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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

Note: The following memorandum supercedes the HED residue chemistry review dated 11/12/01 (J. Tyler; Barcode D275619).

DATE: 05-DEC-2001

SUBJECT: PP# 0E06185. Diflufenzopyr in/on Sweet Corn, Pop Corn, and Grass. **Evaluation of Residue Data and Analytical Methods**. MRID#s 45040203, 45154001 and 45154002. Chemical 005107. Barcode D279534. Case 293208. Submission S590359.

FROM: Jennifer R. Tyler, Chemist
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THRU: G. Jeffrey Herndon, Branch Senior Scientist
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TO: Robert Forrest/Shaja Brothers, PM Team 05
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RD (7505C)

INTRODUCTION

The Interregional Research Project No. 4 (IR-4), on behalf of the Agricultural Experiment Stations of Minnesota, North Dakota, and Wisconsin, has submitted an application for tolerances for residues of the herbicide diflufenzopyr [2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid] in/on pastures, pop corn, and sweet corn. Section F of the current petition proposes the establishment of the following permanent tolerances for residues of diflufenzopyr and its metabolites convertible to M1 (8-methylpyrido[2,3-d]pyridazin-5(6H)-one):

Corn, sweet, forage	0.05 ppm
Corn, sweet, fresh	0.05 ppm
Corn, sweet, stover	0.05 ppm
Corn, pop, stover	0.05 ppm

Crop Group 17, Grass forage, fodder, and hay:

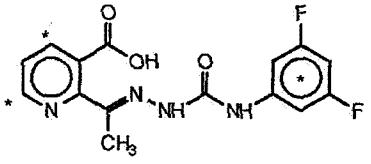
Forage	3.0 ppm
Hay	1.5 ppm

Concurrently, the petitioner has submitted a request for Section 3 registration of Distinct® Herbicide (EPA Reg. No. 7969-150), a multiple active ingredient water-dispersible granule (WDF) formulation containing 21.4% diflufenzopyr and 55% dicamba, for use on the aforementioned raw agricultural commodities (RACs) for the control of various weeds. This residue chemistry review deals with the use of diflufenzopyr on these RACs. Issues pertaining to dicamba are addressed in a separate memo (Memo, G. Kramer, 7/26/01; D275611).

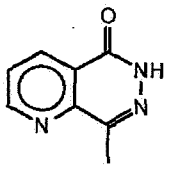
Diflufenzopyr is a postemergence herbicide which acts by inhibiting the polar transport of naturally occurring auxin (indoleacetic acid, or IAA) and synthetic auxin-like compounds (e.g., dicamba). This results in an abnormal accumulation of IAA and synthetic auxin agonists in meristematic shoot and root regions, disrupting the auxin balance needed for plant growth.

Permanent tolerances are currently established for the combined residues of diflufenzopyr and its metabolites convertible to M1 in/on field corn forage, grain, and stover at 0.05 ppm [40 CFR §180.549(a)].

Structural Formulae:

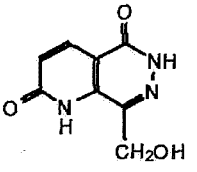


diflufenzopyr



M1

M10



M19

Executive Summary of Chemistry Deficiencies

- Revised Section B (see Conclusions 1 and 12b).
- Revised Section F (see Conclusions 8b, 9b and 11b).
- Livestock analytical enforcement method (including independent laboratory validation (ILV) and radiovalidation) which measures all residues of concern (see Conclusions 4b and 11b).
- Ruminant feeding study (see Conclusions 4b and 11b).

RECOMMENDATIONS

Provided revised Sections B and F and an **adequate analytical enforcement method for livestock commodities** (including ILV and radiovalidation) are submitted, the available residue chemistry database supports a ***conditional registration*** and the following:

permanent tolerances for residues of diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, in/on:

corn, sweet, forage	0.05 ppm
corn, sweet, fresh	0.05 ppm
corn, sweet, stover	0.05 ppm
corn, pop, grain	0.05 ppm
corn, pop, stover	0.05 ppm
grass, forage	22 ppm
grass, hay	7.0 ppm

time-limited tolerances for residues of diflufenzopyr and its metabolites convertible to M1, and free and acid-released M19, expressed as diflufenzopyr, in:

meat*	0.60 ppm
kidney*	4.0 ppm
meat by-products (except kidney)*	0.50 ppm
fat*	0.30 ppm
milk	3.0 ppm

* of cattle, goat, hog, horse, and sheep

The registration should be conditional upon submission of adequate livestock feeding study. A human health risk assessment will be prepared in a separate document.

NOTE TO RD: The appropriate tolerance expressions to be included in 40 CFR §180.549(a) are 1) for corn and grass: "diflufenzopyr, 2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, and its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, expressed as diflufenzopyr, in/on..." and 2) for livestock commodities: "diflufenzopyr, 2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, its metabolites convertible to 8-

methylpyrido[2,3-d]pyridazin-5(6H)-one, and free and acid-released 8-hydroxymethylpyrido[2,3-d] pyridazine-2,5(1H,6H)-dione, expressed as diflufenzopyr, in/on..."

CONCLUSIONS

OPPTS GLN 860.1200: Proposed Uses

1. The proposed use directions for sweet corn, pop corn, and pasture and rangeland grasses are supported by the submitted residue data. **The petitioner should submit a revised Section B to include a 30-day plantback interval (PBI) restriction.**

OPPTS GLN 860.1300: Nature of the Residue - Plants

2a. The nature of the residue in field corn is understood. An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled separately in the pyridine and phenyl rings has been performed in field corn. The urea bond is cleaved to yield metabolites containing a new bicyclic ring system. No diflufenzopyr was detected in any of the corn matrices; metabolites comprising >10% of the total radioactive residues (TRR) include M1 (8-methylpyrido[2,3-d]pyridazin-5(6H)-one), M10 (8-hydroxymethyl-5(6H)-pyrido[2,3-d]pyridazone) and its glucose conjugate, and M9 (8-methylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione in forage and fodder, and 6-14% TRR lignin was found in fodder. Corn grain contained 3-4 discrete unknowns, all at <10% TRR or <0.05 ppm each.

