



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

MEMORANDUM

Date: November 30, 2004

Subject: Fluometuron. Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document.

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Case Number: 0040
40 CFR §: 180.229

PC Code: 035503
Chemical Class: Phenylurea

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Executive Summary

Acute, chronic, and cancer dietary (food and water) exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The acute, chronic, and cancer dietary risk assessments were conducted for all supported fluometuron food uses and were performed to support the reregistration eligibility decision.

Acute Dietary Exposure Results and Characterization of Input Data

A moderately refined probabilistic (Monte-Carlo) acute dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. No monitoring data for residues of fluometuron are available from the FDA and/or USDA's Pesticide Data Program (PDP). The anticipated residue (AR) estimates in this assessment are based on available field trial and field accumulation data (MRID 43218101), and incorporate percent crop treated (%CT) estimates reported by the Biological and Economic Analysis Division (BEAD). Feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities. Processing data were used on a number of crops when available along with a DEEM 7.81 default processing factor for one commodity. Dietary risk estimates are provided for females 13-49 years old only. For the general population there is no study to support an effect from a single dose. This assessment concludes that for all supported commodities, the acute dietary risk estimate does not exceed HED's level of concern (less than 100% of the aPAD) at the 99.9th exposure percentile for females 13-49 years old at 34% of the aPAD.

Chronic Dietary Exposure Results and Characterization of Input Data

A moderately refined chronic dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. No monitoring data for residues of fluometuron are available from the FDA and/or USDA's PDP. The AR estimates in this assessment are based on available field trial and field accumulation data (MRID 43218101), and incorporate %CT estimates reported by BEAD. Feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities. Processing data were used on a number of crops when available along with a DEEM 7.81 default processing factor for one commodity. Dietary risk estimates are provided for the general U.S. population and various population subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concludes that for all supported commodities, the chronic dietary risk estimates exceed HED's level of concern (greater than 100% of the cPAD) for all infants less than one year old at 306% of the cPAD, children 1-2 years old at 141% of the cPAD, and children 3-5 years old at 131% of the cPAD. The chronic dietary risk estimate does not exceed HED's level of concern (less than 100% of the cPAD) for the U.S. population at 94% of the cPAD.

The significant chronic risk contributor has been identified as water (direct, all sources and indirect, all sources). For food alone (no water), the chronic dietary risk estimates do not exceed

HED's level of concern for the U.S. population at 1% of the cPAD and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 3% of the cPAD. The unrefined groundwater estimate provided by the Environmental Fate and Effects Division (EFED) was calculated using the SCI-GROW model and may have overestimated the chronic dietary risk of fluometuron.

Cancer Dietary Exposure Results and Characterization of Input Data

A moderately refined cancer dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. No monitoring data for residues of fluometuron are available from the FDA and/or USDA's PDP. The AR estimates in this assessment are based on available field trial and field accumulation data (MRID 43218101), and incorporate %CT estimates reported by BEAD. Feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities. Processing data were used on a number of crops when available along with a DEEM 7.81 default processing factor for one commodity. The estimated exposure of the general U.S. population to fluometuron is 0.005147 mg/kg/day. Applying the Q_1^* of 1.80×10^{-2} (mg/kg/day)⁻¹ to the exposure value results in a cancer risk estimate of 9.27×10^{-5} . Therefore, the cancer dietary risk estimate exceeds HED's level of concern of 1.0×10^{-6} .

For comparison, the estimated surface water estimate was used in the cancer dietary exposure assessment. The estimated exposure of the general U.S. population to fluometuron is 0.000476 mg/kg/day. Applying the Q_1^* of 1.80×10^{-2} (mg/kg/day)⁻¹ to the exposure value results in a cancer risk estimate of 8.58×10^{-6} . It is also noted that the cancer risk estimate for either groundwater or surface water alone (without food) results in a cancer risk of 9.14×10^{-5} and 7.36×10^{-6} , respectively. The estimated cancer risk for food alone (no water) is 1.22×10^{-6} .

The significant cancer risk contributors have been identified as water (direct, all sources and indirect, all sources), wheat (flour), soybean (oil), and rice (white). The AR estimates are considered moderately refined, although are considered highly conservative based on the nature of the residue data source since field trial and field accumulation studies use maximum application rates and minimum pre-harvest intervals (PHI). Such AR estimates are likely to overestimate the dietary exposure and risk from the agricultural pesticide use of fluometuron. The %CT estimates provided by BEAD were for application to cotton only and not for the rotational crops planted after cotton. The %CT estimates provided for cotton were incorporated into the rotational crop residues used in the analysis and may have overestimated the cancer dietary risk of fluometuron. The unrefined groundwater estimate provided by the Environmental Fate and Effects Division (EFED) was calculated using the SCI-GROW model and may have overestimated the cancer dietary risk of fluometuron.

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

Reference Dose (RfD) divided by the special FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic dietary 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: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/1999).

II. Residue Information

Tolerances for residues of fluometuron in/on raw agricultural commodities can be found in 40 CFR §180.229. Tolerances are presently established only for cotton, undelinted seed, at 0.1 ppm. There are no tolerances established for livestock commodities. The tolerances listed in 40 CFR must be reorganized in order to incorporate the recommendations made by the HED Metabolism Committee concerning the fluometuron residues of concern that need to be regulated for plant and animal commodities. Also, tolerances are needed to cover fluometuron residues of concern in/on the raw agricultural commodities and processed commodities of rotational crops.

The reregistration requirements for plant metabolism are fulfilled. An acceptable study, depicting the qualitative nature of the residue in cotton plants, has been submitted and evaluated. On February 22, 1996 the HED Metabolism Committee concluded that for plants, the residues of concern consist of the parent fluometuron and its metabolites determined as trifluoromethyl aniline (TFMA), namely CGA-41685 and CGA-41686 (S. Funk, HED Metabolism Committee Memorandum, 2/22/1996). Acceptable studies depicting the qualitative nature of the residue in ruminants and poultry have been submitted and evaluated. Based on the results of these studies, it was determined that there is a potential for secondary transfer of fluometuron residues of concern to livestock commodities; therefore, tolerances for livestock commodities must be established. The HED Metabolism Committee has determined that the residues of concern in meat, milk, poultry, and eggs consist of the parent and its metabolites determined as TFMA, and the hydroxylated metabolites CGA-236431, CGA-236432, CGA-13211, and their conjugates (S. Funk, HED Metabolism Committee Memorandum, 2/22/1996). For risk assessment, the parent (fluometuron) endpoint will be used, and all metabolites of concern will be calculated as fluometuron equivalents.

A summary of the fluometuron tolerance reassessment and recommended modifications in commodity definitions are presented in Table 1 (S. Ary, D300553, 11/30/2004). The calculation of dietary burdens of fluometuron to livestock are presented in Table 2. The anticipated residues used for acute, chronic, and cancer dietary analyses calculated from cattle feeding and poultry feeding studies are presented in Table 3.

Table 1. Tolerance Reassessment Summary for Fluometuron.			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments (correct commodity definition)
Cotton Tolerances Required Under 40 CFR §180.229 (a)			
Cotton, gin byproducts	None	3.5	None
Cotton, undelinted seed	0.1	1.0 ¹	None
Livestock Tolerances Required Under 40 CFR §180.229 (b)			
Cattle, meat byproducts	None	0.10	These recommendations are tentative pending submission of supporting storage stability data for the hydroxylated metabolites.
Goat, meat byproducts	None	0.10	
Hog, meat byproducts	None	0.10	
Horse, meat byproducts	None	0.10	
Sheep, meat byproducts	None	0.10	
Milk	None	0.02	
Egg	None	0.10	
Poultry, fat	None	0.10	
Poultry, meat	None	0.10	
Poultry, meat byproducts	None	0.10	
Rotational Crop Tolerances Required Under 40 CFR §180.229 (c):			
Grain, cereal, group 15	None	0.50	None
Grain, cereal, forage, group 16	None	3.0	
Grain, cereal, fodder, and straw, group 16	None	6.0	
Peanut	None	0.10	
Peanut, hay	None	4.0	
Soybean, seed	None	2.0	
Soybean, forage	None	3.0	
Soybean, hay	None	3.0	
Processed Commodity Tolerances Required Under 40 CFR §180.229 (d):			
Peanut, meal	None	0.20	None
Rice, hulls	None	1.0	
Wheat, milled byproducts	None	1.0	

1. Additional data are required for the DF formulation. These data may indicate the need for additional tolerance reevaluation.

