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone and stored frozen at -18 °C. Samples were maintained frozen and three subsamples were removed and analyzed at various intervals (0, 6, and 11 months) for residues using the methods described above. Each analysis included two freshly fortified control. The results demonstrate that residues of sulfentrazone and its metabolites are stable during frozen storage in corn RACs for up to 11 months.

CBTS's Conclusion: The maximum storage intervals for samples from the field corn residue trials was 10 months. CBTS thus concludes that storage stability in field corn RAC samples is not an issue for this petition. This deficiency is now resolved.

Deficiency - Conclusion 3c (from Memo, G. Kramer 9/19/95)

3c. Based on the results of this study, rotational crop residue trials will also be required to support the proposed interval for barley. Until the required data for rotational barley, rice and peanuts are submitted, all plantback intervals of 1 year or less should be removed from the sulfentrazone label, except for soybeans, wheat and corn.

Petitioner's Response: Submission of:

Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Rice as a Rotated Crop Following Soybeans Treated with Authority 75DF at 0.375 Pounds Active per Acre. MRID# 439268-08

Field Accumulation Studies on Rotational Crops: Magnitude of the Residue of Sulfentrazone and its Metabolites in/on Rice and the Processed Parts of Rice as a Rotated Crop Following

Soybeans Treated with Authority 4F at 0.375 Pounds Active per Acre. MRID# 439268-09

A total of five rotational field trials were conducted in the states of AR (2), LA, MS, and TX in 1994/95. The petitioner claims that a total of eight trials were performed. However, all of the MS and two of the AR 'trials' were performed concurrently at the same location. CBTS thus considers these 'trials' to be separate plots of single trials. Sulfentrazone 75DF or 4F was applied at a rate of 0.375 lbs. ai/A (1X). Preplant soil incorporation (PPI) was employed in all trials and plots with preemergence application were used in the MS trial. Soybeans were planted, grown and harvested. Rotational rice was planted 267-280 days after sulfentrazone application. Rice grain and straw were harvested 131-176 days after planting. After harvest, samples were stored frozen until analysis. The maximum storage interval was 4 months. The proposed enforcement method was used for residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (see Memo, G. Kramer 4/3/95 for review). The method was validated in rice straw and grain over a range of 0.025-0.10 ppm. The average recovery for sulfentrazone was 86 ± 14% (n=11); for 3-desmethyl sulfentrazone, 98 ± 17% (n=11); and for 3-hydroxymethyl sulfentrazone, 84 ± 14% (n=11). Analysis of the treated samples showed that the total residues of sulfentrazone and its metabolites was a maximum of 0.077 ppm in grain, and 0.101 ppm in straw (Table 3).

Samples from one of the MS plots were shipped to TX A & M for processing into polished rice, hulls and bran. The maximum storage interval was 4 months. The proposed enforcement method was used for residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (see Memo, G. Kramer 4/3/95 for review). The method was validated in rice fractions over a range of 0.025-0.10 ppm. The average recovery for sulfentrazone was 98 ± 18% (n=11); for 3-desmethyl sulfentrazone, 102 ± 12% (n=11); and for 3-hydroxymethyl sulfentrazone, 82 ± 15% (n=11). Residues were found to concentrate in hulls (3.9X) and bran (1.9X) (Table 4).

Table 3- Results of limited field trials for rice in which Sulfentrazone 75DF or 4F was applied to the primary crop at a rate of 0.375 lbs. ai/A. Values of 0.005-0.025 ppm in grain and 0.01-0.05 ppm in straw are above the LOD, but below the LOQ.

Location	DAT[1]	Method	RAC	Crop Age (Days)	Maximum Residue (ppm)			
					Sulfent.	DMS	HMS	Total
AR	271	PPI[2]	Straw	176	ND	0.007	0.023	0.030
			Grain	176	ND	0.029	0.017	0.046
		PPI[2]	Straw	176	ND	0.017	0.012	0.029
			Grain	176	ND	0.014	0.029	0.043
MS	272	PRE[2]	Straw	174	ND	0.094	ND	0.094
			Grain	174	ND	0.018	0.018	0.036
		PPI[2]	Straw	174	ND	0.080	0.021	**0.101**
			Grain	174	ND	0.018	0.031	0.049
		PRE[3]	Straw	174	ND	0.071	0.012	0.083
			Grain	174	ND	0.025	0.052	**0.077**
		PRE[2]	Straw	NR	NR	NR	NR	NR
			Grain	174	ND	0.016	0.023	0.039
AR	277	PPI[3]	Straw	151	ND	0.013	0.011	0.024
			Grain	151	ND	ND	0.007	0.007
LA	267	PPI[3]	Straw	148	ND	0.013	ND	0.013
			Grain	148	ND	ND	0.010	0.010
TX	280	PPI[3]	Straw	131	ND	0.030	0.014	0.044
			Grain	131	ND	0.009	0.023	0.032

