

WASHINGTON, D.C. 20460

DP Number: 338504

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PC Code: 121903

# **MEMORANDUM**

DATE: March 29, 2007

SUBJECT: Flufenacet – Revised Memorandum: Acute and Chronic Aggregate Dietary

> Exposure and Risk Assessments for the Proposed Section 3 Registration on Wheat, Sweet Corn and Grass Grown for Seed. Petition Number: 6F04631.

PC Code: 121903 Decision Number: 303540

DP Number: 338504

REVIEWER: Susan L. Stanton, Environmental Scientist

Reregistration Branch 3

Health Effects Division (7509P)

THROUGH: Thomas Bloem, Chemist

Sheila Piper, Chemist

Dietary Exposure Science Advisory Council (DESAC)

Health Effects Division (7509P)

and

Will Donovan, Chemist Reregistration Branch 3

Health Effects Division (7509P)

TO: Jack Arthur, Risk Assessor

> Registration Action Branch 3 Health Effects Division (7509P)

> > and

Tobi Colvin-Snyder Herbicide Branch

Registration Division (7505P)

Estimates of U.S. field corn and soybean acreage presented in the previous flufenacet dietary exposure memorandum (S. Stanton; D334695; 12/12/06) were incorrect. They have been corrected in this document. The revisions do not affect the acute or chronic dietary exposure estimates, and no other changes have been made to the document.

DP Number: 338504

PC Code: 121903

# **Executive Summary**

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID<sup>TM</sup>), Version 2.03, which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analyses were performed to support the proposed FIFRA sec. 3 registration of the herbicide, flufenacet, on wheat, sweet corn and grass grown for seed.

Flufenacet is currently registered for food use under FIFRA sec. 3 on field corn and soybean and under FIFRA sec. 18 on wheat. Permanent and temporary tolerances for these commodities have been established under 40 CFR sec. 180.527. Tolerances have also been established to cover secondary residues in livestock (cattle, goat, hog, horse and sheep) and indirect or inadvertent residues in alfalfa, clover, cereal grains (except rice) and grasses (forage, fodder and hay) that may occur as a result of the registered uses (i.e., residues in rotational crops).

Partially refined, Tier 3 acute probabilistic and chronic dietary (food + drinking water) exposure assessments were conducted for all existing and proposed food uses of flufenacet. Anticipated residues for many crops (field corn, soybean, sweet corn and wheat) were developed using field trial data. Anticipated residues for livestock commodities were derived using available feeding and metabolism studies in conjunction with the anticipated dietary burden to ruminants, swine and poultry. Tolerance level residues were used to assess flufenacet exposure from the remaining commodities (i.e., cereal grains). Acute and chronic exposure estimates for all commodities were further refined using percent crop treated (%CT) data, following the guidance provided in HED SOP 99.6 (*Classification of Food Forms with Respect to level of Blending*; 8/20/99). Projected %CT data were used to refine anticipated residues for the new food uses (sweet corn and wheat). Available processing data were used to refine anticipated residues for cereal grains and corn. For all other processed commodities, DEEM (ver. 7.81) default processing factors were assumed.

Estimated drinking water concentrations (EDWCs) were provided by EFED (R. Parker; DP Num: 318616, 318629; 10/04/06) and incorporated directly into the DEEM analyses. For the acute assessment, the entire 30-year distribution of estimated daily surface water concentrations for the Ohio corn crop scenario was used in a probabilistic analysis. For the chronic assessment, the estimated 1-in-10 year annual mean residue in surface water was used as a point estimate in a deterministic analysis.

# **Acute Dietary Exposure Results**

Based on the assumptions described above, estimated acute dietary exposure is below HED's level of concern for the U.S. population and all population subgroups. Combined dietary exposure from food and drinking water at the 99.9<sup>th</sup> percentile of exposure is estimated to be 0.000514 mg/kg/day for the general U.S. population, equivalent to 30% of the acute Population Adjusted Dose (aPAD). The population subgroup with the highest estimated acute dietary exposure is infants, less than 1 year old, with an estimated exposure at the 99.9<sup>th</sup> percentile of

0.001514 mg/kg/day, equivalent to 89% of the aPAD. The major contributor to dietary exposure for all population subgroups is drinking water. Estimated acute dietary exposure from food alone is less than or equal to 13% of the aPAD for the general U.S. population and all subgroups.

DP Number: 338504

PC Code: 121903

# Chronic Dietary Exposure Results

Chronic dietary exposure estimates for food and drinking water combined are well below HED's level of concern. Using the DEEM-FCID software, chronic dietary exposure is estimated at 0.000049 mg/kg/day for the general U.S. population (2.9% of the chronic Population Adjusted Dose (cPAD)) and 0.000156 mg/kg/day (9.2% of the cPAD) for infants <1 year old, the population subgroup with the highest estimated chronic dietary exposure to flufenacet. As with the acute assessment, the major contributor to estimated chronic dietary exposure is drinking water. Estimated chronic dietary exposure from food alone represents less than 1% of the aPAD for the general U.S. population and all subgroups.

#### I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the point of departure (POD; e.g., NOAEL, LOAEL) divided by the appropriate uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: <a href="http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf">http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf</a>; or see SOP 99.6 (8/20/99).

The most recent HED dietary risk assessment for flufenacet was conducted by William D Wassell (Memo, dated 05/14/03; DP Num 289838) to support a FIFRA §18 emergency exemption request for the use of flufenacet on wheat.

#### **II.** Food Residue Information

Residues of Concern: The nature of flufenacet residues in plants is understood for the existing and proposed commodities, based on adequate studies using a preplant application to corn and soybeans and a postemergence application to corn and wheat. The Metabolism Assessment Review Committee (MARC) concluded in a meeting on 7/16/97 that the residues of concern in plants for both tolerance expression and risk assessment are parent and the metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety.

The nature of the residue in livestock is also understood, based on adequate goat and poultry metabolism studies using <sup>14</sup>C-labeled parent and plant metabolites. The metabolism of flufenacet and its plant metabolites is similar in ruminants and poultry. Based on the results of these studies, the MARC (DP Num: 241928, N. Dodd, 12/18/97) concluded that the residues of concern in ruminants and poultry for the tolerance expression are parent and the metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety. The dietary risk assessment for

livestock commodities should also include thiadone related residues, glycoside conjugate (THNG) and the malonylalanine conjugate of thiadone.

DP Number: 338504

PC Code: 121903

The MARC also concluded at its 7/16/97 meeting that thiadone residues should be included, along with parent flufenacet, in the drinking water risk assessment.

Tolerances: Permanent tolerances have been established for flufenacet and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in/on raw agricultural commodities [field corn forage (0.4 ppm), grain (0.05 ppm), and stover (0.4 ppm); and soybean seed (0.1 ppm)] under 40 CFR §180.527(a); and at 0.1 ppm for indirect or inadvertent residues in/on alfalfa and clover; cereal grains (crop group 15), except rice; and forage, fodder and straw of cereal grains (crop group 16), except rice; and the forage, fodder and hay of grass (crop group 17) under 40 CFR 180.527(d). In addition, time-limited tolerances have been established in connection with Section 18 emergency exemption under 40 CFR 180.527(b) for livestock commodities at 0.05 ppm in fat and meat of cattle, goats, hogs, horses, and sheep; 0.10 ppm in meat byproducts except kidney of cattle, goats, hogs, horses, and sheep; and 0.50 ppm in kidney of cattle, goats, hogs, horses, and sheep and for wheat forage (10 ppm), grain (1.0 ppm), hay (2.0 ppm) and straw (0.50 ppm). These time-limited tolerances are set to expire on 6/30/07. No tolerances have been established for milk, eggs or poultry commodities.

Based on its review of data submitted with the current petition, including additional residue data to support a revised use pattern for field corn, HED has determined that tolerances for flufenacet and its metabolites should be revised as shown in Table 1 (A. Acierto; 11/29/06; DP Num: 288564 & 288565). Where appropriate, the tolerance levels were determined using the Tolerance/MRL Harmonization Spreadsheet.

Table 1. Recommended Tolerances for Flufenacet						
Commodity Recommended Tolerance						
\$180.527(a). Tolerances for the combined residues of the Herbicide, <i>N</i> -(4-fluoropheny <i>N</i> -(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro- <i>N</i> -methylethyl benzenamine moiety.						
Corn, field, forage	0.45					
Corn, field, grain	0.05					
Corn, field, stover	0.30					
Corn, sweet, forage	0.45					
Corn, sweet, kernel plus cob with husks removed	0.05					
Corn, sweet, stover	0.30					
Soybean, seed <sup>1</sup>	0.05					
Wheat, bran	0.80					
Wheat, forage	6.0					
Wheat, grain	0.60					
Wheat, hay	1.2					
Wheat, straw	0.35					
Cattle, kidney	0.05					

Table 1. Recommended Tolerances for Flufenacet							
Commodity	Recommended Tolerance (ppm)						
Goat, kidney	0.05						
Hog kidney	0.05						
Horse, kidney	0.05						
Sheep, kidney	0.05						
40CFR 180.527(c). <i>N</i> -(4-fluorophenyl)- <i>N</i> -(1-meththiadiazol-2-yl]oxy]acetamide and its metabolites benzenamine moiety, with regional registration.							
Grass, forage	7.0						
Grass, hay	0.4						
40CFR 180.527(d). <i>N</i> -(4-fluorophenyl)- <i>N</i> -(1-meththiadiazol-2-yl]oxy]acetamide and its metabolites benzenamine moiety for indirect or inadvertent res	containing the 4-fluoro-N-methylethyl						
Alfalfa, forage	2.0						
Alfalfa, hay	2.0						
Alfalfa, seed	0.10						
Clover, forage	2.0						
Clover, hay	2.0						
Cereal, grain, crop group 15, except rice	0.10						
Cereal, grain, forage, fodder, and straw, crop group 16, except rice	2.0						
Grass, forage, fodder and hay, crop group 17							

PC Code: 121903

#### Residue Data used for the Acute and Chronic Assessments:

Food: Refined, Tier 3 acute probabilistic and chronic dietary exposure assessments were conducted for all existing and proposed new food uses of flufenacet and drinking water. Anticipated residues for many crops (field corn, soybean, sweet corn and wheat) were developed using field trial data. Anticipated residues for livestock commodities were derived using available feeding and metabolism studies in conjunction with the anticipated dietary burden to ruminants, swine and poultry. Tolerance level residues were used to assess flufenacet exposure from the remaining commodities (i.e., cereal grains). Pesticide Data Program (PDP) monitoring data are available for wheat flour (2003,2004), wheat grain (2005) and pork fat/muscle (2005). The PDP data were not used to develop anticipated residues for wheat commodities, since they reflect the historical, regional section 18 use of flufenacet on wheat in the Pacific Northwest, rather than the proposed section 3 national use. Since wheat makes up 80% of the theoretical swine diet, the PDP data for pork commodities are also considered inappropriate for estimating anticipated residues in these commodities.

<sup>&</sup>lt;sup>1</sup> The available soybean data support the established tolerance of 0.10 ppm for soybean seeds. However, in light of the proposed reduced application rate (0.45 lb ai/A instead of 0.9 lb ai/A) and the European tolerance level of 0.05 ppm, HED now recommends that the soybean, seed tolerance be lowered to 0.05 ppm.

