Dicamba Reg Std File

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MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Subject: **PP# 6F4604 - DICAMBA (BANVAL®) ON COTTON, ASPARAGUS, GRASS FORAGE AND HAY, AND WHEAT FORAGE AND HAY.**
Review of Crop Field Trial Data for Amended Registrations for Use on Cotton, Asparagus, and Grass Forage and Hay.
Review of Residue Data and Analytical Method for Use on Wheat Forage and Hay.
CHEMICAL CODES 029802, 029806, AND 128931.
(MRID #s 428832-01, 438140-01, 438140-01, 432745-01, and 433707-01) [CBTS #s 16431, 16432, 16433, and 16434]
{DP Barcodes D220469, D220471, D220473, and D220430}

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support

To: D. McCall, Acting Section Head
Risk Characterization and Analysis Branch

Thru: E. Zager, Acting Branch Chief
Chemistry Branch I - Tolerance Support

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- REVISE DIRECTIONS FOR USE
- NEW CONFINED ROTATIONAL CROP STUDY
- ADDITIONAL CROP FIELD TRIALS FOR WHEAT FORAGE AND HAY, AND COTTON GIN BYPRODUCTS
- RUMINANT FEEDING STUDY
- REVISE TOLERANCES

INTRODUCTION

Sandoz Agro, Inc., has submitted crop field trial residue data to support amended registrations and [sic] tolerances for its herbicide dicamba, trade named Banval® and Clarity®, (salts or esters of 3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid in/on asparagus and cottonseed at 3 ppm, cottonseed meal at 6 ppm, grass forage at 400 ppm, grass hay at 250 ppm, wheat forage at 80 ppm, and wheat hay at 20 ppm. To support this petition and respond to the dicamba (SRR) Reregistration Standard (June 30, 1989) Sandoz has previously submitted new product chemistry

data for the TGAI, ruminant and poultry metabolism studies, confined rotational crop studies, magnitude of the residue data for asparagus, wheat forage and hay, and grass forage and hay. These data have been reviewed by CBRS during the past several years, and will be briefly summarized in this review.

CONCLUSIONS

1. CBTS Conclusion on **Product Chemistry/Chemical Identity**

After reviewing the product chemistry data for the 86% TGAI CBTS concludes that the impurities present in the TGAI are not expected to be a residue problem in cottonseed, asparagus, grass forage and hay, and wheat forage and hay when the TGAI is formulated into Banval® or Clarity® and used as directed. CBTS reiterates that there are no concerns for dioxin or nitrosamine levels in the TGAI.

2. CBTS Conclusions on the **Directions for Use/Labeling**

a. The petitioner has proposed an adequate set of directions for use of Clarity Herbicide and Banval SGF Herbicide on cotton fields in the spring.

b. CBTS considers spray applications of < 2 gallons per acre in mid to late season applications to be an ultra low volume use, thus, additional crop field trial residue data are necessary. The petitioner has the option of submitting a revised label for Banval Herbicide (DMA salt of dicamba) proposing aerial applications from 2 to 10 gallons/acre, or generating additional crop field trial data from a 1 gallon spray per acre for the mid to late season uses; ie, on the grass forages and hay, wheat forage and hay, and asparagus.

c. Since the petitioner has not provided residue data to support the proposed use of Banval Herbicide on barley and oats forage and hay, the petitioner has the options of removing these crops from the label, or submitting an adequate amount of varietal and geographically representative field trial data for barley and oats forage and hay, or submitting sufficient crop field trial residue data for corn forage, wheat forage, and another cereal grain forage to support a crop group tolerance for the forage, fodder, and straw of cereal grains (Crop Group XVI).

d. The petitioner has proposed an adequate set of directions for use of dicamba on asparagus provided the aerial application directions are changed to remove directions for an ultra low volume application, or the petitioner generates sufficient additional magnitude of the residue data to support an ultra low volume application on asparagus.

e. In absence of adequate rotational crop data CBTS suggests that the petitioner propose rotational crop restrictions on all current dicamba labels to limit rotation to only those crops that have established tolerances.

3. CBTS Conclusion on the **Nature of the Residue - Plants**

CBTS reiterates that the nature of the dicamba residue on cottonseed, asparagus, wheat, and grasses is adequately understood. The residues of concern in asparagus are dicamba and its 3,6-dichloro-2-hydroxybenzoic acid; while in cottonseed, grasses, and wheat the residues of concern are dicamba and its 3,6-dichloro-5-hydroxybenzoic acid metabolite.

4. CBTS Conclusion on the **Nature of the Residue - Livestock**

CBTS reiterates that the nature of the residue in ruminants and poultry is adequately understood. The residues to be regulated are dicamba and its 3,6-dichlorosalicylic acid (DCSA, or 3,6-dichloro-2-hydroxybenzoic acid).

5. CBTS Conclusion on the **Confined Accumulation Studies on Rotational Crops**

CBTS reiterates that the nature of the residue in confined rotational crop is **not** adequately understood. The petitioner should consult the EPA document dated March 23, 1993, titled "Guidance on How to Conduct Rotational Crop Studies."

6. CBTS Conclusions on the **Residue Analytical Method**

a. CBTS reiterates that the ILV data are acceptable to support an Agency tolerance method validation (TMV) for method AM-0691B-0593-3.

b. The petitioner has presented an adequately validated capillary EC-GC residue analytical method to gather the magnitude of the residue crop field trial residue data. While CBTS will initiate a request to ACB/BEAD for a TMV on method AM-0691B-0593-3, the results of the TMV will not be a bar to a favorable recommendation on tolerances.

c. CBTS notes there are adequate enforcement methods available to FDA and the states in PAM-II for determination of residues of dicamba and its metabolites.

7. CBTS Conclusion on **Storage Stability**

CBTS reiterates that the petitioner has presented adequate frozen storage stability data for wheat, asparagus, and sorghum. Residues of dicamba and its 5-hydroxy metabolite are stable for 10-12 months of frozen storage in wheat forage and hay, and for at least 4-5 months of frozen storage in sorghum and asparagus. CBTS concludes that these data are adequate to support the magnitude of the residue data in this petition.

