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MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: PP#3F4215 -- Metsulfuron-methyl (Ally®) for Use in/on Grain Sorghum. Evaluation of Analytical Methods and Residue Data.

DP Barcodes: D191296, D191298. CBTS #'s 11868, 11869. MRID #'s 427590-01, 427590-02.

FROM: Michael T. Flood, Ph.D., Chemist Mike Flood 6/7/94
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

THROUGH: Esther Saito, Chief Esther Saito
Chemistry Branch I -- Tolerance Support
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TO: Robert Taylor/Vickie Walters, PM 25
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With letter dated April 8, 1993, E.I. du Pont de Nemours and Company, Inc. (DuPont) is proposing the following tolerances for residues of metsulfuron methyl (Ally Herbicide) in/on grain sorghum:

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

The chemical name for metsulfuron methyl is methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]-sulfonyl]benzoate.

Tolerances for the combined residues of metsulfuron methyl and its metabolite methyl 2-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate [A1] are established under 40 CFR 180.428(a) for barley, grain; barley, green forage; barley, hay; and barley, straw at 0.05 ppm, 5.0 ppm, 20 ppm and 0.1 ppm, respectively; for grass, fodder; grass, forage; and grass hay at 15.0 ppm; and for wheat, grain; wheat, green forage; wheat, hay; and wheat, straw at 0.05 ppm,

5.0 ppm, 20.0 ppm and 0.1 ppm, respectively.

Tolerances are established only for metsulfuron methyl, per se, under §180.428(b) for the fat, meat, mbyp of cattle, goats, hogs, horses and sheep at 0.1 ppm; for the kidney of cattle, goats, hogs, horses and sheep at 0.5 ppm; and for milk at 0.05 ppm. There are currently no food or feed additive tolerances.

A tolerance of 0.05 ppm is pending for metsulfuron methyl in/on sugarcane (PP#3E4094).

Conclusions

1a. 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."

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.

2a. The nature of the residue in plants is adequately understood. The residue to be regulated is metsulfuron methyl, per se, and its two metabolites (A and A1). (Metabolite A is converted to and measured as Metabolite A1.)

2b. The nature of the residue in ruminants is adequately understood for purposes of this petition. The residue to be regulated is metsulfuron methyl, per se.

Any subsequent use which results in a significant contribution to the ruminant dietary intake of the herbicide will require submission of a new ruminant metabolism study in which the triazine portion of the molecule is labeled, the dose level is appropriate (≥ 1X rate and at least 10 ppm) and residues in muscle, fat, kidney, liver and milk are fully characterized.

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.

4a. Regulatory methods are available for enforcement of tolerances for metsulfuron methyl and its A and A1 metabolites in sorghum. A regulatory method is available for enforcement of tolerances in bovine tissue and milk.

4b. Metsulfuron methyl is not recovered under FDA's multiresidue protocols.

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).

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.

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.

7. Metsulfuron methyl and its metabolites do not concentrate in processed sorghum products, nor do they concentrate in grain dust (aspirated grain fractions).

8. Existing tolerances on meat and milk will not be exceeded due to the proposed use in/on sorghum. The

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

9. An International Residue Limits Status sheet is appended to this review (Attachment 2). There are no Codex, Canadian, or Mexican maximum residue limits for metsulfuron methyl in/on grain sorghum. Compatibility is therefore not an issue.

Recommendation

CBTS recommends against the proposed tolerances for reasons given in Conclusions 1a,b (revised Section B); 3b (poultry metabolism); 5 (storage stability); 6a (additional residue trials); 6b (Section F) and 8 (possible need for poultry tolerances).

Detailed Considerations

Manufacture and Formulation

The manufacturing process was summarized in J. Worthington's 7/1/86 memo for PP#6G3398. No problems with impurities were anticipated.

The structure of metsulfuron methyl and two of its metabolites is given in Attachment 1 to this memo.

The formulation to be used is Du Pont's ALLY® Herbicide (EPA Reg. No. 352-435), a dry flowable granular herbicide containing 60% active ingredient.

Proposed Use

Ally herbicide is recommended to be applied at 1/20 oz/A (0.03 oz ai/A, or 0.0019 lb ai/A) in tank mixture with 2,4-D amine for use on irrigated or dryland grain sorghum in CO, KS, NE, NM, OK and TX. For ground application use 10-30 GPA. For aerial applications apply at 1 to 5 GPA. Do not exceed one application per year. Do not use on grain sorghum grown for seed production or syrup. Do not use on forage sorghum.