Table 2. Calculation of Dietary Burdens of Fluometuron to Livestock.							
Feed Commodity	% Dry Matter ¹	% Diet ¹	Reassessed Tolerance (ppm) ²	% CT Max.	Dietary Contribution for Acute (ppm) ³	% CT Avg.	Dietary Contribution for Chronic and Cancer (ppm) ³
Beef Cattle							
corn, field, grain	88	35	0.50	35	0.070	20	0.040
corn, field, stover	83	20	6.0	35	0.51	20	0.29
cotton, gin byproducts	90	5	3.5	35	0.068	20	0.039
cotton, undelinted seed	88	10	1.0	35	0.040	20	0.023
peanut, meal	85	10	0.20	35	0.0082	20	0.0047
soybean, hay	85	20	3.0	35	0.25	20	0.14
TOTAL BURDEN	N/A⁴	100	N/A	N/A	0.95	N/A	0.54
Dairy Cattle							
corn, field, forage	40	15	3.0	35	0.39	20	0.23
corn, field, grain	88	30	0.50	35	0.060	20	0.034
cotton, gin byproducts	90	5	3.5	35	0.068	20	0.039
cotton, undelinted seed	88	20	1.0	35	0.080	20	0.045
peanut, meal	85	10	0.20	35	0.0082	20	0.0047
soybean, hay	85	20	3.0	35	0.25	20	0.14
TOTAL BURDEN	N/A	100	N/A	N/A	0.86	N/A	0.49
Poultry							
corn, field, grain	N/A	50	0.50	35	0.088	20	0.050
wheat, milled byproducts	N/A	35	1.0	35	0.12	20	0.070
peanut, meal	N/A	15	0.20	35	0.011	20	0.0060
TOTAL BURDEN	N/A	100	N/A	N/A	0.22	N/A	0.13
Swine							
corn, field, grain	N/A	85	0.50	35	0.15	20	0.085
peanut, meal	N/A	15	0.20	35	0.011	20	0.0060
TOTAL BURDEN	N/A	100	N/A	N/A	0.16	N/A	0.091

1. OPPTS Guideline 860.1000, Table 1 (August 1996).
2. Reassessed tolerances from Table 1.
3. Contribution = (reassessed tolerance) x (% crop treated) / (% dry matter) x (% diet).
4. N/A = Not applicable.

Table 3. Anticipated Residues (AR¹) Used for Chronic and Cancer Dietary Analyses Calculated from Ruminant Feeding and Poultry Feeding Studies.²			
Beef Cattle			
Matrix	Fluometuron, TFMA metabolites, and hydroxylated metabolites (ppm) from feeding study	Acute AR	Chronic and/or Cancer AR
Liver	0.15 (10 ppm feeding level; fluometuron and TFMA) and 0.042 (33 ppm feeding level; hydroxylated metabolites)	0.015	0.0088
Kidney	0.12 (110 ppm feeding level)	0.0010	0.00059

Table 3. Anticipated Residues (AR¹) Used for Chronic and Cancer Dietary Analyses Calculated from Ruminant Feeding and Poultry Feeding Studies.²			
Dairy Cattle			
Matrix	Fluometuron, TFMA metabolites, and hydroxylated metabolites (ppm) from feeding study	Acute AR	Chronic and/or Cancer AR
Whole Milk	0.13 (110 ppm feeding level)	0.0010	0.00058
Poultry			
Matrix	Fluometuron, TFMA metabolites, and hydroxylated metabolites (ppm) from feeding study	Acute AR	Chronic and/or Cancer AR
Eggs	0.05 (2 ppm feeding level)	0.0055	0.0033
Tissues	0.05 (2 ppm feeding level)	0.0055	0.0033
Swine³			
Matrix	Fluometuron, TFMA metabolites, and hydroxylated metabolites (ppm) from feeding study	Acute AR	Chronic and/or Cancer AR
Liver	0.15 (10 ppm feeding level; fluometuron and TFMA) and 0.042 (33 ppm feeding level; hydroxylated metabolites)	0.0026	0.0015
Kidney	0.12 (110 ppm feeding level)	0.00017	0.000099

1. Anticipated Residue (AR) = (total dietary contribution, Table 2) / (feeding level) x (residue from feeding studies).
2. For complete details of the feeding studies see the “Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document” (S. Ary, D300553, 11/30/2004).
3. A hog feeding study is not available; therefore, maximum potential residues resulting from dietary exposure were estimated using data from the ruminant feeding study.

Acute Assessment

For the acute dietary risk assessment, reported residues were averaged for all blended commodities and were based on field trial and field accumulation data. A distribution of residues were used for sweet corn. If a commodity had no reported detectable residues in the field trial or field accumulation studies, half the limit of detection (LOD) was used to account for possible exposure that could not be more precisely quantified. The AR estimates are considered moderately refined, although are considered highly conservative based on the residue data source, since field trial and field accumulation studies use maximum application rates and minimum PHIs. Such AR estimates are likely to overestimate the dietary exposure and risk from the agricultural pesticide use of fluometuron. The maximum %CT estimates were incorporated into all acute residue estimates. Feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities.

Chronic and Cancer Assessment

For chronic and cancer dietary risk assessments, reported residues were averaged and were based on field trial and field accumulation data. The AR estimates are considered moderately refined, although are considered highly conservative based on the residue data source, since field trial and field accumulation studies use maximum application rates and minimum PHIs. Such AR estimates are likely to overestimate the dietary exposure and risk from the agricultural pesticide use of fluometuron. For commodities with no detectable residues from field trial or field accumulation studies, half the LOD was used for fluometuron. The average estimate of %CT

was incorporated into all chronic and cancer residue estimates when available. Feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities.

Processing Factors

Data from the processing studies were used in this assessment for several commodities along with a DEEM 7.81 default processing factor for peanut butter. Acceptable processing studies are available for cotton, field corn, rice, grain sorghum, wheat, peanuts, and soybeans (MRID 43218101). A processing factor of 0.7x was utilized for peanut oil, 0.1x for soybean oil, 1.2x for soybean flour, 1.6x for wheat bran, and 0.6x for wheat flour. All other processed commodities showed little or no concentration in the available processing studies. For detailed considerations of processing factors see the “Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document” under guideline section 860.1520 (S. Ary, D300553, 11/30/2004). For peanut butter, a DEEM 7.81 default factor of 1.9x was used.

Usage Information

Dietary risk estimates are based, in part, on estimates of the percent usage of fluometuron on cotton. BEAD has estimated fluometuron use (J. Aldsedak, Usage Report in Support of Reregistration for Fluometuron, 3/15/2004) based on available pesticide survey usage data for the years 1998 to 2002 (Attachment 14). BEAD estimates are provided to HED as an average and as an estimated maximum. The estimated maximum %CT for cotton was used for the acute dietary risk assessment and the estimated average %CT for cotton was used for the chronic and cancer dietary risk assessments. The %CT estimates provided by BEAD were for application to cotton only and not for the rotational crops planted after cotton. The %CT estimates provided for cotton were incorporated into the rotational crop residues used in the analysis.

Residue Estimates for Crops

Fluometuron residue estimates used in this assessment are based primarily on crop field trials for cotton and field accumulation trials for rotational crops planted after cotton while incorporating the %CT estimates from BEAD. For the acute, chronic, and cancer analyses, feeding studies along with %CT on feed items were used to calculate AR estimates for livestock commodities. All fluometuron acute, chronic, and cancer residue estimates for crop commodities are listed in Attachment 1.

