PP#4407
3-21-96

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

MAR 21 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 4F04407. Sulfentrazone (Authority Herbicide) for Use on Soybeans. Amendment of 8/24/95. MRID#s 437617-01 thru -06. Chemical# 129081. Barcode D219093. CBTS# 16159.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Team I
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: E. Zager, Acting Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: JoAnne Miller, Product Manager
Dianne Morgan, Team 23 Reviewer
Registration Division (7505C)

And

Debbie McCall, Acting Section Head
Registration Section, RCAB
Health Effects Division (7509C)

FMC has submitted an application 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). The end use products, Authority 75DF Herbicide and Authority 4F Herbicide, are proposed to be registered for use on soybeans. To cover use on the primary crop, the petitioner has proposed the following tolerances (expressed as parent plus the metabolite 3-hydroxymethyl sulfentrazone):

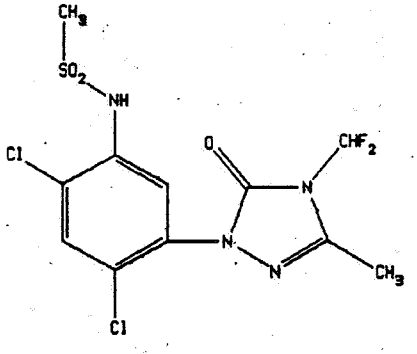
Soybean Seed	--	0.05 ppm

For residues in rotational crops (inadvertent residues), the petitioner has proposed the following tolerances (expressed as 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]):

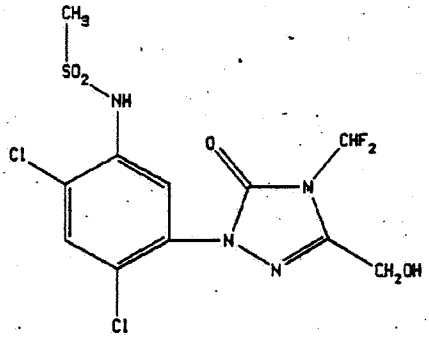
Wheat Forage	--	0.10 ppm
Wheat Straw	--	0.10 ppm
Wheat Grain	--	0.10 ppm
Corn Fodder	--	0.20 ppm
Corn Forage	--	0.20 ppm
Corn Grain	--	0.10 ppm
Rice Straw	--	0.20 ppm
Rice Grain	--	0.10 ppm

The current amendment addresses deficiencies 1a-f, 2a-d, 3c, 4d, 9, 10b, 10d, 11, 12c, 14b, 14c and 15 identified in CBTS's review of 4/3/95 (Memo, G. Kramer; CBTS# 14993) and deficiency 6b identified in CBTS's review of 9/19/95 (Memo, G. Kramer; CBTS# 15851). Deficiencies 4a, 4b, 4c, 5 and 10g of the 4/3/95 Memo were addressed in a previous amendment (Memo, G. Kramer 9/19/95; CBTS# 15851).

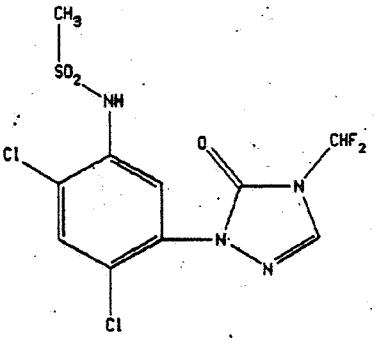
The structures of sulfentrazone and its metabolites are shown below:



Sulfentrazone



3-Hydroxymethyl Sulfentrazone



3-Desmethyl Sulfentrazone

RECOMMENDATIONS

CBTS recommends against the proposed tolerances for residues of sulfentrazone and 3-hydroxymethyl sulfentrazone on soybeans and for inadvertent residues of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone on corn, rice and wheat RACs for reasons detailed in conclusions 2, 4, 5, 6, 7, 8b, 8c, 10 and 11b below and conclusions 1b, 1c, 2b, 2c, 3c, 4b, 5b, 5d, 5f and 5g of Memo, G. Kramer 9/19/95.