As discussed in a later section, either the label must be revised to specify a minimum aerial application spray volume of two gallons per acre or additional residue data must be submitted.

Ally is not to be applied during the boot, flowering, or dough stages. For simplicity and greater clarity, a revised Section B should be submitted which states that the herbicide

should only be applied before the boot stage. Also, the label should specify a PHI of 30 days for forage/silage.

Minimum rotation intervals from 1 to 22 months are specified explicitly for wheat, field corn, soybeans and cotton. For all other crops, the minimum rotation interval is 34 months.

Nature of the Residue

Plants. Plant metabolism of metsulfuron methyl has been reviewed by J. Worthington (PP#3G2834, memo of 4/13/83), P. Errico (PP#4F3127, memo of 6/21/85) and K. Arne (PP#4F3127, memo of 11/4/85). Metabolism studies were conducted on wheat (3 studies) and barley. The nature of the residue is understood for cereal grains. The residue to be regulated consists of metsulfuron methyl and its metabolites methyl 2-[[[[(4-methyoxy-6-methyltriazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-beta-D-glycopyranosylbenzoate (metabolite A) and methyl 2-[[[[(4-methoxy-6-methyltriazin-2-yl)amino]carbonyl]amino]sulfonyl]-4-hydroxybenzoate (metabolite A1). The latter metabolite can be formed from metabolite A through enzymatic hydrolysis. In all these studies, total residues declined with time, as did the percentage of identified residue. The percentages of metabolites in the total residue increases as the percentage of metsulfuron methyl itself declines. No additional studies are needed for this proposed use.

Animals. Metabolism studies for metsulfuron methyl in rat and goat and metabolite A in goat were reviewed by P. Errico in his memo of 6/21/85. The residue to be regulated was determined to be parent only. Metsulfuron methyl was the major component in milk. Saccharin was the major component in liver and was judged not to be of concern. Levels in other tissues were ≤20 ppb. However, the dose level of 3.4 ppm in the diet was only about equal to the calculated dietary intake (for PP#4F3127), and there are no studies in which the triazine moiety was labeled. Liver and milk were the only tissues characterized, and a sample chromatogram was submitted from the milk analysis only. A subsequent petition (PP#8F3647, for grass forage, hay and fodder) resulted in a potentially higher contribution to the diet of ruminants -- 15 ppm (J. Garbus, memo of 3/30/89). The question arises whether a new ruminant metabolism study is warranted. Since the proposed use in/on sorghum commodities would result in no significant increase in the maximum dietary intake of metsulfuron methyl, a new ruminant metabolism study will not be required for this petition. Any subsequent use which results in a significant contribution to the dietary intake of the herbicide will require submission of a new ruminant metabolism study in which the triazine portion of the molecule is labeled, the dose level is appropriate (≥ 1X rate and at least 10 ppm) and residues in muscle, fat, kidney, liver and milk are fully characterized.

Sorghum grain can constitute up to 80% of the diet of poultry. No poultry metabolism study has heretofore been submitted. Since the time of the first petition (PP#4F3127), our data requirements have changed. We now require animal metabolism studies if the commodities for which tolerances are sought are animal feed items whether or not quantifiable residues are expected in animal tissues. Depending on the results of the metabolism study and the expected residue levels in the animal feed, a feeding study may not be required. However, a poultry metabolism study should be submitted for this petition.

Analytical Method

Metsulfuron methyl residues were determined in sorghum grain, forage, hay, stover and processed fractions using DuPont's method AMR 1797-90, Revision No. 1: "Analytical Method for the Quantitation of DPX-T6376 (ally) in Wheat Grain and Straw," 1991.

Sorghum grain, forage, hay and stover samples (20 g grain, 7 g for the other samples) are extracted with 100 mL "alkaline (pH 8.0) buffer"/methanol solution (75:25, v/v). Processed sorghum samples(20 g) are extracted with 100 mL 20% methanol/K_2HPO_4 buffer (pH 8). Each extract is diluted in 300 mL water, adjusted to pH 10 with KOH and partitioned with 100 mL dichloromethane (DCM). The DCM phase is discarded, the remaining sample acidified to pH ≤2 and the solution reextracted with DCM. The DCM solution was concentrated to about 5 mL, an equal volume of the original extracting solution added, and the solution concentrated to remove DCM. The sample is then reconstituted to 50 mL with the 20% MeOH/K_2HPO_4 and the solution acidified to pH 2.5-3.5 with 10% phosphoric acid. After filtration the sample is cleaned up and analyzed by two HPLC chromatographs. The quantitation limit is based on spike recoveries and is reportedly 0.050 ppm for sorghum grain and 0.10 ppm for forage hay and stover. For processed commodities the quantitation limit for process and steep water fractions was 0.02 ppm and 0.050 ppm for all other fractions.