8. CBTS Conclusions on **Magnitude of the Residue - Crop Field Trials**

a. The petitioner has presented an adequate amount of geographical representative crop field trial residue data for the

use of dicamba on asparagus. The data show that when dicamba is formulated into Banval and used as directed residues will exceed the established 3 ppm tolerance. Since the petitioner states in the cover letter he wishes a national use, CBTS will need a revised Section F proposing a 3.5 ppm tolerance on asparagus for 40 CFR §180.227(b) for dicamba and its 2-hydroxy metabolite and at the same time deleting the 3 ppm dicamba tolerance on asparagus in 40 CFR §180.227(a).

b. The petitioner has presented an adequate number and amount of varietal data on grasses to support a crop group tolerance. The petitioner needs to submit a revised Section F proposing a tolerance for total residues of dicamba for the grass forage, fodder, and hay crop group (crop group XVII). The data show that when dicamba is formulated into Banval and used as directed residues will not exceed the proposed 400 ppm tolerance on grass forage at 0 day PHI and 250 ppm on grass hay at 7 days PHI.

c. In a memorandum dated March 11, 1996, (Barcode # D207649, L. Cheng) CBRS concluded that an appropriate tolerance for total residues of dicamba for grass hay would be 600 ppm based on residues in grass hay at zero days. The petitioner made no proposal for a PHI for grass hay in the CBRS action which is why CBRS chose a tolerance level for hay based on the zero day data. In this amended use request, however, the petitioner is proposing a 7 day PHI for grass hay. CBTS now recommends that a tolerance level of 250 ppm for total residues of dicamba in/on grass hay would be appropriate when a PHI of 7 days is prescribed.

d. The petitioner needs to generate dicamba magnitude of the residue data from 13 additional wheat forage and hay field trials. For the existing 7 wheat forage trials the petitioner needs to identify the Region where each of these trials was performed. In total, the petitioner needs residue data from 20 wheat forage and hay field trials as follows: 1 from Region II, 1 from region IV, 5 from Region V, 1 from Region VI, 5 from Region VII, 6 from Region VIII, and 1 from Region XI. The additional dicamba wheat forage/hay crop field trials should be proportioned between winter and spring wheat planting reflecting the actual acreage planted.

e. CBTS considers residue data from the use of additional formulations on wheat forage as supporting amended registrations, not as additional field trials. The petitioner needs to have 3/4 of the number of trials as required for the first formulation, thus for each additional dicamba formulation to have a use on wheat the petitioner will need 8 additional trials for a total of 15 field trials to support the requested additional registrations for use on wheat.

f. CBTS defers judgement on the adequacy of these data and the proposed total dicamba tolerances on wheat forage at 80 ppm and on wheat hay at 20 ppm until the petitioner has presented the requested additional crop field trial residue data to support

the use of the DMA formulation and additional data to support the other formulations.

g. Since the petitioner is proposing a geographical restriction for the amended use on cotton to west of the Rockies and since climatic conditions in the South favor spring weed growth and limit cultivation techniques, CBTS concludes these data are adequate to support an amended registration use on cotton for cottonseed, but not cotton gin byproducts commonly called gin trash. Total residues of dicamba on cottonseed are not expected to exceed the established tolerance of 3 ppm when formulated into Banval and used as directed.

h. CBTS has no dicamba cotton gin trash residue data from the fall application of 2 lbs ai/acre of dicamba in order to establish a dicamba tolerance on the rac gin byproducts. The petitioner needs to conduct 6 additional dicamba cotton field trials for residues on gin trash from the 2 lbs ai/acre fall application. These trials should be concentrated in Regions IV, VIII, and X. To produce cotton gin trash the cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residues from the ginning process. At least 3 field trials for each type of harvesting (stripper and picker) are needed. The petitioner will need to propose a dicamba tolerance on cotton gin byproducts in a revised section F once the field trials are completed.

9. CBTS Conclusions on **Magnitude of the Residue - Processed Food/ Feed**

a. Table II (September 1995) does not list any processed asparagus commodities, thus no dicamba asparagus processing study is required.

b. Table II (September 1995) does not list any processed grass commodities, thus no dicamba grass processing study is required.

c. While no processing study is required for use on wheat forage and hay, the petitioner has previously presented a wheat processing study that had detectable residues in the grain from an exaggerated use rate which showed no concentration of dicamba and its 5-hydroxy metabolite in wheat processed commodities. CBTS reiterates that no food or feed additive dicamba tolerances, or Section 701 maximum residue limits (MRLs) are necessary for processed wheat commodities. CBTS notes that while the wheat processing study did not present residue data for the aspirated grain fractions, this issue is being handled in the dicamba reregistration by SRRD.

d. CBTS reiterates that cottonseed meal is not a ready-to-eat (RTE) feedstuff. CBTS concludes that a revised Section F needs to be submitted proposing a Section 701 MRL for total residues of dicamba on cottonseed meal at 5 ppm. The feed additive 409 dicamba tolerance on cottonseed meal at 6 ppm need to be with-

drawn. Food/feed additive tolerances, or Section 701 MRLs on other cottonseed processed commodities are not required.

10. CBTS Conclusions on **Magnitude of the Residue - Meat/Milk/ Poultry/Eggs**

a. The petitioner will need to conduct an supplementary bovine feeding study using a 1000 ppm feeding level to cover the potential dietary burden of 965 ppm in dairy cows. The feeding of dicamba should be for at least 30 days, or until residues plateau in milk. Data should also be collected during a depuration period. Once the supplemental feeding study has been completed the petitioner will need to submit a revised section F proposing new numerical dicamba tolerances for milk; and meat, fat, and meat byproducts (including kidney and liver) for cattle, goats, hogs, horses, and sheep.

b. The are no poultry feedstuffs associated with this petition.