Translation of Residue Data

The analyses relied on translating existing crop field accumulation data from wheat to barley, buckwheat, millet, oat, rye, and triticale. Field corn crop field accumulation data were translated to pop corn, and rice data were translated to wild rice.

III. Drinking Water Data

The values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED) in the following memorandum: “Fluometuron Drinking Water Assessment for the Health Effects Division (HED) Reregistration Eligibility Decision Document” (I. Abdel-Saheb, D300554, 12/3/2004). Water residues were incorporated in the

DEEM-FCID™ into the food categories “water, direct, all sources” and “water, indirect, all sources”.

The estimated surface drinking water concentrations for fluometuron were moderately refined and calculated using PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) for use in the human health risk assessment. The estimated groundwater concentrations for fluometuron were unrefined and calculated using SCI-GROW (Screening Concentration In Ground Water) for use in the human health risk assessment. The estimated drinking water concentrations (EDWCs) for fluometuron were calculated based on a maximum application rate of 6.0 lb ai/A. Fluometuron and its major degradate (CGA-41686) identified in the soil metabolism studies were evaluated in the water assessment. Due to the low levels found in the metabolism studies, the other degradates of concern were excluded. The concentration used in the acute and chronic/cancer dietary assessments was calculated from groundwater at 0.241 ppm. Also, for the cancer dietary assessment, the surface water (36-year annual mean) value of 0.0194 ppm was used for comparison purposes with the groundwater value of 0.241 ppm.

IV. DEEM-FCID™ Program and Consumption Information

Fluometuron acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA’s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-1996 and 1998 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 1994-1996 and 1998 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 (less than 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.

For chronic dietary exposure assessment, 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

Fluometuron is of low to moderate toxicity with toxicity categories of III and IV, except for dermal and eye irritation (II). The spleen, kidney, or liver appear to be the organs primarily affected following exposure of rats and dogs to moderate doses of the test material in subchronic, chronic, developmental, and reproductive studies. Reproductive and developmental effects were observed in available studies, but no increased sensitivity was associated with this chemical.

Fluometuron is classified as Group C ($Q_1^* 1.80 \times 10^{-2}$) as a possible human carcinogen based on statistically significant increases in combined adenomas/carcinomas of the lungs in male mice at the highest dose tested and malignant lymphocytic lymphomas in female mice at all dose levels. However, genotoxicity studies with fluometuron were negative.

Table 3. Toxicology Endpoints for Fluometuron			
Exposure Scenario	Dose (mg/kg/day)	FQPA Safety Factor and Level of Concern for Risk Assessment	Endpoint for Risk Assessment
Dietary Risk Assessments			
Acute Dietary females 13+	NOAEL= 10 UF= 100 Acute RfD = 0.1	FQPA SF =1 <u>acute RfD</u> FQPA SF = 0.1 mg/kg/day	Acute-Developmental, Rat LOAEL=100 mg/kg/day, based on reduced food consumption, darkened spleens, and increased incidence of abortions and decreased maternal body-weight gain.
Chronic Dietary all populations	NOAEL = 0.55 UF = 100 Chronic RfD = 0.0055	FQPA SF = 1 cPAD = <u>chronic RfD</u> FQPA SF = 0.005 mg/kg/day	Chronic-Chronic/Carcinogenicity, Rat LOAEL=100 mg/kg/day, based on decreased body weight gain (9%), and increased splenic hemosiderin pigment deposition.
Cancer	Not mutagenic. Classified as Group C (Possible Human Carcinogen) with a Q_1^* (mg/kg/day) ⁻¹ of 1.80×10^{-2} in human equivalents (3/4's scaling factor to convert from animals to humans).		

UF = uncertainty factor, AF = absorption 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, MOE = margin of exposure, LOC = level of concern, NA = not applicable. Hazard and toxicological profile prepared by E. Reaves (E. Reaves, HED Fluometuron Risk Assessment Memorandum, 12/7/2004).

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™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The acute dietary exposure analysis results reported in Table 4 and 5 are for females 13-49 years old. The chronic dietary exposure analysis results reported in Table 5 are for the general U.S. population, all infants (less than 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. Cancer risk is determined for the general U.S. population only.

Results of Acute Dietary Exposure Analysis

This assessment concludes that for all supported commodities, the acute dietary risk estimate does not exceed HED’s level of concern (less than 100% of the aPAD) at the 99.9th exposure percentile for females 13-49 years old at 34% of the aPAD. The results of the acute dietary exposure analysis at the 95th, 99th, and 99.9th percentiles of exposure are reported in Table 4. The results of the acute dietary exposure analysis at the 99.9th percentile are reported in Table 5 along with chronic and cancer dietary exposure analyses for easy comparison.

Table 4. Results of Acute Dietary Exposure Analysis Using DEEM FCID.							
Population Subgroup	aPAD (mg/kg/day)	95 th Percentile		99 th Percentile		99.9 th Percentile	
		Exposure (mg/kg/day)	% aPAD*	Exposure (mg/kg/day)	% aPAD*	Exposure (mg/kg/day)	% aPAD*
Females 13-49 years old	0.1	0.011812	12	0.019203	19	0.033720	34

Results of Chronic Dietary Exposure Analysis

This assessment concludes that for all supported commodities, the chronic dietary risk estimates exceed HED’s level of concern (greater than 100% of the cPAD) for all infants less than one year old at 306% of the cPAD, children 1-2 years old at 141% of the cPAD, and children 3-5 years old at 131% of the cPAD. For the U.S. population, the chronic dietary risk estimate does not exceed HED’s level of concern (less than 100% of the cPAD) at 94% of the cPAD. The significant chronic risk contributor has been identified as water (direct, all sources and indirect, all sources). The results of the chronic dietary exposure analysis are reported below in Table 5.

Results of Cancer Dietary Exposure Analysis

The estimated exposure of the general U.S. population to fluometuron is 0.005147 mg/kg/day. Applying the Q_1^* of $1.80 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ to the exposure value results in a cancer risk estimate of 9.27×10^{-5} . Therefore, the cancer dietary risk estimate exceeds HED’s level of concern of 1.0×10^{-6} . The significant cancer risk contributors have been identified as water (direct, all sources and indirect, all sources), wheat (flour), soybean (oil), and rice (white). The results of the cancer dietary exposure analysis are reported below in Table 5.

Table 5. Summary of Dietary Exposure and Risk for Fluometuron.						
Population Subgroup	Acute Dietary (99.9 th Percentile)		Chronic Dietary		Cancer	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	Risk
General U.S. Population	N/A	N/A	0.005147	94	0.005147	9.27 x 10⁻⁵
All Infants (< 1 year old)	N/A	N/A	0.016807	306	N/A	N/A
Children 1-2 years old	N/A	N/A	0.007726	141		
Children 3-5 years old	N/A	N/A	0.007221	131		
Children 6-12 years old	N/A	N/A	0.004973	90		
Youth 13-19 years old	N/A	N/A	0.003734	68		
Adults 20-49 years old	N/A	N/A	0.004798	87		
Adults 50+ years old	N/A	N/A	0.005030	92		
Females 13-49 years old	0.033720	34	0.004773	87		

The **bolded** values represent the highest exposed populations for each of the risk assessments.

VII. Conclusions

Acute, chronic, and cancer dietary (food and water) risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The acute, chronic, and cancer dietary risk assessments were conducted for all supported fluometuron food uses and were performed to support the reregistration eligibility decision.

Acute Dietary Exposure Results and Characterization

A moderately refined probabilistic (Monte-Carlo) acute dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. Dietary risk estimates are provided for females 13-49 years old only. For the general population there is no study to support an effect from a single dose. This assessment concludes that for all supported commodities, the acute dietary risk estimate does not exceed HED's level of concern (less than 100% of the aPAD) at the 99.9th exposure percentile for females 13-49 years old at 34% of the aPAD.