Metabolites A and A1 were determined by a procedure derived from Dupont's AMR 238-84 and AMR 1934-91, Revision 1. The immobilized enzyme hydrolysis procedure of the latter method was replaced by the β-glucosidase hydrolysis of AMR 238-84. Samples (20 g) are homogenized with 100 mL of 20% methanol/K_2HPO_4 (pH 8) and centrifuged. A measured aliquot was removed and adjusted to pH 6.0 with 10% phosphoric acid solution. About 100 mg β-glucosidase is added to convert any Metabolite A to A1. After hydrolysis, water is added, the pH adjusted to 2.5-3.5, and the sample partitioned with DCM. The DCM is concentrated to 2 mL, 5 mL extracting solution added, and the sample concentrated again to remove DCM. The final volume is adjusted to 25 mL, and a 5 mL aliquot is removed, acidified and stored in a freezer for 15 minutes. Analysis is by HPLC with UV detection. The limit of

quantitation is the same as for the metsulfuron methyl method. The methods for the metabolites in the RACs and processed commodities are identical.

Percent recoveries of metsulfuron methyl from sorghum grain, forage, hay and stover are given in Table VI of DuPont Report No. AMR 2005-91 (MRID #427590-01). At fortification levels varying from 0.02 to 0.17 ppm, recoveries in grain averaged 81±11%; at fortification levels varying from 0.048 to 0.10 ppm, recoveries in forage averaged 89±12%; at fortification levels varying from 0.096 to 0.30 ppm, recoveries in hay averaged 90±30%; and at fortification levels varying from 0.15 to 0.36 ppm recoveries in stover averaged 83±11%. The high variability observed in the hay recoveries was due to one very high recovery (146%). One sample per RAC from each of the six field trial sites was used in the fortification study.

Recoveries of Metabolites A and A1 from sorghum RACS are given in Table VII of the same report. At fortification levels varying from 0.045 to 0.18 ppm, recoveries from grain averaged 96±19%; at fortification levels varying from 0.10 to 0.60 ppm, recoveries from forage averaged 107±20%; at fortification levels varying from 0.10 to 0.13 ppm recoveries from hay averaged 114±9%; and at fortification levels varying from 0.10 to 0.51 ppm, recoveries from stover averaged 109±12%. From page 21 of the report it would appear that samples were fortified with Metabolite A, the glucose conjugate, which is converted to Metabolite A1 by the β-glucosidase hydrolysis; however, the submitted chromatograms were only from samples fortified with Metabolite A1.

Percent recoveries of metsulfuron methyl from sorghum grain and both dry- and wet-milled processed fractions are given in Table III of DuPont's Report No. AMR 2006-91 (MRID #427590-02). Recoveries from whole grain at fortification levels of 0.05 and 0.047 ppm averaged 106%. Recoveries from bran, small grits, grits and flour (dry-milled fractions) at fortification levels 0.05-0.20 ppm averaged 85.8±14.8%. Recoveries from grain dusts of sizes ranging from less than 420 μ to 2540 μ at fortification levels 0.05-0.20 averaged 91.9±23.3%. Recoveries from steep water, germ, coarse gluten, starch, gluten, process water and bran (wet-milled fractions) at fortification levels ranging from 0.005-0.23 ppm averaged 97±14.7%. Corresponding recoveries of Metabolites A and A1 are given in Table IV. Recoveries from dry-milled fractions at fortification levels 0.05-0.1 ppm averaged 91±23%; recoveries from wet-milled fractions at fortification levels 0.05-0.2 averaged 92±10%. Again, it is not clear that Metabolite A was used in the validation.