2b. The HED Metabolism Assessment Review Committee (MARC) met on September 28, 1998 to discuss the toxicological significance of metabolites of diflufenzopyr. The Committee concluded that diflufenzopyr and metabolites convertible to metabolite M1 need to be included in the tolerance expression. Furthermore, for dietary exposure assessment, metabolite M10 should be included in addition to diflufenzopyr and metabolites convertible to M1 (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

OPPTS GLN 860.1300: Nature of the Residue - Livestock

3a. The nature of the residue in ruminants and poultry is understood. The HED MARC met on 9/28/98 to discuss the metabolism of diflufenzopyr in livestock.

Ruminants

3b. An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled separately in the pyridine and phenyl ring has been performed in goats. Based on the metabolites identified, the metabolism of diflufenzopyr in ruminants is similar to that in corn. Major metabolites include M1, M5 (6-((3,5-difluorophenylcarbamoyl-8-methyl-pyrido[2,3-d]-5-pyridazinone) and M19 (8-hydroxymethylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione). A substantial amount (8-50%) of diflufenzopyr was also found in milk, kidney, and liver. The Committee concluded if any livestock feeding studies are conducted in the future, analyses should be done for parent, metabolites convertible to M1, and free and acid-released M19 (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

3c HED notes that the new use of diflufenzopyr on pasture and rangeland grasses significantly increases the calculated ruminant theoretical dietary burden (TDB) to 53 ppm (See section entitled OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs). Using the new diet, the submitted ruminant metabolism studies were performed at 0.19x the TDB. It is possible that more metabolites could be identified if the metabolism studies are performed at a higher dose. However, as liver was the only ruminant commodity that had a high amount of minor unidentified bands and liver is not a major human consumption item, **HED concludes that additional ruminant metabolism data are not necessary *at this time.*** If new uses are submitted which will significantly increase the ruminant TDB, then additional ruminant metabolism data performed at a higher dose may be required.

Poultry

3d. An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled in the pyridine or phenyl ring has been performed in hens. Based on the metabolism results, diflufenzopyr was not detected in poultry, and M1 was the only significant metabolite identified, and in egg white only. The Committee commented that since the dose administered in the poultry metabolism studies had been at such an exaggerated level (250x), transfer of secondary residues to poultry would not be expected (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

OPPTS GLN 860.1340: Residue Analytical Methods - Plants and Livestock

4a. An adequate enforcement method (Method D9709) is available for enforcement of the proposed tolerances. The reported method limits of detection and quantitation (LOD and LOQ) are 0.02 ppm and 0.05 ppm, respectively. HED has conducted a successful petition method validation (PMV) of Method D9709 (Memo, J. Tyler, 10/31/01; D278522). The method will be forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Method Volume (PAM) Vol. II.

4b. No analytical method has been submitted for livestock. **Based on the calculated TDB and the results of the ruminant metabolism study, tolerances for residues of diflufenzopyr and a ruminant feeding study are required. An adequate analytical enforcement method (including ILV and radiovalidation data) should be submitted.**

OPPTS GLN 860.1360: Multiresidue Method

5. The results of multiresidue testing of diflufenzopyr and its metabolites M1 and M10 have been forwarded to the FDA for inclusion in PAM Vol. I (Memo, J. Tyler; 10/11/01; D278336). Neither diflufenzopyr nor M1 was detected through Protocol C, however, M10 was detected through Protocol C.

OPPTS GLN 860.1380: Storage Stability Data

6. The results of a freezer storage stability study were submitted in support of the use of diflufenzopyr on field corn (PP#7F4848) and reviewed by HED (Memo, J. Tyler, 10/11/01; D254989). The previously submitted storage stability data indicate that residues of diflufenzopyr (M1 and M10 residues) are relatively stable under frozen storage conditions in/on fortified samples of field corn forage, grain and fodder for up to

24 months. The submitted storage stability data are adequate to support the storage conditions and intervals of the samples from the sweet corn, and pasture and rangeland grasses field trial studies (24 months and 8 months, respectively).

OPPTS GLN 860.1500: Crop Field Trials

Sweet Corn

7a. A total of 9 field residue trials were conducted in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (3 trials), 6 (1 trial), 10 (1 trial) and 12 (1 trial). The locations of the field trials do not match that required for sweet corn: 12 trials conducted in Regions 1 (2 trials), 2 (1 trial), 3 (1 trial), 5 (5 trials), 10 (1 trial), 11 (1 trial) and 12 (1 trial). However, the petitioner previously submitted the results of 24 field corn residue trials conducted in 1995 and 1996. In that study, the field corn samples were treated with 2 applications of Distinct® at 0.1 lb. diflufenzopyr/A for a total of 0.2 lb. diflufenzopyr/A (2.7x proposed maximum sweet corn application rate). The results showed that residues of diflufenzopyr and metabolites convertible to M1 resulting from proposed use would not exceed 0.05 ppm. HED can generally translate field corn forage and stover data to sweet corn. Therefore, additional sweet corn residue trials will not be required.

7b. The submitted field trials are adequate to support the proposed tolerances for residues of diflufenzopyr in/on sweet corn forage, ears, and fodder. Based on the available data, the following tolerances for residues of the herbicide diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate: "corn, sweet, forage" at 0.05 ppm; "corn, sweet, fresh" at 0.05 ppm; and "corn, sweet, stover" at 0.05 ppm.

Pop Corn

8a. No pop corn field trial data were submitted in support of this petition. HED can generally translate field corn grain/stover data to pop corn grain/stover provided the use patterns are the same and there is adequate field corn data. As mentioned previously, adequate field corn residue data have been submitted by the petitioner. In addition, the proposed use pattern for pop corn is the same as the use pattern for field corn: maximum of 2 applications/season; maximum single application of 0.1 lb. diflufenzopyr/A with a maximum seasonal application rate of 0.125 lb. diflufenzopyr/A; 72-day preharvest interval (PHI) for grain and stover. Therefore, pop corn field trial data will not be required.

8b. Based on the available data, the following tolerances for residues of the herbicide diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate: "corn, pop, grain" at 0.05 ppm and "corn, pop, stover" at 0.05 ppm. **A revised Section F should be submitted.**

Pasture and Rangeland Grasses

9a. The number and geographic representation of data are adequate for the proposed use on pasture and rangeland. A total of 13 field residue trials (5 bermuda grass, 4 bluegrass, and 4 bromegrass) were performed in Regions 2 (1 trial), 4 (1 trial), 5 (2 trials), 6 (1 trial), 7 (2 trials), 8 (1 trial), 9 (2 trials), 10 (2 trials) and 11 (1 trial).