Acute and chronic exposure estimates for all commodities were further refined using %CT data, following the guidance provided in HED SOP 99.6 (*Classification of Food Forms with Respect to level of Blending*; 8/20/99). Projected %CT data were used to refine anticipated residues for the new food uses (sweet corn and wheat). Available processing data were used to refine anticipated residues for cereal grains and corn. For all other processed commodities, DEEM (ver. 7.81) default processing factors were assumed.

DP Number: 338504

PC Code: 121903

Anticipated residues for *plant* commodities were calculated in accordance with HED guidance for Tier 3 assessments as follows:

# Acute Assessment:

- Field corn, soybean and wheat (blended commodities): Average field trial residues were calculated and multiplied by the maximum %CT or projected %CT (wheat) estimate in the acute DEEM analysis. A residue value equal to ½ the Limit of Quantitation (LOQ) was assumed for all field trial samples with non-detectable residues.
- Other cereal grains (blended commodities): Flufenacet is not registered for direct application to these crops; however, inadvertent residues may occur in these crops from flufenacet's use on other crops. In the DEEM analysis, the tolerance level of 0.1 ppm for inadvertent residues was multiplied by the maximum projected %CT estimate for wheat (the field crop with the highest estimated or projected maximum %CT).
- Sweet corn (not blended or partially blended): All sweet corn field trial samples contained non-detectable residues of flufenacet. For the acute assessment, a residue distribution file was constructed using ½ the LOQ for non-detectable residues and incorporating zeros to account for the percent of the crop not likely to be treated with flufenacet.

### **Chronic Assessment**:

- Field corn, soybean, wheat (blended commodities) and sweet corn (not blended or partially blended): Average field trial residues were calculated and multiplied by the average %CT or projected %CT (wheat) estimate in the chronic DEEM analysis. A residue value equal to ½ the Limit of Quantitation (LOQ) was assumed for all field trial samples with non-detectable residues.
- Other cereal grains (blended commodities): Flufenacet is not registered for direct application to these crops; however, inadvertent residues may occur in these crops from flufenacet's use on other crops. In the DEEM analysis, the tolerance level of 0.1 ppm for inadvertent residues was multiplied by the average projected %CT estimate for wheat (the field crop with the highest estimated or projected average %CT).

The residue data for plant commodities used in the chronic and acute dietary assessments are summarized in Table 2. Residue distribution files (RDFs) used in the acute assessment are included in the attachments.

Table 2. Data and	l Residu	e Estimates Use	ed in Dietary	Analyses								
RAC	Food	Classification <sup>1</sup>	Data	No. of	No. of Detectable	LOQ	%(	СТ	Processing		Anticipated Residue Estimates/Tolerance	
RAC	Forms	Ciassification	Source	Samples	Residues	(ppm)	Ave.	Max.	Factors	Acute (Tol., AR, RDF) <sup>5</sup>	Chronic (Tol., AR)	
Cereal Grains (Barley, Buckwheat, Millet, Oat, Popcorn, Rye, Sorghum)	All	В	Tolerance	N/A	N/A	N/A	1 <sup>2</sup>	32	Flour: 0.44x <sup>3</sup> Bran: 2.1x <sup>3</sup>	0.1 ppm adjusted by 3%CT	0.1 ppm adjusted by 1%CT	
Corn, field	All	В	Ave. Field Trial; MRID: 45012405 & 45012407	62	0	0.05	<14	<2.54	All: 1x <sup>5</sup>	0.025 ppm adjusted by 2.5%CT	0.025 ppm adjusted by 1%CT	
Corn, sweet	All	NB/PB	Field Trial; MRID: 45012405 & 45012407	18	0	0.05	36	10 <sup>6</sup>	N/A	RDF:  'Sweet Corn, using maximum projected 10%CT  TOTALZ=90  TOTALLOD=10  LODRES=0.025	0.025 ppm adjusted by 3%CT	
Soybean	All	В	Ave. Field Trial: MRID: 43850093	22	2	0.05	<14	<2.54	1x <sup>5</sup>	0.03 ppm adjusted by 2.5%CT	0.03 ppm adjusted by 1%CT	
Wheat/Triticale	All	В	Ave. Field Trial: MRID: 45012401	38	38 (29 above LOQ)	0.05	1 <sup>6</sup>	36	Flour: 0.44x <sup>3</sup> Bran: 2.1x <sup>3</sup>	0.13 ppm adjusted by 3%CT	0.13 ppm adjusted by 1%CT	

- DP Number: 338504 PC Code: 121903
- 1. Classification of blended (B), partially blended (PB), not blended (NB).
- 2. Based on projected %CT for wheat, the field crop with the highest estimated ave. and max. %CT.
- 3. Based on processing data for wheat: MRID#45012408; A. Acierto; DP Num: 288564; 07/27/06.
- 4. Screening Level Usage Analysis; BEAD; 08/18/2005
- 5. N. Dodd; DP Num: 224142: 12/12/96
- 6. Projected Percent Crop Treated for Herbicide Flufenacet (PC 121903) on Sweet Corn, Wheat and Grasses Grown for Seed; N. Zinn & A Grube; DP Nums: 320497, 321194; 10/25/2006

Anticipated residues for *livestock* commodities were calculated as described in the following sections. As mentioned above, the residues of concern for risk assessment in livestock include parent flufenacet *plus* thiadone related residues, glycoside conjugate (THNG) and the malonylalanine conjugate of thiadone. So, while tolerances are only required for a few animal commodities (kidney of cattle, goat, hog, horse and sheep), anticipated residues for flufenacet and thiadone compounds have been calculated for all livestock commodities, including ruminants, swine and poultry.

DP Number: 338504

PC Code: 121903

The DEEM input values calculated for ruminants, swine and poultry were incorporated into the acute and chronic analyses as follows:

- The calculated anticipated residues for livestock were used probabilistically in the acute assessment following the procedures outlined in the 4/6/99 e-mail from David Miller to Novigen. These procedures were subsequently summarized and posted on the Dietary Exposure Scientific Advisory Committee (DE SAC) database by Christina Swartz (10/14/99). Residue distribution files (RDFs) were constructed using the calculated anticipated residue value for the percentage of the livestock commodity expected to contain residues and zeros for the percentage of the commodity expected to be residue-free. The percentage of the commodity expected to contain residues was assumed to equal to the highest maximum %CT estimate for any single feed item. For ruminants, swine and poultry, the feed item with the highest %CT estimate is wheat (3% projected). Therefore, RDFs were constructed for each livestock commodity with a 3% probability of encountering the calculated anticipated residue and a 97% probability of encountering a zero.
- The calculated anticipated residues for livestock were used deterministically in the chronic assessment. The point estimates were adjusted by the highest average %CT estimate. Again, the highest average %CT estimate for any single feed item is wheat (1% projected). Therefore, 1% was incorporated as an adjustment factor for each livestock commodity in the chronic DEEM analysis.

Note: BEAD's maximum and average projected %CT estimates for sweet corn are 10% and 3%, respectively, which are higher than the estimates for wheat used to refine the exposure estimates for livestock commodities in the acute and chronic analyses. Sweet corn was not included in the proposed livestock diets and the projected %CT estimates were not used to adjust exposures for livestock commodities, because the sweet corn acreage is small compared to the acreage planted to corn, soybeans and wheat. Over the last 5 years, less than 1 million acres of sweet corn have been planted in the U.S., compared to approximately 60 million acres of wheat, 75 million acres of soybeans and 80 million acres of field corn (from USDA's National Agricultural Statistics Service website).

#### Cattle, goats, horses, and sheep:

To determine anticipated residues for cattle, goat, sheep and horse tissues, the dietary burden to these livestock was determined using the proposed diet developed by J. Stokes and B. Schneider (DP Num:332410; 09/13/06). Table 3 summarizes the dietary burden for beef and dairy cattle.

Table 3. Antici	Table 3. Anticipated Flufenacet Residues in the Diet of Dairy <sup>1</sup> and Beef Cattle								
Feed Item	AR <sup>2</sup> (ppm)	% Dry Matter	% Diet Dairy Cattle	% Diet– Beef Cattle	Diary Cattle Residue (ppm)	Beef Cattle Residue (ppm)			
Field Corn Forage	0.36	40	20	15	0.18	0.135			
Field Corn Stover	0.15	83	10	1	0.018	1			
Field Corn Grain	0.025	88	35	30	0.01	0.0085			
Wheat, Milled Byproducts	$0.13 (grain)^3$	88	10	20	0.015	0.03			
Wheat, Hay	0.95	88	10	20	0.108	0.216			
Soybean Meal	0.03 (seed)	92	15	15	0.005	0.005			
	Anticipated		0.34	0.39					

A 29-day dairy cattle feeding study was conducted using FOE oxalate (MRID 43850090). This metabolite was used because it was a major plant metabolite, whereas no parent flufenacet was found in plant metabolism studies. The cattle feeding study was reviewed and found acceptable (Memo, 1/7/97, N. Dodd, DP Num:224142). Milk samples from the 82.4 and 24.67 ppm groups from various treatment days were analyzed for residues of FOE oxalate. Residue levels in all milk samples were <0.01 ppm. The results of this study are summarized in Table 4.

Table 4. Maximum FOE Oxalate Residues from the Cattle Feeding Study									
Treatment Level (ppm)   Liver (ppm)   Fat (ppm)   Muscle (ppm)   Milk (ppm)									
82.4	0.64	0.19	0.10	0.09	< 0.01				
24.7	0.32	0.057	< 0.05	< 0.05	< 0.01				
7.80	0.058	< 0.05	Not analyzed	Not analyzed	Not analyzed				

The results of the feeding study corrected for the rate of exaggeration (based on the anticipated dietary burdens for beef and dairy cattle) are summarized in Table 5.

<sup>&</sup>lt;sup>1</sup>Flufenacet is also proposed for use on grass grown for seed in the Pacific Northwest and sweet corn, both of which may be fed to cattle. However, these crops were not included in the proposed diet because of the limited acreage compared to the acreage planted to field corn, wheat and soybeans.

<sup>&</sup>lt;sup>2</sup>ARs for forage, hay and stover (Non-blended feed items) are the HAFT value from the crop field trials while the ARs for field corn grain, wheat milled byproducts and soybean meal (Blended feed items) are the average residue levels from the field trials.

<sup>&</sup>lt;sup>3</sup>Processing data (MRID 45012408) indicate that residues do not concentrate in milled byproducts (shorts, middlings, AGF).

PC Code: 121903

A metabolism study using 166 ppm [thiadiazole-2-<sup>14</sup>C] flufenacet was conducted on a lactating goat. This dose rate corresponds to an exaggerated rate of 426x the anticipated dietary burden calculated for beef cattle and 488x for diary cattle. The results of this metabolism study are discussed in HED's review of 6/30/97 (Memo, N. Dodd, DP Num: 236252) and are summarized in Table 6.

Table 6. 1 Sheep.	Table 6. Derivation of DEEM Input Values for Livestock Commodities of Cattle, Goat, Horse, and Sheep.								
Matrix	Residue	% TRR	ppm (426x/488x)	ppm (1x <sup>1</sup> )	Flufenacet <sup>2</sup> Anticipated Residue (AR) Level ppm	DEEM <sup>3</sup> input ppm			
fat	thiadone	89	2.533	0.006	0.00045	0.0064			
kidney	thiadone glucuronide thiadone	9 89	1.837 18.164	0.0043 0.0426	0.0037	0.051			
liver	thiadone glucuronide thiadone	5 86	0.848 14.582	0.002 0.034	0.001	0.037			
muscle	thiadone	84	3.205	0.0075	0.0004	0.0079			
milk- avg <sup>4</sup>	thiadone glucuronide thiadone	10 40	0.054 0.23	0.00011 0.00047	0.000045	0.00062			

Normalized to 1X rate based on anticipated dietary burden for beef cattle (fat, kidney, liver and muscle) or dairy cattle (milk).