Two regulatory analytical methods are given in PAM II for metsulfuron methyl and its metabolites:

"High-Performance Liquid Chromatographic Determination of Metsulfuron Methyl Residues in Crops," L.W. Hershberger, DuPont Document No. AMR-104-82, Revision B, February 20, 1986. [PAM II, Method I]

Residues of metsulfuron methyl are extracted with acetone-aqueous buffer solution. The extract is diluted with basic buffer and the solution extracted with methylene chloride, which is discarded. The aqueous solution is acidified with HCl and partitioned with toluene. The toluene solution is purified on a silica Bond Elut cartridge. Metsulfuron methyl is determined by normal-phase HPLC with photoconductivity detection.

"High-Performance Liquid Chromatographic Determination of Residues of Metsulfuron Methyl Metabolites A and A1 in cereal Grain Crops," L.W. Hershberger, Du Pont Document No. AMR-238-84, Revision B, March 27, 1986. [PAM II, Method III]

After extraction with methanol and concentration to small volume, aqueous buffer is added and the resulting solution made basic with NaOH. The solution is washed with chloroform, which is discarded. Metabolite A is hydrolyzed to Metabolite A1 with β-glucosidase. The solution is acidified and partitioned with chloroform. The chloroform solution is purified on a silica Bond Elut cartridge. Metabolite A1 is determined using normal phase HPLC with UV detection. This method does not distinguish between metabolites A and A1.

A regulatory method is available for enforcement of tolerances in bovine tissue and milk (Method II in PAM II).

We conclude that adequate methods are available for enforcement in PAM II.

Recoveries of metsulfuron methyl under FDA's multiresidue protocols are "not likely". (Pestrak, December, 1989)

Storage Stability

Samples from the crop field trials were frozen as soon as feasible after sampling and maintained under frozen conditions until analysis at Enviro-Test Laboratories in Edmonton, Alberta. RAC samples were extracted within 6 months of storage (for analyses for parent) and within 7.5 months of storage (for analyses for metabolites). Analyses for metabolites occurred within a few days of extraction, but corresponding analyses for parent were done up to six weeks after initial extraction. 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).

The intervals between grain sampling and analyses of processed sorghum fractions varied from 7 to 7.5 months. No storage stability data are available for processed grain fractions. However, since our updated Table II to our guidelines no longer lists sorghum processed fractions as feed items, storage stability data will not be required.

No new storage stability data are reported in this petition. The petitioner has submitted results from a storage stability study on wheat grain, straw and green forage to support analyses in RACs and processed fractions. Metsulfuron methyl is stable in grain for up to 64 months, in straw for up to 49 months, and in forage for up to 46 months. Preliminary data from this study were reviewed by K. Arne in his 11/4/85 memo for PP#4F3127 and found acceptable. However there appear to be no data to demonstrate stability of metabolites A or A1 under frozen storage conditions. Storage stability of both metabolites should be demonstrated in the various sorghum RAC matrices for 7.5 months.

Magnitude of Residue

Residue data appear in the following report:

"Magnitude of Residues of Metsulfuron Methyl in Grain Sorghum Forage, Hay and Grain Following Application of Ally® Herbicide;" V. Gaddamidi, P. Devine; 6/8/92; Performing Laboratories: DuPont Agricultural Products, Wilmington, DE, Project ID: AMR 2005-91, Enviro-Test Laboratories, Edmonton, Alberta, Project ID 91-P1516.REP. (MRID # 427590-01)

Crop field trials were held in six states. Ally® Herbicide was ground applied at either 0.03 oz ai/A or 0.06 oz ai/A in NC, KS, OK and CA. In a field trial held in TX, one treated plot received a ground application at 0.03 oz ai/A, another plot was treated aerially at a rate of 0.0265 oz ai/A (2 GPA). In a field trial held in MO the herbicide was applied aerially at a rate of 0.03 oz ai/A.

The herbicide was applied to grain sorghum at the 10-leaf stage. Samples of forage were collected about 30 days after application, and additional forage was collected for conversion to hay. Forage was converted to hay by air drying for 6 days. At grain maturity (66-97 days after application -- average 84 days), samples of sorghum seed and stover were collected. All residues of metsulfuron methyl and its metabolites were below the limits of quantitation -- 0.05 ppm for grain, 0.10 ppm for forage, hay and stover. Sample chromatograms have been submitted.

The residue data support the proposed tolerances, but since the LOQ's for metsulfuron methyl and the combination Metabolites A and A1 are each 0.05 ppm, the appropriate tolerances are 0.1

ppm for the combined residues in grain and 0.2 ppm for the combined residues in hay, forage and fodder (stover). A revised Section F should be submitted in which these tolerances are proposed. Also, since our updated Table II of Subdivision O (April, 1994) no longer lists sorghum hay as a feed item and hay residues do not exceed those in forage, the tolerance for hay can be deleted.