CONCLUSIONS

1. All product chemistry data requirements for the sulfentrazone TGAI have been fulfilled.

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 restrictior 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.

3. The nature of the residue in rotational crops is now considered to be understood. The major metabolites identified were 3-hydroxymethyl sulfentrazone, desmethyl des(difluoromethyl) sulfentrazone, sulfentrazone carboxylic acid/3-desmethyl sulfentrazone and methyl triazole (4-difluoromethyl-3-methyl-1H-1,2,4-triazol-5(4H)-one).

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.

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.**

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.

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.

8a. No data have been supplied on the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in the corn and wheat RACs during frozen storage.

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.

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.

9. The samples from the corn processing study were stored for a maximum of 3 months. The registrant has demonstrated that residues of sulfentrazone and its metabolites are stable during storage in corn processed substrates for up to 6 months. These data were required to support the corn processing study in which residues were found not to concentrate in any processed fraction. CBTS thus

concludes that food/feed additive tolerances will not be required for rotational corn.

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.

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.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1a-e (from Memo, G. Kramer 4/3/95)

1. The following product chemistry data requirements remain outstanding: a) for GLN § 61-1, One of the impurities (I9) is incorrectly identified. This compound should be identified and the CSF revised to include its chemical name; b) for GLN § 62-1, Once commercial production is initiated, the five-batch analysis should be repeated and the CSF revised if necessary; c) for GLN § 62-3, The registrant should demonstrate the repeatability (precision), accuracy and linearity of Test Methods AGC 294, 295, 296 and 297 for each impurity measured by the respective method; d) for GLN § 62-3, CBTS notes that in the representative chromatogram included with Method AGC 294, Peaks 8, 9, 10 and 11 were listed as being unknowns. All of these peaks were larger than Peak 7 (FMC 119903), an impurity for which certified limits were required. The registrant should provide quantitative data for these compounds and, if present at a level of ≥0.1%, identify the impurity and revise the CSF as required; e) for GLN § 62-3, Several peaks were not labelled in the representative chromatogram included with Method AGC 295. The registrant should report whether these peaks are unknowns or are identified impurities accounted for in Method 294. If any are unknowns, then the registrant should provide quantitative data for these compounds and, if present at a level of ≥0.1%, identify the impurity and revise the CSF as required.

Petitioner's Response: Submission of:

Response to EPA Memo PP#4F04407 Supplemental Information for MRID#s 433454-01 and 433454-02. MRID# none.

a) This impurity was identified and is now listed in the revised CSF as "FMC 116978." b) Once commercial production is initiated, the five-batch analysis will be repeated and the CSF revised if necessary. c) Validation data for all methods. d) These impurities were identified and are now listed in the revised CSF. e) These peaks are accounted for in Method 294.

CBTS's Conclusion: The requested information has been provided. This deficiency is now resolved. The revised CSF is shown in the confidential appendix.

Deficiency - Conclusion 1f (from Memo, G. Kramer 4/3/95)

1. f) for GLN § 63-13, The registrant should report on the stability of the solid TGAI to sunlight.

Petitioner's Response: Submission of:

F6285 TGAI Stability to Sunlight. MRID# 437617-01

Sulfentrazone TGAI was found to be stable in the presence of sunlight.

CBTS's Conclusion: The requested information has been provided. This deficiency is now resolved.

Deficiency - Conclusion 2a-d (from Memo, G. Kramer 4/3/95)

2. The following deficiencies in the directions for use were noted: a) The proposed crop rotation restrictions are greater than 12 months in some cases. CBTS considers such restrictions to be impractical in regards to reducing the possibility of residues in rotational crops. The maximum crop rotation interval CBTS will accept in regards to residues is 12 months. However, crop rotation restrictions of longer than 12 months may be retained if necessitated by problems with phytotoxicity. In this case, the label should state that the intervals in excess of 12 months are necessitated by phytotoxicity concerns. b) All rotational crops with plantback intervals of one year or less; except corn (10 months), wheat (winter- 4 months, spring 9 months) and soybeans (no restriction); should be removed from list of rotational crops (see conclusion 4b). c) No instructions in regards to adjuvant use were included. As adjuvants were not employed in the field residue trials, a label restriction prohibiting their use should be added. d) The registrant has not proposed tolerances for soybean forage and hay. Therefore, a label restriction prohibiting the feeding of treated forage and hay to livestock must be included on the label. A revised Section B is required.

