

MEMORANDUM

SUBJECT: PP#3F4215 -- Metsulfuron-methyl (Ally®) for Use in/on Grain Sorghum. DuPont's 12/16/94 Response to CBTS' 6/7/94 Memo. DP Barcodes: 211881, 211879. CBTS #'s 15092, 15093.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

THROUGH: Edward Zager, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

TO: Robert Taylor/Vickie Walters, PM 25
Fungicide-Herbicide Branch
Registration Division (7505C)

E.I. du Pont de Nemours and Company, Inc. has proposed the following tolerances for residues of metsulfuron methyl {methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]-amino]sulfonyl]benzoate} in/on grain sorghum:

Sorghum, Grain	0.1 ppm
Sorghum, Forage	0.3 ppm
Sorghum, Fodder	0.3 ppm
Sorghum, Hay	0.3 ppm

Deficiencies in the petition were outlined in our memo dated 6/7/94. DuPont has addressed these deficiencies in a submission dated 12/16/94.

DuPont also requests establishment of time limited tolerances for the use of Ally® Herbicide on grain sorghum.

Conclusions (pertaining to this memo only)

1. The proposed label has been revised to incorporate our suggested changes.
2. The nature of the residue in poultry is not understood. The registrant must conduct a poultry metabolism study. The dosing material should be parent and the dose level should be at least 10 ppm in the diet.
3. Stability of Metabolites A and A1 under frozen storage must be demonstrated in the various sorghum RAC matrices for at least 7.5 months.

Extraction of the sorghum RAC samples occurred up to

six weeks before final chromatographic analysis for metsulfuron methyl. The petitioner must demonstrate that metsulfuron methyl is stable in extracts for six weeks under storage conditions corresponding to the residue analyses.

4. Assuming residues remain below the LOQ, an additional three trials will be necessary in Regions 4, 5 and 7. If quantifiable residues are found, an additional six trials will be necessary (making a total of 12 trials). Trials should be carried out in Regions 4, 5(2), 6, 7, and 8.

If the registrant wishes to conduct two field trials in Region 8 only, he must demonstrate that either the proposed use is a minor use or that use of the herbicide is not probable outside the region. Supporting information must be reviewed by the Biological and Economics Analysis Division (BEAD).

5. A revised Section F has been submitted in which tolerances of 0.1 ppm, 0.2 ppm and 0.2 ppm have been proposed for sorghum grain, forage and fodder, respectively. The proposed tolerance of sorghum hay has been deleted. The Section F is now acceptable.
6. The need for a poultry feeding study and possible tolerances for poultry commodities will be assessed on receipt and evaluation of the poultry metabolism study.

Recommendation

CBTS continues to recommend against the proposed tolerances for reasons given in Conclusions 2 (poultry metabolism); 3 (storage stability); 4 (residue data); and 6 (poultry feeding study).

Sorghum grain can constitute up to 80% of the diet of poultry. For this reason CBTS is reluctant to recommend for any time-limited tolerance before evaluation of the poultry metabolism study. We understand that the decision to grant a time-limited tolerance is not in the purview of CBTS.

Detailed Considerations

Deficiencies given in our 6/7/94 memo are given with DuPont's response and CBTS' comments:

CBTS Deficiency #1a (Conclusion #1a from our 6/7/94 memo)

The proposed label contains the statement "Do not treat during the boot, flowering, or dough stages." The petitioner should submit a revised Section B which states "Apply only

before the boot stage" and "Do not use for forage or silage within 30 days of application."

CBTS Deficiency #1b

The proposed label specifies a minimum aerial spray volume of 1 gallon per acre (GPA). The petitioner must either submit a revised Section B in which the minimum spray volume is specified at 2 GPA or additional residue data from three side-by-side field trials should be submitted in which residues from 1 GPA are compared with corresponding residues from ground application or aerial application at rates >2 GPA. These side-by-side studies could be part of the additional field trials required in Conclusion 6.

DuPont Response

A revised Section B has been submitted in which the requested changes are incorporated.