Thus, for the dietary risk assessment, anticipated residue values for livestock commodities represent a sum of the anticipated-residue level selected for flufenacet and metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety added to the calculated level of thiadone-related compounds based on the anticipated dietary burden. The appropriate residue level for meat byproducts and other organ meats is that of kidney, as this anticipated residue level is considered the worst-case value for all tissues.

<sup>\*</sup> In parenthesis are the exaggeration rates based on the anticipated DB of 0.39 ppm for beef cattle/0.34 ppm for dairy cattle.

<sup>&</sup>lt;sup>2</sup> From Table 5.

<sup>&</sup>lt;sup>3</sup> Sum of [thiadone + thiadone glucuronide] + flufenacet AR.

<sup>&</sup>lt;sup>4</sup> Values for milk in the above table are averaged over the 3-day study.

#### Swine:

In order to determine ARs for swine tissues, the dietary burden to swine was determined using a reasonable diet (A. Acierto; 11/29/06; DP Num: 288564 & 288565) and anticipated (average field trial) residues for the feed items. Table 7 summarizes the anticipated dietary burden for swine.

DP Number: 338504

PC Code: 121903

Table 7. Anticipated Flufenacet Dietary Burden for Swine								
Feed Item	Possible Residue (ppm)							
Wheat grain	0.13	80	0.104					
Soybean meal	Soybean meal 0.03		0.006					
	Anticipated Dietary Burden for Swine							

Table 7 shows that the anticipated swine dietary burden for flufenacet is 0.11 ppm. ARs for swine were determined in a way similar to that for ruminants, using the cattle feeding and goat metabolism studies, as described below. The corrected results of the cattle feeding study based on the anticipated swine dietary burden are summarized in Table 8.

Table 8. Corrected FOE Oxalate Residues from the Cattle Feeding Study								
Treatment Level (ppm)*	Kidney (ppm)	Liver (ppm)	Fat (ppm)	Muscle (ppm)				
82.4 (749x)	0.00085	0.00025	0.00013	0.00012				
24.7 (224x)	0.0014	0.00025	0.00011	0.00011				
7.80 (71x)	0.00082	0.00035	Not analyzed	Not analyzed				
Average	0.0010	0.00028	0.00012	0.00012				

<sup>\*</sup> In parenthesis is the exaggeration rate based on the anticipated DB of 0.11 ppm for swine.

The goat metabolism study was conducted using a dose of 166 ppm [thiadiazole-2-<sup>14</sup>C] flufenacet, which corresponds to an exaggerated rate of 1509x the anticipated DB calculated for swine. The results of this metabolism study are discussed in HED's review of 6/30/97 (Memo, N. Dodd, DP Num: 236252) and summarized below in Table 9.

Table 9. D	Table 9. Derivation of DEEM Input Values for Livestock Commodities of Swine.								
Matrix	Residue	% TRR	ppm (1509x)	ppm (1x <sup>1</sup> )	Flufenacet <sup>2</sup> Residue Level ppm	DEEM <sup>3</sup> input ppm			
fat	thiadone	89	2.533	0.0017	0.00012	0.0018			
kidney	thiadone glucuronide thiadone	9 89	1.837 18.164	0.0012 0.012	0.0010	0.014			
liver	thiadone glucuronide thiadone	5 86	0.848 14.582	0.00056 0.0097	0.00028	0.011			
muscle	thiadone	84	3.205	0.0022	0.00012	0.0023			

PC Code: 121903

Thus, for the dietary risk assessment, residue values for pork commodities represent a sum of the anticipated residue level of flufenacet and metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety added to the calculated level of thiadone-related compounds based on the anticipated swine dietary burden. The appropriate residue level for meat byproducts and other organ meats is that of kidney, as this anticipated residue value is considered the worst-case value for all tissues. For DEEM commodities designated as "skin" such as "Pork, skin", the anticipated residue level for fat was used.

### Poultry:

In order to determine ARs for poultry tissues, the dietary burden to poultry was determined using a reasonable diet (A. Acierto; 11/29/06; DP Num: 288564 & 288565) and anticipated (average field trial) residues for the feed items. Table 10 summarizes the anticipated dietary burden for poultry.

Table 10. Anticipated Flufenacet Dietary Burden for Poultry.							
Feed Item AR (ppm) % in Diet–Poultry Possible Residue (ppr							
Wheat grain	0.13	80	0.104				
Soybean meal	0.03	20	0.006				
	Anticipated Dietary Burden for Poultry						

Table 10 shows that the anticipated poultry dietary burden of flufenacet from treated feed items is 0.11 ppm. No flufenacet poultry feeding study is available for review. However, poultry metabolism studies using [thiadiazole-2-<sup>14</sup>C] flufenacet (MRID 43850076), [fluorophenyl-UL-<sup>14</sup>C] flufenacet (MRID 43850074), and [fluorophenyl-UL-<sup>14</sup>C] FOE oxalate (MRID 438500798) at 78 ppm are available. Collectively, these studies show that no tolerances are needed for flufenacet and its metabolites containing the 4-fluoro-N-methylethyl benzenamine moiety in poultry commodities. But, as with the ruminants, thiadone-related residues predominate. The hen metabolism study using [thiadiazole-2-<sup>14</sup>C] flufenacet at 78 ppm (corresponding to an

Normalized to 1X rate based on the anticipated swine dietary burden.

<sup>&</sup>lt;sup>2</sup> From Table 8.

<sup>&</sup>lt;sup>3</sup> Sum of [thiadone + thiadone glucuronide] + flufenacet AR.

exaggeration rate of 709x the anticipated DB) gave results for thiadone-related residues as discussed in the HED memo of 6/30/97 (Memo, N. Dodd, DP Num: 236252) and as summarized in Table 11.

DP Number: 338504

PC Code: 121903

Table 11. Derivation of DEEM Input Values for Poultry Commodities								
Matrix	Metabolite	% TRR	ppm (flufenacet equivalents)		DEEM input ppm			
			1000x	$1x^1$				
fat	thiadone	80	1.430	0.0020	0.0020			
liver	thiadone glucuronide thiadone	9 83	0.935 8.620	0.0013 0.012	0.013			
muscle	thiadone	86	1.920	0.0027	0.0027			
Eggs - avg <sup>2</sup>	thiadone	90	0.408	0.00058	0.00058			

<sup>&</sup>lt;sup>1</sup> Normalized to 1X rate based on the anticipated DB to poultry.

Thus, for the dietary risk assessment, anticipated residue values for poultry commodities represent the calculated level of thiadone-related compounds based on the anticipated dietary burden. The appropriate residue level for meat byproducts and other organ meats is that of liver, as this is considered the worst-case value for all tissues. For DEEM commodities designated as "skin", such as "chicken, skin" or "poultry, other, skin", the anticipated residue level for fat was used.

## III. Drinking Water Data

Reference: Revised Estimated Drinking Water Concentrations of Flufenacet and Degradate Thiadone for the Use in Human Health Risk Assessment; Ronald Parker; DP Num: 318616, 318629; 10/04/06.

The residues of concern in drinking water include flufenacet and its degradate, thiadone. The Environmental Fate and Effects Division (EFED) provided estimated drinking water concentrations (EDWCs) of flufenacet and thiadone in surface water using the Tier II PRZM/EXAMS models. Groundwater EDWCs were provided for parent flufenacet only using the Tier I SCIGROW model.

Ground Water: For ground water, the acute and chronic flufenacet EDWC from the SCIGROW model is 0.10 ppb. Ground-water monitoring information provided by the registrant supports the SCIGROW model result as a reasonable estimate of groundwater concentrations. Acute and chronic concentrations of 0.18 ppb and 0.03 ppb, respectively, were seen in a small-scale prospective groundwater study conducted by the registrant in a Nebraska aquifer that could reasonably be expected to be used for drinking water. (FOE 5043; Reregistration Eligibility Document; October,1997). The Agency has been unable to locate any other field monitoring data for flufenacet in groundwater.

<sup>&</sup>lt;sup>2</sup> Values for eggs in the above table are averaged over the 3 days of the study.

Surface Water: For surface water, the combined one-in-ten-year peak (acute) and one-in-ten-year mean (chronic) estimated concentrations of flufenacet and thiadone are presented in Table 12 for two Midwest corn belt cropping scenarios (Ohio corn and Illinois corn). Thiadone concentrations are expected to average 11 percent of parent flufenacet concentrations at the time of year when combined concentrations are the highest. Therefore, combined concentrations of flufenacet and thiadone were derived by multiplying parent flufenacet concentrations by a factor of 1 11

DP Number: 338504

PC Code: 121903

Table 12. Combined Acute and Chronic Surface Water Concentrations for Parent Chemical Flufenacet Plus Degradate Thiadone.								
PRZM	Acute Parent Flufenacet	Chronic Parent Flufenacet	Acute Degradate Thiadone	Chronic Degradate Thiadone	Sum: Acute Parent Plus Degradate	Sum: Chronic Parent Plus Degradate		
Scenario	(ppb)	(ppb)	(ppb)	(ppb)	(ppb)	(ppb)		
Ohio								
Corn	7.78	2.01	0.86	0.22	8.64	2.23		
Illinois	9.07	2.55	1.00	0.28	10.07	2 83		
Corn	9.07	2.55	1.00	0.28	10.07	2.83		

Of all the labeled crops, the highest surface water concentrations would be expected for corn and soybeans, because the application rate is higher and there is more area planted to these crops; and surface water EDWCs for these two crops should not be different. The Ohio and Illinois corn scenarios were chosen as the most appropriate national-level scenarios based on their location in the Midwestern corn belt. The modeling results for these two scenarios are similar, with the Illinois scenario returning only slightly higher values. This slight difference is not due to differences in soil vulnerability in Ohio and Illinois; rather, it is an artifact of planting date selection relative to rainfall events at these two locations. EFED selected application dates 14 days before recommended planting dates without regard to rainfall dates for the two scenarios. Since growers seek to maximize the benefit of pesticide applications, they would be expected to apply flufenacet when dry weather is forecast. Therefore, the model results for the Ohio corn scenario were selected as appropriate for use in the dietary assessment. The selection of the Ohio scenario also provides consistency with the previous 2003 dietary assessment which used drinking water estimates based on the Ohio corn scenario.

The estimated surface water concentrations of flufenacet are nearly 2 orders of magnitude higher than estimated groundwater concentrations. Therefore, the PRZM/EXAMS surface water modeling results were used in the dietary assessment. For the acute assessment, the entire 30-year distribution of estimated daily concentrations from the Ohio corn scenario was used in a probabilistic analysis. For the chronic assessment, the estimated 1-in-10 year annual mean residue was used as a point estimate in a deterministic analysis.