The submitted residue data are acceptable, but additional data are needed in accordance with our recent guidance document (June, 1994) concerning numbers of field trials. Assuming residues remain below the quantitation limit, an additional three trials will be necessary (total = 9). Suggested geographic regions are Regions 4, 5 and 7. (Regions are defined in Attachment 1). If quantifiable residues are found, an additional six trials will be necessary (total = 12). Trials should be carried out in Regions 4, 5 (2), 6, 7 and 8.

The proposed label permits aerial applications in spray volumes/acre of 1-5 GPA. At this time the minimum spray volume not necessitating aerial/ground side-by-side trials is 2 GPA (12/6/91 letter from R.S. Quick to R. Holt, DuPont). Unless the label is revised to specify a minimum volume of 2 GPA, the petitioner must conduct three side-by-side field trials in which ground application is compared with aerial application using 1 GPA spray volume. These side-by-side studies could be part of the additional field trials required above.

Processing Study

Processing data have been submitted in the following report:

"Magnitude of Residues of Metsulfuron Methyl in the Processed Fractions of Sorghum Seed Following Application of Ally® Herbicide;" V. Gaddamidi, P. Devine; 6/25/92; Performing Laboratories: Du Pont Agricultural Products, Wilmington, DE, Project ID AMR 2006-91; Engineering Biosciences Research Center, Texas A&M University, College Station, TX, Project ID #ALLY-2006-91; Enviro-Test Laboratories, Alberta, Canada, Project ID 91-P1517. (MRID # 427590-02)

In a field trial held in MS, sorghum was treated with postemergence broadcast spray of Ally® Herbicide in one application at 0.06 oz/A (2x). Another plot was treated at 4x. Grain was harvested 28 days later, and samples from the highest rate were processed at Texas A&M. Grain was dry-milled into bran, small grits, grits and flour and wet-milled into grain dust (2540 μ, 2030 μ, 1190 μ, 841 μ, 420 μ, <420 μ), steep water, germ, coarse gluten, starch, gluten, process water and bran. (Grain dust is not, strictly speaking, a processed fraction, for it rises from natural abrasion during storage and handling.)

Neither metsulfuron methyl nor the combined residues of Metabolites A and A1 exceeded 0.05 ppm. No concentration of residues was observed. Sample chromatograms are included in the report.

Meat, Milk, Poultry and Eggs

According to our updated livestock feeds table (Table II for Subdivision O of the Pesticide Assessment Guidelines), sorghum grain can constitute 80% and 60% of the diet of beef and dairy cattle, respectively, and 80% of the diet of poultry. Forage can constitute up to 90% and 75% of the diets of beef and dairy cattle, respectively. The corresponding percentages for fodder (stover) are 20% and 10%. Finally, aspirated grain fractions can constitute up to 20% of the diet of either beef or dairy cattle.

A cattle feeding study was reviewed in P. Errico's 6/21/85 memo and K. Arne's 11/4/85 memo for PP#4F3127. Existing tolerances for meat and milk were compatible with a diet containing 15 ppm metsulfuron methyl from grass hay or forage (PP#8F3647, J. Garbus, memo of 3/30/89). Replacement of grass hay or forage, having tolerances of 15 ppm, with sorghum grain, forage or fodder, having proposed tolerances ≤0.3 ppm could only result in a lowering of the dietary intake of metsulfuron methyl. Hence, existing tolerances on meat and milk will not be exceeded from the proposed use.

No poultry feeding study has been submitted. Depending on the results from the requested metabolism study, such a feeding study may not be necessary.

Other Considerations

An International Residue Limits Status sheet is appended to this review. There are no Codex, Canadian or Mexican maximum residue limits for metsulfuron methyl in/on grain sorghum. Compatibility is not an issue.

Attachments:
1. Geographic Regions Definitions.
2. International Residue Limits Status Sheet.

cc: RF, Circu., PP#3F4215, Mike Flood, E. Haeberer.
7509C:CBTS:Reviewer(MTF):CM#2:Rm804P:703-305-7990:typist(mtf):6/3/94.
RDI:SectionHead:ETHaeberer:6/3/94:BranchSeniorScientist:RALoranger:
6/3/94.

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