Petitioner's Response: Submission of revised labels for Authority 4F and 75DF in which crop rotation is limited to corn (10 months), wheat (winter- 4 months, spring- 9 months) and soybeans (no restriction). A restriction prohibiting the feeding of treated forage and hay to livestock has been included on the label. The restriction for adjuvant use is not required for a preemergent herbicide as adjuvants are not used for this type of application.

CBTS's Conclusion: 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. CBTS concurs that the restriction for adjuvant use is not required for a preemergent herbicide as these compounds are primarily a concern for foliar applications.

Deficiency - Conclusion 3c (from Memo, G. Kramer 4/3/95)

3c. The nature of the residue in rotational crops can not be considered to be understood due to deficiencies in the characterization of bound residues. Minimal analysis was performed only on the 30 DAT samples. CBTS requests that registrant analyze the bound residues from the 364 DAT samples of barley straw (both phenyl- and triazole-labelled). The methods employed should include treatment with enzymes, surfactants, dilute acid and base and refluxing with 6 N acid and base.

Petitioner's Response: Submission of:

> Confined Accumulation Studies on Rotational Crops: F6285 Herbicide in Barley, Lettuce and Radish. MRID# 437617-02

The bound residues of 364 DAT barley straw, 364 DAT barley forage, 245 DAT barley grain, 364 DAT radish top, 367 DAT radish root and 364 DAT lettuce leaf were analyzed by successive treatment with: 1) sonication in methanol/water (1/1), 2) cellulase, 3) amylase, 4) pectinase, 5) protease, 6) decomplexing agents, 7) 6N HCl with refluxing, 8) 4.3N KOH and 9) sulfuric acid. The bound residues remaining after these treatments did not exceed 0.05 ppm and 10% of the TRR in any sample.

CBTS's Conclusion: The released residues in any fraction of any sample did not exceed 0.05 ppm and 10% of the TRR so that further analysis is not required. The nature of the residue in rotational crops is now considered to be understood. The major metabolites identified were 3-hydroxymethyl sulfentrazone, desmethyl des(difluoromethyl) sulfentrazone, sulfentrazone carboxylic acid/3-desmethyl sulfentrazone and methyl triazole (4-difluoromethyl-3-methyl-1H-1,2,4-triazol-5(4H)-one). Similar results were obtained in the soybean metabolism studies (Memo, G. Kramer 9/19/95).

Deficiency - Conclusion 4d (from Memo, G. Kramer 4/3/95)

4d. As noted above, tolerances are required for wheat grain, straw, forage and hay. 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 (see conclusion 12c). Also, the tolerance expression for wheat should be revised to incorporate the following language: "Tolerances are established for the indirect or inadvertent combined residues of..." Alternatively, the registrant may choose to withdraw the proposed tolerances for wheat RACs and include a prohibition against rotation to wheat on the sulfentrazone labels.

Petitioner's Response: Submission of a revised Section F in which tolerances for indirect or inadvertent residues are proposed for the herbicide sulfentrazone plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in/on:

Wheat Forage	--	0.10 ppm
Wheat Straw	--	0.10 ppm
Wheat Grain	--	0.10 ppm
Corn Fodder	--	0.20 ppm
Corn Forage	--	0.20 ppm
Corn Grain	--	0.10 ppm
Rice Straw	--	0.20 ppm
Rice Grain	--	0.10 ppm

CBTS's Conclusion: The correct language has been inserted into the tolerance expression. However, 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.**

Deficiency - Conclusion 9 (from Memo, G. Kramer 4/3/95)

9. CBTS will refer to the Metabolism Committee on the toxicological significance of metabolites once the deficiencies associated with plant metabolism studies have been addressed. 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 methodology, and storage stability data may be needed.