# IV. DEEM-FCID<sup>TM</sup> Program and Consumption Information

Flufenacet acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID<sup>TM</sup>, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g.

apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

DP Number: 338504

PC Code: 121903

For chronic dietary exposure assessments, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. 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 exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only 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, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

### V. Toxicological Information

On April 23, 2003, the HED Hazard Identification Assessment Review Committee (HIARC) reviewed the recommendations of the toxicology reviewer for flufenacet with regard to the appropriate toxicological endpoints and doses for human health risk assessments. The potential for increased susceptibility of infants and children from exposure to flufenacet was also evaluated as required by the Food Quality Protection Act (FQPA) of 1996. The doses and toxicological endpoints selected for the various dietary exposure scenarios are summarized in Table 13.

Exposure Scenario	Dose (mg/kg/day) Uncertainty Factor (UF)	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Endpoint for Dietary Risk Assessment
Acute Dietary (all populations)	LOAEL = 1.7 mg/kg/day UF = 1000X <sup>1</sup> Acute RfD = 0.0017 mg/kg/day	FQPA SF = 1X $aPAD = 0.0017$ $mg/kg/day$	Developmental-neurotoxicity study in rats LOAEL = 1.7 mg/kg/day, based on decreased body weight/body weight gain and missing morphometric measurements in caudate/putamen in pups.
Chronic Dietary (all populations)	LOAEL= 1.7 mg/kg/day UF = 1000X <sup>1</sup> Chronic RfD = 0.0017 mg/kg/day	FQPA SF = $1X$ cPAD = 0.0017 mg/kg/day	Developmental-neurotoxicity study in rats LOAEL = 1.7 mg/kg/day, based on decreased body weight/body weight gain in pups.
Cancer Classification	E (Not likely to be a Hun	nan Carcinogen)	

PC Code: 121903

#### VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID<sup>TM</sup> analyses estimate the dietary exposure of the U.S. population and various population subgroups. The acute and chronic results reported below are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

### Results of Acute Dietary Exposure Analysis

Based on the assumptions described above, estimated acute dietary exposure is below HED's level of concern for the U.S. population and all population subgroups. Combined dietary exposure from food and drinking water at the 99.9<sup>th</sup> percentile of exposure is estimated to be 0.000514 mg/kg/day for the general U.S. population, equivalent to 30% of the acute Population Adjusted Dose (aPAD). The population subgroup with the highest estimated acute dietary exposure is infants, less than 1 year old, with an estimated exposure at the 99.9<sup>th</sup> percentile of 0.001514 mg/kg/day, equivalent to 89% of the aPAD. The acute dietary exposure results at the 99.9<sup>th</sup> percentile are compared to the results at the 95<sup>th</sup> and 99<sup>th</sup> percentiles in Table 14.

<sup>&</sup>lt;sup>1</sup>The 1000-fold uncertainty factor includes 10X interspecies, 10X intraspecies and 10X for the lack of a NOAEL in the DNT and the requirement of a comparative thyroid study.

<sup>&</sup>lt;sup>2</sup>UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

Population	aPAD	95 <sup>th</sup> Per		er) Exposure Ana 99th Perc		99.9th Percentile	
Subgroup	(mg/kg/day)	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
General U.S. Population		0.000115	6.8	0.000230	14	0.000514	30
All Infants (< 1 year old)		0.000396	23	0.000790	46	0.001514	89
Children 1-2 years old		0.000185	11	0.000361	21	0.000720	42
Children 3-5 years old		0.000171	10	0.000325	19	0.000635	37
Children 6-12 years old	0.0017	0.000118	7.0	0.000227	13	0.000444	26
Youth 13-19 years old		0.000088	5.2	0.000178	10	0.000389	23
Adults 20-49 years old		0.000105	6.2	0.000206	12	0.000424	25
Adults 50+ years old		0.000104	6.1	0.000190	11	0.000344	20
Females 13-49 years old		0.000106	6.2	0.000207	12	0.000418	25

PC Code: 121903

The major contributor to dietary exposure for all population subgroups is drinking water. Estimated acute dietary exposure from food alone is less than or equal to 13% of the aPAD for the general U.S. population and all subgroups. Estimated acute exposures (99.9<sup>th</sup> percentile) from food alone and drinking water alone are compared to exposures for food and water combined in Table 15, below. Please note that the analyses for food, drinking water, and food + drinking water were conducted separately and that the results are not additive (i.e., food exposure + drinking water exposure  $\neq$  the combined exposure for food and drinking water).

Population Subgroup	aPAD (mg/kg/day)	Food Alone		Drinking Wa	ater Alone	Food and Drinking Water		
		Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	
General U.S. Population		0.000102	6.0	0.000503	30	0.000514	30	
All Infants (< 1 year old)		0.000110	6.4	0.001520	89	0.001514	89	
Children 1-2 years old		0.000215	13	0.000690	41	0.000720	42	
Children 3-5 years old		0.000223	13	0.000611	36	0.000635	37	
Children 6-12 years old	0.0017	0.000148	8.7	0.000428	25	0.000444	26	
Youth 13-19 years old		0.000085	5.0	0.000377	22	0.000389	23	
Adults 20-49 years old		0.000069	4.1	0.000419	25	0.000424	25	
Adults 50+ years old	1	0.000063	3.7	0.000339	20	0.000344	20	
Females 13-49 years old	1	0.000073	4.3	0.000413	24	0.000418	25	

PC Code: 121903

# Results of Chronic Dietary Exposure Analysis

Chronic dietary exposure estimates for food and drinking water combined are well below HED's level of concern. Using the DEEM-FCID software, chronic dietary exposure is estimated at 0.000049 mg/kg/day for the general U.S. population (2.9% of the chronic Population Adjusted Dose (cPAD)) and 0.000156 mg/kg/day (9.2% of the cPAD) for infants <1 year old, the population subgroup with the highest estimated chronic dietary exposure to flufenacet. As with the acute assessment, the major contributor to estimated chronic dietary exposure is drinking water. Estimated chronic dietary exposure from food alone represents less than 1% of the aPAD for the general U.S. population and all subgroups. Estimated chronic exposures from food alone and drinking water alone are compared to exposures for food and water combined in Table 16, below.

Table 16. Summary of Chronic Dietary Exposure and Risk for Flufenacet <sup>1</sup>									
	Food C	Only	Drinking W	ater Only	Tota	Total			
Population Subgroup	Exposure (mg/kg/day)	1 % CPAII 1 1 % CPAII 1		Exposure (mg/kg/day)	% cPAD				
		cPAD = 0.0017  mg/kg/day							
General U.S. Population	0.000002	<1	0.000047	2.8	0.000049	2.9			
All Infants (< 1 year old)	0.000002		0.000154 9.1		0.000156	9.2			
Children 1-2 years old	0.000005	<1	0.000070	4.1	0.000075	4.4			
Children 3-5 years old	0.000005	<1	0.000065	3.8	0.000070	4.1			
Children 6-12 years old	0.000003	<1	0.000045	2.7	0.000048	2.9			
Youth 13-19 years old	0.000002	<1	0.000034	2.0	0.000036	2.1			
Adults 20-49 years old	0.000002	<1	0.000044	2.6	0.000046	2.7			
Adults 50+ years old	0.000001	<1	0.000046	2.7	0.000048	2.8			
Females 13-49 years old	0.000002	<1	0.000044	2.6	0.000045	2.7			

PC Code: 121903

# VII. Characterization of Inputs/Outputs

Both the acute and chronic dietary analyses may be considered partially refined. A characterization of the inputs/outputs and uncertainties regarding the assessment is provided below.

#### Food:

- The assessment for food incorporates anticipated residue estimates for most crops and livestock commodities that were derived using field trial data. Although field trial data provide more refined exposure estimates than tolerances, the results may still be considered somewhat conservative, since field trials are conducted under maximum use conditions (maximum allowed application rate, minimum PHI, etc.). In actual practice, flufenacet is likely to be applied using a range of rates and PHIs, and treated commodities may be stored for various time periods (beyond the minimum PHI) prior to consumption by humans or livestock.
- Anticipated residues for food commodities were adjusted for %CT, using screening level usage estimates for the existing crops (field corn and soybeans) and projected %CT estimates for new uses (sweet corn and wheat), both of which are intended to provide "protective" exposure estimates.

<sup>&</sup>lt;sup>1</sup>The population subgroup with the highest estimated chronic dietary (food + drinking water) exposure and risk is indicated by bold text.

### Drinking Water:

• Drinking water is the risk "driver" in both the acute and chronic dietary analyses. PRZM-EXAMS surface water modeling data were used probabilistically in the acute analysis and deterministically in the chronic analysis. The modeling estimates were partially refined in that they took into consideration crop-specific percent cropped area (PCA). PRZM/EXAMS data represent the range of concentrations that are estimated to result from the annual use of flufenacet over a 30 year period at the maximum application rate. Although the PRZM/EXAMS models provide more refined estimates of surface water residues than the Tier 1 FIRST model, the drinking water inputs may be considered conservative, since they assume that applications will be made at maximum application rates to the entire crop within the watershed every year for 30 years.

DP Number: 338504

PC Code: 121903

• The PRZM/EXAMS results for the Ohio corn scenario were used in this assessment and in the previous 2003 dietary assessment for flufenacet. Although the Illinois corn scenario returned a slightly higher 1-in-10 year peak concentration in EFED's current analysis, the difference is so small (10 ppb vs. 8.6 ppb) that it would not be expected to significantly impact the risk assessment results. The results for the Ohio corn scenario are considered to provide a reasonable, high-end estimate of drinking water exposure to residues of flufenacet.

#### VIII. Conclusions

These partially refined, Tier 3 dietary exposure analyses using DEEM-FCID™ indicate that acute and chronic dietary exposures to flufenacet from food and drinking water are below HED's level of concern for this pesticide for the general U.S. population and all population subgroups.

# IX. List of Attachments

- **♣** RDF Files Used in the Acute Dietary Analyses
- ♣ Acute Food Only Input File
- ♣ Acute Food Only Results File
- ♣ Acute Drinking Water Only Input File
- ♣ Acute Drinking Water Only Results File
- ♣ Acute Food + Drinking Water Input File
- ♣ Acute Food + Drinking Water Results File
- ♣ Chronic Food Only Input File
- ♣ Chronic Food Only Results File
- ♣ Chronic Drinking Water Only Input File
- ♣ Chronic Drinking Water Only Results File
- ♣ Chronic Food + Drinking Water Input File
- ♣ Chronic Food + Drinking Water Results File

# RDF Files Used in the Acute Dietary Analyses

PC Code: 121903

DP Number: 338504

1.	2.	3.
'meat	'meatfat	'meatbyproducts
TOTALNZ=3	TOTALNZ=3	TOTALNZ=3
TOTALZ=97	TOTALZ=97	TOTALZ=97
0.0079	0.0064	0.051
0.0079	0.0064	0.051
0.0079	0.0064	0.051
4.	5.	6.
'meatliver	'pork meat	'porkfat
TOTALNZ=3	TOTALNZ=3	TOTALNZ=3
TOTALZ=97	TOTALZ=97	TOTALZ=97
0.037	0.0023	0.0018
0.037	0.0023	0.0018
0.037	0.0023	0.0018
7.	8.	9.
'pork kidney	'pork liver	'poultry meat
TOTALNZ=3	TOTALNZ=3	TOTALNZ=3
TOTALZ=97	TOTALZ=97	TOTALZ=97
0.014	0.011	0.0027
0.014	0.011	0.0027
0.014	0.011	0.0027
10.	11.	12.
'poultry fat	'poultry liver	'eggs
TOTALNZ=3	TOTALNZ=3	TOTALNZ=3
TOTALZ=97	TOTALZ=97	TOTALZ=97
0.0020	0.013	0.00058
	1 0 0 1 0	0.00058
0.0020	0.013	
0.0020	0.013	0.00058

