



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 12/12/01

SUBJECT: **DIFLUFENZOPYR**. Acute and Chronic Dietary Exposure Assessments for Section 3 Registration on Sweet Corn, Pop Corn and Grass. PC Code 0051076 DP Barcode D278338. Case 293208. Submission S590359.

FROM/TO: Jennifer R. Tyler, Chemist
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509C)

THROUGH: G. Jeffrey Herndon, Branch Senior Scientist
RAB1/HED (7509C)

and

Sheila Piper, Chemist
Manying Xue, Chemist
Dietary Exposure Science Advisory Council (DESAC)/HED (7509C)

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 pasture and rangeland grasses, pop corn, and sweet corn (PP# 1E06265). Acute and chronic dietary exposure assessments were requested to determine the dietary exposure estimates associated with the use of diflufenzopyr on these commodities. As pasture and rangeland grass crops are not human consumption items, they were not included in the dietary exposure assessment. Unrefined, Tier 1 acute and chronic dietary exposure assessments were conducted for all supported (i.e., currently registered and proposed) diflufenzopyr food uses using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.73. The acute dietary exposure estimates are provided for females 13-50 years old only. No appropriate endpoint attributable to a single exposure was identified by the HIARC for the general U.S. population including infants and children. This assessment concludes that the acute dietary exposure estimates are below HED's level of concern (<100% acute population adjusted dose (aPAD)) at the 95th exposure percentile for females 13-50 years old (4% of the aPAD). The chronic dietary exposure estimates are provided for the general U.S. population and all population subgroups. This assessment also concludes that the chronic dietary exposure estimates are below HED's level of concern (<100% chronic population adjusted dose (cPAD)) for the general U.S. population (9% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1-6 years old at 32% of the cPAD.



EPA Reviewer: Jennifer R. Tyler, Date 12-DEC-2001

STUDY TYPE: Acute and Chronic Dietary Exposure Assessments for Section 3 Registration for Use of Diflufenzopyr on Sweet Corn, Pop Corn and Grass.

ACTIVE INGREDIENT: Diflufenzopyr

SYNONYMS: 2-(1-[[3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid

RESIDUE OF CONCERN: Plants: For tolerance purposes - diflufenzopyr and its metabolites convertible to M1. For risk assessment purposes - diflufenzopyr and its metabolites convertible to M1, and metabolite M10.

Livestock: For both tolerance and risk assessment purposes - diflufenzopyr, metabolites convertible to M1, and free and acid-released M19.

Executive Summary

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 in/on pasture and rangeland grasses, pop corn, and sweet corn (PP# 1E06265). Acute and chronic dietary exposure assessments were requested to determine the dietary exposure estimates associated with the use of diflufenzopyr on these commodities. As pasture and rangeland grass crops are not human consumption items, they were not included in the dietary exposure assessment. The most recent acute and chronic dietary exposure analyses were performed in conjunction with a Section 3 request for the use of diflufenzopyr on field corn (Memo, B. Steinwand, 10/23/98; D250529).

Unrefined, Tier 1 acute and chronic dietary exposure assessments were conducted for all supported (i.e., currently registered and proposed) diflufenzopyr food uses. The acute dietary exposure estimates are provided for females 13-50 years old only. No appropriate endpoint attributable to a single exposure was identified by the HIARC for the general U.S. population including infants and children. This assessment concludes that the acute dietary exposure estimates are below HED's level of concern (<100% acute population adjusted dose (< aPAD¹))

¹aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

at the 95th exposure percentile for females 13-50 years old (4% of the aPAD). The chronic dietary exposure estimates are provided for the general U.S. population and various population subgroups. This assessment concludes that the chronic dietary exposure estimates are below HED's level of concern (<100% chronic population adjusted dose (cPAD²)) for the general U.S. population (9% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1-6 years old at 32% of the cPAD.

I. Introduction

Exposure to pesticides can occur through food, water, residential and occupational means. Risk assessment incorporates both exposure and toxicity of a given pesticide. The risk is expressed as a percentage of a dose that could be expressed as a daily or a long term dose, to pose no adverse effects. This is called the PAD, and risk is expressed as %PAD. References are available on the EPA/pesticides web site which discuss the acute and chronic risk assessments in more detail: "Available Information on Assessing Exposure from Pesticides, A User's Guide", 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6, 8/20/99. The purpose of this memorandum is to summarize the results of the dietary exposure assessment for the general U.S. population and various population subgroups resulting from exposure to diflufenzopyr through food. This risk assessment is an updated dietary exposure analysis that has been conducted for diflufenzopyr.