[1]Days after treatment of soil with sulfentrazone when wheat was planted
[2]4F Formulation, [3]75DF Formulation
PPI = preplant incorporation; PRE = preemergence
ND = Not Detected; i.e., below the LOD (0.005 ppm for grain, 0.01 ppm for straw); NR = Not Reported.
HMS = Hydroxy Methyl Sulfentrazone
DMS = Des-Methyl Sulfentrazone

Table 4- Residues of sulfentrazone, 3-desmethyl sulfentrazone and 3-hydroxymethyl sulfentrazone in soybeans and processed fractions

Matrix	Average Residue (ppm)				Concentration Factor
	Sulfent.	DMS	HMS	Total	
RAC	ND	0.015	0.013	0.028	-
Polished Rice	ND	0.009	ND	0.009	0.3
Hulls	ND	0.019	0.089	0.108	3.9
Bran	ND	0.045	0.009	0.054	1.9

ND = Not Detected (<0.005 ppm)

CBTS's Conclusion: The petitioner previously submitted the results of 4 rotational rice trials (Memo G. Kramer 9/19/95). Together with the residue data submitted with this amendment, the petitioner has provided the results of 9 rice trials, conducted in Regions 4 (8 trials) and 6 (1 trial). The number and regional distribution does not correspond to that required for rice as a primary crop (i.e., 16 trials are required in Regions 4, 5, 6 and 10). CBTS thus concludes that an additional 7 rice field trials are required. Conclusions on the adequacy of the proposed tolerances will be withheld pending submission and review of additional residue data.

Total residues of sulfentrazone and its metabolites were found to concentrate in rice hulls (3.9X) and bran (1.9X). The petitioner has proposed tolerances for these commodities. However, these feed items are not ready-to-eat. As the dilution factors used to calculate the percentages in a ready-to-eat diet (5X for rice hulls and 4X for rice bran) exceed observed concentration factors, Section 701 MRLs will be required for rice bran and hulls. A conclusion on the appropriate levels for these MRLs will be withheld pending submission and review of additional residue data.

The revised labels for Authority 4F and 75DF still contain crop rotation restrictions of 12 months or less for crops for which residue data has not been provided (10 months for sorghum and 12 months for alfalfa, barley, dry beans, peanuts, sunflowers, tobacco, and sugarcane). The petitioner has justified the barley restriction by stating that this crop will be covered by a crop group tolerance. However, neither a tolerance for the cereal grains group has been proposed nor has residue data been submitted for all of the representative commodities (sweet corn, field corn, rice, grain sorghum, and wheat). Based on the residue data submitted, all plantback intervals of 1 year or less should be removed from the sulfentrazone label except for soybeans, wheat and field corn.

Deficiency - Conclusion 4b (from Memo, G. Kramer 9/19/95)

4b. CBTS will refer to the Metabolism Committee on the toxicological significance of the sulfentrazone metabolites. A decision by CBTS concerning which residues to regulate will then follow. A tolerance based on the parent and 3-hydroxymethyl sulfentrazone may not be appropriate; in such an instance a revised Section F and additional field studies, analytical methodology, and storage stability data may be needed.

Petitioner's Response: None required.

CBTS's Conclusion: The Metabolism Committee has decided that a soybean tolerance based on the parent and 3-hydroxymethyl sulfentrazone is appropriate (Memo, G. Kramer; in preparation). This deficiency is now resolved.

Deficiency - Conclusion 5b (from Memo, G. Kramer 9/19/95)

5b. An ILV of this method was performed by North Coast Laboratories. Acceptable recoveries were obtained by the laboratory for all analytes. The method and ILV have been sent to Beltsville for PMV (Memo, G. Kramer 8/30/95). CBTS will withhold a final conclusion on the adequacy of this method as an analytical enforcement method pending receipt of the PMV report.

Petitioner's Response: None required.

CBTS's Conclusion: The PMV was unsuccessful (Memo, G. Kramer 3/13/96). However, the petitioner has developed a streamlined method (P-3063M, MRID# 440056-01) which simultaneously measures all three analytes in rotational crops. This method is also very similar to the analytical enforcement method for soybeans. In a recent meeting with representatives of FMC, CBTS was informed that the current methodology fails to release a significant portion of the conjugated 3-hydroxymethyl sulfentrazone. The petitioner is in the process of developing a new enforcement method for soybeans and rotational crops. The revised method will be submitted along with an ILV. CBTS will then initiate a PMV. The petitioner has also agreed to reanalyze selected field samples of every RAC associated with this petition using the new method. At least six samples of each RAC will be analyzed, including those which contained the greatest residues when analyzed with the previous methods. Supporting storage stability data will also be provided. As new methodology is being developed, this deficiency is no longer relevant.