	Laa	
13. (Only the first few daily	14.	15.
concentration values from the		
drinking water distribution of	'milk	'Sweet Corn, using maximum
more than 10,000 daily values are	MOMATNE 2	projected 10%CT TOTALZ=90
shown)	TOTALNZ=3 TOTALZ=97	TOTALLOD=10
	0.00062	LODRES=0.025
'OH Corn Flufenacet + Thiadone	0.00062	
'Parent * 1.11 with 0.46 PCA factor	0.00062	
1.33E-03		
1.33E-03		
1.32E-03		
1.32E-03		
1.31E-03		
1.31E-03		
1.30E-03		
1.30E-03		
1.30E-03		
1.29E-03		
1.29E-03		
1.28E-03		
1.28E-03		
1.27E-03		
1.27E-03		

PC Code: 121903

### **Acute Food Only Input File**

U.S. Environmental Protection Agency Ver. 2.02 DEEM-FCID Acute analysis for FLUFENACET Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Acute\Flufenacet Acute Food Only.R98 Analysis Date 12-05-2006 Residue file dated: 12-05-2006/13:14:18/8 Reference dose: aRfD = 0.0017 mg/kg bw/day NOEL = 1.7 mg/kg bw/day Comment: Flufenacet Acute - Food Only \_\_\_\_\_\_ RDL indices and parameters for Monte Carlo Analysis: Index Dist Parameter #1 Param #2 Param #3 Comment # Code 1 6 Meat.rdf 6 Meat Fat.rdf 3 6 Meat Byproducts.rdf 4 6 Meat Liver.rdf 5 6 Pork Meat.RDF 6 6 Pork Fat.rdf 7 6 Pork Kidney.RDF 8 6 Pork Liver.RDF 9 6 Poultry Meat.RDF 10 6 Poultry Fat.RDF 11 6 Poultry Liver.RDF 12 6 Eggs.RDF 13 6 OH Corn Flufenacet + Thiadone.RDF 14 6 Milk.rdf 15 6 Sweet Corn.RDF Def Res Adj. Factors RDL Comment EPA Crop Food Name Code Grp (ppm) #1 #2 Pntr 15000250 15 Barley, pearled barley 0.100000 1.000 0.030 15000251 15 Barley, pearled barley-babyfood 0.100000 1.000 0.030 15000260 15 Barley, flour 0.100000 0.440 0.030 15000261 15 Barley, flour-babyfood 0.100000 0.440 0.030 15000270 15 Barley, bran 0.100000 2.100 0.030 21000440 M Beef, meat 1.000000 1.000 1.000 1 21000441 M Beef, meat-babyfood 1.000000 1.000 1.000 1 21000450 M Beef, meat, dried 1.000000 1.920 1.000 1 21000460 M Beef, meat byproducts 1.000000 1.000 1.000 3 21000461 M Beef, meat byproducts 1.000000 1.000 1.000 3 21000471 M Beef, fat babyfood 1.000000 1.000 1.000 2 2 21000471 M Beef, fat babyfood 1.000000 1.000 1.000 2 1.000000 1.000 1.000 2
1.000491 M Beef, liver 1.000000 1.000 1.000 4
15000650 15 Buckwheat 0.100000 1.000 1.000 4
15000660 15 Buckwheat, flour 0.100000 0.440 0.030
15000660 15 Buckwheat, flour 0.100000 1.000 1.000 9
10000930 P Chicken, meat 1.000000 1.000 1.000 9
10000931 P Chicken, meat-babyfood 1.000000 1.000 1.000 9
10000940 P Chicken, liver 1.000000 1.000 1.000 11
10000950 P Chicken, meat byproducts 1.000000 1.000 1.000 11
10000951 P Chicken, meat byproducts 1.000000 1.000 1.000 11
10000960 P Chicken, fat 1.000000 1.000 1.000 11
10000961 P Chicken, fat 1.000000 1.000 1.000 10
10000970 P Chicken, skin 1.000000 1.000 1.000 10
10000971 P Chicken, skin 1.000000 1.000 1.000 10 21000471 M Beef, fat-babyfood 1.000000 1.000 1.000 40000961 P Chicken, skin 1.000000 1.

26003430 M	Sheep, liver	1.000000	1.000	1.000	4
15003440 15	Sorghum, grain	0.100000	1.000	0.030	
15003450 15	Sorghum, syrup	0.100000	1.000	0.030	
06003470 6	Soybean, seed	0.030000	1.000	0.025	
06003480 6	Soybean, flour	0.030000	1.000	0.025	
06003481 6	Soybean, flour-babyfood	0.030000	1.000	0.025	
06003490 6	Soybean, soy milk	0.030000	1.000	0.025	
06003491 6	Soybean, soy milk-babyfood or in	0.030000	1.000	0.025	
06003500 6	Soybean, oil	0.030000	1.000	0.025	
06003501 6	Soybean, oil-babyfood	0.030000	1.000	0.025	
15003810 15	Triticale, flour	0.130000	0.440	0.030	
15003811 15	Triticale, flour-babyfood	0.130000	0.440	0.030	
50003820 P	Turkey, meat	1.000000	1.000	1.000	9
50003821 P	Turkey, meat-babyfood	1.000000	1.000	1.000	9
50003830 P	Turkey, liver	1.000000	1.000	1.000	11
50003831 P	Turkey, liver-babyfood	1.000000	1.000	1.000	11
50003840 P	Turkey, meat byproducts	1.000000	1.000	1.000	11
50003841 P	Turkey, meat byproducts-babyfood	1.000000	1.000	1.000	11
50003850 P	Turkey, fat	1.000000	1.000	1.000	10
50003851 P	Turkey, fat-babyfood	1.000000	1.000	1.000	10
50003860 P	Turkey, skin	1.000000	1.000	1.000	10
50003861 P	Turkey, skin-babyfood	1.000000	1.000	1.000	10
15004010 15	Wheat, grain	0.130000	1.000	0.030	
15004011 15	Wheat, grain-babyfood	0.130000	1.000	0.030	
15004020 15	Wheat, flour	0.130000	0.440	0.030	
15004021 15	Wheat, flour-babyfood	0.130000	0.440	0.030	
15004030 15	Wheat, germ	0.130000	1.000	0.030	
15004040 15	Wheat, bran	0.130000	2.100	0.030	

# **Acute Food Only Results File**

PC Code: 121903

DP Number: 338504

U.S. Environmental Protection Agency Ver. 2.02
DEEM-FCID ACUTE Analysis for FLUFENACET (1994-98 data)

Residue file: Flufenacet Acute Food Only.R98 Adjustment factor #2 used.

Analysis Date: 12-05-2006/13:35:31 Residue file dated: 12-05-2006/13:14:18/8

NOEL (Acute) = 1.700000 mg/kg body-wt/day

Daily totals for food and foodform consumption used.

Run Comment: "Flufenacet Acute - Food Only"

-----

#### Summary calculations (per capita):

95th	Percenti	le	99th	Percenti	le	99.9th	n Percent	cile
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure %	å aRfD	MOE
U.S. Popula	ation:							
0.000016	0.94	106267	0.000033	1.93	51860	0.000102	6.00	16680
All infants	S:							
0.000017	1.00	100121	0.000030	1.76	56925	0.000110	6.45	15512
Children 1-	-2 yrs:							
0.000034	1.97	50689	0.000075	4.39	22766	0.000215	12.63	7914
Children 3-	-5 yrs:							
0.000030	1.74	57387	0.000065	3.83	26111	0.000223	13.11	7626
Children 6-	-12 yrs:							
0.000021		81312	0.000046	2.71	36957	0.000148	8.70	11490
Youth 13-19	yrs:							
0.000013	0.78	128730	0.000026	1.54	65046	0.000085	5.01	19965
Adults 20-4	-							
0.000011	0.66	152634	0.000023	1.34	74620	0.000069	4.06	24655
Adults 50+	yrs:							
0.000009	0.53	188236	0.000019	1.10	90738	0.000063	3.70	27061
Females 13-	-49 yrs:							
0.000011	0.62	161747	0.000021	1.22	81894	0.000073	4.31	23222

# **Acute Drinking Water Only Input File**

U.S. Environmental Protection Agency

Ver. 2.02

PC Code: 121903

DEEM-FCID Acute analysis for FLUFENACET

Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Acute\Flufenacet Acute DW only\_OH Corn Scenario.R98 Analysis Date 11-24-2006 Residue file dated: 11-01-2006/08:06:36/8

Reference dose (aRfD) = 0.0017 mg/kg bw/day

Comment: Drinking Water Only using PRZM-EXAMS Distribution for OH Corn Scenario

RDL indices and parameters for Monte Carlo Analysis:

Index Dist Parameter #1 Param #2 Param #3 Comment # Code

1 6 OH Corn Flufenacet + Thiadone.RDF

EPA	Crop	Food Name	Def Res	Adj.Fa	ctors	RDL	Comment
Code	Grp		(ppm)	#1	#2	Pntr	
86010000	0	Water, direct, all sources	1.000000	1.000	1.000	1	
86020000	0	Water, indirect, all sources	1.000000	1.000	1.000	1	

# **Acute Drinking Water Only Results File**

DP Number: 338504

Ver. 2.02

DEEM-FCID ACUTE Analysis for FLUFENACET

(1994-98 data)

PC Code: 121903

U.S. Environmental Protection Agency

Residue file: Flufenacet Acute DW only OH Corn Scenario.R98

Adjustment factor #2 used.

Analysis Date: 11-24-2006/09:08:46 Residue file dated: 11-01-2006/08:06:36/8

Daily totals for food and foodform consumption used.