II. Toxicological Information

On September 24, 1998, the HED Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology database of diflufenzopyr, established a Reference Dose (RfD) and selected the toxicological endpoints for acute and chronic dietary as well as occupational exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to diflufenzopyr as required by the Food Quality Protection Act (FQPA) of 1996 (HED Doc. No. 012894, W. Dykstra, 10/6/98). A summary of the doses and toxicological endpoints chosen by HIARC is listed in Table 1.

Cancer:

In accordance with the *1996 Proposed Guidelines for Carcinogenicity Risk Assessments*, diflufenzopyr was classified as "Not Likely" to be a human carcinogen. This classification is based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were judged to be adequate to assess carcinogenicity (HED Doc. No. 012894, W. Dykstra, 10/6/98).

FQPA Recommendation:

The HED FQPA Safety Factor Committee met on October 5, 1998 to evaluate the hazard and exposure data for diflufenzopyr and recommended that the FQPA safety factor (as required by

²aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

FQPA of August 3, 1996) be removed (i.e. reduced to 1x) in assessing the risk posed by this chemical. (HED Doc. No. 012904, B. Tarplee, 10/14/98).

Table 1. Summary of Toxicological Dose and Endpoints for Diflufenzopyr for Use in Dietary Exposure Assessment.

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary <u>Females 13-50</u>	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 1x aPAD = acute RfD FQPA SF = 1.0 mg/kg/day	Rabbit Developmental Study. LOAEL = 300 mg/kg/day based on extra ribs and other skeletal variations in the rabbit developmental study. These effects can occur from a single dose and females 13+ are the population subgroup of concern. The developmental findings occurred at a level of severe maternal toxicity.
Acute Dietary <u>general population</u>	An appropriate endpoint attributable to a single exposure for this population subgroup was not identified in the oral toxicity studies including the maternal effects in rat and rabbit developmental studies.		
Chronic Dietary <u>all populations</u>	NOAEL= 26 mg/kg/day UF=100 Chronic RfD = 0.26 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD FQPA SF = 0.26 mg/kg/day	52-week Dog Feeding Study. LOAEL = 299 mg/kg/day based on compensated hemolytic anemia in both sexes of dogs
Cancer (oral, dermal, inhalation)	None	Q* = None	In accordance with the <i>1996 Proposed Guidelines for Carcinogenicity Risk Assessments</i> , diflufenzopyr was classified as " Not Likely " to be a human carcinogen. This classification is based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were judged to be adequate to assess carcinogenicity.

III. Residue Information

Registered and Proposed Diflufenzopyr Tolerances:

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)]. The current Section 3 request is for tolerances for residues of diflufenzopyr in/on pop corn, sweet corn, and grass. As grass is not considered to be a human consumption item, it was not included in the dietary exposure assessment. In addition, HED has determined that tolerances for meat, kidney, meat by-products (except kidney), and fat of cattle, goat, hog, horse,

and sheep, and milk are necessary. Table 2 lists the recommended tolerance and residue values used in dietary exposure assessment.

Acute Assessment:

The acute dietary exposure assessment was performed for females 13-50 years old using tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites), and assuming 100% crop treated for all commodities. No appropriate dietary endpoint for the general U.S. Population (including infants and children) was chosen by the HIARC.

Chronic Assessment:

The chronic dietary exposure analysis was performed for the general U.S. Population and all population subgroups using tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites), and assuming 100% crop treated for all registered and proposed commodities.

Nature of the Residue:

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). 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).

Percent Crop Treated Information:

No percent crop treated information was incorporated into the acute and chronic assessments. Therefore, 100% crop treated was assumed for both assessments.

Processing Information:

There are no processed commodities associated with sweet corn, pop corn or pasture and rangeland grasses. Residues of diflufenzopyr, M1 and M10 do not concentrate in corn processed fractions upon dry or wet milling of field corn treated at 8x the proposed label rate (Memo, L. Cheng; 11/2/98; D239675). Therefore, DEEM™ default concentration factors were used for all commodities.

Residue Estimates:

For ruminant commodities, recommended tolerance levels were used.

For plant commodities, the residues of concern for tolerance purposes differ from the residues of concern for risk assessment purposes. Therefore, the total residues of concern (parent and metabolites) used in dietary exposure assessment were determined from the submitted residue field trial studies (Memo, J. Tyler; 11/13/01; D275619).