CBTS Comment

These deficiencies are resolved.

CBTS Deficiency #3b

Sorghum grain is a poultry feed item, but no poultry metabolism study has been submitted. The petitioner should conduct a poultry metabolism study. The dosing material should be parent and the dose level should be at least 10 ppm in the diet.

DuPont Response

The registrant will conduct a new poultry metabolism study and will submit it to the Agency on/before June 30, 1998.

CBTS Comment

This deficiency remains, pending receipt and evaluation of the study.

CBTS Deficiency #5

There are no data to demonstrate storage stability of Metabolites A and A1 under frozen storage. Storage stability of both metabolites should be demonstrated in the various sorghum RAC matrices for at least 7.5 months.

Extraction of the sorghum RAC samples occurred up to six weeks before final chromatographic analysis for metsulfuron methyl. The petitioner must demonstrate that metsulfuron methyl is stable in extracts for six weeks under storage conditions corresponding to the residue analyses -- extracts are usually maintained at refrigeration temperatures (0°C).

DuPont Response

The registrant will conduct a new storage stability study (for metabolites A and A1) and will submit it to the Agency on/before December 31, 1996.

CBTS Comment

This deficiency remains, pending receipt and evaluation of the storage stability study. Note that stability in extracts must also be demonstrated.

CBTS Deficiency #6a

Data from six field trials showed no residues at or above the quantitation limit (LOQ). Additional residue data are needed. Assuming residues remain below the LOQ, an additional three trials will be necessary in Regions 4, 5, and 7 (see Attachment 1). If quantifiable residues are found, an additional six trials will be necessary (making a total of 12 trials). Trials should be carried out in Regions 4, 5(2), 6, 7, and 8.

DuPont Response

The proposed label is limited in geography to Region 8....We have previously conducted 3 trials in Region 8. Since Region 8 accounts for 29% of the sorghum produced in the US, a total of four studies are required. We will conduct two additional trials and will submit the results to the Agency on/before June 30, 1996.

[Attachment A] The currently proposed label for the low use rate of Ally (0.05 oz/acre) is for the control of just 3 weed species (pigweed, puncturevine, and velvetleaf) that are major weed problems within the area defined above. Sorghum areas to the east, south, and north of this area have generally different types of weed problems that are not well controlled by these low rates of "Ally" (grasses, cocklebur, morning glory, etc.).

CBTS Comment

Restrictions limiting the use of a pesticide to a specific geographical region are generally not allowed unless it is certain that the pesticide cannot be used for pest control in other regions or it is determined that the proposed use is a minor use. Other than for low dietary intake crops, which do not include sorghum, BEAD must determine whether either of the above two conditions are satisfied. DuPont should submit relevant information to BEAD (via the PM). In the absence of a positive response from BEAD, this deficiency remains.

CBTS Deficiency #6b

If residues remain below the LOQ of metsulfuron methyl and the LOQ of the combined metabolites A and A1, appropriate tolerances would be 0.1 ppm for grain and 0.2 ppm for forage and fodder. A revised Section F should be submitted in which these tolerances are proposed. Also, since sorghum hay is no longer a feed item in Table II of Subdivision O (April, 1994) and hay residues do not exceed those in forage, the tolerance for hay can be deleted.

DuPont Response

A revised Section F has been submitted with the requested changes.

CBTS Comment

This deficiency is resolved.

CBTS Deficiency #8

.....The need for a feeding study and tolerances for poultry commodities will be assessed upon evaluation of the requested metabolism study.

CBTS Comment

This deficiency remains, pending receipt and evaluation of the poultry metabolism study.

cc: RF, Circu., Mike Flood, E. Haeberer.
7509C:CBTS:Reviewer(MTF):CM#2:Rm804P:703-305-7990:typist(mtf):4/5/95.
RDI:SectionHead:ETHaeberer:4/3/95:BranchSeniorScientist:RALoranger:
4/3/95:ActingBranchChief:EZager:4/4/95.