11. CBTS Conclusion on **Harmonization of Tolerances**

Since there are no Codex MRLs, compatibility is not a problem. Compatibility cannot be achieved with the Canadian negligible residue limits or with Mexican tolerances.

RECOMMENDATION

CBTS cannot at this time recommend for the requested amended registrations and proposed tolerances for residues of dicamba and its metabolites on asparagus at 3 ppm, cottonseed at 3 ppm, cottonseed meal at 6 ppm, grass forage at 400 ppm, grass hay at 250 ppm, wheat forage at 80 ppm, and wheat hay at 20 ppm for the reasons cited above in the Executive Summary and further described in Conclusions 2, 8, and 10.

A DRES analysis should not be initiated at this time.

DETAILED CONSIDERATIONS

BACKGROUND

Tolerances have been established for dicamba and its 5-hydroxy metabolite on asparagus at 3 ppm resulting from a regional registration for California, Washington, and Oregon (40 CFR §180.227(a)). Tolerances have been established for wheat, oats, and barley grain; and wheat, oats, and barley straw at 0.5 ppm. There are existing dicamba tolerances in 40 CFR § 180.227(a) for grass hay, pasture, and rangeland at 40 ppm. Secondary tolerances for dicamba and its 2-hydroxy metabolite on cattle, goats, hogs, horses, and sheep meat, fat, and meat byproducts at 0.2 ppm, liver and kidney at 1.5 ppm (40 CFR §180.227(b)). A tolerance for dicamba and its 5-hydroxy metabolite from the use of the sodium salt has been established on cotton-

seed at 3 ppm. A food and feed additive tolerance has been established for dicamba and its 5-hydroxy metabolite on sugarcane molasses at 2 ppm (40 CFR §185.1800 and 40 CFR §186.1800). A feed additive tolerance has also been established for dicamba and its 5-hydroxy metabolite on cottonseed meal at 6 ppm.

Outstanding deficiencies/data gaps remaining from the 1989 SRR dicamba reregistration standard that overlap this petition include directions for use, confined rotational crop studies, additional field trial residue data for wheat grass and hay, and revised tolerances.

The most recent Section 18 receiving CBTS recommendation was for 92MS08 for use on cottonseed at 3 ppm and on cottonseed meal at 6 ppm (see memorandum by L. Cheng dated September 2, 1992). The most recent Special Local Need 24[c] registration that received a favorable CBTS recommendation was ND940005 for use on millet (see memorandum by D. Davis dated August 19, 1994).

PRODUCT CHEMISTRY/CHEMICAL IDENTITY

The revised product chemistry data for the TGAI were reviewed by CBRS as a response to the SRR for dicamba. The registrant has adequately identified the active ingredient, described the starting materials and listed the sources for each, and described the manufacturing process. A detailed discussion on the formation of impurities, both actual and theoretical has been presented.

CBTS concludes that after reviewing the results of the preliminary analysis and the certified limits for the TGAI the impurities present are not expected to be a residue problem in asparagus, cotton, grass forage and hay, and wheat forage and hay when the 86% TGAI is formulated into Banval and Clarity and used as directed. CBTS reiterates that there are no concerns for the dioxin or nitrosamine levels in the TGAI.

DIRECTIONS FOR USE/LABELLING

Dicamba is proposed for use as a herbicide to control annual weeds; eg, pigweed, beggerweed, carpetweed, etc., biennial weeds; eg, Queen Anne's lace, plantin, etc., perennial weeds; eg, dandelion, dock, etc., and woody weeds; eg, honeysuckle, poison ivy, etc.

The petitioner proposed use of the formulation Banval SGF (EPA Reg. No. 55497-28), containing 23.15% of the sodium salt of dicamba or 21.06% of the acid (2 lbs ai/gallon). The label has a use on wheat reflecting application to the hard dough stage when the green color is gone. This is not a use for wheat hay as wheat should be cut for hay to the soft dough stage. The petitioner has proposed a new preplant use on cotton. Apply Banval SGF at a rate of 1 pt (0.25 lb ai)/acre in the spring up to 21 day prior to planting cotton when weeds are at the 2-4 leaf stage. The maximum application to cotton from the post-harvest fall use and the spring use is not to exceed 2 lbs a.i./acre per growing season. Several tank mates are suggested for the control of weeds in cotton fields prior to planting. There

will be a restriction to use west of the Rockies. The petitioner has proposed an adequate set of directions for use of Banval SGF on cotton fields in the spring.

Another formulation proposed for use is Clarity® Herbicide (EPA Reg. No. 55947-46) containing 56.8% of the diglycolamine (DGM) ester of dicamba which is equivalent to 38.5% of the acid, or 4 lbs ai/ gallon. This label also has a use on wheat applying at the hard dough stage when the green color is gone. This is not a use for wheat hay as wheat should be cut for hay to the soft dough stage. The petitioner has proposed a new preplant use on cotton. Apply Clarity Herbicide at a rate of 1/2 pt (0.25 lb ai)/acre in the spring up to 21 day prior to planting cotton when weeds are at the 2-4 leaf stage. The maximum application to cotton from the post-harvest fall use and the spring use is not to exceed 2 lbs a.i./acre per growing season. Several tank mates are suggested for the control of weeds in cotton fields prior to planting. There will be a restriction to use west of the Rockies. The petitioner has proposed an adequate set of direction for use of Clarity Herbicide on cotton fields in the spring.

One formulation to be used on crops is Banval® Herbicide (EPA Reg. No. 55497-1) containing 48.2% of the dimethylamine (DMA) ester of dicamba which is equivalent to 40% of the acid or 4 lbs ai/gallon. Apply as a dilute spray using ground equipment in 3 to 50 gallons water per acre, or 1-10 gallons/acre by aerial application. The petitioner has the option of submitting a revised label proposing aerial applications from 2 to 10 gallons/acre, or generating additional crop field trial data for the mid to late season uses; ie, on the grass forages and hay, wheat forage and hay, and asparagus. CBTS considers spray application of < 2 gallons per acre to be an ultra low volume use, thus, additional crop field trial residue data are necessary to support the use. To avoid uneven coverage and damage to sensitive plants do not apply when the wind is above 15 mph.