Field corn and pop corn: The results of the field corn residue field trials showed that residues of diflufenzopyr and metabolites convertible to M1, and the metabolite M10 were <0.05 ppm and <0.01 ppm, respectively. The field corn data was translated to pop corn. Therefore, for dietary exposure analysis, a residue value of 0.06 ppm was used to estimate combined residues of diflufenzopyr, M1 and M10 in field corn and pop corn.

Sweet corn: The results of the field trials showed that residues of diflufenzopyr and metabolites convertible to M1, and the metabolite M10 were <0.05 ppm and <0.05, respectively. Therefore, for dietary exposure analysis, a residue value of 0.10 ppm was used to estimate the combined residues of diflufenzopyr, M1 and M10 in sweet corn.

Table 2 lists the recommended tolerance and residue values used in dietary exposure assessment. A summary of the residue information used in the acute and chronic analyses is attached (Attachment 1).

Table 2. Recommended Tolerance and Residue Values Used in Dietary Exposure Assessment.

Commodity	Recommended Tolerance (ppm)	Residue Value in Dietary Exposure Assessment (ppm)
Plants ¹		
field corn	0.05	0.06
sweet corn	0.05	0.1
pop corn	0.05	0.06
Livestock ²		
meat ³		0.6
kidney ³		4
meat by-products (except kidney) ³		0.5
fat ³		0.3
milk		3

1. For tolerance purposes, the residues of concern are parent and all metabolites convertible to M1. For risk assessment purposes, the residues of concern are parent, all metabolites convertible to M1, and metabolite M10.
2. For both tolerance and risk assessment purposes, the residues of concern are parent, all metabolites convertible to M1, and metabolite M19.
3. Commodities of cattle, goat, hog, horse, and sheep.

IV. DEEM™ Program and Consumption Information

Diflufenzopyr acute and chronic dietary exposure assessments were conducted using the DEEM™ software Version 7.73, which incorporates consumption data from USDA's Continuing

Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the ePAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups from the general U.S. population which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, risks estimated for these population subgroups were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

V. Results/Discussion

HED's level of concern is 100% of the PAD. That is, estimated exposures above this level are of concern, while estimated exposures at or below this level are not of concern. The DEEM analyses estimate the dietary exposure of the U.S. population and 26 population subgroups. The results reported in Tables 3 and 4 are for the U.S. Population (total), all infants (<1 year old), children 1-6, children 7-12, females 13-50, males 13-19, males 20+, and seniors 55+. The results

for the other population subgroups are not reported in Tables 3 and 4 . This is because the numbers of respondents in the other subgroups were not sufficient, and thus the exposure estimates for these subgroups contained higher levels of uncertainty. However, the respondents in these subgroups were also part of larger subgroups which are listed in Tables 3 and 4 . For example, nursing and non-nursing infants are included in all infants. The subgroups which are broken down by region, season, and ethnicity are also not included.

Results of Acute Dietary Exposure Analysis

Table 3. Results of Acute Dietary Exposure Analysis at the 95th Percentile of Exposure.

Population Subgroup	aPAD (mg/kg/day)	Exposure (mg/kg/day)	% aPAD
Females 13-50 years old	1	0.038926	4

Chronic Dietary Exposure Analysis

Table 4. Results of Chronic Dietary Exposure Analysis.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.26	0.022356	9
All Infants (< 1 year)	0.26	0.036425	14
Children 1-6 years	0.26	0.082228	32
Children 7-12 years	0.26	0.042522	16
Females 13-50	0.26	0.012571	5
Males 13-19	0.26	0.024247	9
Males 20+ years	0.26	0.011552	4
Seniors 55+	0.26	0.011438	4

VI. Conclusions

The Tier 1 acute and chronic dietary exposure assessments were conducted for all supported diflufenzopyr food uses. The acute dietary exposure estimates are provided for females 13-50 years old only. No appropriate endpoint attributable to a single exposure was identified for the general U.S. population including infants and children. This assessment concludes that the acute dietary exposure estimates are below HED's level of concern (<100% aPAD) at the 95th exposure percentile for females 13-50 (4% of the aPAD). The chronic dietary exposure estimates are provided for the general U.S. population and various population subgroups. This assessment

also concludes that the chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population (9% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1-6 years old at 32% of the cPAD.