Petitioner's Response: none required

CBTS's Conclusion: All deficiencies pertaining to the nature of the residue in plants have been resolved. CBTS will refer the results to the HED Metabolism Committee on the toxicological significance of the sulfentrazone metabolites.

Deficiency - Conclusion 10b (from Memo, G. Kramer 4/3/95)

10b. An ILV of this method [P-2811M] was performed by ADPEN 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 2/16/95). 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: 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 to the EPA repository in RTP and a revised version of the proposed analytical enforcement method (P-2811M) as specified in conclusions 2-8 of the aforementioned Memo. Until the receipt of the standard and the revised method, the requirements for an analytical enforcement method will remain unfulfilled.

Deficiency - Conclusion 10d (from Memo, G. Kramer 4/3/95)

10d. A sample from the plant metabolism study was subjected only to the initial hydrolysis step of the proposed enforcement method (see conclusion 10a). Of the TRR, 96% was solubilized by this method. As the conjugated residues were shown to be released by acid hydrolysis with 1 N HCl in the plant metabolism study, CBTS can reach no conclusion on whether conjugated residues are released by the proposed enforcement method. Radiovalidation should be performed by running the entire method on samples from the plant metabolism study.

Petitioner's Response: Submission of:

> Radiovalidation of Residue Methodology for Sulfentrazone and 3-Hydroxymethyl Sulfentrazone in/on Soybean Seed. MRID# 437617-03

Using a soybean sample from the metabolism study, the initial extraction step of the proposed enforcement method (acetone/0.25N HCl reflux) step released 72% of the TRR. Residues of sulfentrazone and 3-hydroxymethyl sulfentrazone were both below 0.005 ppm. This experiment was repeated using a modified version of the method in which the initial extraction was performed in 1N HCl. Residues of sulfentrazone and 3-hydroxymethyl sulfentrazone were still both below 0.005 ppm. In the metabolism study, the initial extraction (methanol/water) released 77% of the TRR and 35% of the TRR (0.025 ppm) was identified as hydroxymethyl sulfentrazone and 2.5% (0.002) as sulfentrazone *per se*.

CBTS's Conclusion: The purpose of this radiovalidation 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 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 necessary.

Deficiency - Conclusion 11 (from Memo, G. Kramer 4/3/95)

11. No analytical method for meat, milk and eggs has been submitted by the registrant. Since no tolerances have been proposed for animal RACs, an analytical enforcement method for animals is not required at this time. If, however, the required ruminant feeding studies (see conclusion 15) demonstrate a potential for transfer of residues to meat or milk, then the registrant will be required to propose tolerances for these RACs and develop the appropriate analytical enforcement methodology. Any required enforcement methods for meat and milk will need successful ILVs and PMVs before being judged to be acceptable by CBTS.

Petitioner's Response: none required

CBTS's Conclusion: CBTS has determined that, based on the proposed tolerances, the results of the metabolism studies preclude the need for conventional feeding studies (see below). Meat and milk tolerances and analytical enforcement methodology for animal RACs are thus not required at this time.

Deficiency - Conclusion 12c (from Memo, G. Kramer 4/3/95)

12c. No data have been supplied on the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in corn and wheat RACs. The registrant must demonstrate the stability of sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in corn forage or silage 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. 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: These data will be submitted at a later date.

CBTS's Conclusion: This deficiency remains outstanding.

Deficiency - Conclusion 14b (from Memo, G. Kramer 4/3/95)

14b. Sulfentrazone and 3-hydroxymethyl sulfentrazone residues do not concentrate

in [soybean] processed commodities. Feed/feed additive tolerances for sulfentrazone and 3-hydroxymethyl sulfentrazone are thus not required for this petition. If, however, metabolites other than 3-hydroxymethyl sulfentrazone are determined to be of regulatory significance, then residue data for soybean processed fractions will be required for all such metabolites.

Petitioner's Response: none required

CBTS's Conclusion: If metabolites other than 3-hydroxymethyl sulfentrazone are determined to be of regulatory significance by the HED Metabolism Committee, then residue data for soybean processed fractions will be required for all such metabolites.