Chronic Dietary Exposure Results and Characterization

A moderately refined chronic dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. Dietary risk estimates are provided for the general U.S. population and various population subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concludes that for all supported commodities, the chronic dietary risk estimates exceed HED's level of concern (greater than 100% of the cPAD) for all infants less than one year old at 306% of the cPAD, children 1-2 years old at 141% of the cPAD, and children 3-5 years old at 131% of the cPAD.

For the U.S. population, the chronic dietary risk estimate does not exceed HED's level of concern (less than 100% of the cPAD) at 94% of the cPAD.

The significant chronic risk contributor has been identified as water (direct, all sources and indirect, all sources). For food alone (no water), the chronic dietary risk estimates do not exceed HED's level of concern for the U.S. population at 1% of the cPAD and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 3% of the cPAD. The unrefined groundwater estimate provided by the Environmental Fate and Effects Division (EFED) was calculated using the SCI-GROW model and may have overestimated the chronic dietary risk of fluometuron.

Cancer Dietary Exposure Results and Characterization

A moderately refined cancer dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of fluometuron. The estimated exposure of the general U.S. population to fluometuron is 0.005147 mg/kg/day. Applying the Q_1^* of 1.80×10^{-2} (mg/kg/day)⁻¹ to the exposure value results in a cancer risk estimate of 9.27×10^{-5} . Therefore, the cancer dietary risk estimate exceeds HED's level of concern of 1.0×10^{-6} .

For comparison, the estimated surface water estimate was used in the cancer dietary exposure assessment. The estimated exposure of the general U.S. population to fluometuron is 0.000476 mg/kg/day. Applying the Q_1^* of 1.80×10^{-2} (mg/kg/day)⁻¹ to the exposure value results in a cancer risk estimate of 8.58×10^{-6} . It is also noted that the cancer risk estimate for either groundwater or surface water alone (without food) results in a cancer risk of 9.14×10^{-5} and 7.36×10^{-6} , respectively. The estimated cancer risk for food alone (no water) is 1.22×10^{-6} .

The significant cancer risk contributors have been identified as water (direct, all sources and indirect, all sources), wheat (flour), soybean (oil), and rice (white). The AR estimates are considered moderately refined, although are considered highly conservative based on the nature of the residue data source since field trial and field accumulation studies use maximum application rates and minimum pre-harvest intervals (PHI). Such AR estimates are likely to overestimate the dietary exposure and risk from the agricultural pesticide use of fluometuron. The %CT estimates provided by BEAD were for application to cotton only and not for the rotational crops planted after cotton. The %CT estimates provided for cotton were incorporated into the rotational crop residues used in the analysis and may have overestimated the cancer dietary risk of fluometuron. The unrefined groundwater estimate provided by the Environmental Fate and Effects Division (EFED) was calculated using the SCI-GROW model and may have overestimated the cancer dietary risk of fluometuron.

VIII. List of Attachments

- Attachment 1. Data and Residue Estimates Used in Dietary Analyses.
- Attachment 2. Acute Food and Groundwater Residue Input File.
- Attachment 3. Acute Food and Groundwater Results File.
- Attachment 4. Chronic Food and Groundwater Residue Input File.
- Attachment 5. Chronic Food and Groundwater Results File.
- Attachment 6. Critical Commodity Contribution Analysis for Chronic.
- Attachment 7. Chronic Food (No Water) Results File.

- Attachment 8. Cancer Food and Groundwater Results File.
- Attachment 9. Critical Commodity Contribution Analysis for Cancer.
- Attachment 10. Cancer Results for Food Only (No Water).
- Attachment 11. Cancer Results for Groundwater Only (No Food).
- Attachment 12. Cancer Results for Surface Water (36-Year Overall Mean) Only (No Food).
- Attachment 13. Cancer Food and Surface Water (36-Year Overall Mean) Results File.
- Attachment 14. Usage Report in Support of Reregistration for Fluometuron.

Attachment 1. Data and Residue Estimates Used in Dietary Analyses.

RAC	Classification ¹	Data Source	Years	No. of Samples	No. of Detectable Residues	Avg. LOD (ppm)	% CT Avg. ²	% CT Max. ²	Processing Factors ³	Anticipated Residue Estimates/Tolerance	
										Acute (Tol., AR, RDF)	Chronic and Cancer (Tol., AR)
Barley, pearled barley pearled barley, babyfood flour flour, babyfood bran	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)
Beef, meat byproducts meat byproducts, babyfood	N/A	Ruminant feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.016)	AR (0.0094)
Buckwheat Buckwheat, flour	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)
Chicken, meat meat, babyfood meat byproducts meat byproducts, babyfood fat fat, babyfood	N/A	Poultry feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.0055)	AR (0.0033)
Corn, field, flour flour, babyfood meal meal, babyfood bran starch starch, babyfood syrup syrup, babyfood oil oil, babyfood	B	Rotational crop field trial data, MRID 43218101	1986 and 1990	26	2 0.16, 0.12	0.05	20	35	None	AR (0.03385)	AR (0.03385)
Corn, pop	B	Rotational crop field trial data (Corn, field), MRID 43218101	1986 and 1990	26	2 0.16, 0.12	0.05	20	35	None	AR (0.03385)	AR (0.03385)

Attachment 1. Data and Residue Estimates Used in Dietary Analyses.

RAC	Classification ¹	Data Source	Years	No. of Samples	No. of Detectable Residues	Avg. LOD (ppm)	% CT Avg. ²	% CT Max. ²	Processing Factors ³	Anticipated Residue Estimates/Tolerance	
										Acute (Tol., AR, RDF)	Chronic and Cancer (Tol., AR)
Corn, sweet sweet, babyfood	NB or PB	Rotational crop field trial data, MRID 43218101	1990	6	0	0.05	20	35	None	1 RDF 0 detects 65 zeros 35 @ 0.025	AR (0.025)
Cottonseed, oil oil, babyfood	B	Field trial data, MRID 43218101	1986 and 1990	56	27 0.05, 0.07, 0.07, 0.065, 0.21, 0.15, 0.19, 0.18, 0.533, 0.383, 0.06, 0.06, 0.05, 0.09, 0.10, 0.06, 0.07, 0.07, 0.06, 0.06, 0.06, 0.07, 0.07, 0.13, 0.20, 0.187, 0.13	0.05	20	35	None	AR (0.07416)	AR (0.07416)
Egg, whole whole, babyfood white white, babyfood yolk yolk, babyfood	N/A	Poultry feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.0055)	AR (0.0033)
Goat, meat byproducts	N/A	Ruminant feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.016)	AR (0.0094)
Milk, fat fat, babyfood nonfat solids nonfat solids, babyfood water water, babyfood sugar, babyfood	N/A	Ruminant feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.0010)	AR (0.00058)
Millet, grain	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)

Attachment 1. Data and Residue Estimates Used in Dietary Analyses.

RAC	Classification ¹	Data Source	Years	No. of Samples	No. of Detectable Residues	Avg. LOD (ppm)	% CT Avg. ²	% CT Max. ²	Processing Factors ³	Anticipated Residue Estimates/Tolerance	
										Acute (Tol., AR, RDF)	Chronic and Cancer (Tol., AR)
Oat, bran flour flour, babyfood groats/rolled oats groats/rolled oats, babyfood	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)
Peanut Peanut, butter oil	B	Rotational crop field trial data, MRID 43218101	1986 and 1990	14	7 0.06, 0.06, 0.06, 0.07, 0.06, 0.10, 0.10	0.05	20	35	1.9 for butter (DEEM) and 0.7 for oil (MRID 43218101)	AR (0.04893)	AR (0.04893)
Pork, meat byproducts meat byproducts, babyfood	N/A	Ruminant feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.0028)	AR (0.0016)
Rice, white white, babyfood brown brown, babyfood flour flour, babyfood bran bran, babyfood	B	Rotational crop field trial data, MRID 43218101	1990	8	6 0.26, 0.24, 0.11, 0.13, 0.09, 0.15	0.05	20	35	None	AR (0.12875)	AR (0.12875)
Rye, grain flour	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)
Sheep, meat byproducts	N/A	Ruminant feeding study, see Table 3	N/A	N/A	N/A	N/A	No data	No data	None	AR (0.016)	AR (0.0094)
Sorghum, grain syrup	B	Rotational crop field trial data, MRID 43218101	1986 and 1990	20	2 0.08, 0.08	0.05	20	35	None	AR (0.033)	AR (0.033)

Attachment 1. Data and Residue Estimates Used in Dietary Analyses.