Table 5. Summary of Dietary Exposure and Risk for Diflufenzopyr.

Population Subgroup	Acute Dietary ¹		Chronic Dietary ²	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	NA	NA	0.022356	9
All Infants (< 1 year)			0.036425	14
Children 1-6 years			0.082228	32
Children 7-12 years			0.042522	16
Females 13-50	0.038926	4	0.012571	5
Males 13-19	NA	NA	0.024247	9
Males 20+ years			0.011552	4
Seniors 55+			0.011438	4

1. Acute dietary endpoint applies to females 13-50 years old. No appropriate acute dietary endpoint was chosen for the general U.S. Population (including infants and children).

2. Chronic dietary endpoint applies to general U.S. Population and all population subgroups.

VII. List of Attachments

Attachment 1: Diflufenzopyr Residue File for Acute and Chronic DEEM™ Analyses.

Attachment 2: Diflufenzopyr Acute DEEM™ Analysis.

Attachment 3: Diflufenzopyr Chronic DEEM™ Analysis.

DP Barcode D278338
DIFLUFENZOPYR / PC Code 005107

Dietary exposure assessment / 9

Cc (w/ Attachments): M.Sahafeyen (CEB1); R. Forrest/S. Brothers (RD 7505C)
RDI: DE SAC [S. Piper (12/10/01), M. Xue (12/10/01)]; G. Herndon (12/11/01)
J.Tyler:806W:CM#2:(703)305-5564: 7509C:RAB1

DP Barcode D278338
DIFLUFENZOPYR / PC Code 005107

Dietary exposure assessment / 10

Attachment 1

Filename: C:\MyFiles\DEEM\Distinct\005107.rs7

Chemical: Diflufenzopyr

RfD(Chronic): .26 mg/kg bw/day NOEL(Chronic): 26 mg/kg bw/day

RfD(Acute): 1 mg/kg bw/day NOEL(Acute): 100 mg/kg bw/day

Date created/last modified: 11-05-2001/14:25:17/8 Program ver. 7.75

Comment: PP#0E06185: Section 3 request for use on sweet corn, pop corn and grass. Acute: Females 13-50 only. Chronic: US Pop. and All Pop. Subgrps. FQPA SF was reduced to 1x; therefore, acute and chronic RfDs and PADs are equivalent.

Food Crop Code Grp	Food Name	Def Res (ppm)	Adj. Factors		Comment
			#1	#2	
323 M	Beef-dried	0.600000	1.920	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
324 M	Beef-fat w/o bones	0.300000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
325 M	Beef-kidney	4.000000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
327 M	Beef-lean (fat/free) w/o bones	0.600000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
326 M	Beef-liver	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
321 M	Beef-meat byproducts	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
322 M	Beef-other organ meats	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
330 M	Goat-fat w/o bone	0.300000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
331 M	Goat-kidney	4.000000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
333 M	Goat-lean (fat/free) w/o bone	0.600000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
332 M	Goat-liver	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
328 M	Goat-meat byproducts	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
329 M	Goat-other organ meats	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
334 M	Horsemeat	0.600000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
344 M	Pork-fat w/o bone	0.300000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
345 M	Pork-kidney	4.000000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
347 M	Pork-lean (fat free) w/o bone	0.600000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
346 M	Pork-liver	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
342 M	Pork-meat byproducts	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.
343 M	Pork-other organ meats	0.500000	1.000	1.000	PP#0E06185 New; Parent and metabolites M1 and M19.