9b. The submitted field residue trials are adequate and indicate that residues of diflufenzopyr will not exceed 22 ppm in forage and 7.0 ppm in hay when treated with a single application of 0.1 lbs. diflufenzopyr/A (1x). Therefore, based on the available field trial data, the following tolerances for residues of diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate: "grass, forage" at 22 ppm and "grass, hay" at 7.0 ppm. **A revised Section F should be submitted.**

OPPTS GLN: 860.1520: Processed Food/Feed

10. As there are no processed commodities associated with sweet corn, pop corn or pasture and rangeland grasses, processing studies are not required to support the subject petition.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

11a. No livestock feeding studies have been submitted in support of this petition. There are livestock feed items associated with the registered and proposed uses of diflufenzopyr.

11b. Based on the calculated TDB and the results of the ruminant metabolism study, **tolerances for residues of diflufenzopyr in ruminant commodities and a ruminant feeding study are required**. The study should be performed at 1x, 3x, and 10x the calculated TDB of 53 ppm. In order to account for possible dietary exposure to diflufenzopyr residues in ruminant commodities, appropriate tolerances were calculated by extrapolating the results of the ruminant metabolism study (0.19x TDB) to10x the TDB. A level of 10x was chosen rather than 1x to account for differences in the species and durations of dosing in ruminant feeding (cow) and metabolism (goat) studies. **Provided an adequate analytical enforcement method (including ILV and radiovalidation) is submitted,** the following time-limited tolerances for residues of diflufenzopyr and its metabolites convertible to M1, and free and acid-released M19, expressed as diflufenzopyr, in ruminant commodities (cattle, goats, hogs, horses and sheep) are appropriate: meat at 0.60 ppm, kidney at 4.0 ppm, meat by-products (except kidney) at 0.50 ppm, fat at 0.30 ppm, and milk at 3.0 ppm. **A revised Section F should be submitted.**

11c. HED previously concluded that based on the exaggerated dose administered in the poultry metabolism study (250x), transfer of secondary residues of diflufenzopyr to poultry and eggs are not expected. Therefore, tolerances for poultry commodities are not needed.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

12a. The results of a confined accumulation in rotational crop study were submitted in support of the use of diflufenzopyr on field corn (PP#7F4848). In a memo dated 11/2/98, HED concluded that the "confined" rotational crop study is not acceptable since diflufenzopyr was not applied directly to the soil before planting the rotated crops (Memo, L. Cheng; D239675). Furthermore, the TRR's in the rotational crops were fractionated among several organic solvents without identification of the metabolites. HED recommended that a new confined rotational crop study be submitted along with a revised Section B be

submitted to impose a 1-year label restriction prohibiting rotation to any crop other than field corn. However, in a memo dated 11/23/98, RD requested that the registrant be given the option to submit either a new confined rotational crop study or limited field rotational crop study to fulfill the rotational crop data gap (Memo, J. Miller, no DP Barcode). The registrant would need to submit trials for 3 representative crops (2 sites for each crop): a small grain crop, a root crop, and a leafy vegetable crop. In a memo dated 1/13/99, HED concurred with RD's request (Memo, O. Odiott, no DP Barcode).

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

13. In response to the rotational crop data gap, BASF submitted the results of a limited field trial. The results of this study were reviewed by HED (Memo, J. Tyler, 10/11/01; D254989). The results of the limited field rotational crop study are acceptable. Residues of diflufenzopyr were less than the method's LOQ of 0.05 ppm in/on all treated representative rotational crops (radish roots and tops, lettuce, and winter wheat grain, forage, and hay) from the 30-day PBI. Therefore, no tolerances on rotational crops are needed. However, as residues were found at a 30-day PBI in the previously submitted confined rotational crop study, a PBI is required. **The petitioner should submit a revised Section B to include a 30-day PBI restriction.**

Other Considerations

14. There are currently no established Codex, Mexican maximum residue limits (MRLs) for residues of diflufenzopyr in/on plant or livestock commodities. A Canadian MRL of 0.05 ppm for residues of diflufenzopyr, expressed as the parent and metabolites convertible to M1, has been established for corn. No compatibility issues exist with regard to the existing and proposed U.S. tolerances.

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

Product chemistry data for the diflufenzopyr technical product were reviewed (memos, S. Mathur, 2/4/97, A. Smith, 1/14/98, H. Podall, 4/2/98, Registration Division). These reviews concluded that the available product chemistry data were adequate to fulfill the requirements for technical diflufenzopyr.

OPPTS GLN 860.1200: Proposed Uses

The petitioner provided a proposed label for Distinct® Herbicide (EPA Reg. No. 7969-150), a selective herbicide containing both diflufenzopyr and dicamba as active ingredients. This product contains 20% diflufenzopyr or 0.20 lb. ae/ lb. product. Distinct® is proposed for use on pop corn, sweet corn and pastures for the control of various weeds. Surfactants (0.25% v/v) should be added to the postemergence finished spray. The application volume is 3-50 gal/acre by ground equipment. Rotational crops can be planted 120 days after the last application of

Distinct®. However, in the event of crop failure, corn can be planted 7 or more days after application. Table 1 lists a summary of the proposed use patterns.

Table 1. Summary of Proposed Use Patterns for Diflufenzopyr on Pasture and Rangeland Grass, Pop Corn and Sweet Corn.

Commodity	Max. Appl. Rate (lb. diflufenzopyr/A)		Max. No. of Appl.	RTI[1] (days)	PHI[2] (days)	Comments/Restrictions
	Per Application	Per Season				
Pasture and Rangeland Grass	0.1	0.1	2	14	0	Areas treated with Distinct® can be grazed or harvested for feed immediately after application.
Pop corn	0.1	0.125	2	14	72 - stover	Do not apply without first verifying the selectivity of Distinct® on specific hybrid.
Sweet Corn	0.05	0.075	2	14	32 - forage and fresh 72 - stover	Do not apply without first verifying the selectivity of Distinct® on specific hybrid. Do not use on sweet corn grown for seed.