Deficiency - Conclusion 5d (from Memo, G. Kramer 9/19/95)

5d. Radiovalidation should be performed by running the entire method on barley samples from the confined rotational crop study.

Petitioner's Response: Submission of a radiovalidation study (MRID# 439268-13). The total recovery of sulfentrazone and its metabolites using the analytical method was 32% as compared to the metabolism study. However, as new methodology is being developed, this study will not be reviewed in detail.

CBTS's Conclusion: Radiovalidation of the new enforcement method for soybeans and rotational crops will be required.

Deficiency - Conclusion 5f & g (from Memo, G. Kramer 9/19/95)

5f. The registrant employed a different analytical method for each corn RAC. These methods closely resembled either the proposed enforcement methods for soybeans or wheat RACs with the exception that sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone are measured in a single GC run. Due to the similarity to these other methods, CBTS does not feel that an ILV is necessary for the corn methods. The registrant should submit the complete protocol for the corn methodology so that a PMV can be requested.

5g. The method employed for rice grain was the same as the corn grain method. The method employed for sulfentrazone and 3-desmethyl sulfentrazone in rice straw was the same as the corn forage method with the exception that only two analytes were determined. The method employed for 3-hydroxymethyl sulfentrazone in straw was very similar to the wheat method for 3-hydroxymethyl sulfentrazone. As the rice methods closely resemble those employed for wheat and corn, CBTS will not require that they be validated (ILV and PMV). The registrant should, however, include the rice procedures in the requested protocol for the corn methodology.

Petitioner's Response: Submission of a streamlined method (see above).

CBTS's Conclusion: As new methodology is being developed, these deficiencies are no longer relevant.

Deficiency - Conclusion 2 (from Memo, G. Kramer 3/21/96)

2. The phrase "Do not feed treated forage or hay to livestock" has been added to the "Rotational Crop Guidelines" portion of the labels. As this restriction actually applies only to soybeans (both primary and rotational), it should be modified to "Do not feed treated soybean forage or soybean hay to livestock" and be included in both the "Precautions" and "Rotational Crop Guidelines" portions of the labels.

Petitioner's Response: In the labels submitted with this amendment, the phrase "Do not graze treated fields or harvest for forage or hay" has been added to the "Directions for Use" portion of the labels.

CBTS's Conclusion: As this restriction actually applies only to soybeans (both primary and rotational), it should be modified to "Do not feed treated soybean forage or soybean hay to livestock"

and be included in both the "Directions for Use" and "Rotational Crop Guidelines" portions of the labels. This deficiency is not resolved.

Deficiency - Conclusion 4 (from Memo, G. Kramer 3/21/96)

4. All deficiencies pertaining to the nature of the residue in plants have been resolved. CBTS can now refer to the HED Metabolism Committee on the toxicological significance of the sulfentrazone metabolites. A decision by CBTS concerning which residues to regulate will then follow. If additional residues are determined to be of regulatory concern, then a revised Section F and additional field studies, analytical methods, and storage stability data may be needed.

Petitioner's Response: None required.

CBTS's Conclusion: The Metabolism Committee decided that, for the proposed use on soybeans, there is no scientific objection to establishing the soybean tolerance in terms of parent plus the metabolite 3-hydroxymethyl sulfentrazone and to establishing the rotational crop tolerances in terms of parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (Memo, G. Kramer; in preparation). This deficiency is now resolved.

Deficiency - Conclusion 5 (from Memo, G. Kramer 3/21/96)

5. A proposed tolerance is required for wheat hay in addition to the tolerances proposed for forage, straw and grain. Also, the corn tolerances should be expressed as "corn, field, grain; corn, field, fodder; and corn, field, forage." The proposed rice tolerances should be withdrawn as the revised label no longer permits rotation to this crop. **A revised Section F is required.**

Petitioner's Response: A revised Section F (see page 2 of this memo).

CBTS's Conclusion: The proposed rice and sorghum tolerances should be withdrawn as there are insufficient residue data available for these crops. Also, the corn tolerances should be expressed as "corn, field, grain; corn, field, stover; and corn, field, forage." **A revised Section F is required.**

Deficiency - Conclusion 6 (from Memo, G. Kramer 3/21/96)

6. A successful PMV of the proposed enforcement method for soybeans has been completed by ACL (Memo, G. Kramer 12/14/95; CBTS# 16506). However, the registrant should submit standards with the accompanying MSDS's to the EPA Repository in RTP. Also, a revised version of the proposed analytical enforcement method (P-2811M) as specified in conclusions 2-8 of the

aforementioned Memo should be submitted to CBTS. Until the receipt of the standard and the revised method, the requirements for an analytical enforcement method will remain unfulfilled.