To control weeds in asparagus apply the DMA ester of dicamba at a rate of 1 pt (0.5 lb ai)/acre in 40-60 gallon water once per growing season. Allow 24 hours from application to the next cutting of asparagus. 2,4-D may be tank mixed with Banval for use on asparagus. The revised label deletes the geographical restriction for use only in California, Oregon, and Washington. The petitioner has proposed an adequate set of national directions for use of dicamba on asparagus, provided the aerial application directions are changed to remove the directions for an ultra low volume application, or the petitioner generates sufficient additional magnitude of the residue data to support an ultra low volume application on asparagus.

For application to wheat, barley, and oats forages, apply Banval at a rate of 1/4 pt (0.125 lb ai dicamba)/acre/application. There is no PHI proposed for grazing the forages, but the petitioner has proposed a 14 day PHI proposed before cutting the forage for hay. Since the petitioner has no provided residue data to support the proposed use on barley and oats the petitioner has the options of removing the crops from the label, or submitting an adequate amount of varietal and geographically representative field trial data for

barley and oats, or submitting sufficient crop field trial residue data for corn forage, wheat forage, and another cereal grain forage to support a crop group tolerance for the forage, fodder, and straw of cereal grains.

Banval Herbicide may be applied before, during, or after planting of the cereal grains. Apply 4 oz of Banval (0.125 lb ai)/acre/application to fall seeded wheat, barley, and oats forages prior to jointing and to spring wheat and oats forages before it exceeds the 5 leaf stage (4 leaf stage for spring seeded barley forage). With these biological time frames for application CBTS considers a 14 day PHI is reasonable for wheat hay. Banval may be tank mixed with a number of other herbicides for a better spectrum of weed control.

Banval Herbicide may be applied to pastures, grass for hay, rangeland, and general farmstead for broadleaf weed and brush control. Banval may be applied at rates from 1/2 pt (0.25 lb ai) for small annual weeds up to 2 qts (2 lbs ai dicamba) for perennials and woody brush in 3 to 600 gallons with ground equipment, or 1 to 40 gallons with aerial equipment per acre. There are no forage grazing restrictions for cattle, but there is a 7 day PHI for cutting grass for hay from the 2 lbs ai/acre application. Directions for spot and/or band applications are provided. The petitioner has presented an adequate set of directions for use of Banval on pasture and rangeland grasses and hay.

NATURE OF THE RESIDUE - PLANTS

The nature of the residue in plants is adequately understood. In most plants there is oxidation on the ring at the 5 position to form the 5-hydroxy metabolite. In asparagus and soybeans there is demethylation on the ring at the 2 position to form the 2-hydroxy metabolite. CBTS reiterates that the residues to be regulated in cotton, wheat, and grasses are dicamba and its 5-hydroxy metabolite, and in asparagus the residues to be regulated are dicamba and the 2-hydroxy or DCSA metabolite.

NATURE OF THE RESIDUE - LIVESTOCK

The nature of the residue in ruminants and poultry is adequately understood (see memorandum by L. Cheng dated March 7, 1996). In ruminants the metabolic pathway is the same as in asparagus and soybeans which is demethylation and formation of the 2-hydroxy metabolite. The same basic metabolic pathway exist in poultry; however there is a very minor pathway producing a small amount of 2-amino-3,6-dichlorophenol found only in poultry liver. CBTS reiterates that the residue to be regulated in livestock are dicamba and its DCSA or 2-hydroxy metabolite.

CONFINED ACCUMULATION STUDIES ON ROTATIONAL CROPS

The petitioner has previously submitted a confined ^{14}C-dicamba rotational crop study which has been reviewed by CBRS (see memorandum by L. Cheng dated February 16, 1996). From an application of 0.5 lb (0.25X) the TRR at a 32 day plantback ranged from 0.02 ppm, to 0.03

ppm in wheat forage, and was 0.21 ppm in mustard greens. Characterization and identification of the TRR at the 32 day plantback was incomplete as residues of dicamba and its 2-hydroxy and 5-hydroxy metabolites were all <0.01 ppm. The TRR at the 131 and 369 day plantback were <0.01 ppm which precluded adequate characterization and identification of residues. An accurate assessment of the proper plantback interval can not be determined from this 1986 study.

CBTS reiterates that the nature of the residue in confined rotational crop is **not** adequately understood. The petitioner should consult the EPA document dated March 23, 1993, titled "Guidance on How to Conduct rotational Crop Studies" on how to conduct rotational crop studies.

In absence of adequate rotational crop data CBTS suggests that the petitioner propose rotational crop restrictions on all current dicamba labels to limit rotation to only those crops that have established tolerances.

RESIDUE ANALYTICAL METHOD

The petitioner submitted an updated residue analytical method titled "Determination of Dicamba 5-Hydroxy Dicamba Residues in Barley, Corn, Cotton, Cotton Processed Fractions, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC)" by N. Jimenez dated July 30, 1993, and coded Report No. AM-0691B-0593-3 and **MRID # 438140-02**. The petitioner has previously submitted independent laboratory validation data (ILV) data in a report titled "Confirmatory Method Trial of the Residue Method. AM-0691B-0593-2, 'Determination of Dicamba 5-Hydroxy Dicamba Residues in Barley, Corn, Cotton, Cotton Processed Fractions,Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC)'" by J. Pfaff dated August 10, 1993, and coded lab project number 930901 and **MRID # 428832**.

The ILV data have been previously reviewed by CBRS (see memo by D. Miller dated December 13, 1993). Dicamba and its 5-hydroxy metabolite were fortified separately at 0.25, 0.5, and 1 ppm in corn grain and forage with acceptable recoveries. CBRS concluded that the ILV was acceptable to support an Agency tolerance method validation (TMV) for method AM-0691B-0593-3. CBRS recommended that a new TMV be conducted.