1. RTI = Retreatment Interval
2. PHI = Preharvest Interval

NOTE TO RD: There is a discrepancy between the submitted Section B and Supplemental Label concerning the proposed maximum single and seasonal application rates on pop corn and grass. The Section F reads "Pasture and popcorn have a maximum single application rate of 8 ounces per acre with a maximum seasonal use of 10 ounces per acre." The Supplemental Label reads 1) for pasture and rangeland "Do not exceed 8 ounces of Distinct® per acre per calendar year" and 2) for pop corn "Apply 4 to 6 ounces of Distinct® per acre....." and no maximum seasonal application rate is specified. Per personal communication with BASF, the appropriate maximum single and seasonal application rates for pop corn are 8 oz. Distinct®/A (0.1 lb. diflufenzopyr/A) and 10 oz. Distinct®/A (0.125 lb. diflufenzopyr/A), respectively; and the appropriate maximum seasonal application rate on grass is 8 oz. Distinct®/A (0.1 lb. diflufenzopyr/A) (personal communication between J. Tyler and M. Graben; 11/2/01). These proposed application rates are reflected in this document.

HED Conclusions: The proposed use directions for sweet corn, pop corn, and pasture and rangeland grasses are supported by the submitted residue data. **The petitioner should submit a revised Section B to include a 30-day PBI restriction.**

GLN 860.1300: Nature of the Residue - Plants

The nature of the residue in field corn is understood. An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled separately in the pyridine and phenyl rings has been performed on field corn. The urea bond is cleaved to yield metabolites containing a new bicyclic ring system. No diflufenzopyr was detected in any of the corn matrices; metabolites comprising >10% TRR

include M1 (8-methylpyrido[2,3-d]pyridazin-5(6H)-one), M10 (8-hydroxymethyl-5(6H)-pyrido[2,3-d]pyridazone) and its glucose conjugate, and M9 (8-methylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione in forage and fodder, and 6-14% TRR lignin was found in fodder. Corn grain contained 3-4 discrete unknowns, all at <10% TRR or <0.05 ppm each.

The HED MARC met on September 28, 1998 to discuss the toxicological significance of metabolites of diflufenzopyr. The Committee concluded that diflufenzopyr and metabolites convertible to metabolite M1 need to be included in the tolerance expression. Furthermore, for dietary exposure assessment, metabolite M10 should be included in addition to diflufenzopyr and metabolites convertible to M1 (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

GLN 860.1300: Nature of the Residue - Livestock

The nature of the residue in ruminants and poultry is understood. The HED MARC met on 9/28/98 to discuss the metabolism of diflufenzopyr in livestock.

Ruminants: An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled separately in the pyridine and phenyl ring has been performed in goats. Based on the metabolites identified, the metabolism of diflufenzopyr in ruminants is similar to that in corn. Major metabolites include M1, M5 (6-((3,5-difluorophenylcarbamoyl-8-methyl-pyrido[2,3-d]-5-pyridazinone) and M19 (8-hydroxymethylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione). A substantial amount (8-50%) of diflufenzopyr was also found in milk, kidney, and liver. The Committee concluded if any livestock feeding studies are conducted in the future, analyses should be done for parent, metabolites convertible to M1, and free and acid-released M19 (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

HED notes that the new use of diflufenzopyr on pasture and rangeland grasses significantly increases the calculated ruminant TDB to 53 ppm (See section entitled OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs). Using the new diet, the submitted ruminant metabolism studies were performed at 0.19x the TDB. It is possible that more metabolites could be identified if the metabolism studies are performed at a higher dose. However, as liver was the only ruminant commodity that had a high amount of minor unidentified bands and liver is not a major human consumption item, **HED concludes that additional ruminant metabolism data are not necessary *at this time.*** If new uses are submitted which will significantly increase the ruminant TDB, then additional ruminant metabolism data performed at a higher dose may be required.

Poultry: An acceptable metabolism study using [^{14}C]-diflufenzopyr labeled in the pyridine or phenyl ring has been performed in hens. Based on the metabolism results, diflufenzopyr was not detected in poultry, and M1 was the only significant metabolite identified, and in egg white only. The Committee commented that since the dose administered in the poultry metabolism studies had been at such an exaggerated level (250x), transfer of secondary residues to poultry would not be expected (Decision memo, L. Cheng, 10/29/98, No DP Barcode).

OPPTS GLN 860.1340: Residue Analytical Methods

Plants: The company has proposed the GC/MS Method D9709 for enforcement of the proposed tolerances on sweet corn, pop corn, and pasture and rangeland grasses. Briefly, diflufenzopyr and M1 are extracted from corn matrices by shaking with dilute aqueous sodium bicarbonate and ammoniated acetone. The extract is filtered, and an aliquot is acidified with concentrated hydrochloric acid to convert diflufenzopyr to M1. The solution is evaporated to dryness and purified by mini-Oasis HLB™ chromatography column; the eluant if evaporated to dryness and the residue is dissolved in MeOH and analyzed by GC/MS. Quantitation is via SIM using m/z 161 which is the molecular weight for M1. The report states an LOQ of 0.05 ppm and an LOD of 0.02 ppm.

For the measurement of the metabolite M10, Method D9702 (Draft Method for Determination of 8-Hydroxymethyl-5(6H)-pyrido[2,3-d]pyridazone Residues in Corn RAC, and Corn Process Fractions by LC/MS, S. Abdel-Baky and S. A. Baumann, 8/11/97) was used in the submitted sweet corn residue field trial study. Briefly, M10 it is extracted from the homogenized corn matrices using 1N sulfuric acid at 95 C for an hour. This step hydrolyzes the glucoside metabolite M11 to M10 (mol wt=177). After filtration to remove solid material, an aliquot is purified by a mini chromatography column. M10 is eluted with 5% methanol:water. The eluant is evaporated to dryness and the residue is dissolved in buffer solution (ammonium formate) and injected into LC equipped with a mass spectrometer detector. For determination of M10, ions in the range of *m/z* 178 to 104 are monitored. The report states a LOQ of 0.05 ppm and an LOD of 0.02 ppm. Recovery data are summarized below.

HED Conclusions: An adequate enforcement method (Method D9709) is available for enforcement of the proposed tolerances. The reported method LOD and LOQ are 0.02 ppm and 0.05 ppm, respectively. HED has conducted a successful PMV of Method D9709 (Memo, J. Tyler, 10/31/01; D278522). The method will be forwarded to the FDA for inclusion in PAM Vol. II.