Petitioner's Response: Submission of standards to RTP and submission of a revised method (MRID# 439538-01).

CBTS's Conclusion: As new enforcement methodology is being developed, this deficiency is no longer relevant.

Deficiency - Conclusion 7 (from Memo, G. Kramer 3/21/96)

7. The purpose of the submitted radiovalidation study was to determine whether conjugated residues are released by the hydrolysis step of the proposed enforcement method. Based on the results of the metabolism study, quantifiable residues of 3-hydroxymethyl sulfentrazone (0.025 ppm) should have been present in the radiolabelled soybean sample. When analyzed by the proposed enforcement method, 3-hydroxymethyl sulfentrazone residues were found to be <0.005 ppm. This result indicates that either the residues in the sample had degraded during storage or that the proposed enforcement method does not work on field-incurred residues. In either case, Method P-2811M has not been radiovalidated. CBTS requests that this study be repeated on a soybean seed sample which contains quantifiable residues of 3-hydroxymethyl sulfentrazone. If the recovery of 3-hydroxymethyl sulfentrazone by Method P-2811M is found to be inadequate, then the development of a new enforcement method may be necessary.

Petitioner's Response: None.

CBTS's Conclusion: As new enforcement methodology is being developed, this deficiency is no longer relevant.

Deficiency - Conclusion 8b (from Memo, G. Kramer 3/21/96)

8b. If the corn field residue data submitted with this petition are to be used for setting rotational crop tolerances, then the registrant must demonstrate the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in corn forage samples for at least 10 months of storage; and fodder samples, for 9 months. The registrant must also demonstrate the stability of 3-desmethyl sulfentrazone in corn grain samples for at least 9 months of storage. The soybean storage stability data for sulfentrazone and 3-hydroxymethyl sulfentrazone can be translated to corn grain.

Petitioner's Response: Submission of a corn storage stability study (see above).

CBTS's Conclusion: CBTS concludes that storage stability in field corn RAC samples is not an issue for this petition. This deficiency is now resolved.

Deficiency - Conclusion 8c (from Memo, G. Kramer 3/21/96)

8c. If the wheat field residue data submitted with this petition are to be used for setting rotational crop tolerances, then the registrant must demonstrate the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in wheat forage samples for at least 20 months of storage; wheat grain samples, for 14 months; and wheat straw samples, for 13 months.

Petitioner's Response: Submission of a wheat storage stability study (see above).

CBTS's Conclusion: CBTS concludes that storage stability in wheat RAC samples is not an issue for this petition. This deficiency is now resolved.

Deficiency - Conclusion 10 (from Memo, G. Kramer 3/21/96)

10. If metabolites other than 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone are determined to be of regulatory significance by the HED Metabolism Committee, then residue data for soybean and corn processed fractions will be required for all such metabolites.

Petitioner's Response: None required.

CBTS's Conclusion: The Metabolism Committee decided that, for the proposed use on soybeans, there is no scientific objection to establishing the soybean tolerance in terms of parent plus the metabolite 3-hydroxymethyl sulfentrazone and to establishing the rotational crop tolerances in terms of parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone (Memo, G. Kramer; in preparation). This deficiency is now resolved.

Deficiency - Conclusion 11 (from Memo, G. Kramer 3/21/96)

11a. Based on extrapolation of the TRR in the ruminant metabolism study (phenyl label) observed at a dosing level of 4.9 ppm to the maximum theoretical dietary burdens of 0.3 ppm (dairy) and 0.2 ppm (beef), the expected residues in milk would be 0.00007 ppm in milk and 0.0005 ppm in kidney. These values are well below the expected LOQ of a analytical enforcement method (0.05-0.10 ppm). A dietary exposure of 10X would not result in quantifiable residues. A conventional feeding study will not be required. Meat and milk tolerances and analytical enforcement methods for animal RACs are thus not required for this petition.

11b. CBTS will reevaluate this decision if the results of the required wheat and corn field trials result in an increase in the rotational crop tolerances.

Petitioner's Response: None required.

CBTS's Conclusion: CBTS will reevaluate the need for a cow feeding study once the appropriate tolerance levels are determined for

soybeans and rotational crops by reanalysis of field residue samples with the new enforcement method.

cc: PP#4F04407, Kramer, Circ., R.F., J. Miller/D. Morgan (PM Team 23, RD, 7505C)
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