RAC	Classification ¹	Data Source	Years	No. of Samples	No. of Detectable Residues	Avg. LOD (ppm)	% CT Avg. ²	% CT Max. ²	Processing Factors ³	Anticipated Residue Estimates/Tolerance	
										Acute (Tol., AR, RDF)	Chronic and Cancer (Tol., AR)
Soybean, seed flour flour, babyfood soy milk soy milk, babyfood oil oil, babyfood	B	Rotational crop field trial data, MRID 43218101	1986 and 1990	24	24 0.51, 0.51, 0.235, 0.395, 1.6, 1.5, 0.56, 0.56, 0.35, 0.40, 1.1, 1.0, 2.6, 2.95, 1.4, 2.0, 0.49, 0.39, 1.6, 1.3, 0.94, 1.0, 0.20, 0.19	0.05	20	35	0.1 for oil and 1.2 for flour (MRID 43218101)	AR (0.99083)	AR (0.99083)
Triticale, flour flour, babyfood	B	Rotational crop field trial data (Wheat), MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	None	AR (0.09042)	AR (0.09042)
Water, direct, all sources indirect, all sources	N/A	EDWCs ⁴	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Groundwater AR (0.241)	Groundwater AR (0.241) Surface Water (36-Year Overall Mean) AR (0.0194)
Wheat, grain grain, babyfood flour flour, babyfood germ bran	B	Rotational crop field trial data, MRID 43218101	1986 and 1990	30	17 0.05, 0.06, 0.125, 0.0525, 0.445, 0.325, 0.06, 0.09, 0.28, 0.28, 0.06, 0.06, 0.13, 0.17, 0.07, 0.05, 0.08	0.05	20	35	1.6 for bran and 0.6 for flour (MRID 43218101)	AR (0.09042)	AR (0.09042)
Wild rice	B	Rotational crop field trial data (Rice), MRID 43218101	1990	8	6 0.26, 0.24, 0.11, 0.13, 0.09, 0.15	0.05	20	35	None	AR (0.12875)	AR (0.12875)

1. Classification of blended (B), partially blended (PB), not blended (NB).
2. When no data were available for percent crop treated (%CT) average and/or maximum, 100%CT was used in the dietary assessment.
3. Processing study information may be found in the Chemistry Review Document under guideline section 860.1520 Processed Food and Feed (S. Ary, D300553, 11/30/2004).
4. EDWCs = Estimated Drinking Water Concentrations.
5. N/A = Not applicable.

Attachment 2. Acute Food and Groundwater Residue Input File.

U.S. Environmental Protection Agency Ver. 2.02
 DEEM-FCID Acute analysis for FLUOMETURON
 Residue file name: C:\Documents and
 Settings\sary\Desktop\Fluometuron\Dietary\Acute\Fluometuron acute.R98
 Analysis Date 12-06-2004 Residue file dated: 12-06-2004/17:31:36/8
 Reference dose (aRfD) = 0.1 mg/kg bw/day
 Comment: Food and Groundwater

 RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3	Comment
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1	6	C:\Fluometuron\Dietary\RDF Files\Sweet Corn.rdf			
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EPA Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	RDL Pntr	Comment
15000250	15	Barley, pearled barley	0.090420	1.000	0.350		
15000251	15	Barley, pearled barley-babyfood	0.090420	1.000	0.350		
15000260	15	Barley, flour	0.090420	1.000	0.350		
15000261	15	Barley, flour-babyfood	0.090420	1.000	0.350		
15000270	15	Barley, bran	0.090420	1.000	0.350		
21000460	M	Beef, meat byproducts	0.016000	1.000	1.000		
21000461	M	Beef, meat byproducts-babyfood	0.016000	1.000	1.000		
15000650	15	Buckwheat	0.090420	1.000	0.350		
15000660	15	Buckwheat, flour	0.090420	1.000	0.350		
40000930	P	Chicken, meat	0.005500	1.000	1.000		
40000931	P	Chicken, meat-babyfood	0.005500	1.000	1.000		
40000950	P	Chicken, meat byproducts	0.005500	1.000	1.000		
40000951	P	Chicken, meat byproducts-babyfo	0.005500	1.000	1.000		
40000960	P	Chicken, fat	0.005500	1.000	1.000		
40000961	P	Chicken, fat-babyfood	0.005500	1.000	1.000		
15001200	15	Corn, field, flour	0.033850	1.000	0.350		
15001201	15	Corn, field, flour-babyfood	0.033850	1.000	0.350		
15001210	15	Corn, field, meal	0.033850	1.000	0.350		
15001211	15	Corn, field, meal-babyfood	0.033850	1.000	0.350		
15001220	15	Corn, field, bran	0.033850	1.000	0.350		
15001230	15	Corn, field, starch	0.033850	1.000	0.350		
15001231	15	Corn, field, starch-babyfood	0.033850	1.000	0.350		
15001240	15	Corn, field, syrup	0.033850	1.000	0.350		
15001241	15	Corn, field, syrup-babyfood	0.033850	1.000	0.350		
15001250	15	Corn, field, oil	0.033850	1.000	0.350		
15001251	15	Corn, field, oil-babyfood	0.033850	1.000	0.350		
15001260	15	Corn, pop	0.033850	1.000	0.350		
15001270	15	Corn, sweet	0.025000	1.000	1.000	1	
15001271	15	Corn, sweet-babyfood	0.025000	1.000	1.000	1	
95001280	O	Cottonseed, oil	0.074160	1.000	0.350		
95001281	O	Cottonseed, oil-babyfood	0.074160	1.000	0.350		
70001450	P	Egg, whole	0.005500	1.000	1.000		
70001451	P	Egg, whole-babyfood	0.005500	1.000	1.000		
70001460	P	Egg, white	0.005500	1.000	1.000		
70001461	P	Egg, white (solids)-babyfood	0.005500	1.000	1.000		
70001470	P	Egg, yolk	0.005500	1.000	1.000		
70001471	P	Egg, yolk-babyfood	0.005500	1.000	1.000		
23001700	M	Goat, meat byproducts	0.016000	1.000	1.000		
27002220	D	Milk, fat	0.001000	1.000	1.000		
27002221	D	Milk, fat - baby food/infant for	0.001000	1.000	1.000		
27012230	D	Milk, nonfat solids	0.001000	1.000	1.000		
27012231	D	Milk, nonfat solids-baby food/in	0.001000	1.000	1.000		
27022240	D	Milk, water	0.001000	1.000	1.000		
27022241	D	Milk, water-babyfood/infant form	0.001000	1.000	1.000		
27032251	D	Milk, sugar (lactose)-baby food/	0.001000	1.000	1.000		
15002260	15	Millet, grain	0.090420	1.000	0.350		
15002310	15	Oat, bran	0.090420	1.000	0.350		
15002320	15	Oat, flour	0.090420	1.000	0.350		
15002321	15	Oat, flour-babyfood	0.090420	1.000	0.350		
15002330	15	Oat, groats/rolled oats	0.090420	1.000	0.350		