Livestock: No analytical method has been submitted for livestock. Based on the calculated TDB and the results of the ruminant metabolism study, **tolerances for residues of diflufenzopyr and a ruminant feeding study are required. An adequate analytical enforcement method (including ILV and radiovalidation data) should be submitted.**

OPPTS GLN 860.1360: Multiresidue Method

The results of multiresidue testing of diflufenzopyr and its metabolites M1 and M10 have been forwarded to the FDA for inclusion in PAM Vol. I (Memo, J. Tyler, 10/11/01; D278336). Neither diflufenzopyr nor M1 was detected through Protocol C, however, M10 was detected through Protocol C.

OPPTS GLN 860.1380: Storage Stability Data

The results of a freezer storage stability study were submitted in support of the use of diflufenzopyr on field corn (PP#7F4848) and reviewed by HED (Memo, J. Tyler, 10/11/01; D254989). In that study, control corn forage, grain and fodder samples were fortified at a level of 0.1 ppm with metabolites M1 and M10. They were analyzed for residues and recoveries initially after fortification (0 months), and after 4, 14, 19, and 24 months of frozen storage (<10°C). The 0- and 4-month samples were analyzed at Sandoz Agro, Inc. and the data were summarized in an interim report. The remainder of the sample analyses were performed at BASF Corporation, Research Triangle Park, NC. The samples were analyzed by BASF Method Numbers D9709 and D9702 for residues of M1 and M10, respectively. Analysis of the samples indicates that M1 and M10 residues remained stable between the 0-month and 24-month storage intervals.

HED Conclusions: The previously submitted storage stability data indicate that residues of diflufenzopyr (M1 and M10 residues) are relatively stable under frozen storage conditions in/on fortified samples of field corn forage, grain and fodder for up to 24 months. The submitted storage stability data are adequate to support the storage conditions and intervals of the samples from the sweet corn, and pasture and rangeland grasses field trial studies (24 months and 8 months, respectively).

OPPTS GLN 860.1500: Crop Field Trials

Sweet Corn:
Submitted with this petition:

> MRID# 45154001. Sweet Corn Residues of Diflufenzopyr and Dicamba Resulting From Application of Distinct ™ (BAS 662 H).

Nine field residue trials were conducted in 1996. These trials were located in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (3 trials), 6 (1 trial), 10 (1 trial) and 12 (1 trial). Four plots were established at each site. Treatment 1 was the untreated control. Treatment 2 consisted of 2 applications of diflufenzopyr at a rate of 0.05 lbs. ai/A for a total of 0.1 lbs. ai/A. Treatment 3 consisted of 2 applications of Distinct® at a rate of 0.05 lbs. diflufenzopyr/A for a total of 0.1 lb. diflufenzopyr/A (1.2x the proposed maximum application rate). Treatment 4 consisted of 2 applications of dicamba at a rate of 0.25 lbs. ai/A for a total of 0.50 lbs. ai/A.

Two replicate samples were harvested from each treated plot 4-7 weeks (forage and ears) and 5-16 weeks (stover) after application. The samples were frozen and shipped to Sandoz Agro, Inc. (Des Plaines, Iowa). Representative sweet corn forage, fodder, and ear samples from the untreated and Distinct®-treated plot (Treatment 3) were analyzed for residues of M1, including all residues converted to M1, and the metabolite M10. Ear samples from site 631-01 were not analyzed due to sample loss during transition of study from Sandoz Agro, Inc. to BASF; and as fodder samples from site 664-02 were not collected, analysis was not performed. Sample analyses for M1 and M10 were performed using BASF Analytical Method Numbers D9709 and

D9702, respectively. The methods were validated at 0.05 ppm for diflufenzopyr (expressed as M1 equivalents), 0.05 ppm for M1, and 0.05 and 0.50 ppm for M10. The overall average recoveries were 90 ± 14% (n=9) for BAS 654 H, 110 ± 12% (n=9) for M1, and 90 ± 12% (n-18) for M10.

Analyses of the treated samples (Table 2) indicate that at residues of diflufenzopyr were not detected above the LOQ (0.05 ppm) in the sweet corn forage, ear, and fodder samples when treated with 2 applications of Distinct® at 0.1 lb. diflufenzopyr/A (1.2x; Treatment 3). In addition, residues of M10 were below the LOQ (0.05 ppm) in sweet corn, ears and fodder in all sites.

Table 2. Diflufenzopyr Residues in Sweet Corn Forage, Ears, and Fodder.

Trial Site	PHI (Weeks)	Residues[1] (ppm)	
		M1[2] (Reps A & B)	M10 (Reps A & B)
Sweet Corn Forage			
WI (608-01)	7	<0.05	<0.05
		<0.05	<0.05
MN (613-01)	6	<0.05	<0.05
		<0.05	<0.05
IN (615-01)	7	<0.05	<0.05
		<0.05	<0.05
OR (631-01)	8	<0.05	<0.05
		<0.05	<0.05
CA (660-01)	6	<0.05	<0.05
		<0.05	<0.05
WA (661-01)	4	<0.05	<0.05
		<0.05	<0.05
GA (664-02)	6	<0.05	<0.05
		<0.05	<0.05
FL (670-01)	4	<0.05	<0.05
		<0.05	<0.05
NY (671-01)	4	<0.05	<0.05
		<0.05	<0.05
Sweet Corn Ears[3]			
WI (608-01)	10	<0.05	<0.05
		<0.05	<0.05
MN (613-01)	9	<0.05	<0.05
		<0.05	<0.05
IN (615-01)	11	<0.05	<0.05
		<0.05	<0.05
OR (631-01)	16	<0.05	<0.05
		<0.05	<0.05

Trial Site	PHI (Weeks)	Residues[1] (ppm)	
		M1[2] (Reps A & B)	M10 (Reps A & B)
CA (660-01)	13	<0.05	<0.05
		<0.05	<0.05
WA (661-01)	10	<0.05	<0.05
		<0.05	<0.05
GA (664-02)	NC [3]	<0.05	<0.05
		<0.05	<0.05
FL (670-01)	5	<0.05	<0.05
		<0.05	<0.05
NY (671-01)	10	<0.05	<0.05
		<0.05	<0.05
Sweet Corn Fodder [4]			
WI (608-01)	7	<0.05	<0.05
		<0.05	<0.05
MN (613-01)	6	<0.05	<0.05
		<0.05	<0.05
IN (615-01)	7	<0.05	<0.05
		<0.05	<0.05
OR (631-01)	8	<0.05	<0.05
		<0.05	<0.05
CA (660-01)	6	<0.05	<0.05
		<0.05	<0.05
WA (661-01)	4	<0.05	<0.05
		<0.05	<0.05
GA (664-02)	6	<0.05	<0.05
		<0.05	<0.05
FL (670-01)	4	<0.05	<0.05
		<0.05	<0.05
NY (671-01)	4	<0.05	<0.05
		<0.05	<0.05

1. Residues are <0.05 ppm for reps A & B for all samples.
2. M1 includes parent and residues convertible to M1.
3. The ears at site 631-02 were not analyzed for residues due to lost samples.
4. The fodder at 664-02 was not analyzed for residues because the plot was disked before the samples were collected.