The original version of method, AM-0691B, was initially reviewed in PP# 4F3041 by F. Griffith in his memo dated November 4, 1988 (qv). In principle, the method has not changed in 8 years. In brief, samples are treated with 1N HCl and hydrolyzed for 1.5 hours in a 95 °C water bath. The hydrolysate is adjusted to pH $\geq$ 8 with a 50 ml aliquot removed for analysis, then acidified to pH < 1, and extracted twice with diethyl ether. The combined ether extracts are concentrated the methylated with diazomethane. Cleanup is by silica gel columns. Determination of the ME residues is by capillary ^{63}NiEC-GC. However, since the initial review there have been minor evolutionary changes in the extraction step (no extraction with 80% ethanol in 1 N

HCl), changes in the GC columns, and the addition of a GC-MSD confirmatory step. These changes now warrant a TMV for method AM-0691B-0593-3.

The confirmatory step uses a HP 5890 GC with 5971A Mass selective detector, a 12 m HP-1 capillary column, and helium as the carrier gas. The ions monitored for dicamba methyl ester (ME) are m/e 203, 205, and 234. The ions monitored for the 5-hydroxy ME are m/e 233, 235, and 266. Dicamba and the 5-hydroxy metabolite are well separated on the HP-1 column. UAR's are not a problem at the elution of dicamba and its metabolite.

The petitioner presented recovery data for the LOQ of 0.01 ppm with the LD at 0.005 ppm. Recovery data for asparagus, wheat forage and hay, grass forage and hay have been reviewed by CBRS and were acceptable to support the method as suitable to gather the magnitude of the residue data.

The petitioner has presented an adequately validated capillary EC-GC residue analytical method to gather the magnitude of the residue crop field trial residue data. While CBTS will initiate a request to ACB/BEAD for a TMV on method AM-0691B-0593-3, the results of the TMV will not be a bar to a favorable recommendation on tolerances. CBTS notes there are adequate enforcement methods available to FDA and the states in PAM-II for the determination of residues of dicamba and its metabolites in plant matrices, and meat and milk.

STORAGE STABILITY

As part of the response to the dicamba SRR request for magnitude of the residue data the petitioner generated storage stability data for each crop. These data have been reviewed by CBRS (see memoranda by L. Cheng dated March 11, 1996, for storage stability data for grasses; and May 1996 for storage stability data on wheat, asparagus, and sorghum).

CBTS reiterates that the petitioner has presented adequate frozen storage stability data for grass forage and hay, wheat, asparagus, and sorghum. Residues of dicamba and its 5-hydroxy metabolite are stable for 10-12 months of frozen storage in wheat forage and hay and in grass forage and hay; and for at least 4-5 months of frozen storage in sorghum and asparagus. CBTS concludes that these data are adequate to support the magnitude of the residue data in this petition.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

ASPARAGUS

The petitioner previously presented dicamba residue magnitude of the residue data on asparagus from 8 field trials in Washington (3), California (3), and Michigan (2) for the 1993 and 1994 crop years. When the number and location of crop field trials presented are reviewed against the data requirements in the "EPA Guidance on Number and Location of Domestic Crop Field trials for Establishment of

Pesticide Residue Tolerances," June 1994, the petitioner appears to need an additional asparagus field trial from Region II. CBTS notes that the petitioner has generated the required number of asparagus field trials, and although no dicamba on asparagus field trial was conducted in Region II, all of the asparagus crop field trial data were generated prior to new requirements. CBTS can recommend for the amended registration and a higher dicamba tolerance on asparagus without any additional crop field trial residue data.

In summary, each trial consisted of a control plot and 3 test plots. Each treated test plot received 0.5 lb ai dicamba/acre in 50-60 gallon using ground equipment with harvest 24 hours after application. Samples were promptly frozen and usually duplicate samples were analyzed by the residue analytical method reviewed above. At each trial the petitioner used 3 different formulations of dicamba; the DMA ester, the DGA ester, and the Na salt, all applied at the same rate.

All field trials from the DMA dicamba application had positive results ranging from 0.4 to 3.2 ppm averaging 0.96 $\pm$ 0.89 ppm with 3 trials having total dicamba residues above 1 ppm. Total dicamba residues from the other two formulation applications to asparagus were in the same range as were the residues from the DMA dicamba application. These data support the registration of all 3 dicamba formulations for use on asparagus. No dicamba residues were detected in the control samples.

The petitioner has presented an adequate amount of geographical representative crop field trial residue data for the use of dicamba on asparagus. The data show that when dicamba is formulated into Banval and used as directed residues will exceed the established 3 ppm tolerance. Since the petitioner states in the cover letter he wishes a national use, CBTS will need a revised Section F proposing a 3.5 ppm tolerance on asparagus for 40 CFR §180.227(b) for dicamba and its 2-hydroxy metabolite and at the same time deleting the 3 ppm dicamba tolerance on asparagus in 40 CFR §180.227(a).

GRASS FORAGE AND HAY (MRID # 433707-01)

The petitioner previously presented dicamba residue magnitude of the residue data on grass forage and hay from 13 field trials one each in Florida, Georgia, Oregon, Indiana, Kansas, Tennessee, Mississippi, Nebraska, Oklahoma (2), Missouri, Texas, and Wisconsin for the 1993 crop year. When the number and location of the grass crop field trials presented are reviewed against the data requirements the petitioner has generated the required number of grass field trials. To have a crop group tolerance on the grass forage, fodder, and hay group (Crop Group XVII) the petitioner needs to have 4 trials each of Bermuda, blue, and brome or fescue grasses. The petitioner has presented an adequate number and amount of varietal data on grasses to support a crop group tolerance. The petitioner needs to submit a revised Section F proposing a tolerance for total residues of dicamba for the grass forage, fodder, and hay crop group.