MC seed = 100

Run Comment: "Drinking Water Only using PRZM-EXAMS Distribution for OH Corn Sc enario"

\_\_\_\_\_\_

Summary calculations (per capita):

	95th Percentile		99th Perc	entile	99.9th Percentile		
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD	
U.S. Population:							
	0.000106	6.26	0.000220	12.95	0.000503	29.61	
All infants:	0.000392	23.04	0.000785	46.17	0.001520	89.41	
Children 1-2 yrs:	0.000352	23.04	0.000783	40.17	0.001320	07.41	
-	0.000164	9.62	0.000335	19.72	0.000690	40.60	
Children 3-5 yrs:	0.000150	8.82	0.000302	17.78	0.000611	35.95	
Children 6-12 yrs:	0.000130	0.02	0.000302	17.70	0.000011	33.73	
_	0.000104	6.10	0.000211	12.39	0.000428	25.18	
Youth 13-19 yrs:	0.000080	4.72	0.000171	10.04	0.000377	22.18	
Adults 20-49 yrs:	0.000000	4.72	0.000171	10.04	0.000377	22.10	
_	0.000099	5.85	0.000200	11.77	0.000419	24.64	
Adults 50+ yrs:	0.000099	5.84	0.000185	10.85	0.000339	19.93	
Females 13-49 yrs:	0.000099	5.84	0.000185	10.85	0.000339	19.93	
1	0.000100	5.87	0.000201	11.84	0.000413	24.29	

# **Acute Food + Drinking Water Input File**

U.S. Environmental Protection Agency Ver. 2.02 DEEM-FCID Acute analysis for FLUFENACET Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Acute\Flufenacet Acute Food + Water OH Corn Scenario.R98 Analysis Date 12-05-2006 Residue file dated: 12-05-2006/13:10:39/8 Reference dose: aRfD = 0.0017 mg/kg bw/day NOEL = 1.7 mg/kg bw/day Comment: Flufenacet Acute - Food + Drinking Water - OH Corn Scenario \_\_\_\_\_\_ RDL indices and parameters for Monte Carlo Analysis: Index Dist Parameter #1 Param #2 Param #3 Comment # Code 1 6 Meat.rdf 6 Meat Fat.rdf 6 Meat Byproducts.rdf 4 6 Meat Liver.rdf 6 Pork Meat.RDF 5 6 6 Pork Fat.rdf 7 6 Pork Kidney.RDF 8 6 Pork Liver.RDF 9 6 Poultry Meat.RDF 10 6 Poultry Fat.RDF 11 6 Poultry Liver.RDF 12 6 Eggs.RDF 13 6 OH Corn Flufenacet + Thiadone.RDF 14 6 Milk.rdf 15 6 Sweet Corn.RDF Def Res Adj. Factors RDL Comment EPA Crop Food Name Code Grp (ppm) #1 #2 Pntr 

 15000250 15
 Barley, pearled barley
 0.100000
 1.000
 0.030

 15000251 15
 Barley, pearled barley-babyfood
 0.100000
 1.000
 0.030

 15000260 15
 Barley, flour
 0.100000
 0.440
 0.030

 15000270 15
 Barley, bran
 0.100000
 2.100
 0.030

 15000250 15 Barley, pearled barley 0.100000 1.000 0.030 15000270 15 Barley, bran 3 21000470 M Beef, fat 1.000000 1.000 1.000 21000471 M Beef, fat-babyfood 1.000000 1.000 1.000 21000471 M Beef, late babylood 21000480 M Beef, kidney 21000490 M Beef, liver 21000491 M Beef, liver-babyfood 15000650 15 Buckwheat 1.000000 1.000 1.000 1.000000 1.000 1.000 1.000000 1.000 1.000 0.100000 1.000 0.030 0.100000 0.440 0.030 15000660 15 Buckwheat, flour 40000930 P Chicken, meat 

 40000930 P
 Chicken, meat
 1.000000
 1.000
 1.000
 9

 40000931 P
 Chicken, meat-babyfood
 1.000000
 1.000
 1.000
 9

 40000940 P
 Chicken, liver
 1.000000
 1.000
 1.000
 11

 40000950 P
 Chicken, meat byproducts
 1.000000
 1.000
 1.000
 11

 40000951 P
 Chicken, meat byproducts-babyfoo
 1.000000
 1.000
 1.000
 11

 40000960 P
 Chicken, fat
 1.000000
 1.000
 1.000
 1.000
 10

 40000961 P Chicken, fat-babyfood 40000970 P Chicken skin 1.000000 1.000 1.000 10 40000970 P Chicken, skin 40000971 P Chicken, skin-babyfood 1.000000 1.000 1.000 10 1.000000 1.000 1.000 10 15001200 15 Corn, field, flour 0.025000 1.000 0.025

26003430 M	Sheep, liver	1.000000	1.000	1.000	4
15003440 15	Sorghum, grain	0.100000	1.000	0.030	
15003450 15	Sorghum, syrup	0.100000	1.000	0.030	
06003470 6	Soybean, seed	0.030000	1.000	0.025	
06003480 6	Soybean, flour	0.030000	1.000	0.025	
06003481 6	Soybean, flour-babyfood	0.030000	1.000	0.025	
06003490 6	Soybean, soy milk	0.030000	1.000	0.025	
06003491 6	Soybean, soy milk-babyfood or in	0.030000	1.000	0.025	
06003500 6	Soybean, oil	0.030000	1.000	0.025	
06003501 6	Soybean, oil-babyfood	0.030000	1.000	0.025	
15003810 15	Triticale, flour	0.130000	0.440	0.030	
15003811 15	Triticale, flour-babyfood	0.130000	0.440	0.030	
50003820 P	Turkey, meat	1.000000	1.000	1.000	9
50003821 P	Turkey, meat-babyfood	1.000000	1.000	1.000	9
50003830 P	Turkey, liver	1.000000	1.000	1.000	11
50003831 P	Turkey, liver-babyfood	1.000000	1.000	1.000	11
50003840 P	Turkey, meat byproducts	1.000000	1.000	1.000	11
50003841 P	Turkey, meat byproducts-babyfood	1.000000	1.000	1.000	11
50003850 P	Turkey, fat	1.000000	1.000	1.000	10
50003851 P	Turkey, fat-babyfood	1.000000	1.000	1.000	10
50003860 P	Turkey, skin	1.000000	1.000	1.000	10
50003861 P	Turkey, skin-babyfood	1.000000	1.000	1.000	10
86010000 O	Water, direct, all sources	1.000000	1.000	1.000	13
86020000 O	Water, indirect, all sources	1.000000	1.000	1.000	13
15004010 15	Wheat, grain	0.130000	1.000	0.030	
15004011 15	Wheat, grain-babyfood	0.130000	1.000	0.030	
15004020 15	Wheat, flour	0.130000	0.440	0.030	
15004021 15	Wheat, flour-babyfood	0.130000	0.440	0.030	
15004030 15	Wheat, germ	0.130000	1.000	0.030	
15004040 15	Wheat, bran	0.130000	2.100	0.030	

# **Acute Food + Drinking Water Results File**

DP Number: 338504

U.S. Environmental Protection Agency

Ver. 2.02

DEEM-FCID ACUTE Analysis for FLUFENACET

(1994-98 data)

PC Code: 121903

Residue file: Flufenacet Acute Food + Water OH Corn Scenario.R98

Adjustment factor #2 used.

Analysis Date: 12-05-2006/13:53:11 Residue file dated: 12-05-2006/13:10:39/8

NOEL (Acute) = 1.700000 mg/kg body-wt/day

Daily totals for food and foodform consumption used.

MC seed = 100

Run Comment: "Flufenacet Acute - Food + Drinking Water - OH Corn Scenario"

\_\_\_\_\_\_

#### Summary calculations (per capita):

95th P	ercentil	le	99th	Percentil	е	99.9th	Percenti	le
<del>-</del>			_			Exposure %		
U.S. Populat								
0.000115		14793	0.000230	13.54	7387	0.000514	30.24	3307
All infants:								
0.000396	23.32	4288	0.000790	46.45	2152	0.001514	89.05	1123
Children 1-2	yrs:							
0.000185	10.90	9173	0.000361	21.26	4703	0.000720	42.36	2360
Children 3-5	yrs:							
0.000171		9932	0.000325	19.14	5224	0.000635	37.33	2678
Children 6-1	2 yrs:							
0.000118	6.95	14393	0.000227	13.35	7490	0.000444	26.12	3828
Youth 13-19	yrs:							
0.000088	5.20	19223	0.000178	10.47	9551	0.000389	22.88	4370
Adults 20-49	yrs:							
0.000105		16151	0.000206	12.13	8246	0.000424	24.97	4005
Adults 50+ y	rs:							
0.000104	6.13	16319	0.000190	11.16	8964	0.000344	20.25	4939
Females 13-4	9 yrs:							
0.000106	6.21	16108	0.000207	12.15	8230	0.000418	24.58	4068

# **Chronic Food Only Input File**

U.S. Environmental Protection Agency

Ver. 2.00

DEEM-FCID Chronic analysis for FLUFENACET

1994-98 data

Residue file: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Chronic\Flufenacet Chronic Food Only.R98

Adjust. #2 used

Analysis Date 11-24-2006 Residue file dated: 11-24-2006/08:29:32/8

Reference dose (RfD) = 0.0017 mg/kg bw/day
Comment:Flufenacet Chronic - Food Only

\_\_\_\_\_\_

Food Crop EPA Code Grp	Food Name	Residue (ppm)	Adj.Factors		Comment
ZIII code oip		(PP)	#1	#2	
15000250 15	Barley, pearled barley	0.100000	1.000	0.010	
15000250 15	Barley, pearled barley-babyfood		1.000	0.010	
15000251 15	Barley, flour	0.100000	0.440	0.010	
15000261 15	Barley, flour-babyfood	0.100000	0.440	0.010	
15000270 15	Barley, bran	0.100000	2.100	0.010	
21000440 M	Beef, meat	0.007900	1.000	0.010	
21000441 M	Beef, meat-babyfood	0.007900	1.000	0.010	
21000450 M	Beef, meat, dried	0.007900	1.920	0.010	
21000460 M	Beef, meat byproducts	0.051000	1.000	0.010	
21000461 M	Beef, meat byproducts-babyfood		1.000	0.010	
21000470 M	Beef, fat	0.006400	1.000	0.010	
21000471 M	Beef, fat-babyfood	0.006400	1.000	0.010	
21000480 M	Beef, kidney	0.051000	1.000	0.010	
21000490 M	Beef, liver	0.037000	1.000	0.010	
21000491 M	Beef, liver-babyfood		1.000	0.010	
15000650 15	Buckwheat	0.100000	1.000	0.010	
15000660 15	Buckwheat, flour	0.100000	0.440	0.010	
40000930 P	Chicken, meat	0.002700	1.000	0.010	
40000931 P	Chicken, meat-babyfood	0.002700	1.000	0.010	
40000940 P	Chicken, liver	0.013000	1.000	0.010	
40000950 P	Chicken, meat byproducts	0.013000	1.000	0.010	
40000951 P	Chicken, meat byproducts-babyfoo		1.000	0.010	
40000960 P	Chicken, fat	0.002000	1.000	0.010	
40000961 P	Chicken, fat-babyfood	0.002000	1.000	0.010	
40000970 P	Chicken, skin	0.002000	1.000	0.010	
40000971 P	Chicken, skin-babyfood	0.002000	1.000	0.010	
15001200 15		0.025000	1.000	0.010	
15001201 15	Corn, field, flour-babyfood	0.025000	1.000	0.010	
15001210 15	Corn, field, meal	0.025000	1.000	0.010	
15001211 15	Corn, field, meal-babyfood	0.025000	1.000	0.010	
15001220 15	Corn, field, bran	0.025000	1.000	0.010	
15001230 15	Corn, field, starch	0.025000	1.000	0.010	
15001231 15	Corn, field, starch-babyfood		1.000	0.010	
15001240 15	Corn, field, syrup	0.025000	1.000	0.010	
15001241 15	Corn, field, syrup-babyfood	0.025000	1.000	0.010	
15001250 15	Corn, field, oil	0.025000	1.000	0.010	
15001251 15	Corn, field, oil-babyfood	0.025000	1.000	0.010	
15001260 15	Corn, pop	0.100000	1.000	0.010	
15001270 15	Corn, sweet	0.025000	1.000	0.030	
15001271 15	Corn, sweet-babyfood	0.025000	1.000	0.030	
70001450 P	Egg, whole	0.000580	1.000	0.010	
70001451 P	Egg, whole-babyfood	0.000580	1.000	0.010	
70001460 P	Egg, white	0.000580	1.000	0.010	
70001461 P	Egg, white (solids)-babyfood	0.000580	1.000	0.010	