15002331	15	Oat, groats/rolled oats-babyfood	0.090420	1.000	0.350
95002630	O	Peanut	0.048930	1.000	0.350
95002640	O	Peanut, butter	0.048930	1.900	0.350
95002650	O	Peanut, oil	0.048930	0.700	0.350
25002920	M	Pork, meat byproducts	0.002800	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.002800	1.000	1.000
15003230	15	Rice, white	0.128750	1.000	0.350
15003231	15	Rice, white-babyfood	0.128750	1.000	0.350
15003240	15	Rice, brown	0.128750	1.000	0.350
15003241	15	Rice, brown-babyfood	0.128750	1.000	0.350
15003250	15	Rice, flour	0.128750	1.000	0.350
15003251	15	Rice, flour-babyfood	0.128750	1.000	0.350
15003260	15	Rice, bran	0.128750	1.000	0.350
15003261	15	Rice, bran-babyfood	0.128750	1.000	0.350
15003280	15	Rye, grain	0.090420	1.000	0.350
15003290	15	Rye, flour	0.090420	1.000	0.350
26003400	M	Sheep, meat byproducts	0.016000	1.000	1.000
15003440	15	Sorghum, grain	0.033000	1.000	0.350
15003450	15	Sorghum, syrup	0.033000	1.000	0.350
06003470	6	Soybean, seed	0.990830	1.000	0.350
06003480	6	Soybean, flour	0.990830	1.200	0.350
06003481	6	Soybean, flour-babyfood	0.990830	1.200	0.350
06003490	6	Soybean, soy milk	0.990830	1.000	0.350
06003491	6	Soybean, soy milk-babyfood or in	0.990830	1.000	0.350
06003500	6	Soybean, oil	0.990830	0.100	0.350
06003501	6	Soybean, oil-babyfood	0.990830	0.100	0.350
15003810	15	Triticale, flour	0.090420	1.000	0.350
15003811	15	Triticale, flour-babyfood	0.090420	1.000	0.350
86010000	O	Water, direct, all sources	0.241000	1.000	1.000
86020000	O	Water, indirect, all sources	0.241000	1.000	1.000
15004010	15	Wheat, grain	0.090420	1.000	0.350
15004011	15	Wheat, grain-babyfood	0.090420	1.000	0.350
15004020	15	Wheat, flour	0.090420	0.600	0.350
15004021	15	Wheat, flour-babyfood	0.090420	0.600	0.350
15004030	15	Wheat, germ	0.090420	1.000	0.350
15004040	15	Wheat, bran	0.090420	1.600	0.350
15004050	15	Wild rice	0.128750	1.000	0.350

Attachment 3. Acute Food and Groundwater Results File.

U.S. Environmental Protection Agency Ver. 2.02
 DEEM-FCID ACUTE Analysis for FLUOMETURON (1994-98 data)
 Residue file: Fluometuron acute.R98 Adjustment factor #2 used.
 Analysis Date: 12-06-2004/17:36:40 Residue file dated: 12-06-2004/17:31:36/8
 Daily totals for food and foodform consumption used.
 MC iterations = 1000 MC list in residue file MC seed = 1
 Run Comment: "Food and Groundwater"

Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.012783	12.78	0.023925	23.93	0.047772	47.77
All infants:	0.047984	47.98	0.069136	69.14	0.121537	121.54
Children 1-2 yrs:	0.020341	20.34	0.034191	34.19	0.048205	48.20
Children 3-5 yrs:	0.018391	18.39	0.028678	28.68	0.046751	46.75
Children 6-12 yrs:	0.012782	12.78	0.021195	21.20	0.028796	28.80
Youth 13-19 yrs:	0.010407	10.41	0.017291	17.29	0.031099	31.10
Adults 20-49 yrs:	0.011791	11.79	0.019646	19.65	0.035379	35.38
Adults 50+ yrs:	0.010593	10.59	0.015135	15.13	0.024603	24.60
Females 13-49 yrs:	0.011812	11.81	0.019203	19.20	0.033720	33.72

Attachment 4. Chronic Food and Groundwater Residue Input File.

U.S. Environmental Protection Agency Ver. 2.00
 DEEM-FCID Chronic analysis for FLUOMETURON 1994-98 data
 Residue file: C:\Fluometuron\Dietary\Chronic\Fluometuron chronic (groundwater).R98
 Adjust. #2 used
 Analysis Date 12-06-2004 Residue file dated: 12-06-2004/14:21:59/8
 Reference dose (RfD) = 0.0055 mg/kg bw/day
 Comment: Food and Groundwater

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj. Factors		Comment
				#1	#2	
15000250	15	Barley, pearled barley	0.090420	1.000	0.200	
15000251	15	Barley, pearled barley-babyfood	0.090420	1.000	0.200	
15000260	15	Barley, flour	0.090420	1.000	0.200	
15000261	15	Barley, flour-babyfood	0.090420	1.000	0.200	
15000270	15	Barley, bran	0.090420	1.000	0.200	
21000460	M	Beef, meat byproducts	0.009400	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.009400	1.000	1.000	
15000650	15	Buckwheat	0.090420	1.000	0.200	
15000660	15	Buckwheat, flour	0.090420	1.000	0.200	
40000930	P	Chicken, meat	0.003300	1.000	1.000	
40000931	P	Chicken, meat-babyfood	0.003300	1.000	1.000	
40000950	P	Chicken, meat byproducts	0.003300	1.000	1.000	
40000951	P	Chicken, meat byproducts-babyfo	0.003300	1.000	1.000	
40000960	P	Chicken, fat	0.003300	1.000	1.000	
40000961	P	Chicken, fat-babyfood	0.003300	1.000	1.000	
15001200	15	Corn, field, flour	0.033850	1.000	0.200	
15001201	15	Corn, field, flour-babyfood	0.033850	1.000	0.200	
15001210	15	Corn, field, meal	0.033850	1.000	0.200	
15001211	15	Corn, field, meal-babyfood	0.033850	1.000	0.200	
15001220	15	Corn, field, bran	0.033850	1.000	0.200	
15001230	15	Corn, field, starch	0.033850	1.000	0.200	
15001231	15	Corn, field, starch-babyfood	0.033850	1.000	0.200	
15001240	15	Corn, field, syrup	0.033850	1.000	0.200	
15001241	15	Corn, field, syrup-babyfood	0.033850	1.000	0.200	
15001250	15	Corn, field, oil	0.033850	1.000	0.200	
15001251	15	Corn, field, oil-babyfood	0.033850	1.000	0.200	
15001260	15	Corn, pop	0.033850	1.000	0.200	
15001270	15	Corn, sweet	0.025000	1.000	0.200	
15001271	15	Corn, sweet-babyfood	0.025000	1.000	0.200	
95001280	O	Cottonseed, oil	0.074160	1.000	0.200	
95001281	O	Cottonseed, oil-babyfood	0.074160	1.000	0.200	
70001450	P	Egg, whole	0.003300	1.000	1.000	
70001451	P	Egg, whole-babyfood	0.003300	1.000	1.000	
70001460	P	Egg, white	0.003300	1.000	1.000	
70001461	P	Egg, white (solids)-babyfood	0.003300	1.000	1.000	
70001470	P	Egg, yolk	0.003300	1.000	1.000	
70001471	P	Egg, yolk-babyfood	0.003300	1.000	1.000	
23001700	M	Goat, meat byproducts	0.009400	1.000	1.000	
27002220	D	Milk, fat	0.000580	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.000580	1.000	1.000	
27012230	D	Milk, nonfat solids	0.000580	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.000580	1.000	1.000	
27022240	D	Milk, water	0.000580	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.000580	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.000580	1.000	1.000	
15002260	15	Millet, grain	0.090420	1.000	0.200	
15002310	15	Oat, bran	0.090420	1.000	0.200	
15002320	15	Oat, flour	0.090420	1.000	0.200	
15002321	15	Oat, flour-babyfood	0.090420	1.000	0.200	
15002330	15	Oat, groats/rolled oats	0.090420	1.000	0.200	
15002331	15	Oat, groats/rolled oats-babyfood	0.090420	1.000	0.200	
95002630	O	Peanut	0.048930	1.000	0.200	
95002640	O	Peanut, butter	0.048930	1.900	0.200	
95002650	O	Peanut, oil	0.048930	0.700	0.200	
25002920	M	Pork, meat byproducts	0.001600	1.000	1.000	