HED Conclusions: A total of 9 field residue trials were conducted in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (3 trials), 6 (1 trial), 10 (1 trial) and 12 (1 trial). The locations of the field trials do not match that required for sweet corn when detectable residues are not expected (<LOQ): 9 trials conducted in Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), 5 (3 trials), 10 (1 trial), 11 (1 trial) and 12 (1 trial). However, the petitioner previously submitted the results of 24 field

corn residue trials conducted in 1995 and 1996. In that study, the field corn samples were treated with 2 applications of Distinct® at 0.1 lb. diflufenzopyr/A for a total of 0.2 lb. diflufenzopyr/A (2.7x proposed maximum sweet corn application rate). The results showed that residues of diflufenzopyr and metabolites convertible to M1 resulting from proposed use would not exceed 0.05 ppm. HED can generally translate field corn forage and stover data to sweet corn. Therefore, additional sweet corn residue trials will not be required

The submitted field trials are adequate to support the proposed tolerances for residues of diflufenzopyr in/on sweet corn forage, ears, and fodder. **Based on the available data, the following tolerances for residues of the herbicide diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate:**

Corn, sweet, forage ..... 0.05 ppm
Corn, sweet, fresh ..... 0.05 ppm
Corn, sweet, stover ..... 0.05 ppm

For dietary exposure analysis, a residue value of 0.10 ppm should be used to estimate combined residues of diflufenzopyr, M1 and M10 in sweet corn.

Pop Corn:
No pop corn field trial data were submitted in support of this petition. HED can generally translate field corn grain/stover data to pop corn grain/stover provided the use patterns are the same and there is adequate field corn data. As mentioned previously, adequate field corn residue data have been submitted by the petitioner. In addition, the proposed use pattern for pop corn is the same as the use pattern for field corn: maximum of 2 applications/season; maximum single application of 0.1 lb. diflufenzopyr/A with a maximum seasonal application rate of 0.125 lb. diflufenzopyr/A; and a 72-day PHI for grain and stover. Therefore, pop corn field trial data will not be required.

Based on the available data, the following tolerances for residues of the herbicide diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate:

Corn, pop, grain ..... 0.05 ppm
Corn, pop, stover ..... 0.05 ppm

A revised Section F to include a tolerance for corn, pop, grain should be submitted. For dietary exposure analysis, a residue value of 0.06 ppm should be used to estimate combined residues of diflufenzopyr, M1 and M10 in pop corn.

Pasture and Rangeland Grasses:
Submitted with this petition:

MRID# 45154002. Magnitude of BAS 654 H Residues in Pasture and Rangeland Grasses. BASF Study Number: 63778.

Thirteen pasture and rangeland field residue trials (5 bermuda grass, 4 bluegrass, and 4 bromegrass) were conducted in 1999. These trials were located in Regions 2 (1 trial), 4 (1 trial), 5 (2 trials), 6 (1 trial), 7 (2 trials), 8 (1 trial), 9 (2 trials), 10 (2 trials) and 11 (1 trial). Four plots were established at each site. Treatment 1 was the untreated control. Treatment 2 consisted of one application of BAS 514 34 H at a rate of 0.75 lbs. ai/A. The results of this analysis were previously reported (BASF Reg. Doc. 1999/5165). Treatment 3 consisted of one spray application of Distinct® at a rate of 0.1 lb. diflufenzopyr/A (1x the proposed maximum application rate). The results from the analysis of the treatment were provided in the report. Treatment 4 consisted of one spray application of BAS 514 34 H at 0.75 lb. ai/A plus BAS 662 01 H at 0.35 lb. ai/A as a tank mix application. The results of this treatment were not reported.

All applications were made when the pasture and rangeland grasses were at the 6 to 8-inch tall to boot stage of plant development. The forage samples were collected 0 days after treatment (DAT), and the hay was cut 7-8 DAT and allowed to dry for 1-4 days prior to collection.

The samples were frozen and shipped to BASF Agricultural Products Center (APC) in Research Triangle Park, NC. Representative forage and hay samples from Distinct® (BAS 662 H) treated plot (Treatment 3) were analyzed for M1 and all residues convertible to M1 (including parent diflufenzopyr) using BASF Analytical Method Number D9709. The method was validated by fortifying control forage and hay samples with BAS 654 H and M1 at a range of 0.05-15.0 ppm. The overall average recovery was 98 ± 13.8% (n=37). Analyses of the treated samples (Table 3) indicate that residues of diflufenzopyr were 0.07-10.12 ppm in forage and 0.37-3.27 ppm in hay when treated with a single application of Distinct® at 0.35 lb. ai/A (0.1 lbs. diflufenzopyr/A; 1x).

Table 3. Diflufenzopyr Residues in Pasture and Rangeland Grass Samples.

Trial Site (EPA Region)	Grass Type	PHI[1]	Residues of M1 (ppm)[2]	Residues of Diflufenzopyr (ppm)[3]
Forage				
AR (4)	Bermuda Grass	0	6.54, 7.91 (7.23)	13.6, 16.4 (15.0)
NE (5)	Bluegrass	0	0.66, 0.86 (0.76)	1.37, 1.78 (1.58)
NE (5)	Bromegrass	0	1.79, 1.91(1.85)	3.71, 3.96 (3.84)
OK (6)	Bermuda Grass	0	3.54, 2.46 (3.00)	7.34, 5.10 (6.22)
ND (7)	Bluegrass	0	**10.12**, 8.57 (9.35)	**21.0**, 17.8 (19.4)
ND (7)	Bromegrass	0	3.16, 4.02 (3.59)	7.50, 8.34 (7.92)
TX (8)	Bromegrass	0	1.24, 1.54 (1.39)	2.57, 3.19 (2.88)