In summary, each trial consisted of a control plot and 3 test plots. One treated test plot received one 2 lb ai dicamba/acre application in 7-23 gallon of water using ground equipment. Grass forage samples were harvested at a 0 day PHI. The other test plots received 0.5 lb ai dicamba/acre, or 1 lb ai dicamba/acre once with grass forage samples harvested a 0 day PHI. Grass hay samples from all test plots were cut 7 days later and generally allowed to field dry 2-6 days before collection/harvest as grass hay. CBTS notes that the hay samples were generally harvested during hot weather. However, data generally were lacking on humidity/rain during the drying period to show that the grass hay samples were **approximately** 88% dry matter when harvested. Since the dicamba grass field trials were conducted in 1993, well before the data requirements as outlined in Table II (September 1995) were published, CBTS will not request the petitioner show that the grass forage and hay contained the generally expected amount of dry matter. All samples were promptly frozen and usually duplicate samples were analyzed by the residue analytical method reviewed above. In each trial the petitioner used 3 different formulations of dicamba; the DMA ester, the DGA ester, and the Na salt to support use of these formulations for weed control on pasture and rangelands.

All field trials from the DMA dicamba application to grass forage had positive residues at 0 day PHI ranging from 66 to 273 ppm and to 358 ppm from the sodium salt application with 4 trials having total dicamba residues above 200 ppm. Total dicamba residues from the sodium and DGA formulation applications to grass forage were in the same range as were the residues from the DMA dicamba application. While there are only 5 trials with residue data from all 3 formulations CBTS will accept these data as adequate for additional registrations as the data requirement for 3/4 of the number of required trials for amended registration was not published until June 1994. CBTS concludes that dicamba residues are not dependent on which formulation is used, but may depend on the location where used. These data support the registration of all 3 dicamba formulations for use on grass forage and hay.

Since all grass forage samples were positive for total dicamba it is logical that all grass hay samples would also be positive. Total dicamba residues in grass hay at 7 days PHI field dried ranged from 25 to 201 ppm. When residues on grass hay are compared to the 7 day PHI grass forage residues CBTS notes most samples do not show significant concentration of residues from grass forage to grass hay. CBTS will not raise an issue as we have not previously required data to show percent dry matter in forage and hay as described in Table II (September 1995) endnote 33.

Dicamba residues were detected in the some of the control grass forage and hay samples ranging to 0.29 ppm dicamba and 0.22 ppm 5-hydroxy dicamba. CBTS does not consider these dicamba equivalents in control samples to be a concern as the minimum residue detected in treated grass forage is 66 ppm and in treated grass hay the minimum residue is 25 ppm, or the residues in the control samples are 0.01 of the residues in treated samples.

The data show that when dicamba is formulated into Banval and used as directed residues will not exceed the proposed 400 ppm tolerance on grass forage at 0 day PHI and 250 ppm on grass hay at 7 days PHI. In a memorandum dated March 11, 1996, (Barcode # D207649, L. Cheng) CBRS concluded that an appropriate tolerance for total residues of dicamba for grass hay would be 600 ppm based on residues in grass hay at zero days. The petitioner made no proposal for a PHI for grass hay in the CBRS action which is why CBRS chose a tolerance level for hay based on the zero day data. In this amended use request, however, the petitioner is proposing a 7 day PHI for grass hay. CBTS considers a 7 day PHI is reasonable for cutting grass for hay (see Table II (September 1995) endnote 33). CBTS now recommends that a tolerance level of 250 ppm for total residues of dicamba in/on grass hay would be appropriate when a PHI of 7 days is prescribed.

WHEAT FORAGE AND HAY (MRID # 432745-01)

The petitioner previously presented dicamba magnitude of the residue data on wheat forage and hay from 7 field trials one each in Florida, Georgia, Oregon, Indiana, Kansas, Tennessee, Mississippi, Nebraska, and Kansas (2), Missouri, Texas, and Wisconsin for the 1993 crop year. Five of these trials were with winter wheat varieties and two were with spring wheat varieties. Six varieties of wheat were used. When the number and location of the wheat crop field trials presented are reviewed against the data requirements the petitioner needs to generate dicamba magnitude of the residue data from 13 additional wheat forage and hay field trials. For the existing 7 wheat forage trials the petitioner need to identify the Region where each of these trials was performed. The guidance offered by EPA in the June 2, 1994 document suggests that the petitioner needs residue data from 20 wheat forage and hay field trials in the following crop growing regions: 1 from Region II, 1 from region IV, 5 from Region V, 1 from Region VI, 5 from Region VII, 6 from Region VIII, and 1 from Region XI. The additional dicamba wheat forage/hay crop field trials should be proportioned between winter and spring wheat planting reflecting the actual acreage planted.

Each trial consisted of a control plot and 6 test plots for 3 different dicamba formulations at 2 different application rates. Three treated test plots received one application of 0.125 lb ai dicamba (proposed use) per acre in 9-31 gallons in water using ground equipment with wheat forage samples harvested at a 0 day PHI. When CBTS reviewed the planting dates against the treatment dates we concluded that the petitioner had followed the proposed label use directions. The other 3 test plots received one application of 0.5 lb ai dicamba/acre with wheat forage samples harvested a 0 day PHI. Wheat hay samples from all test plots were cut 14 days later and generally allowed to field dry 3-7 days before collection/harvest as wheat hay. CBTS notes that the hay samples were generally harvested during hot weather. However, data generally were lacking on humidity/rain during the drying period to show that the wheat hay samples were **approximately** 80-90% dry matter when harvested. Since the dicamba wheat field trials were conducted in 1993 and 1994 well before the data requirements as outlined in Table II (September 1995) were published, CBTS will not request the petitioner show that the

wheat forage and hay contained the generally expected amount of dry matter. All samples were promptly frozen and usually duplicate samples were analyzed by the residue analytical method reviewed above.