25002921	M	Pork, meat byproducts-babyfood	0.001600	1.000	1.000
15003230	15	Rice, white	0.128750	1.000	0.200
15003231	15	Rice, white-babyfood	0.128750	1.000	0.200
15003240	15	Rice, brown	0.128750	1.000	0.200
15003241	15	Rice, brown-babyfood	0.128750	1.000	0.200
15003250	15	Rice, flour	0.128750	1.000	0.200
15003251	15	Rice, flour-babyfood	0.128750	1.000	0.200
15003260	15	Rice, bran	0.128750	1.000	0.200
15003261	15	Rice, bran-babyfood	0.128750	1.000	0.200
15003280	15	Rye, grain	0.090420	1.000	0.200
15003290	15	Rye, flour	0.090420	1.000	0.200
26003400	M	Sheep, meat byproducts	0.009400	1.000	1.000
15003440	15	Sorghum, grain	0.033000	1.000	0.200
15003450	15	Sorghum, syrup	0.033000	1.000	0.200
06003470	6	Soybean, seed	0.990830	1.000	0.200
06003480	6	Soybean, flour	0.990830	1.200	0.200
06003481	6	Soybean, flour-babyfood	0.990830	1.200	0.200
06003490	6	Soybean, soy milk	0.990830	1.000	0.200
06003491	6	Soybean, soy milk-babyfood or in	0.990830	1.000	0.200
06003500	6	Soybean, oil	0.990830	0.100	0.200
06003501	6	Soybean, oil-babyfood	0.990830	0.100	0.200
15003810	15	Triticale, flour	0.090420	1.000	0.200
15003811	15	Triticale, flour-babyfood	0.090420	1.000	0.200
86010000	0	Water, direct, all sources	0.241000	1.000	1.000
86020000	0	Water, indirect, all sources	0.241000	1.000	1.000
15004010	15	Wheat, grain	0.090420	1.000	0.200
15004011	15	Wheat, grain-babyfood	0.090420	1.000	0.200
15004020	15	Wheat, flour	0.090420	0.600	0.200
15004021	15	Wheat, flour-babyfood	0.090420	0.600	0.200
15004030	15	Wheat, germ	0.090420	1.000	0.200
15004040	15	Wheat, bran	0.090420	1.600	0.200
15004050	15	Wild rice	0.128750	1.000	0.200

Attachment 5. Chronic Food and Groundwater Results File.

U.S. Environmental Protection Agency Ver. 2.00
 DEEM-FCID Chronic analysis for FLUOMETURON (1994-98 data)
 Residue file: C:\Fluometuron\Dietary\Chronic\Fluometuron chronic (groundwater).R98
 Adjustment factor #2 used.
 Analysis Date 12-06-2004/14:22:50 Residue file dated: 12-06-2004/14:21:59/8
 Reference dose (RfD, Chronic) = 0.0055 mg/kg bw/day
 COMMENT 1: Food and Groundwater

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=====
                        Total exposure by population subgroup
-----

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Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.005147	93.6%
U.S. Population (spring season)	0.005103	92.8%
U.S. Population (summer season)	0.005525	100.4%
U.S. Population (autumn season)	0.004978	90.5%
U.S. Population (winter season)	0.004978	90.5%
Northeast region	0.004701	85.5%
Midwest region	0.005202	94.6%
Southern region	0.004891	88.9%
Western region	0.005898	107.2%
Hispanics	0.005839	106.2%
Non-hispanic whites	0.005020	91.3%
Non-hispanic blacks	0.004888	88.9%
Non-hisp/non-white/non-black	0.006351	115.5%
All infants (< 1 year)	0.016807	305.6%
Nursing infants	0.006234	113.3%
Non-nursing infants	0.020819	378.5%
Children 1-6 yrs	0.007259	132.0%
Children 7-12 yrs	0.004712	85.7%
Females 13-19 (not preg or nursing)	0.003628	66.0%
Females 20+ (not preg or nursing)	0.005115	93.0%
Females 13-50 yrs	0.004968	90.3%
Females 13+ (preg/not nursing)	0.004998	90.9%
Females 13+ (nursing)	0.007102	129.1%
Males 13-19 yrs	0.003808	69.2%
Males 20+ yrs	0.004608	83.8%
Seniors 55+	0.005026	91.4%
Children 1-2 yrs	0.007727	140.5%
Children 3-5 yrs	0.007221	131.3%
Children 6-12 yrs	0.004973	90.4%
Youth 13-19 yrs	0.003734	67.9%
Adults 20-49 yrs	0.004799	87.2%
Adults 50+ yrs	0.005030	91.5%
Females 13-49 yrs	0.004773	86.8%

Attachment 6. Critical Commodity Contribution Analysis for Chronic.

U.S. Environmental Protection Agency Ver. 2.00
 DEEM-FCID Chronic analysis for FLUOMETURON (1994-98 data)
 Residue file: C:\Fluometuron\Dietary\Chronic\Fluometuron chronic (groundwater).R98
 Adjustment factor #2 used.
 Analysis Date 12-06-2004/14:27:05 Residue file dated: 12-06-2004/14:21:59/8
 Reference dose (RfD, Chronic) = 0.0055 mg/kg bw/day
 COMMENT 1: Food and Groundwater

=====
 Critical Commodity Contribution Analysis for
 U.S. Population (total)

Total Exposure =.0051474 mg/kg bw/day

Crop groups with total exposure contribution > 99%
 Foods/Foodforms with exposure contribution > .1%

Crop group Food Foodform	-----Exposure Analysis-----		
	mg/kg body wt/day	% of Total Exposure	Percent of RfD

Crop Group = (0) Other			
Water, direct, all sources (86010000):			
FoodForm N/S	0.0029244	56.81%	53.17%
Water, indirect, all sources (86020000):			
FoodForm N/S	0.0021553	41.87%	39.19%

Total for crop group	0.0050812	98.71%	92.39%
Crop Group = (6) Legume Vegetables (Succulent or Dried)			
Soybean, oil (06003500):			
FoodForm N/S	0.0000082	0.16%	0.15%

Total for crop group	0.0000176	0.34%	0.32%
Crop Group = (15) Cereal Grains			
Corn, field, syrup (15001240):			
FoodForm N/S	0.0000072	0.14%	0.13%
Rice, white (15003230):			
FoodForm N/S	0.0000061	0.12%	0.11%
Wheat, flour (15004020):			
FoodForm N/S	0.0000166	0.32%	0.30%

Total for crop group	0.0000415	0.81%	0.75%
Total for crop groups listed above:	0.0051402	99.86%	93.5%

Attachment 7. Chronic Food (No Water) Results File.

U.S. Environmental Protection Agency Ver. 2.00
 DEEM-FCID Chronic analysis for FLUOMETURON (1994-98 data)
 Residue file: C:\Fluometuron\Dietary\Chronic\Fluometuron chronic (food only).R98
 Adjustment factor #2 used.
 Analysis Date 12-06-2004/16:20:50 Residue file dated: 12-06-2004/16:18:54/8
 Reference dose (RfD, Chronic) = .0055 mg/kg bw/day
 COMMENT 1: Food Only (No Water)

=====
 Total exposure by population subgroup
 =====

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000068	1.2%
U.S. Population (spring season)	0.000068	1.2%
U.S. Population (summer season)	0.000068	1.2%
U.S. Population (autumn season)	0.000068	1.2%
U.S. Population (winter season)	0.000067	1.2%
Northeast region	0.000067	1.2%
Midwest region	0.000066	1.2%
Southern region	0.000062	1.1%
Western region	0.000078	1.4%
Hispanics	0.000074	1.3%
Non-hispanic whites	0.000064	1.2%
Non-hispanic blacks	0.000066	1.2%
Non-hisp/non-white/non-black	0.000124	2.2%
All infants (< 1 year)	0.000153	2.8%
Nursing infants	0.000057	1.0%
Non-nursing infants	0.000189	3.4%
Children 1-6 yrs	0.000162	2.9%
Children 7-12 yrs	0.000098	1.8%
Females 13-19 (not preg or nursing)	0.000054	1.0%
Females 20+ (not preg or nursing)	0.000044	0.8%
Females 13-50 yrs	0.000053	1.0%
Females 13+ (preg/not nursing)	0.000059	1.1%
Females 13+ (nursing)	0.000064	1.2%
Males 13-19 yrs	0.000071	1.3%
Males 20+ yrs	0.000056	1.0%
Seniors 55+	0.000039	0.7%
Children 1-2 yrs	0.000183	3.3%
Children 3-5 yrs	0.000160	2.9%
Children 6-12 yrs	0.000102	1.9%
Youth 13-19 yrs	0.000062	1.1%
Adults 20-49 yrs	0.000056	1.0%
Adults 50+ yrs	0.000041	0.7%
Females 13-49 yrs	0.000050	0.9%

Attachment 8. Cancer Food and Groundwater Results File.