Trial Site (EPA Region)	Grass Type	PHI[1]	Residues of M1 (ppm)[2]	Residues of Diflufenzopyr (ppm)[3]
CO (9)	Bromegrass	0	4.03, 2.71 (3.37)	8.36, 5.62 (6.99)
MT (9)	Bluegrass	0	1.87, 1.92 (1.90)	3.88, 3.98 (3.93)
CA (10)	Bermuda Grass	0	5.05, 3.24 (4.15)	10.5, 6.72 (8.61)
CA (10)	Bermuda Grass	0	0.11, 0.11 (0.11)	0.23, 0.23 (0.23)
ID (11)	Bluegrass	0	3.46, 3.80 (3.63)	7.18, 7.88 (7.53)
GA (2)	Bermuda Grass	0	0.08, 0.07 (0.08)	0.17, 0.15 (0.16)
Hay				
AR (4)	Bermuda Grass	7	1.39, 1.54 (1.47)	2.88, 3.19 (3.04)
NE (5)	Bluegrass	7	0.59, 0.52 (0.56)	1.22, 1.08 (1.15)
NE (5)	Bromegrass	7	1.21, 0.92 (1.07)	2.51, 1.91 (2.21)
OK (6)	Bermuda Grass	7	1.02, 0.81 (0.91)	2.11, 1.68(1.89)
ND (7)	Bluegrass	7	1.0, 1.15 (1.08)	2.07, 2.38 (2.23)
ND (7)	Bromegrass	7	1.58, 1.15 (1.37)	3.28, 2.38 (2.83)
TX (8)	Bromegrass	7	2.62, 2.05 (2.34)	5.43, 4.25 (4.84)
CO (9)	Bromegrass	8	0.90, 0.70 (0.80)	1.87, 1.45 (1.66)
MT (9)	Bluegrass	7	0.88, 0.86 (0.87)	1.82, 1.78 (1.80)
CA (10)	Bermuda Grass	7	1.15, 1.58 (1.37)	2.38, 3.28 (2.83)
CA (10)	Bermuda Grass	7	**3.27**, 3.05 (3.16)	**6.78**, 6.32 (6.55)
ID (11)	Bluegrass	7	2.54, 1.59 (2.07)	5.27, 3.30 (4.28)
GA (2)	Bermuda Grass	7	0.37, 0.37 (0.37)	0.77, 0.77 (0.77)

1. PHI = preharvest interval. Based on the day the hay was cut. The hay was cut and left in the field for 2-3 days to dry.
2. Average of duplicate analyses in parentheses.
3. Calculated by reviewer using molecular weight conversion factor of 2.074.

Forage and hay samples for residue decline analysis were collected at 3,7,10 and 15 DAT and 0,3,10, and 15 DAT, respectively. The results of the residue decline study (Table 4) indicate that diflufenzopyr residues decrease with increasing pre-harvest intervals for forage and hay.

Table 4. Results of the Residue Decline Study.

Trial Site (EPA Region)	Grass Type	PHI[1]	Residues of M1(ppm)[2]
Forage			
TX (8)	Bromegrass	0	1.24, 1.54 (1.39)
		3	1.03, 1.15 (1.09)
		7	0.92, 0.79 (0.86)
		10	0.39, 0.49 (0.44)
		15	0.46, 0.35 (0.41)
Hay			
TX (8)	Bromegrass	0	3.42, 4.32 (3.87)
		3	2.99, 3.23 (3.11)
		7	2.62, 2.05 (2.34)
		10	0.85, 0.78 (0.82)
		15	0.94, 1.24 (1.09)

1. PHI = preharvest interval. Based on the day the hay was cut. The cut hay was left in field for 2-3 days to dry.
2. Average of duplicate analyses in parentheses.

HED Conclusions: The number and geographic representation of data are adequate for the proposed use on pasture and rangeland. A total of 13 field residue trials (5 bermuda grass, 4 bluegrass, and 4 bromegrass) in Regions 2 (1 trial), 4 (1 trial), 5 (2 trials), 6 (1 trial), 7 (2 trials), 8 (1 trial), 9 (2 trials), 10 (2 trials) and 11 (1 trial).

The submitted field residue trials are adequate and indicate that residues of diflufenzopyr will not exceed 22 ppm in forage and 7.0 ppm in hay when treated with a single application of 0.1 lbs. diflufenzopyr/A (1x). **Therefore, based on the available field trial data, the following tolerances for residues of diflufenzopyr and its metabolites convertible to M1, expressed as diflufenzopyr, are appropriate:**

Grass, forage ..... 22 ppm
Grass, hay ..... 7.0 ppm

A revised Section F to include the recommended tolerances should be submitted.

OPPTS GLN 860.1520: Processed Food/Feed

As there are no processed commodities associated with sweet corn, pop corn or pasture and rangeland grasses, processing studies are not required to support the subject petition.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

No livestock feeding studies have been submitted in support of this petition. There are livestock feed items associated with the registered and proposed uses of diflufenzopyr.

Ruminants:

The petitioner previously submitted the results of a radiolabelled ruminant metabolism study. The TDB of diflufenzopyr to beef and dairy cattle is estimated to be 53 ppm; see Table 6. Based on these calculations, the goat metabolism study was conducted at 0.19x the TDB to beef and dairy cattle. In the pyrimidine-labeled study, the total toxic residue (TTR; parent, metabolites convertible to M1, and free and acid-released M19) was identified at up to 0.061 ppm in kidney, 0.0084 ppm in liver, 0.0501 ppm in milk. Although the TTR was not quantifiable in fat, the results indicate that it is <0.005 ppm. Muscle samples were not extracted further because the TRR was <0.010 ppm (0.0099 ppm). If those residues are extrapolated down to a 10x feeding level (the highest feeding level that would be required in a feeding study), expected residues would be 0.52 ppm in muscle (using TRR), 3.2 ppm in kidney, 0.44 ppm in liver, 2.6 ppm in milk, and 0.26 ppm in fat.

Table 5. Summary of TTR (parent and metabolites) for Livestock Commodities.

Ruminant Commodity	TTR[1] (ppm)		
	0.19x	1x	10x
Muscle [2]	0.0099	0.052	0.52
Kidney	0.061	0.32	3.2
Liver	0.0084	0.044	0.44
Milk	0.0501	0.26	2.6
Fat [3]	0.005	0.026	0.26

1. TTR (total toxic residues): parent, metabolites convertible to M1, and free and acid-released M19.
2. Muscle samples were not extracted because the TRR was <0.010 ppm; therefore, the TRR was used.
3. TTR was not quantifiable in fat, but shown to be <0.005.