70001470 P	Egg, yolk	0.000580	1.000	0.010
70001471 P	Egg, yolk-babyfood	0.000580	1.000	0.010
23001690 M	Goat, meat	0.007900	1.000	0.010
23001700 M	Goat, meat byproducts	0.051000	1.000	0.010
23001710 M	Goat, fat	0.006400	1.000	0.010
23001720 M	Goat, kidney	0.051000	1.000	0.010
23001730 M	Goat, liver	0.037000	1.000	0.010
24001890 M	Horse, meat	0.007900	1.000	0.010
27002220 D	Milk, fat	0.000620	1.000	0.010
27002220 D	Milk, fat - baby food/infant for	0.000620	1.000	0.010
27012231 D	Milk, nonfat solids	0.000620	1.000	0.010
27012230 D 27012231 D	Milk, nonfat solids-baby food/in	0.000620	1.000	0.010
27012231 D 27022240 D	Milk, water	0.000620	1.000	0.010
27022240 D 27022241 D	Milk, water-babyfood/infant form	0.000620	1.000	
				0.010
27032251 D	Milk, sugar (lactose)-baby food/	0.000620	1.000	0.010
15002260 15	Millet, grain	0.100000	1.000	0.010
15002310 15	Oat, bran	0.100000	2.100	0.010
15002320 15	Oat, flour	0.100000	0.440	0.010
15002321 15	Oat, flour-babyfood	0.100000	0.440	0.010
15002330 15	Oat, groats/rolled oats	0.100000	1.000	0.010
15002331 15	Oat, groats/rolled oats-babyfood	0.100000	1.000	0.010
25002900 M	Pork, meat	0.002300	1.000	0.010
25002901 M	Pork, meat-babyfood	0.002300	1.000	0.010
25002910 M	Pork, skin	0.001800	1.000	0.010
25002920 M	Pork, meat byproducts	0.014000	1.000	0.010
25002921 M	Pork, meat byproducts-babyfood	0.014000	1.000	0.010
25002930 M	Pork, fat	0.001800	1.000	0.010
25002931 M	Pork, fat-babyfood	0.001800	1.000	0.010
25002940 M	Pork, kidney	0.014000	1.000	0.010
25002950 M	Pork, liver	0.011000	1.000	0.010
60003010 P	Poultry, other, meat	0.002700	1.000	0.010
60003020 P	Poultry, other, liver	0.013000	1.000	0.010
60003030 P	Poultry, other, meat byproducts	0.013000	1.000	0.010
60003040 P	Poultry, other, fat	0.002000	1.000	0.010
60003050 P	Poultry, other, skin	0.002000	1.000	0.010
15003280 15	Rye, grain	0.100000	1.000	0.010
15003290 15	Rye, flour	0.100000	0.440	0.010
26003390 M	Sheep, meat	0.007900	1.000	0.010
26003390 M	Sheep, meat-babyfood	0.007900	1.000	0.010
26003391 M	Sheep, meat byproducts	0.051000	1.000	0.010
26003400 M	Sheep, fat	0.006400	1.000	0.010
26003410 M	Sheep, fat-babyfood	0.006400	1.000	0.010
26003411 M	Sheep, kidney	0.051000	1.000	0.010
26003420 M 26003430 M	Sheep, liver			
	<del>-</del>	0.037000	1.000	0.010
15003440 15	Sorghum, grain	0.100000	1.000	0.010
15003450 15	Sorghum, syrup	0.100000	1.000	0.010
06003470 6	Soybean, seed	0.030000	1.000	0.010
06003480 6	Soybean, flour	0.030000	1.000	0.010
06003481 6	Soybean, flour-babyfood	0.030000	1.000	0.010
06003490 6	Soybean, soy milk	0.030000	1.000	0.010
06003491 6	Soybean, soy milk-babyfood or in	0.030000	1.000	0.010
06003500 6	Soybean, oil	0.030000	1.000	0.010
06003501 6	Soybean, oil-babyfood	0.030000	1.000	0.010
15003810 15	Triticale, flour	0.130000	0.440	0.010
15003811 15	Triticale, flour-babyfood	0.130000	0.440	0.010
50003820 P	Turkey, meat	0.002700	1.000	0.010
50003821 P	Turkey, meat-babyfood	0.002700	1.000	0.010
50003830 P	Turkey, liver	0.013000	1.000	0.010
50003831 P	Turkey, liver-babyfood	0.013000	1.000	0.010
50003840 P	Turkey, meat byproducts	0.013000	1.000	0.010

Flufenacet Dietary Exposure As	sessment DP Number: 338	504	PC C	Code: 121903	
50003841 P Turkey,	meat byproducts-babyfood	0.013000	1.000	0.010	
50003850 P Turkey,	fat	0.002000	1.000	0.010	
50003851 P Turkey,	fat-babyfood	0.002000	1.000	0.010	
50003860 P Turkey,	skin	0.002000	1.000	0.010	
50003861 P Turkey,	skin-babyfood	0.002000	1.000	0.010	
15004010 15 Wheat, g	grain	0.130000	1.000	0.010	
15004011 15 Wheat, g	grain-babyfood	0.130000	1.000	0.010	
15004020 15 Wheat, f	lour	0.130000	0.440	0.010	
15004021 15 Wheat, f	lour-babyfood	0.130000	0.440	0.010	
15004030 15 Wheat, g	germ	0.130000	1.000	0.010	
15004040 15 Wheat.	oran	0.130000	2.100	0.010	

# **Chronic Food Only Results File**

DP Number: 338504

U.S. Environmental Protection Agency

Ver. 2.00

DEEM-FCID Chronic analysis for FLUFENACET

(1994-98 data)

PC Code: 121903

Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Chronic\Flufenacet Chronic Food Only.R98

Adjustment factor #2 used.

Analysis Date 11-24-2006/09:26:17 Residue file dated: 11-24-2006/08:29:32/8

Reference dose (RfD, Chronic) = .0017 mg/kg bw/day
COMMENT 1: Flufenacet Chronic - Food Only

\_\_\_\_\_\_

# Total exposure by population subgroup

------

	Total Exposure	
Population Subgroup	body wt/day	Percent of Rfd
U.S. Population (total)	0.000002	0.1%
U.S. Population (spring season) U.S. Population (summer season) U.S. Population (autumn season) U.S. Population (winter season)	0.000002 0.000002 0.000002 0.000002	0.1% 0.1% 0.1% 0.1%
Northeast region Midwest region Southern region Western region	0.000002 0.000002 0.000002 0.000002	0.1% 0.1% 0.1% 0.1%
Hispanics Non-hispanic whites Non-hispanic blacks Non-hisp/non-white/non-black	0.000002 0.000002 0.000002 0.000002	0.1% 0.1% 0.1% 0.1%
All infants (< 1 year) Nursing infants Non-nursing infants Children 1-6 yrs Children 7-12 yrs	0.000002 0.000001 0.000002 0.000005 0.000003	0.1% 0.0% 0.1% 0.3% 0.2%
Females 13-19 (not preg or nursing) Females 20+ (not preg or nursing) Females 13-50 yrs Females 13+ (preg/not nursing) Females 13+ (nursing)	0.000002 0.000001 0.000002 0.000002 0.000002	0.1% 0.1% 0.1% 0.1% 0.1%
Males 13-19 yrs Males 20+ yrs Seniors 55+	0.000002 0.000002 0.000001	0.1% 0.1% 0.1%
Children 1-2 yrs Children 3-5 yrs Children 6-12 yrs Youth 13-19 yrs Adults 20-49 yrs Adults 50+ yrs Females 13-49 yrs	0.000005 0.000005 0.000003 0.000002 0.000002 0.000001 0.000002	0.3% 0.3% 0.2% 0.1% 0.1% 0.1%

# **Chronic Water Only Input File**

DP Number: 338504

U.S. Environmental Protection Agency

Ver. 2.00

DEEM-FCID Chronic analysis for FLUFENACET

1994-98 data

PC Code: 121903

Residue file: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID

Files\Flufenacet\Flufenacet Chronic\Flufenacet Chronic DW only OH Corn Scenario.R98

Adjust. #2 used

Analysis Date 11-24-2006

Residue file dated: 11-01-2006/10:26:45/8

Reference dose (RfD) = 0.0017 mg/kg bw/day

Comment:Drinking Water Only using PRZM-EXAMS Mean for OH Corn Scenario

Food Crop EPA Code Grp Food Name	Residue (ppm)	Adj.F	actors	Comment
-		#1	#2	
86010000 O Water, direct, all sources	0.002230	1.000	1.000	
86020000 O Water, indirect, all sources	0.002230	1.000	1.000	

# **Chronic Water Only Results File**

DP Number: 338504

U.S. Environmental Protection Agency

Ver. 2.00

DEEM-FCID Chronic analysis for FLUFENACET

(1994-98 data)

PC Code: 121903

Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID Files\Flufenacet\Flufenacet Chronic\Flufenacet Chronic DW only\_OH Corn Scenario.R98

Adjustment factor #2 used.

Analysis Date 11-24-2006/09:27:47 Residue file dated: 11-01-2006/10:26:45/8

Reference dose (RfD, Chronic) = .0017 mg/kg bw/day

COMMENT 1: Drinking Water Only using PRZM-EXAMS Mean for OH Corn Scenario \_\_\_\_\_\_

Total exposure by population subgroup

#### \_\_\_\_\_\_ Total Exposure

Population Subgroup	mg/kg body wt/day	
U.S. Population (total)	0.000047	2.8%
U.S. Population (spring season)	0.000047	2.7%
U.S. Population (summer season)	0.000050	3.0%
U.S. Population (autumn season)	0.000045	2.7%
U.S. Population (winter season)	0.000045	2.7%
Northeast region	0.000043	2.5%
Midwest region	0.000048	2.8%
Southern region	0.000045	2.6%
Western region	0.000054	3.2%
Hispanics	0.000053	3.1%
Non-hispanic whites	0.000046	2.7%
Non-hispanic blacks	0.000045	2.6%
Non-hisp/non-white/non-black	0.000058	3.4%
All infants (< 1 year)	0.000154	9.1%
Nursing infants	0.000057	3.4%
Non-nursing infants	0.000191	11.2%
Children 1-6 yrs	0.000066	3.9%
Children 7-12 yrs	0.000043	2.5%
Females 13-19 (not preg or nursing)	0.000033	1.9%
Females 20+ (not preg or nursing)	0.000047	2.8%
Females 13-50 yrs	0.000045	2.7%
Females 13+ (preg/not nursing)	0.000046	2.7%
Females 13+ (nursing)	0.000065	3.8%
Males 13-19 yrs	0.000035	2.0%
Males 20+ yrs	0.000042	2.5%
Seniors 55+	0.000046	2.7%
Children 1-2 yrs	0.000070	4.1%
Children 3-5 yrs	0.000065	3.8%
Children 6-12 yrs	0.000045	2.7%
Youth 13-19 yrs	0.000034	2.0%
Adults 20-49 yrs	0.000044	2.6%
Adults 50+ yrs	0.000046	2.7%
Females 13-49 yrs	0.000044	2.6%

### **Chronic Food + Water Input File**

U.S. Environmental Protection Agency

Ver. 2.00

DEEM-FCID Chronic analysis for FLUFENACET

1994-98 data

Residue file: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID

 ${\tt Files \backslash Flufenacet\ Chronic \backslash Flufenacet\ Chronic\ Food\ +\ Water\ OH\ Corn\ Scenario.R98}$ 