DEEM-FCID Chronic analysis for FLUOMETURON (1994-98 data)
 Residue file name: C:\Documents and Settings\sary\Desktop\Fluometuron\Dietary\Cancer\Fluometuron cancer (groundwater).R98
 Adjustment factor #2 used.
 Analysis Date 12-06-2004/16:29:53 Residue file dated: 12-06-2004/16:23:02/8
 Q* = 0.018
 COMMENT 1: Food and Groundwater

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .018)
U.S. Population (total)	0.005147	9.27E-05

Attachment 9. Critical Commodity Contribution Analysis for Cancer.

Adjustment factor #2 used.

Analysis Date 12-07-2004/05:50:16 Residue file dated: 12-06-2004/16:23:02/8
 Q* = 0.018

COMMENT 1: Food and Groundwater

=====
 Critical Commodity Contribution Analysis for
 U.S. Population (total)

Total Exposure =.0051473 mg/kg bw/day

Crop groups with total exposure contribution > 99%
 Foods/Foodforms with exposure contribution > .1%

Crop group Food Foodform	-----Exposure analysis-----		
	mg/kg body wt/day	% of Total Exposure	Lifetime Risk (Q*= .018)

Crop Group = (0) Other			
Water, direct, all sources (86010000):			
FoodForm N/S	0.0029244	56.81%	5.26E-05
Water, indirect, all sources (86020000):			
FoodForm N/S	0.0021553	41.87%	3.88E-05
-----	-----	-----	-----
Total for crop group	0.0050812	98.72%	9.15E-05
Crop Group = (6) Legume Vegetables (Succulent or Dried)			
Soybean, oil (06003500):			
FoodForm N/S	0.0000082	0.16%	1.48E-07
-----	-----	-----	-----
Total for crop group	0.0000176	0.34%	3.16E-07
Crop Group = (15) Cereal Grains			
Corn, field, syrup (15001240):			
FoodForm N/S	0.0000072	0.14%	1.29E-07
Rice, white (15003230):			
FoodForm N/S	0.0000061	0.12%	1.10E-07
Wheat, flour (15004020):			
FoodForm N/S	0.0000166	0.32%	2.99E-07
-----	-----	-----	-----
Total for crop group	0.0000415	0.81%	7.46E-07
Total for crop groups listed above:	0.0051402	99.86%	9.25E-05

Attachment 10. Cancer Results for Food Only (No Water).

U.S. Environmental Protection Agency Ver. 2.00
 DEEM-FCID Chronic analysis for FLUOMETURON (1994-98 data)
 Residue file name: C:\Documents and
 Settings\sary\Desktop\Fluometuron\Dietary\Cancer\Fluometuron cancer (food only).R98
Adjustment factor #2 used.
 Analysis Date 12-06-2004/16:24:12 Residue file dated: 12-06-2004/16:23:54/8
 Q* = 0.018
 COMMENT 1: Food Only

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=====
                        Total exposure by population subgroup
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Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q* = .018)
U.S. Population (total)	0.000068	1.22E-06

Attachment 11. Cancer Results for Groundwater Only (No Food).

U.S. Environmental Protection Agency
 DEEM-FCID Chronic analysis for FLUOMETURON
 Residue file name: C:\Documents and Settings\sary\Desktop\Fluometuron\Dietary\Cancer\Fluometuron cancer (groundwater only).R98

Ver. 2.00
 (1994-98 data)

Adjustment factor #2 used.
 Analysis Date 12-06-2004/16:28:20 Residue file dated: 12-06-2004/12:37:15/8
 Q* = 0.018

COMMENT 1: Groundwater Only (No Food)

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q*= .018)
U.S. Population (total)	0.005080	9.14E-05

Attachment 12. Cancer Results for Surface Water (36-Year Overall Mean) Only (No Food).

U.S. Environmental Protection Agency
 DEEM-FCID Chronic analysis for FLUOMETURON
 Residue file name: C:\Documents and
 Settings\sary\Desktop\Fluometuron\Dietary\Cancer\Fluometuron cancer (surface water
 only).R98

Ver. 2.00
 (1994-98 data)

Adjustment factor #2 used.
 Analysis Date 12-06-2004/16:34:51 Residue file dated: 12-06-2004/12:39:24/8
 Q* = 0.018

COMMENT 1: Surface Water Only (No Food)

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q*= .018)
U.S. Population (total)	0.000409	7.36E-06

Attachment 13. Cancer Food and Surface Water (36-Year Overall Mean) Results File.

U.S. Environmental Protection Agency
 DEEM-FCID Chronic analysis for FLUOMETURON

Ver. 2.00
 (1994-98 data)

Residue file name: C:\Documents and Settings\sary\Desktop\Fluometuron\Dietary\Cancer\Fluometuron cancer (surface water).R98

Adjustment factor #2 used.

Analysis Date 12-06-2004/16:35:46 Residue file dated: 12-06-2004/16:23:25/8
Q* = 0.018

COMMENT 1: Food and Surface Water

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Lifetime risk (Q*= .018)
U.S. Population (total)	0.000477	8.58E-06

Attachment 14. Usage Report in Support of Reregistration for Fluometuron.

Fluometuron – PC 035503

The tables below contain “screening level” usage data for agricultural crops. This information is retrieved from our principal agricultural pesticide usage databases. At the present time data from 1998 to 2002 is being used.

All numbers reported are rounded.

'<500' indicates less than 500 pounds of active ingredient.

'<2.5' indicates less than 2.5 percent of crop is treated.

Maximum percent of crop treated is the highest **observed** percent crop treated during this time period. For some crops there may have been only one or two observations and it is quite possible that if usage information had been available for more years that higher usage might have been observed. This situation is more likely to occur with low acreage crops.

'(CA only)' indicates information was available only for California. California requires reporting of all agricultural pesticide use. Their database may indicate small amounts of usage of a pesticide on crops on which the pesticide is not registered. Possible reasons for this include:

- This use may actually have occurred either as an unregistered use or as an experimental or other use in which the crop was not intended for consumption.
- Data input errors may have occurred and either the crop or the pesticide is incorrect in the database.

Use of the chemical on crops for which only California use is reported may possibly have occurred in other states.

In some cases the percent crop treated column is blank. This is because information on acres grown was not readily available.

Some of the numbers may be based on information that does not cover all 50 states. Therefore, it is possible that if the remaining (usually minor states for the crop) had been included that pounds of active ingredient would be slightly higher.

Arthur Grube 308-8095

Last revised Feb 06, 2004

OBS	Crop	Pounds of Active Ingredient	Percent of Crop Treated	
			Avg	Max
1	Cotton	2,400,000	20	35

All numbers rounded.

'<500' indicates less than 500 pounds of active ingredient.

'<2.5' indicates less than 2.5 percent of crop is treated.

'(CA only)' indicates information was available only for California.

Use of Fluometuron on this crop may also have occurred in other states.

(slua0001.sas Fluometuron)

Prepared by: Jihad Alsadek (703) 308-8140
March 16, 2004