HED's Conclusions: Based on the calculated TDB and the results of the ruminant metabolism study, **tolerances for residues of diflufenzopyr in ruminant commodities and a ruminant feeding study are required.** The study should be performed at 1x, 3x, and 10x the calculated TDB of 53 ppm. In order to account for possible dietary exposure to diflufenzopyr residues in ruminant commodities, appropriate tolerances were calculated by extrapolating the results of the ruminant metabolism study (0.19x TDB) to 10x the TDB. A level of 10x was chosen rather than 1x to account for differences in the species and durations of dosing in ruminant feeding (cow) and metabolism (goat) studies. **Provided an adequate analytical enforcement method (including ILV and radiovalidation) is submitted, the following time-limited tolerances for residues of diflufenzopyr and its metabolites convertible to M1, and free and acid-released M19, convertible to diflufenzopyr, are appropriate:**

meat* ..... **0.60 ppm**
kidney* ..... **4.0 ppm**

meat by-products (except kidney)* ..... **0.50 ppm**
fat* ..... **0.30 ppm**
milk ..... **3.0 ppm**
* of cattle, goat, hog, horse, and sheep

A revised Section F should be submitted.

Poultry:
The petitioner previously submitted the results of a radiolabelled poultry metabolism study. Based on the current tolerance of 0.05 ppm on field corn grain that comprises 80% of the diet, the calculated TDB would be 0.04 ppm; see Table 6. Therefore, the 10 ppm dose in the poultry metabolism study would be equivalent to 250x the TDB.

HED's Conclusions: HED previously concluded that based on the exaggerated dose administered in the poultry metabolism study (250x), transfer of secondary residues of diflufenzopyr to poultry and eggs are not expected. Therefore, tolerances for poultry commodities are not needed.

Table 6. Estimation (based on U.S. feeding practices as reflected in Table 1 of OPPTS 860.1000) of the TDB[1] of diflufenzopyr to livestock.

Feed Commodity	Proposed Tolerance, ppm[3]	% Dry Matter	% of Diet	Burden, ppm [2]
Beef and Dairy Cattle				
Grass (pasture & rangeland), forage	22	25	60	53
Field corn, grain	0.05	88	40	0.023
			TOTAL	53
Poultry[4]				
Field corn, grain	0.05		80	0.04
			TOTAL	0.04

1. TDB = Theoretical Dietary Burden.
2. Burden = [tolerance / % dry matter (if cattle)] x % of diet).
3. Recommended tolerance levels were used all for all commodities.
4. Poultry feed items are not corrected for % dry matter.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

The results of a confined accumulation in rotational crop study were submitted in support of the use of diflufenzopyr on field corn (PP#7F4848). In a memo dated 11/2/98, HED concluded that the "confined" rotational crop study is not acceptable since diflufenzopyr was not applied directly to the soil before planting the rotated crops (Memo, L. Cheng; D239675). Furthermore, the TRR's in the rotational crops were fractionated among several organic solvents without identification of the metabolites. HED recommended that a new confined rotational crop study be submitted along with a revised Section B be submitted to impose a 1-year label restriction prohibiting rotation to any crop other than field corn. However, in a memo dated 11/23/98, RD requested that the registrant be given the option to submit either a new confined rotational crop study or limited field rotational crop study to fulfill the rotational crop data gap (Memo, J. Miller,

no DP Barcode). The registrant would need to submit trials for 3 representative crops (2 sites for each crop): a small grain crop, a root crop, and a leafy vegetable crop. In a memo dated 1/13/99, HED concurred with RD's request (Memo, O. Odiott, no DP Barcode).

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

In response to the rotational crop data gap, BASF submitted the results of a limited field trial. The results of this study were reviewed by HED (Memo, J. Tyler, 10/11/01; D254989). The results of the limited field rotational crop study are acceptable. Residues of diflufenzopyr were less than the method's LOQ of 0.05 ppm in/on all treated representative rotational crops (radish roots and tops, lettuce, and winter wheat grain, forage, and hay) from the 30-day PBI. Therefore, no tolerances on rotational crops are needed. However, as residues were found at a 30-day PBI in the previously submitted confined rotational crop study, a PBI is required. **The petitioner should submit a revised Section B to include a 30-day PBI restriction.**

Other Considerations

There are currently no established Codex, Mexican MRLs for residues of diflufenzopyr in/on plant or livestock commodities. A Canadian MRL of 0.05 ppm for residues of diflufenzopyr, expressed as the parent and metabolites convertible to M1, has been established for corn. No compatibility issues exist with regard to the existing and proposed U.S. tolerances. The International Residue Limit Status (IRLS) sheet is attached (see Attachment 1).

ATTACHMENTS

Attachment 1: IRLS sheet.

cc (w/ attachments): J. Tyler; J. Miller ((RD; 7505C)
RDI: G. Herndon (12/05/01), G. Kramer (12/05/01)
J. Tyler: 806W: CM#2: (703)305-5564: 7509C: RABI

ATTACHMENT 1

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: Diflufenzopyr	Common Name:	X Proposed tolerance □ Reevaluated tolerance □ Other	Date: 10/9/01

Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested	Petition Number: 1E6265 DP Barcode: Other Identifier:
Residue definition (step 8/CXL): N/A	Reviewer/Branch: Jennifer Tyler/RAB1
	Residue definition: diflufenzopyr [2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid] and its metabolites convertible to M1 (8-methylpyrido[2,3-d]pyridazin-5(6H)-one)

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		corn, sweet, forage	0.05 ppm
		corn, sweet, fresh	0.05 ppm
		corn, sweet, stover	0.05 ppm.
		corn, pop, grain	0.05 ppm
		corn, pop, stover	0.05 ppm
		grass, forage	11 ppm
		grass, hay	4.0 ppm

Limits for Canada	Limits for Mexico
□ No Limits □ No Limits for the crops requested	X No Limits □ No Limits for the crops requested
Residue definition: parent and metabolites convertible to M1 (8-methyl-5(6H)-pyrido [2,3-d] pyridazinone	Residue definition: N/A

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
corn	0.05		
(Labels indicate field and Eastern Canadian corn)			

Notes/Special Instructions:
S.Funk, 10/11/01.

Rev. 1998