Dietary exposure assessment / 11

DP Barcode D278338
DIFLUFENZOPYR / PC Code 005107

335	M	Rabbit	0.600000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
338	M	Sheep-fat w/o bone	0.300000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
339	M	Sheep-kidney	4.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
341	M	Sheep-lean (fat free) w/o bone	0.600000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
340	M	Sheep-liver	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
336	M	Sheep-meat byproducts	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
337	M	Sheep-other organ meats	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
429	M	Veal-dried	0.600000	1.920	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
424	M	Veal-fat w/o bones	0.300000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
426	M	Veal-kidney	4.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
425	M	Veal-lean (fat free) w/o bones	0.600000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
427	M	Veal-liver	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
430	M	Veal-meat byproducts	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
428	M	Veal-other organ meats	0.500000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
398	D	Milk-based water	3.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
319	D	Milk-fat solids	3.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
318	D	Milk-nonfat solids	3.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
320	D	Milk sugar (lactose)	3.000000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M19.
267	15	Corn grain-bran	0.060000	1.000	1.000	PP#7F04848;	Parent and metabolites M1 and M10.
266	15	Corn grain-endosperm	0.060000	1.000	1.000	PP#7F04848;	Parent and metabolites M1 and M10.
289	15	Corn grain-oil	0.060000	1.000	1.000	PP#7F04848;	Parent and metabolites M1 and M10.
268	15	Corn grain/sugar/hfcs	0.060000	1.500	1.000	PP#7F04848;	Parent and metabolites M1 and M10.
388	15	Corn grain/sugar-molasses	0.060000	1.500	1.000	PP#7F04848;	Parent and metabolites M1 and M10.
237	15	Corn/pop	0.060000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M10.
238	15	Corn/sweet	0.100000	1.000	1.000	PP#OE06185 New;	Parent and metabolites M1 and M10.

Attachment 2

U.S. Environmental Protection Agency Ver. 7.74
DEEM ACUTE Analysis for DIFLUFENZOPYR (1989-92 data)
Residue file: 005107.rs7 Adjustment factor #2 NOT used.
Analysis Date: 11-16-2001/08:11:19 Residue file dated: 11-16-2001/08:09:05/8
NOEL (Acute) = 100.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: "PP#0E06185: Section 3 request for use on sweet corn, pop corn and grass. Acute: Females 13-50 only. Chronic: US Pop. and All Pop. Subgrps. F QPA SF was reduced to 1x; therefore, acute and chronic RfDs and PADs are equivalent."
=====

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE

Females 13+ (preg/not nursing):								
0.054926	5.49	1820	0.065307	6.53	1531	0.098456	9.85	1015
Females 13+ (nursing):								
0.059589	5.96	1678	0.092771	9.28	1077	0.098440	9.84	1015
Females 13-19 (not preg or nursing):								
0.048391	4.84	2066	0.088857	8.89	1125	0.119188	11.92	839
Females 20+ (not preg or nursing):								
0.032590	3.26	3068	0.050158	5.02	1993	0.081612	8.16	1225
Females 13-50 yrs:								
0.038926	3.89	2568	0.059849	5.98	1670	0.103018	10.30	970

Attachment 3

U.S. Environmental Protection Agency Ver. 7.73
DEEM Chronic analysis for DIFLUFENZOPYR (1989-92 data)
Residue file name: C:\MyFiles\DEEM\Distinct\005107.rs7 Adjustment factor #2 NOT used.
Analysis Date 11-16-2001/08:13:58 Residue file dated: 11-16-2001/08:09:05/8
Reference dose (RfD, Chronic) = .26 mg/kg bw/day
COMMENT 1: PP#0E06185: Section 3 request for use on sweet corn, pop corn and grass.
Acute: Females 13-50 only. Chronic: US Pop. and All Pop. Subgrps. FQPA SF was reduced to 1x; therefore, acute and chronic RfDs and PADs are equivalent.

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.022356	8.6%
U.S. Population (spring season)	0.022299	8.6%
U.S. Population (summer season)	0.021762	8.4%
U.S. Population (autumn season)	0.023374	9.0%
U.S. Population (winter season)	0.021995	8.5%
Northeast region	0.022413	8.6%
Midwest region	0.025325	9.7%
Southern region	0.019988	7.7%
Western region	0.022746	8.7%
Hispanics	0.024133	9.3%
Non-hispanic whites	0.022542	8.7%
Non-hispanic blacks	0.019750	7.6%
Non-hisp/non-white/non-black	0.023193	8.9%
All infants (< 1 year)	0.036425	14.0%
Nursing infants	0.006855	2.6%
Non-nursing infants	0.048871	18.8%
Children 1-6 yrs	0.082228	31.6%
Children 7-12 yrs	0.042522	16.4%
Females 13-19 (not preg or nursing)	0.018405	7.1%
Females 20+ (not preg or nursing)	0.010954	4.2%
Females 13-50 yrs	0.012571	4.8%
Females 13+ (preg/not nursing)	0.021453	8.3%
Females 13+ (nursing)	0.019034	7.3%
Males 13-19 yrs	0.024247	9.3%

DP Barcode D278338
DIFLUFENZOPYR / PC Code 005107

Dietary exposure assessment / 14

Males 20+ yrs	0.011552	4.4%
Seniors 55+	0.011438	4.4%
Pacific Region	0.022632	8.7%