Adjust. #2 used

Analysis Date 11-24-2006

Rebidue

Residue file dated: 11-24-2006/08:28:20/8

Reference dose (RfD) = 0.0017 mg/kg bw/day

Comment:Flufenacet Chronic - Food and Drinking Water (IL Corn Mean)

Food Crop		Residue	Adj.Fa	ctors	Comment
EPA Code Grp	Food Name	(ppm)	U.a.		
			#1	#2 	
15000250 15					
15000251 15	Barley, pearled barley-babyfood			0.010	
15000260 15	Barley, flour	0.100000		0.010	
15000261 15	Barley, flour-babyfood			0.010	
15000270 15	Barley, bran	0.100000		0.010	
21000440 M	Beef, meat	0.007900		0.010	
21000441 M	Beef, meat-babyfood	0.007900		0.010	
21000450 M	Beef, meat, dried	0.007900		0.010	
21000460 M	Beef, meat byproducts	0.051000		0.010	
21000461 M	Beef, meat byproducts-babyfood				
21000470 M	Beef, fat	0.006400			
21000471 M	Beef, fat-babyfood	0.006400	1.000	0.010	
21000480 M	Beef. kidnev		1.000	0.010	
21000490 M	Beef. liver	0.037000		0.010	
21000491 M	Beef, kidney Beef, liver Beef, liver-babyfood	0.037000		0.010	
15000650 15	Buckwheat	0.100000		0.010	
15000660 15	Buckwheat, flour	0.100000		0.010	
40000930 P	Chicken, meat	0.002700		0.010	
40000931 P	Chicken, meat-babyfood				
40000940 P	Chicken, liver	0.013000			
40000950 P	Chicken, meat byproducts	0.013000	1.000	0.010	
40000951 P	Chicken, meat byproducts-babyfoo		1.000	0.010	
40000960 P	Chicken, fat	0.002000	1.000	0.010	
40000961 P	Chicken, fat-babyfood	0.002000	1.000	0.010	
40000970 P	Chicken, skin	0.002000	1.000	0.010	
40000971 P	Chicken skin-babyfood	0.002000	1.000	0.010	
15001200 15	Chicken, skin-babyfood Corn, field, flour	0.025000	1.000	0.010	
15001201 15	Corn, field, flour-babyfood		1.000	0.010	
15001210 15	Corn, field, meal	0.025000	1.000		
15001211 15	Corn, field, meal-babyfood		1.000		
15001220 15		0.025000	1.000	0.010	
15001230 15	Corn field starch	0 025000	1 000	0.010	
15001231 15	Corn, field, starch-babyfood	0.025000	1.000	0.010	
15001240 15	Corn, field, syrup	0.025000	1.000	0.010	
15001241 15	Corn, field, syrup-babyfood	0.025000	1.000	0.010	
15001250 15	Corn, field, oil	0.025000	1.000	0.010	
15001251 15	Corn, field, oil-babyfood	0.025000	1.000	0.010	
15001260 15	Corn, pop	0.100000	1.000	0.010	
15001270 15	Corn, sweet	0.025000	1.000	0.030	
15001271 15	Corn, sweet-babyfood	0.025000	1.000	0.030	
70001271 13	Egg, whole	0.000580	1.000	0.010	
70001450 P	Egg, whole-babyfood	0.000580	1.000	0.010	
70001451 T	Egg, white	0.000580	1.000	0.010	
70001400 T 70001461 P	Egg, white (solids)-babyfood	0.000580	1.000	0.010	
70001401 P	Egg, yolk	0.000580	1.000	0.010	
,00011/0 1	-33/ IOTH	0.00000	1.000	0.010	

70001471 P	Egg, yolk-babyfood	0.000580	1.000	0.010
23001690 M	Goat, meat	0.007900	1.000	0.010
23001700 M	Goat, meat byproducts	0.051000	1.000	0.010
23001710 M	Goat, fat	0.006400	1.000	0.010
23001720 M	Goat, kidney	0.051000	1.000	0.010
23001730 M	Goat, liver	0.037000	1.000	0.010
24001890 M	Horse, meat	0.007900	1.000	0.010
27002220 D	Milk, fat	0.000620	1.000	0.010
27002221 D	Milk, fat - baby food/infant for	0.000620	1.000	0.010
27012230 D	Milk, nonfat solids	0.000620	1.000	0.010
27012231 D	Milk, nonfat solids-baby food/in	0.000620	1.000	0.010
27022240 D	Milk, water	0.000620	1.000	0.010
27022241 D	Milk, water-babyfood/infant form	0.000620	1.000	0.010
27032251 D	Milk, sugar (lactose)-baby food/	0.000620	1.000	0.010
15002260 15	Millet, grain	0.100000	1.000	0.010
15002310 15	Oat, bran	0.100000	2.100	0.010
15002320 15	Oat, flour	0.100000	0.440	0.010
15002321 15	Oat, flour-babyfood	0.100000	0.440	0.010
15002330 15	Oat, groats/rolled oats	0.100000	1.000	0.010
15002331 15	Oat, groats/rolled oats-babyfood	0.100000	1.000	0.010
25002900 M	Pork, meat	0.002300	1.000	0.010
25002901 M	Pork, meat-babyfood	0.002300	1.000	0.010
25002910 M	Pork, skin	0.001800	1.000	0.010
25002920 M	Pork, meat byproducts	0.014000	1.000	0.010
25002921 M	Pork, meat byproducts-babyfood	0.014000	1.000	0.010
25002930 M	Pork, fat	0.001800	1.000	0.010
25002931 M	Pork, fat-babyfood	0.001800	1.000	0.010
25002940 M	Pork, kidney	0.014000	1.000	0.010
25002950 M	Pork, liver	0.011000	1.000	0.010
60003010 P	Poultry, other, meat	0.002700	1.000	0.010
60003020 P	Poultry, other, liver	0.013000	1.000	0.010
60003030 P	Poultry, other, meat byproducts	0.013000	1.000	0.010
60003040 P	Poultry, other, fat	0.002000	1.000	0.010
60003050 P	Poultry, other, skin	0.002000	1.000	0.010
15003280 15	Rye, grain	0.100000	1.000	0.010
15003290 15	Rye, flour	0.100000	0.440	0.010
26003390 M	Sheep, meat behaviored	0.007900	1.000	0.010
26003391 M	Sheep, meat-babyfood	0.007900	1.000	0.010
26003400 M	Sheep, meat byproducts	0.051000	1.000	0.010
26003410 M	Sheep, fat Sheep, fat-babyfood	0.006400	1.000	0.010
26003411 M 26003420 M	Sheep, kidney	0.006400 0.051000	1.000 1.000	0.010
26003430 M	Sheep, kidney Sheep, liver	0.031000	1.000	0.010 0.010
15003440 15	Sorghum, grain	0.100000	1.000	0.010
15003440 15	Sorghum, grain Sorghum, syrup	0.100000	1.000	0.010
06003470 6	Soybean, seed	0.030000	1.000	0.010
06003470 6	Soybean, flour	0.030000	1.000	0.010
06003481 6	Soybean, flour-babyfood	0.030000	1.000	0.010
06003490 6	Soybean, soy milk	0.030000	1.000	0.010
06003490 6	Soybean, soy milk-babyfood or in	0.030000	1.000	0.010
06003191 0	Soybean, oil	0.030000	1.000	0.010
06003500 0	Soybean, oil-babyfood	0.030000	1.000	0.010
15003810 15	Triticale, flour	0.130000	0.440	0.010
15003811 15	Triticale, flour-babyfood	0.130000	0.440	0.010
50003820 P	Turkey, meat	0.002700	1.000	0.010
50003821 P	Turkey, meat-babyfood	0.002700	1.000	0.010
50003830 P	Turkey, liver	0.013000	1.000	0.010
50003831 P	Turkey, liver-babyfood	0.013000	1.000	0.010
50003840 P	Turkey, meat byproducts	0.013000	1.000	0.010
50003841 P	Turkey, meat byproducts-babyfood	0.013000	1.000	0.010
	<del></del>			

Flufenacet Dietary	Exposure Assessment	DP Number: 338504	PC	Code: 121903	
50003850 P	Turkey, fat	0.002000	1.000	0.010	
50003850 P	Turkey, fat-babyfood	0.002000	1.000	0.010	
50003860 P	Turkey, skin	0.002000	1.000	0.010	
50003861 P	Turkey, skin-babyfood	0.002000	1.000	0.010	
86010000 O	Water, direct, all so	urces 0.002230	1.000	1.000	
86020000 O	Water, indirect, all	sources 0.002230	1.000	1.000	
15004010 15	Wheat, grain	0.130000	1.000	0.010	
15004011 15	Wheat, grain-babyfood	0.130000	1.000	0.010	
15004020 15	Wheat, flour	0.130000	0.440	0.010	
15004021 15	Wheat, flour-babyfood	0.130000	0.440	0.010	
15004030 15	Wheat, germ	0.130000	1.000	0.010	
15004040 15	Wheat, bran	0.130000	2.100	0.010	

# Chronic Food + Water Results File

U.S. Environmental Protection Agency

Population

Children 1-2 yrs

Children 3-5 yrs

Youth 13-19 yrs

Adults 20-49 yrs

Females 13-49 yrs

Adults 50+ yrs

Children 6-12 yrs

Ver. 2.00

PC Code: 121903

DEEM-FCID Chronic analysis for FLUFENACET

(1994-98 data)

Residue file name: C:\Documents and Settings\sstanton\My Documents\DEEM-FCID

Files\Flufenacet\Flufenacet Chronic\Flufenacet Chronic Food + Water OH Corn Scenario.R98

DP Number: 338504

Adjustment factor #2 used.

Percent of

4.4%

4.1%

2.9%

2.1%

2.7%

2.8%

2.7%

Total Exposure

Analysis Date 11-24-2006/09:29:00 Residue file dated: 11-24-2006/08:28:20/8

Reference dose (RfD, Chronic) = .0017 mg/kg bw/day

COMMENT 1: Flufenacet Chronic - Food and Drinking Water (IL Corn Mean)

\_\_\_\_

mq/kq

Total exposure by population subgroup

-----

Subgroup	body wt/day	Rfd
U.S. Population (total)	0.000049	2.9%
U.S. Population (spring season)	0.000049	2.9%
U.S. Population (summer season)	0.000053	3.1%
<u>-</u>	0.000048	2.8%
U.S. Population (winter season)	0.000048	2.8%
Northeast region	0.000045	2.6%
Midwest region	0.000050	2.9%
Southern region	0.000047	2.7%
Western region	0.000056	3.3%
Hispanics	0.000055	3.3%
Non-hispanic whites	0.000048	2.8%
Non-hispanic blacks	0.000047	2.7%
Non-hisp/non-white/non-black	0.000060	3.5%
All infants (< 1 year)	0.000156	9.2%
Nursing infants	0.000058	3.4%
Non-nursing infants	0.000193	11.4%
Children 1-6 yrs	0.000071	4.2%
Children 7-12 yrs	0.000046	2.7%
Females 13-19 (not preg or nursing)		2.1%
Females 20+ (not preg or nursing)		2.8%
Females 13-50 yrs	0.000047	2.8%
Females 13+ (preg/not nursing)	0.000047	2.8%
Females 13+ (nursing)	0.000067	3.9%
Males 13-19 yrs	0.000037	2.2%
Males 20+ yrs	0.000044	2.6%
Seniors 55+	0.000048	2.8%

\_\_\_\_\_

0.000075

0.000070

0.000048

0.000036

0.000046

0.000048