In summary, the Agency guidance document clearly defines field trial sites, field trials, and points out that the number of samples collected does not constitute the number of trials. In each of the 7 trials the petitioner used 3 different formulations of dicamba; the DMA ester, the DGA ester, and the Na salt to support use of these formulations for weed control in wheat. Our guidance document states that to have more that one formulation registered for use on a crop the petitioner needs to have 3/4 of the number of trials as required for the initial formulation, thus for each additional dicamba formulation to be used on wheat the petitioner will need 8 additional trials for a total of 15 field trials to support the requested registrations.

All field trials from the 0.125 lb DMA dicamba application to wheat forage had positive residues at 0 day PHI ranging from 6.7 to 16 ppm (2 trials). Maximum residues were 14 ppm when the DGA dicamba was applied, and 12 ppm from the application of the sodium salt. Likewise, all wheat hay samples had positive total dicamba results. Total residues of dicamba on 14 day PHI wheat hay ranged from 0.62 ppm to 4.9 ppm from application of DMA dicamba. Maximum residues were 4.6 ppm from the application of DGA dicamba, and 4.8 ppm from the application of the sodium salt. CBTS defers judgement on the adequacy of these data and the proposed dicamba tolerances on wheat forage at 80 ppm and on wheat hay at 20 ppm until the petitioner has presented the requested additional crop field trial data to support the use of the DMA formulation and additional data to support the other formulations.

No crop field trial residue data were presented for wheat grain and wheat hay. Tolerances for dicamba and its 5-hydroxy metabolite in/on wheat grain and straw at 0.5 ppm have been adequately supported by residue data.

COTTONSEED (MRID # 438140-01)

The petitioner has presented new total dicamba magnitude of the residue data on cottonseed in a study titled "Crop Residue Study with Dicamba on Cotton" by M. Guirguis dated July 12, 1995, and coded Project No.: 480068.

The petitioner presented new dicamba residue magnitude of the residue data on cottonseed and gin trash from 12 field trials as follows: one from Region II [Georgia], 8 from Region IV [Louisiana (3), Mississippi (2), Tennessee, and Arkansas (2)], two from Region VI [Texas], and one from Region VIII [Texas] for the 1994 crop year on 9 varieties of cotton. When the number and location of the cotton crop field trials presented are reviewed against the current data requirements the petitioner appears to needs to generate additional dicamba magnitude of the residue data on cotton. Since the petitioner is proposing a geographical restriction on this amended use west

of the Rockies and since climatic conditions in the South favor spring weed growth and limit cultivation techniques, CBTS concludes these data are adequate to support an amended registration use on cotton.

Each trial consisted of a control plot and a test plot. The dicamba sodium salt formulation was applied once at the 0.5 lb ai (2X exaggeration)/acre rate in 10-20 gallons of water using ground equipment 14 days prior to planting cotton. Cotton was harvested at maturity by hand, ginned with the lint discarded, and the cottonseed and gin trash (consisting of burrs, stems, and leaves) were collected for analysis. All samples were promptly frozen and remained frozen until analyzed in duplicate by the validated residue analytical method discussed above.

Dicamba, per se, residues were not detected in the control cottonseed samples to the LOQ of 0.04 ppm, but 0.05 ppm 5-hydroxy dicamba equivalents were detected in a control sample. CBTS does not consider this dicamba metabolite equivalent to be a concern. The maximum residue detected in cottonseed from the proposed new use is 0.05 ppm of the 5-OH metabolite in only one field trial. Total residues of dicamba on cottonseed from the proposed new use plus the registered uses are not expected to exceed the established tolerance of 3 ppm when formulated into Banval and used as directed.

Several control cotton gin trash samples contained dicamba or 5-OH dicamba equivalents in the 0.04-0.06 ppm range. Treated gin trash samples from these same field trials also contained positive dicamba/5-OH dicamba levels. However, when the control values were subtracted from the treated results the remaining values in cotton gin trash were all < 0.01 ppm, except for 0.02 ppm (0.071 ppm uncorrected) for 5-OH dicamba in one gin trash sample.

CBTS has no dicamba cotton gin trash residue data from the fall application of 2 lbs ai/acre of dicamba in order to establish a dicamba tolerance on the rac cotton gin byproducts. CBTS cannot extrapolate the residue data on gin byproducts from the spring application to cover residues on this feedstuff from the fall application. The petitioner needs to conduct 6 additional dicamba cotton field trials for residues on cotton gin byproducts commonly called gin trash from the 2 lbs ai/acre fall application. These trials should be concentrated in Regions IV, VIII, and X. Cotton gin trash is plant residues from ginning cotton, and consists of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. To produce cotton gin trash the cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residues from the ginning process. At least 3 field trials for each type of harvesting (stripper and picker) are needed. The petitioner will need to propose a dicamba tolerance on cotton gin byproducts in a revised section F once the field trials are completed.

The data show that when dicamba is formulated into Banval and Clarity, and used as directed on cotton fields 14 to 21 days prior to

planting total dicamba residues will not exceed the established cottonseed tolerance of 3 ppm.

MAGNITUDE OF THE RESIDUE - PROCESSED FOOD/FEED

ASPARAGUS

Table II (September 1995) does not list any processed asparagus commodities, thus no dicamba asparagus processing study is required.

GRASS FORAGE AND HAY

Table II (September 1995) does not list any processed grass commodities, thus no dicamba grass processing study is required.

WHEAT FORAGE AND HAY

While no processing study is required for use on wheat forage and hay, the petitioner has previously presented (see CBRS memorandum by L. Cheng dated 23 Apr 93) a wheat processing study that had detectable residues of 0.44 ppm dicamba plus 0.034 ppm 5-OH dicamba in the grain from a 5X exaggerated use rate. The wheat was processed into patent flour (0.023 ppm), middlings (0.07 ppm), shorts and germ (0.266 ppm), and wheat bran (0.0436 ppm). CBRS concluded that the study showed no concentration of dicamba and its 5-hydroxy metabolite in wheat processed commodities. CBTS reiterates that no food or feed additive dicamba tolerances, or Section 701 MRLs are necessary for processed wheat commodities.