Deficiency - Conclusion 14c (from Memo, G. Kramer 4/3/95)

14c. CBTS has determined that a tolerance for aspirated grain fractions is not required as the observed residues in 'grain dust' appear to be the result of soil contamination (Memo, G. Kramer 9/1/94). The proposed tolerance for aspirated grain fractions should thus be withdrawn.

Petitioner's Response: Submission of a revised Section F in which the grain dust tolerance was withdrawn.

CBTS's Conclusion: Section B has been revised as requested. This deficiency is now resolved.

Deficiency - Conclusion 15 (from Memo, G. Kramer 4/3/95)

15. The maximum theoretical dietary burden for ruminants associated with soybeans is 0.011 ppm. Based on the results of the ruminant metabolism study, the registrant claims that a conventional feeding study is not required. The dietary burden used in the phenyl-labelled study, 4.9 ppm, is an exaggeration of 445X based on a maximum dietary burden of 0.011 ppm. The maximum tissue residue observed at this level was 0.013 ppm in kidney. However, CBTS has concluded that rotational crop tolerances are required to support rotation to wheat with a 4 month plantback interval. Based on the limited residue data, the theoretical maximum dietary burden associated with rotational wheat would be at least 0.30 ppm. Considering this dietary burden, the ruminant metabolism feeding level represented only a 16X exaggerated rate. CBTS thus concludes that a conventional ruminant feeding study will be required in order to support the establishment of rotational crop tolerances on wheat RACs. Alternatively, the registrant may choose to withdraw the proposed tolerances for wheat RACs and include a prohibition against rotation to wheat on the sulfentrazone labels. Due to the minimal transfer of residues at 445X, CBTS concludes that, based on the soybean seed tolerance only, a conventional feeding study is not required. If in the future, the registrant wishes to propose tolerances for soybean forage and hay, this conclusion will be reevaluated.

Petitioner's Response: 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 burden of 0.3 ppm (dairy) and 0.2 ppm (beef), the expected residues 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 should thus not be required.

CBTS's Conclusion: CBTS is willing to accept the registrant's argument that detectable residues would not result from a 10X dietary exposure. This deficiency is now resolved. 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.

Deficiency - Conclusion 6b (from Memo, G. Kramer 9/19/95)

6b. Provided that the storage stability of sulfentrazone and its metabolites can be demonstrated in corn grain and processed fractions, CBTS concludes that food/feed additive tolerances will not be required for rotational corn.

Petitioner's Response: Submission of:

> Storage Stability of Sulfentrazone and its Metabolites in/on Laboratory-Fortified Field Corn Processed Parts. MRID# 437617-06

Samples of corn refined oil, flour, meal and starch 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 after 3 and 6 months of storage. Each analysis included two freshly fortified controls. Samplers were analyzed by the corn analytical methods reviewed previously (Memo, G. Kramer 9/19/95). These methods were validated in corn meal, starch and oil at 0.25 ppm. The average recovery for sulfentrazone was 95 ± 6% (n=18); for 3-desmethyl sulfentrazone, 107 ± 7% (n=18); and for 3-hydroxymethyl sulfentrazone, 80 ± 6% (n=18). The results demonstrate that residues of sulfentrazone and its metabolites are stable during storage in corn processed substrates for up to 6 months at -18 °C.

CBTS's Conclusion: The samples from the processing study were stored for a maximum of 3 months. The registrant has demonstrated that residues of sulfentrazone and its metabolites are stable during storage in corn processed substrates for up to 6 months. These data were required to support the corn processing study in which residues were found not to concentrate in any processed fraction. CBTS thus concludes that food/feed additive tolerances will not be required for rotational corn. However, 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 corn processed fractions will be required for all such metabolites.

cc (with confidential appendix): PP#4F04407, Kramer, R.F.
cc (without confidential appendix): Circ.
RDI: TPT1 (3/12/96), R. Perfetti for R. Loranger (3/18/96), E. Zager (3/19/96)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

Substance Review

Page _____ is not included in this copy.

Pages 13 through 16 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

✓ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