CBTS notes that while the wheat processing study did not present residue data for the aspirated grain fractions, this issue is being handled in the dicamba reregistration by SRRD. Residue data for aspirated grain fractions from sorghum have been presented, but the decision on the appropriate dicamba aspiration grain fraction tolerance has been deferred until the data are available from wheat and corn.

COTTONSEED

Cottonseed processing studies have been previously submitted and reviewed (see memorandum in PP# 3F2794 dated 31 Mar 83). On cotton treated foliarily with dicamba at 0.1 lb ai and harvested 41-57 days later. Total dicamba residues were 1.14 ppm in cottonseed. When processed into cottonseed meal residues were 1.8 ppm for a concentration factor of 1.6X. Crude and refined cottonseed oil have <0.035 ppm. Another cottonseed dicamba processing study had 1.55/1.67 ppm (average 1.61 ppm) total dicamba in the seed, and when processed the meal contained 2.5/3.13 ppm (average 2.82 ppm) total dicamba for 1.75X concentration factor. The average concentration factor is 1.68X. The highest field trial level was 2.9 ppm (see PP#3F2794 dated 31 Mar 83 by M. Kovacs).

CBTS reiterates that cottonseed meal is not a ready-to-eat (RTE) feedstuff (see memorandum in PP# 4169 by F. Griffith dated 4 Oct 95). Cottonseed meal is not fed to cattle as a stand alone feedstuff. It

can be an ingredient up to 50% of supplements and concentrates. The minimum dilution factor is 2. By present policy the residue level in cottonseed meal is calculated by multiplying the average concentration factor, 1.68 times the highest field trial value of 2.9 ppm. The yields a residue of 5 ppm. When CBTS divides the 5 ppm dicamba in cottonseed meal by the dilution factor of 2, the level in a RTE livestock feed does not exceed the rac tolerance of 3 ppm. CBTS concludes that a revised Section F needs to be submitted proposing a Section 701 MRL for total residues of dicamba on cottonseed meal at 5 ppm. The feed additive 409 dicamba tolerance on cottonseed meal at 6 ppm needs to be withdrawn. Food/ feed additive tolerances, or MRLs on other cottonseed processed commodities are not required.

MAGNITUDE OF THE RESIDUE - MEAT/MILK/POULTRY/EGGS

RUMINANTS

Bovine feed items in this petition include cottonseeds, cottonseed hulls, cottonseed meal, and gin trash. Cottonseeds can comprise up to 25% of cattle diets contributing a potential dietary burden of 0.85 ppm, and cottonseed meal can comprise up to 15% of cattle diets contributing a potential burden of 1.01 ppm. Cotton gin byproducts can be included in cattle diets up to a level of 20%. Grass forage, hay, and/or silage can comprise up to 60% of cattle diets for a potential dietary burden from grass of 960 ppm [60%in diet/25% dry matter X 400 ppm tolerance = 960 ppm], and a potential dietary burden from grass hay of 170 ppm. Wheat forage and hay can be fed to dairy cattle at 60% of the diet and up to 25% in beef cattle diets. The potential dietary burden in beef cattle from wheat forage is 20 ppm and the dietary burden from wheat hay can be 1.4 ppm. For dairy cattle the potential dietary burden from wheat forage is 48 ppm and from wheat hay is 3.4 ppm.

A cattle diet consisting of 60% grass forage, 15% cottonseed meal, 5% sugarcane molasses, and 20% sorghum has a maximum theoretical dicamba dietary exposure in cattle up to 965 ppm.

A ruminant feeding study has been submitted and discussed in PP# 3F2794. Dairy cows were dosed at 40 ppm, 120 ppm, and 400 ppm. At the 400 ppm level the maximum total residues of dicamba in milk were 0.32 ppm, and the maximum total residues of dicamba in tissues were in kidney at 0.9 ppm. CBTS cannot extrapolate results from a 400 ppm feeding study to cover a 965 ppm potential dietary burden. The petitioner will need to conduct an supplementary bovine feeding study using a 1000 ppm feeding level in dairy cows for at least 30 days, or until residues plateau in milk. Data should also be collected during a depuration period. Once the supplemental feeding study has been completed the petitioner will need to submit a revised section F proposing new numerical dicamba tolerances for milk; and meat, fat, and meat byproducts (including kidney and liver) for cattle, goats, hogs, horses, and sheep.

POULTRY

The are no poultry feedstuffs associated with this petition.

HARMONIZATION OF TOLERANCES

An INTERNATIONAL RESIDUE LIMIT STATUS SHEET (IRL) is attached to this review. Since there are no Codex MRLs, compatibility is not a problem at this time. Compatibility cannot be achieved with the Canadian negligible residue limit at 0.1 ppm as the USA use pattern has residues above 0.1 ppm. Compatibility cannot be achieved with Mexican tolerances at 3 ppm on asparagus and 40 ppm on grasses as the USA use pattern on asparagus and grass forages has residues above the Mexican tolerances. There is no Canadian or Mexican tolerances on cereal grains, forages, and/or hays.

cc:RJTaylor[PM-25]HFB(7505C),R.F.,Circu,Reviewer(FDG),PP#6F4606,DicambaRegStdFile,
RB/SRRD(J.Mitchell).
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:4/15/96:edit:fdg:5/2/96.
RDI:TPT-1:4/18/96:BrSrSci:RBPerfetti:4/25/96BrCh:EZager:5/2/96.

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R111783

Chemical:	**Benzoic acid, 3,6-dichloro-2-methoxy-, c; Dicamba; Benzoic acid, 3,6-dichloro-2-methoxy-, s; Benzoic acid, 3,6-dichloro-2-methoxy-, c**
PC Code:	**029802; 029801; 029806; 128931**
HED File Code	**11000 Chemistry Reviews**
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